

June 6, 2023

Comments on Updates to Circular No. A-4 on Regulatory Analysis

Comments submitted via regulations.gov to the docket ID OMB–2022–0014–0001

These comments are submitted on behalf of the undersigned scientists, community members, and advocacy groups. We declare collectively that we have no direct or indirect financial or fiduciary interest in the subject of these comments. The co-signers' institutional affiliations are included for identification purposes only and do not imply institutional endorsement or support unless indicated otherwise.

We appreciate the opportunity to provide comments on the proposed update to Circular A-4 on Regulatory Analysis, and we commend the Office of Management and Budget (OMB) for pursuing a long-overdue update to Circular A-4 of 2003. The Circular provides critical guidance to federal agencies regarding the analyses required under Executive Order 12866 and other executive orders for proposed and final regulatory actions. Executive Order 14094 on modernizing regulatory review directs OMB to revise Circular A-4 by April 26, 2024, to implement a policy that "Regulatory analysis should facilitate agency efforts to develop regulations that serve the public interest" and that "regulatory analysis...shall recognize distributive impacts and equity."¹

OMB has correctly identified several topics in the Circular for which expanded and/or revised guidance is needed, as well as new topics to add to the Circular. The draft revised Circular takes several important steps forward, but further improvements are necessary to fulfill the policy directive of Executive Order 14094 to improve regulatory analysis and to serve the public interest. In particular, the draft revised Circular falls short of meeting the directive to address distributional effects of regulations. Federal health and safety regulations provide critical opportunities to address extensive health disparities that currently exist across race/ethnicity and income. As recognized in OMB's preamble to the draft revisions, agencies rarely conduct distributional analysis, which means that agencies do not know if their regulations will lead to reduced or increased health inequities. Circular A-4 should be revised to recognize the importance of analyzing the equity impacts of regulations and require Agencies to conduct distributional analysis consistent with Executive Order 14094, including analysis of how benefits of regulations are distributed among population groups defined by race/ethnicity, income, lifestage, and other important factors. In addition, Circular A-4 should be revised to recognize that maximizing aggregate net benefits is not the sole determinant of a desirable policy and that consideration of distributional consequences is of equal importance, elevating the importance of distributional analysis relative to the existing Circular and the proposed revisions. Incorporation of these changes into Circular A-4 is necessary to meet the charge given to OMB in Executive Order 14094, will lead to better-informed agency decisions, and increase opportunities for agency regulations to address existing inequities.

Our detailed comments address the following issues:

- 1. The proposed revisions to Circular A-4 incorporate some improvements regarding the distributional effects of regulations, but there are also critical omissions. Circular A-4 should require estimation of the health and safety benefits of regulations for affected population groups.**

¹ Executive Order 14094. Modernizing Regulatory Review. Sec. 3. Improving Regulatory Analysis. 88 FR 21879, April 11, 2023.

- a. **Draft Circular A-4 does not meet the standard set by the Executive Order 14094 on Modernizing Regulatory Review and other presidential directives.**
 - b. **The draft update to Circular A-4 maintains an excessive focus on determination of net benefits and should instead state that assessing distributional effects is an important purpose of benefit-cost analysis.**
 - c. **Circular A-4 should require distributional analysis for all health and safety regulations.**
- 2. Circular A-4 should incorporate expanded discussion of key issues in assessing the benefits of health and safety regulations.**
- a. **The draft Circular’s discussion of benefits estimation is overly focused on monetization and should incorporate expanded discussion of quantifying benefits.**
 - b. **The draft Circular A-4 revision appropriately highlights the inclusion of uncertain effects in benefit-cost analysis. This is particularly important for estimating the benefits of health risk reductions.**
 - c. **Circular A-4 should direct agencies to use systematic review methods for identifying and evaluating valuation studies.**
- 3. Circular A-4 should incorporate expanded discussion of how considerations like imperfect information and advancing equity can justify the need for federal regulatory action.**
- a. **Revised Circular A-4 should expand its discussion of imperfect information to recognize the limitations of information strategies for addressing toxic chemicals.**
 - b. **The draft Circular A-4 section on promoting distributional fairness and advancing equity as a justification for regulation is inadequate.**

We would also like to commend OMB for other important changes in the proposed revisions to Circular A-4, including an update of the discount rate to be used in conducting regulatory analysis to 1.7%. This update is long overdue and important to the assessment of net benefits of environmental regulations, which often provide the bulk of their benefits many years after costs have been incurred. As a higher interest rate reduces the present value of future benefits, continued use of the outdated 3% and 7% discount rates systematically undervalues health benefits of regulations.

In addition to its instructions to OMB regarding the revision of Circular A-4, E.O. 14094 contains other notable improvements, including requirements for “to promote equitable and meaningful participation by a range of interested or affected parties, including underserved communities.”² OMB should take a

² Executive Order 14094. Modernizing Regulatory Review. Sec. 2. *Affirmative Promotion of Inclusive Regulatory Policy and Public Participation*. 88 FR 21879, April 11, 2023.

leading role in ensuring that agencies fully meet the requirements for improved public participation and should regard this role as equally important to its role in guiding regulatory analysis.

E.O. 14094 also increases the standard for identifying a significant regulatory action subject to OMB review from \$100 million per year to \$200 million per year, to be adjusted every three years.³ This is an important and overdue update, but the new threshold remains too low. The \$100 million threshold was first established in 1981,⁴ and affirmed in E.O. 12866 in 1993.⁵ From 1993 to 2023, U.S. gross domestic product (GDP) has approximately quadrupled, and 2023 GDP is approaching nine times the GDP of 1981.⁶ A full update of the threshold value from 1993 would result in a value of \$400 million. OMB should pursue further changes to this threshold value to, at a minimum, account for growth in GDP from 1993 to today; better still would be full adjustment of the threshold to account for growth in GDP from 1981.

We appreciate the opportunity to provide public input, and we look forward to the issuance of the final updated Circular A-4. OMB should complete the revision to Circular A-4 by Fall 2023 so that agencies can promptly begin implementing the revised guidance in their analyses of forthcoming regulations. Please do not hesitate to contact us with any questions regarding these comments.

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³ Executive Order 14094. Modernizing Regulatory Review. Section 1. Improving the Effectiveness of the Regulatory Review Process. 88 FR 21879, April 11, 2023.

⁴ Executive Order 12291. Federal Regulation. Section 1. Definitions. 46 FR 13193, February 17, 1981.

⁵ Executive Order 12866. Regulatory Planning and Review, Sec. 3. Definitions.. 58 FR 51735, October 4, 1983.

⁶ U.S. Bureau of Economic Analysis, Gross Domestic Product [GDP], retrieved from FRED, Federal Reserve Bank of St. Louis; <https://fred.stlouisfed.org/series/GDP>, May 7, 2023.

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DETAILED COMMENTS

1. The proposed revisions to Circular A-4 incorporate some improvements regarding the distributional effects of regulations, but there are also critical omissions. Circular A-4 should require estimation of the health and safety benefits of regulations for affected population groups.

Increased analysis of distributional effects of regulations would be a critical improvement in how federal regulations are developed. Distributional effects include consideration of how the benefits of a regulation are distributed among groups of interest and may include analysis of the extent to which health risks are increased or decreased for population groups defined by race/ethnicity, income, lifestyle, and other factors of interest. Distributional analysis is necessary to inform agencies regarding how their regulatory decisions may address existing inequities. For example, any regulation of a chemical or pollutant might decrease or increase health inequities. Agencies will not know unless they conduct distributional analysis. To meet the requirements of Executive Order 14094, Circular A-4 must require agencies to conduct distributional analysis and elevate the importance of this analysis relative to the overemphasis on maximizing net benefits in the current Circular.

The existing Circular A-4 contains a brief two-paragraph section on *Distributional Effects*. The proposed revision to Circular A-4 expands this section to five pages, with subsections providing guidance on specifying groups to be considered in distributional analysis, conducting the distributional analysis, and differential weighting of groups (e.g., defined by income) in calculating aggregate net benefits. This expanded treatment of distributional analysis is an important advance in the proposed revisions. However, the draft revisions to the Circular do not include any requirement for agencies to conduct distributional analysis, and this must be corrected in the final revised Circular.

OMB has issued a preamble with useful discussion of many issues addressed in the proposed revisions to the Circular. The preamble correctly states that “analyzing the full welfare effects of regulations **requires** analyzing the incidence, or distribution, of their effects”⁷ (emphasis added). Unfortunately, this statement is not incorporated into the proposed revisions to the Circular itself, and the proposed

⁷ Office of Management and Budget. Preamble: Proposed OMB Circular No. A-4, “Regulatory Analysis,” p.11.
<https://www.whitehouse.gov/wp-content/uploads/2023/04/DraftCircularA-4Preamble.pdf>

revisions do not follow through on the implications of this statement by requiring agencies to conduct distributional analysis of their regulations.

The draft revision to the Circular instead takes an unacceptable step backward by making distributional analysis an option, rather than requiring evaluation of distributional effects as a central and indispensable element of regulatory analysis. As noted in the preamble, the current Circular A-4 requires distributional analysis:

Your regulatory analysis should provide a separate description of distributional effects...so that decision makers can properly consider them along with the effects on economic efficiency.⁸

No such statement appears in the draft revisions, and the preamble indicates that this was a conscious decision:

In developing proposed revisions to Circular A-4, we considered whether the Circular should call for agencies to generally produce distributional analyses in regulatory impact analyses for certain types of rules. After consideration, we have proposed revisions that do not adopt this approach. Regardless of the type of rule, not all rules of a given type will necessarily have important distributional effects, distributional analysis can be a complex undertaking (especially when the expected incidence of benefits and costs is fully analyzed), and agencies' resources for conducting economic analyses of regulatory actions are scarce. For this reason, we have proposed revisions that emphasize agency discretion to perform preliminary screening of rules to determine which are most likely to have significant differentiated effects on particular demographic groups and to analyze important distributional effects in those cases.⁹

As we discuss in further detail below, this statement in the preamble excusing agencies from a requirement to conducting distributional analysis because their rules may not have important distributional effects is highly problematic. Because of the significant health inequities currently observed in the U.S. (for example, non-Hispanic Black people have higher rates of preterm birth, childhood asthma, and chronic kidney disease than other race/ethnicities), it is important that distributional analysis be conducted for each health and safety regulation to determine whether it has important distributional effects. Only upon determining whether regulatory alternatives increase or decrease inequities can agencies move forward in determining how to address them. Leaving the decision to conduct such analyses to agency discretion (and with no requirement for agencies to document their reasoning for not conducting an analysis) will result in regulations that do not comply with requirements of E.O. 14094 and in little improvement to current agency practices that frequently fail to consider disparate effects. A further critical consideration is that absence of a distributional analysis (or any justification for not conducting distributional analysis) deprives disparately affected communities the opportunity to for meaningful participation in the regulatory process, which is required by Executive Order 14094 and 14096 (see below).

In addition, the proposed revisions to the Circular appear to be inconsistent with the preamble, as there seems to be no text regarding "preliminary screening" of rules to assess potential distributional impacts.

⁸ Office of Management and Budget. Circular A-4, Regulatory Analysis., p. 14. September 17, 2003

⁹ Office of Management and Budget. Preamble: Proposed OMB Circular No. A-4, "Regulatory Analysis," pp.11-12. <https://www.whitehouse.gov/wp-content/uploads/2023/04/DraftCircularA-4Preamble.pdf>.

At the absolute minimum, the revised Circular should require agencies to conduct some basic level of distributional analysis for every rule and provide a substantive justification for any conclusion that analysis of distributional effects of a rule is not practicable or appropriate, and to make all relevant information available for public comment.

The preamble states that “expanded guidance on distributional analysis in the proposed revisions to Circular A-4, described in more detail below, is intended to assist agencies in expanding estimation of disparate effects of rules on individual groups,”¹⁰ but removing the statement above requiring distributional analysis undermines this stated objective. As discussed further below, E.O. 14094 (and predecessors) **require** distributional analysis and failing to state this in Circular A-4 will only lead to a partial implementation by federal agencies at best.

An important improvement found in the draft revised Circular regarding distributional effects is the use of differential weighting for different population groups in calculating net benefits. This practice would enable agencies to give greater consideration to impacts on low-income households in calculating net benefits. OMB should enhance this proposed section by providing recommended income groupings and recommended values of the weights by income group that agencies may use in conducting weighted analysis. To promote consistency across federal agencies and greatest use of existing data resources, the recommendations on income groups should take into account income data available from federal surveys that may be used to inform weighted analysis and distributional analysis, including surveys conducted by the National Center for Health Statistics. Finally, Circular A-4 should state clearly that use of weights in calculating net benefits is not a substitute for conducting distributional analysis. Distributional analysis must be conducted whether or not weighted net benefits are calculated.

a. Draft Circular A-4 does not meet the standard set by the Executive Order 14094 on Modernizing Regulatory Review and other presidential directives.

E.O. 14094 directs OMB to revise Circular A-4 to implement the following policy:

Regulatory analysis should facilitate agency efforts to develop regulations that serve the public interest, advance statutory objectives, and are consistent with Executive Order 12866, Executive Order 13563, and the Presidential Memorandum of January 20, 2021 (Modernizing Regulatory Review). **Regulatory analysis**, as practicable and appropriate, **shall recognize distributive impacts and equity**, to the extent permitted by law.¹¹ (emphasis added)

In addition, the Presidential Memorandum on Modernizing Regulatory Review of January 20, 2021 directs OMB to:

propose procedures that take into account the distributional consequences of regulations, including as part of any quantitative or qualitative analysis of the costs and benefits of regulations, to ensure that regulatory initiatives appropriately benefit and do not inappropriately burden disadvantaged, vulnerable, or marginalized communities.¹²

¹⁰ Office of Management and Budget. Preamble: Proposed OMB Circular No. A-4, “Regulatory Analysis,” p. 11. <https://www.whitehouse.gov/wp-content/uploads/2023/04/DraftCircularA-4Preamble.pdf>.

¹¹ Executive Order 14094. Modernizing Regulatory Review. Sec. 3. Improving Regulatory Analysis. 88 FR 21879, April 11, 2023

¹² Presidential Memorandum of January 20, 2021 (Modernizing Regulatory Review). Sec. 2. Implementation

OMB's proposed revisions to Circular A-4 **do not satisfy these directives**. The revisions include no requirements for analysis of distributive impacts and equity, and they do not require agencies to justify – in cases where agencies do not analyze distributional consequences of their rules – that such analysis is not practicable, appropriate or permitted by law.

E.O. 14094 also states that regarding regulatory actions:

Opportunities for public participation shall be designed to promote equitable and meaningful participation by a range of interested or affected parties, including underserved communities.¹³

To inform the development of regulatory agendas and plans, agencies shall endeavor, as practicable and appropriate, to proactively engage interested or affected parties, including members of underserved communities; consumers; workers and labor organizations...These efforts shall incorporate, to the extent consistent with applicable law, best practices for information accessibility and engagement with interested or affected parties, including, as practicable and appropriate, community-based outreach...and expansion of public capacity for engaging in the rulemaking process.¹⁴

E.O 14096 on “Revitalizing Our Nation’s Commitment to Environmental Justice for All” directs that:

Each agency shall, as appropriate and consistent with applicable law...identify, analyze, and address disproportionate and adverse human health and environmental effects (including risks) and hazards of Federal activities, including those related to climate change and cumulative impacts of environmental and other burdens on communities with environmental justice concerns...identify, analyze, and address historical inequities, systemic barriers, or actions related to any Federal regulation, policy, or practice that impair the ability of communities with environmental justice concerns to achieve or maintain a healthy and sustainable environment...provide opportunities for the meaningful engagement of persons and communities with environmental justice concerns who are potentially affected by Federal activities, including by...providing technical assistance, tools, and resources to assist in facilitating meaningful and informed public participation.¹⁵

OMB's proposed revisions to Circular A-4 do not satisfy these E.O. directives. Distributional analysis provides the information necessary for affected communities and groups to be able to fully participate in the regulatory process and is a critical aspect of expanding public capacity of affected groups. Any rulemaking that does not include distributional analysis will not provide meaningful participation and expanded capacity for engagement in the process for underserved communities and other affected groups.

The failure of Circular A-4 to require distributional analysis for health and safety regulations would represent a significant gap in implementing E.O. 14094. Distributional analysis is generally practicable,

¹³ Executive Order 14094. Modernizing Regulatory Review. Sec. 2. Affirmative Promotion of Inclusive Regulatory Policy and Public Participation. 88 FR 21879, April 11, 2023

¹⁴ Executive Order 14094. Modernizing Regulatory Review. Sec. 2. Affirmative Promotion of Inclusive Regulatory Policy and Public Participation. 88 FR 21879, April 11, 2023.

¹⁵ Executive Order 14096. Revitalizing Our Nation's Commitment to Environmental Justice for All. Sec. 3. Government-Wide Approach to Environmental Justice. 88 FR 25251, April 26, 2023.

appropriate, and permitted by law and OMB has failed to provide any rationale for why it is not following through on this Executive Order requirement in the Circular A-4 revision.

We recognize that E.O. 14094 states that distributional analysis is to be conducted when practicable, appropriate, and lawful. Agencies can therefore consider whether distributional analysis is practical, appropriate, and lawful for particular regulations, but the language in the E.O. does not allow discretion for agencies to simply disregard distributional analysis without justification. Circular A-4 should be revised to incorporate an expectation that distributional analysis will be conducted for each regulation, unless the agency in question demonstrates with a strong justification that such analysis is not practicable, not appropriate, or not lawful.

OMB's Office of Information and Regulatory Affairs (OIRA) should take action to ensure that distributional analysis is practicable in all cases where it is appropriate and lawful. Agencies may claim that they do not have sufficient data to conduct distributional analysis of their regulations. OIRA should assist in and promote data collection efforts – through enhancements to existing surveys (such as those conducted by the Census Bureau and the National Center for Health Statistics) or initiation of new surveys – to obtain all information needed for analyzing each regulation by groupings such as race/ethnicity and income. OIRA's statistics office should work with agencies to design any data collection efforts needed, and OIRA should prioritize expedited approval of any Information Collection Requests necessary to make distributional analysis of regulations practicable, including surveys that would meet the needs of multiple agencies.

- b. The draft update to Circular A-4 maintains an excessive focus on determination of net benefits and should instead state that assessing distributional effects is an equally important purpose of benefit-cost analysis.**

Although E.O.14094 clearly directs OMB to revise Circular A-4 in a manner that elevates the importance of distributional consequences in regulatory analysis, the proposed revisions include repeated statements that reflect a strong emphasis on aggregate net benefits, leaving little room for consideration of distributional effects. A focus on net benefits means a strong emphasis on the **total** social benefits and **total** social costs of the regulation, without considering what groups or entities incur the costs and what groups are anticipated to benefit – and the distribution of costs and benefits among those groups. Multiple passages in the draft disregard equity concerns by focusing on economic efficiency without considering existing inequities in the distribution of income, generational wealth, health, and political influence. The analysis of distributional effects informs decisionmakers about whether those most adversely affected by current conditions will realize gains from the regulation, and whether different regulatory alternatives may offer greater or lesser gains to those adversely affected groups. This is critical information that would be missing from an analysis of net benefits that does not include a distributional analysis.

Although the current Circular A-4 includes mentions of distributional analysis, including (as quoted above) a requirement that agencies conduct distributional analysis, it places much more emphasis on the analysis of aggregate net benefits. This bias is maintained in the proposed revisions, resulting in an overall message that is in direct conflict with E.O. 14094 (“Regulatory analysis...shall recognize distributive impacts and equity”¹⁶). The draft revised Circular repeatedly incorporates statements that place emphasis on determination of aggregate net benefits as the primary (or sole) purpose of

¹⁶ Executive Order 14094. Modernizing Regulatory Review. Sec. 3. Improving Regulatory Analysis. 88 FR 21879, April 11, 2023

regulatory analysis and reflects a perspective that all regulatory decisions should strive to maximize aggregate net benefits wherever possible. The critical limitations of the net benefits criterion include the difficulties in quantifying and monetizing many benefits of regulations, the implicit assumption accepting the current distribution of wealth, income, health and influence, and the fact that it conflicts with decision criteria in many statutes. The Circular’s statements favoring the importance of determining aggregate net benefits generally are not accompanied by statements regarding the importance of analyzing the distributional consequences of a regulation. Examples of such passages in the draft revisions that emphasize aggregate net benefits without discussing distributional effects include:

- Section 1.a., *The Need for Analysis of Regulatory Actions* (pp. 2-3), discusses determination of net benefits, along with unquantified benefits and costs, but it does not mention assessment of distributional effects. Although the draft revised Circular appropriately recognizes that use of monetized net benefits as a decision criterion is limited if important costs or benefits are not quantified and monetized (e.g., p. 3), discussion of this point is generally presented in a context that takes maximizing net benefits to society as a whole as the objective of regulatory analysis. These statements fail to recognize the importance of assessing the benefits to particular segments of society, such as groups defined by race/ethnicity, income, or other characteristics.
- In Section 1.b., *Developing a Regulatory Analysis*, the list of “key steps in producing a regulatory analysis” (p. 3) does not mention distributional analysis.
- Section 2.a., *Benefit-Cost Analysis* (BCA), depicts the purpose of analysis as identifying the regulatory alternative that provides the greatest aggregate net benefits: “By measuring incremental benefits and costs of successively more stringent regulatory alternatives, you can identify the alternative that **maximizes net benefits**”¹⁷ (emphasis added). The section continues to discuss the limitations of BCA when important benefits and costs are not monetized, saying “a materially incomplete monetized BCA does not offer an adequate summary of evidence intended to inform determination of the **most net beneficial alternative**”¹⁸ (emphasis added). These statements assume that identifying the alternative that maximizes net benefits is the sole purpose of BCA, and the section does not mention distributional analysis.
- Section 5.a.i. on *Externalities* includes a passage (p. 16) on the theoretical concept that externalities can be efficiently addressed by bargaining and without regulation when property rights are well-defined. While correctly recognizing that absence of the required conditions (e.g., established property rights to clean air, low transaction costs) means that the efficient outcome is not attained and can justify regulation, this text disregards any inequities in the distribution of wealth and political influence, which could indicate that an efficient outcome is not necessarily the preferred outcome and that decision-makers may opt for approaches that give greater consideration to addressing existing disparities.
- Section 7.i. on *Methods for Treating Non-Monetized Benefits, Costs, and Transfers* equates the “most advantageous policy”¹⁹ with the one that maximizes net benefits, without consideration of how distributional consequences may affect the judgment of which policy alternative is the most advantageous and how policy alternatives may affect those currently experiencing the greatest adverse effects. Similar to the above point, a default preference for the policy option that maximizes net benefits disregards critical inequities in the distribution of wealth, health and

¹⁷ Office of Management and Budget. Circular A-4, Regulatory Analysis. Draft for Public Review, p.4, April 6, 2023. <https://www.whitehouse.gov/wp-content/uploads/2023/04/DraftCircularA-4.pdf>.

¹⁸ Office of Management and Budget. Circular A-4, Regulatory Analysis. Draft for Public Review, p. 5, April 6, 2023. <https://www.whitehouse.gov/wp-content/uploads/2023/04/DraftCircularA-4.pdf>.

¹⁹ Office of Management and Budget. Circular A-4, Regulatory Analysis. Draft for Public Review, p. 43, April 6, 2023. <https://www.whitehouse.gov/wp-content/uploads/2023/04/DraftCircularA-4.pdf>.

political influence; consideration of disparities may lead to selection of a different regulatory alternative as the “most advantageous policy.”

The bias towards the net benefits criterion is countered in only one place in the proposed revisions, with this useful statement in the section on *Producing a Distributional Analysis*:

the distributional interest...may lead an agency to select a regulatory alternative with lower monetized net benefits over another with higher monetized net benefits because of the difference in how those net benefits are distributed in each alternative.²⁰

The spirit of this latter statement should be incorporated throughout the revised Circular A-4, reflecting a perspective that achieving maximum aggregate net benefits is not the sole determinant of a desirable policy and that consideration of distributional consequences is of equal importance.

The relative importance of aggregate net benefits vs. distributional effects in agency decision-making across all statutes and programs is not something that can or should be determined by OMB and should not be indicated in Circular A-4. Instead, it is the responsibility of each agency to base each regulatory decision on net benefits, distributional consequences, and other considerations as they judge appropriate given statutory requirements, the facts at hand, and public input (including the meaningful participation of underserved communities, as required by both E.O. 14094 and E.O. 14096). Circular A-4 should therefore be rewritten to place equal emphasis on analysis of net benefits and distributional consequences, elevating the importance of distributional analysis relative to the existing Circular and the proposed revisions.

The section of Circular A-4 on *The Need for Analysis of Regulatory Actions* should incorporate the following passage from the Presidential Memorandum on Regulatory Review, directing that regulatory analysis should:

take into account the distributional consequences of regulations, including as part of any quantitative or qualitative analysis of the costs and benefits of regulations, to ensure that regulatory initiatives appropriately benefit and do not inappropriately burden disadvantaged, vulnerable, or marginalized communities.²¹

The Circular A-4 section on *The Need for Analysis of Regulatory Actions* should also integrate the following insertions to elevate the attention to distributional analysis alongside the language on aggregate net benefits (suggested new text is underlined):

When it is not possible to monetize all of the important benefits and costs, the alternative with the greatest monetized net benefits will not necessarily be the alternative that generates the greatest social welfare. In addition, distributional effects of a regulatory action are an important consideration in determining the preferred alternative. So, while monetized net benefits are one consideration for agencies deciding what course of action to pursue, regulatory analyses should encompass additional relevant factors; in particular, analyses should include any important non-

²⁰ Office of Management and Budget. Circular A-4, Regulatory Analysis. Draft for Public Review, p 64-65, April 6, 2023. <https://www.whitehouse.gov/wp-content/uploads/2023/04/DraftCircularA-4.pdf>.

²¹ Presidential Memorandum of January 20, 2021 (Modernizing Regulatory Review), Sec. 2. Implementation.

monetized and non-quantified effects, and assessment of the distributional consequences of the alternatives.

The section on *Benefit-Cost Analysis* should incorporate this new passage:

Benefit-cost analyses should also provide decision-makers with information related to important considerations other than efficiency, such as public health and safety, racial and economic justice, and equity. Benefit-cost analysis informs these considerations when it provides information regarding the distribution of benefits among population groups defined by important characteristics including race/ethnicity, income, and lifestage, among others. Benefit-cost analysis can often inform these considerations even when benefits are not expressed in monetary units.

The section on *Developing Benefit and Cost Estimates* should incorporate this statement:

Any analysis of health benefits of a regulation should, to the extent possible, report the anticipated quantified and monetized benefits to specific population groups defined by race/ethnicity, income, and lifestage.

The Environmental Protection Agency's (EPA) *Guidelines for Preparing Economic Analyses* includes a useful discussion of how distributional analysis contributes to achieving environmental justice (EJ) objectives and meaningful participation in the regulatory process. This language should be adapted for inclusion in Circular A-4:

Distributional analysis also improves transparency of rulemaking and provides decision makers and the public with more complete information about a given policy's potential effects. Such documentation helps EPA and the public track and measure progress in addressing EJ concerns. Analysts play a role in ensuring meaningful involvement by explaining distributional analysis in plain language, including key assumptions, methods, and results, and by asking for information from the public (e.g., asking for comment in the proposed rulemaking) on exposure pathways, end points of concern, and data sources that may improve the distributional analysis.²²

The revised Circular should also incorporate discussion of the assumptions embedded in using a net benefits criterion for identifying a preferred regulatory alternative - in particular, discussion of the tacit acceptance of the existing (and inequitable) distribution of income, generational wealth, health, and political influence. In addition, the Circular's discussion of the Accounting Statement should incorporate reporting of distributional consequences of a regulation.

c. Circular A-4 should require distributional analysis for all health and safety regulations.

Disparities in health status and disease prevalence in the U.S. are well-documented. For a broad range of health measures, people who are not white and people who have lower incomes are consistently found to have a greater disease burden. Selected examples of these disparities found in federal health statistics include:

²² U.S. EPA. *Guidelines for Preparing Economic Analyses*. Chapter 10: Environmental Justice, Children's Environmental Health and Other Distributional Considerations, May 2014, page 10-4.

- Non-Hispanic Black women are more likely to experience preterm birth than women of any other race/ethnicity.²³
- Non-Hispanic Black women are more likely to have a low-birthweight infant than women of any other race/ethnicity.²⁴
- Non-Hispanic Black and American Indian/Alaska Native women are more likely to die in childbirth than women of any other race/ethnicity.²⁵
- The prevalence of current asthma and the rate of emergency room visits for asthma and other respiratory causes are greater among non-Hispanic Black children than among children of any other race/ethnicity. The prevalence of current asthma is greater for children living below poverty level than for children above poverty level.²⁶
- The prevalence of obesity among non-Hispanic Black children and Hispanic children is greater than for any other race/ethnicity group.²⁷
- The prevalence of attention-deficit/hyperactivity disorder is greater among children living below poverty level than for children above poverty level.²⁸
- The prevalence of chronic kidney disease is greatest among non-Hispanic Black adults.²⁹
- The prevalence of diabetes in adults is highest among American Indians and Alaska Natives, non-Hispanic Blacks, and people of Hispanic origin. Diabetes prevalence is greater in adults living below poverty level than in those above poverty level and is greater among adults with less than a high school education.³⁰
- The heart disease death rate is greater for non-Hispanic Black people than for all other race/ethnicity groups.³¹

E.O. 14096 on environmental justice describes the role that various environmental factors play in contributing to health disparities:

Communities with environmental justice concerns experience disproportionate and adverse human health or environmental burdens. These burdens arise from a number of causes, including inequitable access to clean water, clean air, natural places, and resources for other basic human health and environmental needs; the concentration of pollution, hazardous waste, and toxic exposures; and underinvestment in affordable housing that is safe and healthy and in basic infrastructure and services to support such housing, including safe drinking water and effective sewage management. The cumulative impacts of exposure to those types of burdens and other stressors, including those related to climate change and the environment, further

²³ U.S. EPA. *America's Children and the Environment*. <https://www.epa.gov/americaschildrenenvironment/health-adverse-birth-outcomes>. Accessed 9 May 2023.

²⁴ Federal Interagency Forum on Child and Family Statistics. *America's Children*. <https://www.childstats.gov/americaschildren21/health1.asp>. Accessed 9 May 2023.

²⁵ Petersen EE, Davis NL, Goodman D, et al. Racial/Ethnic Disparities in Pregnancy-Related Deaths – United States, 2007-2016. *MMWR* 2019; 68:762-765.

²⁶ U.S. EPA. *America's Children and the Environment*. <https://www.epa.gov/americaschildrenenvironment/health-respiratory-diseases>. Accessed 9 May 2023.

²⁷ Federal Interagency Forum on Child and Family Statistics. *America's Children*. <https://www.childstats.gov/americaschildren21/health7.asp>. Accessed 9 May 2023.

²⁸ U.S. EPA. *America's Children and the Environment*. <https://www.epa.gov/americaschildrenenvironment/health-neurodevelopmental-disorders>. Accessed 9 May 2023.

²⁹ Centers for Disease Control and Prevention. *Chronic Kidney Disease in the United States, 2021*. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2021.

³⁰ Centers for Disease Control and Prevention. *National Diabetes Statistics Report, 2022*. <https://www.cdc.gov/diabetes/health-equity/diabetes-by-the-numbers.html>

³¹ Centers for Disease Control and Prevention. *Health, United States, 2020–2021*. <https://www.cdc.gov/nchs/hs/topics/heart-disease-deaths.htm>

disadvantage communities with environmental justice concerns. People in these communities suffer from poorer health outcomes and have lower life expectancies than those in other communities in our Nation. Moreover, gaps in environmental and human health data can conceal these harms from public view, and, in doing so, are themselves a persistent and pernicious driver of environmental injustice.³²

As noted above, E.O. 14094 states that “regulatory analysis...shall recognize distributive impacts and equity.”³³ In addition, E.O. 14096 contains further directives to federal agencies to analyze and address health inequities. E.O. 14096 directs federal agencies to consider the

best available science and information on any disparate health effects (including risks) arising from exposure to pollution and other environmental hazards, such as information related to the race, national origin, socioeconomic status, age, disability, and sex of the individuals exposed.³⁴

E.O. 14096 also call on federal agencies to take steps on

disaggregating environmental risk, exposure, and health data by race, national origin, income, socioeconomic status, age, sex, disability, and other readily accessible and appropriate categories.³⁵

In addition to meeting the directives of E.O. 14094, revision of Circular A-4 to require distributional analysis of health and safety regulations would be an important step toward achieving these objectives of E.O. 14096. Any federal health and safety regulation may potentially have an impact on health disparities, but some alternatives for a particular regulation may provide greater advances toward health equity and environmental justice than others, and some alternatives (even if they offer reduced health risks in aggregate) may increase health inequities for groups that are the most disadvantaged. Further, the alternative(s) that provide the greatest reduction in health inequities will not necessarily be the alternative that maximizes aggregate net benefits. To inform decision-makers regarding the impacts of their regulations on health disparities and environmental justice, Circular A-4 should state that agencies are required to conduct analysis of the distribution of health benefits for all health and safety regulations.

The revised Circular’s section 10.b., *When to Perform Distributional Analysis* (p. 62), should incorporate this new text:

It is particularly important to conduct distributional analysis for any rule that may potentially ameliorate or exacerbate known disparities such as inequities in health status and inequities in exposure to chemicals and pollutants. Any rule addressing health and safety risks can be expected to affect existing inequities and conducting distributional analysis is necessary to assess how each alternative may reduce (or increase) those disparities for disadvantaged populations. Analysis of the distributional consequences of health and safety regulations is

³² Executive Order 14096. Revitalizing Our Nation’s Commitment to Environmental Justice for All. Section 1. *Policy*. 88 FR 25251, April 26, 2023.

³³ Executive Order 14094. Modernizing Regulatory Review. 88 FR 21879, April 11, 2023

³⁴ Executive Order 14096. Revitalizing Our Nation’s Commitment to Environmental Justice for All. Sec. 3. *Government-Wide Approach to Environmental Justice*. 88 FR 25251, April 26, 2023

³⁵ Executive Order 14096. Revitalizing Our Nation’s Commitment to Environmental Justice for All. Sec. 5. *Research, Data Collection, and Analysis to Advance Environmental Justice*. 88 FR 25251, April 26, 2023

important to inform the selection of a regulatory alternative, and analysis of distributional consequences should always be presented to decision-makers along with the analysis of aggregate benefits and costs. Agencies are directed to conduct distributional analysis for all proposed and final rules; exceptions are allowed only when there is compelling evidence that the rule will not ameliorate or exacerbate existing disparities.

The revised Circular's section 10.d. on *Producing a Distributional Analysis* (p. 63) should explain that a distributional analysis of health and safety risks should begin with reporting the distribution of risk across groups in the baseline, along with the change in risk for each affected group. Understanding the baseline distribution of risk/disease/health is necessary to understand the distributional consequences of the regulatory alternatives analyzed. EPA's *Guidelines for Preparing Economic Analyses* outline three questions to guide the distributional analysis, and these should be incorporated into revised Circular A-4:

- What is the baseline distribution of health and environmental outcomes across population groups of concern for pollutants affected by the rulemaking?
- What is the distribution of health and environmental outcomes for the options under consideration for the rulemaking effort?
- Under the options being considered, how do the health and environmental outcomes change for population groups of concern?³⁶

EPA conducted a demographic analysis of air toxics cancer risks that generally follows this approach, in support of its recent proposed rule for hazardous air pollutant emissions from chemical manufacturing.³⁷ The analysis found that the population with elevated baseline risk was disproportionately African-American, Hispanic/Latino, and below poverty level income. The analysis found that implementation of the proposed rule would decrease the number of people with elevated risks in all demographic groups, but those remaining at elevated risk after the rule would still be disproportionately African-American, Hispanic/Latino, and below poverty level income, maintaining existing inequities; EPA indicated that the remaining elevated risks would be addressed in forthcoming air toxics regulations.³⁸ This type of analysis should be conducted on a routine basis for proposed and final regulations. EPA's analysis should be regarded as one model for distributional analysis of all health and safety rules, and OMB should describe this approach in the revised Circular A-4.

The draft Circular A-4 section on *Producing a Distributional Analysis* states that "sound monetized estimates are preferred to non-monetized estimates where their production is feasible and appropriate."³⁹ This section should be revised to state that distributional analysis of health benefits should focus primarily on the distribution of changes in health risks (or suitable proxies for health risk) rather than monetized benefits. This is necessary to determine whether the regulation ameliorates or exacerbates health disparities. As stated in EPA's *Guidelines for Preparing Economic Analyses*:

³⁶ U.S. EPA. *Guidelines for Preparing Economic Analyses*. Chapter 10: Environmental Justice, Children's Environmental Health and Other Distributional Considerations, May 2014, pp. 10-6 to 10-7.

³⁷ U.S. EPA. New Source Performance Standards for the Synthetic Organic Chemical Manufacturing Industry and National Emission Standards for Hazardous Air Pollutants for the Synthetic Organic Chemical Manufacturing Industry and Group I & II Polymers and Resins Industry. 88 FR 25080, April 25, 2023. (IV. Summary of Cost, Environmental, and Economic Impacts; F. What analysis of environmental justice did we conduct?)

³⁸ U.S. EPA. Fact Sheet. Understanding the Impact of EPA's Proposed Rules for Chemical Plants: EPA's Community Risk Assessment and Risk-Based Demographic Assessment. <https://www.epa.gov/system/files/documents/2023-04/HON%20P%26R.%20Demographic%20Analysis.Fact%20Sheet.%204.6.23.pdf>

³⁹ Office of Management and Budget. Circular A-4, Regulatory Analysis. Draft for Public Review, April 6, 2023, p. 64. <https://www.whitehouse.gov/wp-content/uploads/2023/04/DraftCircularA-4.pdf>

analyzing the distribution of monetized benefits from a benefit-cost analysis can be problematic. Benefit-cost analyses do not estimate each affected individual's monetized welfare at baseline and policy levels of environmental quality. Instead, they estimate society's willingness to pay for a *change* in environmental quality. Thus, although the distribution of this change in welfare across groups may be of interest in its own right, in isolation it does not inform the question of whether the policy increases or reduces pre-existing disparities.⁴⁰

In addition, this section of the proposed revised Circular discusses potential uncertainties in assessing the incidence of costs (p. 64). The Circular should state clearly that uncertainties in the incidence or distribution of costs of a regulation, or lack of data to assess the distribution of costs, should not be cited by agencies as a reason to not conduct a distributional analysis of the benefits.

2. Circular A-4 should incorporate expanded discussion of key issues in assessing the benefits of health and safety regulations.

OMB has chosen not to update the sections of Circular A-4 concerning health benefits. As stated in the preamble:

While recognizing that potential modifications to material on monetizing health and safety benefits and costs and health and safety metrics could be advantageous, OMB believes that continued reliance on this material is generally appropriate at this time.⁴¹

There are, in fact, multiple deficiencies in these sections of Circular A-4 that should be addressed, as well as some important points that are currently addressed only briefly and should be discussed in more detail.

a. The draft Circular's discussion of benefits estimation is overly-focused on monetization and should incorporate expanded discussion of quantifying benefits.

The draft revised Circular spends several pages discussing approaches to monetizing benefits, with separate sections devoted to the concepts of willingness-to-pay and willingness-to-accept, revealed preference methods, stated preference methods, benefit transfer methods, and treatment of benefits that are not quantified or monetized. These are all important topics, but missing is a discussion of principles or approaches to quantifying health benefits. It is particularly notable as a gap given that the Circular appropriately highlights the importance of considering benefits that are not quantified, or those that are quantified but not monetized – but it skips past the topic of approaches to quantifying benefits. Quantification of effects is treated as an afterthought, discussed in the Circular only in the context of effects that cannot be monetized, when in fact quantification is a prerequisite for monetization.

The Circular should incorporate several general principles related to quantification of benefits, including:

⁴⁰ U.S. EPA. *Guidelines for Preparing Economic Analyses*. Chapter 10: Environmental Justice, Children's Environmental Health and Other Distributional Considerations, May 2014, pp 10-7 to 10-8.

⁴¹ Office of Management and Budget. Preamble: Proposed OMB Circular No. A-4, "Regulatory Analysis," p. 7. <https://www.whitehouse.gov/wp-content/uploads/2023/04/DraftCircularA-4Preamble.pdf>.

- Quantifying all health effects, including those that cannot be monetized, is important and provides valuable information to decision-makers (this principle is currently included on page 43, but it is a point that should be made earlier and in conjunction with the following principles);
- Quantifying effects, even when they cannot be monetized, is particularly valuable for distributional analysis and assessment of whether a regulation marks progress towards environmental justice; and
- All identified health effects that may be reduced by a regulation, including those with uncertain evidence (e.g., those judged to have “suggestive” evidence) should be included and quantified in benefits analysis.⁴²

The circular should also incorporate discussion of methods for estimating dose-response relationships to be used in quantifying health effects. Agencies often state that effects cannot be quantified based on an attachment to familiar customary methods that do not support quantification, when dose-response assessment methods and data are in fact available.⁴³ The first priority should be to use dose-response relationships derived from epidemiologic studies when suitable data are available; meta-analysis should be applied when multiple studies are available and amenable to meta-analysis.^{44,45,46,47} When data from human studies are not available, use of dose-response data from animal studies is an acceptable and recommended approach. Animal data can be modeled to a point of departure (as is done in current customary methods), and probabilistic methods should then be used for extrapolation to estimate risks at lower doses, using for example methods recommended by the National Academies and the World Health Organization and demonstrated in multiple published case studies.^{48,49,50,51,52,53}

The Circular should also discuss the policy implications of a failure to quantify health effects. In many instances the quantified health effects are associated with fatality and occur more frequently in older populations (e.g., cancer, particulate matter mortality) and the effects that remain unquantified are usually non-fatal but may have important impacts on quality of life, especially for children (including several health outcomes with important disparities by race/ethnicity and income, such as low birth

⁴² McGartland A, Revesz R, Axelrad DA, Dockins C, Sutton P, Woodruff TJ. [Estimating the health benefits of environmental regulations](#). *Science*, 2017 August 4;357(6350):457-458. doi:10.1126/science.aam8204.

⁴³ McGartland A, Revesz R, Axelrad DA, Dockins C, Sutton P, Woodruff TJ. [Estimating the health benefits of environmental regulations](#). *Science*, 2017 August 4;357(6350):457-458. doi:10.1126/science.aam8204.

⁴⁴ Lam J, Koustas E, Sutton P, Padula AM, Cabana MD, Vesterinen H, Griffiths C, Dickie M, Daniels N, Whitaker E, Woodruff TJ. Exposure to formaldehyde and asthma outcomes: A systematic review, meta-analysis, and economic assessment. *PLoS One*. 2021 Mar 31;16(3):e0248258.

⁴⁵ Lam J, Lanphear BP, Bellinger D, Axelrad DA, McPartland J, Sutton P, Davidson L, Daniels N, Sen S, Woodruff TJ. Developmental PBDE Exposure and IQ/ADHD in Childhood: A Systematic Review and Meta-analysis. *Environmental Health Perspectives*, 2017 August 3;125(8):086001. doi:10.1289/EHP1632

⁴⁶ Johnson PI, Sutton P, Atchley DS, Koustas E, Lam J, Sen S, Robinson KA, Axelrad DA, Woodruff TJ. The Navigation Guide—Evidence-Based Medicine Meets Environmental Health: Systematic Review of Human Evidence for PFOA Effects on Fetal Growth. *Environmental Health Perspectives*, 122(10):1028–1039

⁴⁷ Axelrad DA, Bellinger DC, Ryan LM, Woodruff TJ. Dose-response relationship of prenatal mercury exposure and IQ: An integrative analysis of epidemiologic data. *Environmental Health Perspectives*, 2007 April; 115(4):609–615.

⁴⁸ National Academies of Sciences. *Toward a Unified Approach to Dose-Response Assessment*. In: *Science and Decisions: Advancing Risk Assessment*. Washington, DC: The National Academies Press; 2009. p. 127–87.

⁴⁹ WHO/IPCS. *Guidance Document on Evaluating and Expressing Uncertainty in Hazard Characterization*. World Health Organization/International Programme on Chemical Safety; 2017.

⁵⁰ Chiu WA, Axelrad DA, Dalajamts C, Dockins C, Shao K, Shapiro AJ, et al. Beyond the RfD: Broad Application of a Probabilistic Approach to Improve Chemical Dose-Response Assessments for Noncancer Effects. *Environ Health Perspect*.

⁵¹ Nielsen GH, Heiger-Bernays WJ, Levy JJ, White RF, Axelrad DA, Lam J, Chartres N, Abrahamsson DP, Rayasam SDG, Shaffer RM, Zeise L, Woodruff TJ, Ginsberg GL. Application of probabilistic methods to address variability and uncertainty in estimating risks for non-cancer health effects. *Environmental Health* 21 (Suppl 1), 129 (2023). doi:10.1186/s12940-022-00918-z

⁵² Blessinger T, Davis A, Chiu WA, Stanek J, Woodall GM, Gift J, Thayer KA, Bussard D. Application of a unified probabilistic framework to the dose-response assessment of acrolein. *Environ Int*. 2020 Oct;143:105953. doi: 10.1016/j.envint.2020.105953.

⁵³ Ginsberg GL. Cadmium risk assessment in relation to background risk of chronic kidney disease. *J Toxicol Environ Health A*. 2012;75(7):374–90.

weight, preterm birth, birth defects, neurodevelopmental effects, asthma and other respiratory effects, etc.). To the extent that quantified and monetized effects tend to have more influence on agency decisions than unquantified effects, the failure to quantify non-fatal effects may result in emphasis of actions that protect aging populations and inappropriately undervalue actions that protect children's health and reduce non-fatal effects with important health disparities across all lifestages. Circular A-4 should discuss how expanded quantification of health effects will better inform agency priorities for regulatory attention and reduce any potential bias away from policies that address unquantified non-fatal outcomes.

Regarding monetization of effects, the Circular does not discuss cost-of-illness studies. For many health effects addressed by environmental regulations, willingness-to-pay studies are not available. In many cases, cost-of-illness studies are available and are a suitable proxy for willingness-to-pay, although likely to underestimate willingness-to-pay due to the omission of quality-of-life impacts. While cost-of-illness studies are not conceptually equivalent to willingness-to-pay, they are far preferable to the implicit assumption that health outcomes lacking a willingness-to-pay study effectively have a value of zero and are entirely excluded from monetized benefits. OMB's exclusion of cost-of-illness contrasts with the Circular's encouragement of the use of quality-adjusted life years (QALYs) in regulatory analysis, particularly as the Institute of Medicine concluded that QALYs are not consistent with willingness-to-pay.⁵⁴ Chapter 7 of EPA's *Guidelines for Preparing Economic Analyses* provides a useful discussion of cost-of-illness that should be incorporated into the revised Circular A-4. When using cost-of-illness studies, agencies should be very clear regarding how they differ from willingness-to-pay studies and the strengths and limitations of each. The Circular should also encourage agencies to apply adjustments to cost-of-illness estimates to account for the difference between these values and willingness-to-pay.

b. The draft Circular A-4 revision appropriately highlights the inclusion of uncertain effects in benefit-cost analysis. This is particularly important for estimating the benefits of health risk reductions.

The revised Circular's Section 11, *Treatment of Uncertainty*, includes this critical point:

An effect of a regulation should not be excluded from a regulatory analysis simply because its estimation is highly uncertain. There may be other reasons to exclude effects (e.g., because the size of the effect is negligible). But even for highly uncertain effects, it is often possible to use available evidence to produce estimates of those effects for inclusion in a regulatory analysis that are more accurate than assuming uncertain effects do not occur or have no benefits or costs. Moreover, inclusion of uncertain effects is necessary for the robustness of a regulatory analysis when those uncertain effects are an important contributor to the benefits, costs, and transfers of a regulation.⁵⁵

A problematic approach frequently applied in benefits analysis is to quantify and monetize only those health effects judged to have strong evidence. For example, the U.S. Environmental Protection Agency's approach to benefits analysis for criteria air pollutants does not include quantification of health effects

⁵⁴ Institute of Medicine (IOM). 2006. *Valuing Health for Regulatory Cost-Effectiveness Analysis*. Washington, DC: The National Academies Press.

⁵⁵ Office of Management and Budget. Circular A-4, Regulatory Analysis. Draft for Public Review, p. 66, April 6, 2023. <https://www.whitehouse.gov/wp-content/uploads/2023/04/DraftCircularA-4.pdf>.

judged to have “suggestive” evidence.^{56,57} A suggestive evidence determination indicates a non-zero probability of an effect, but exclusion of a suggestive effect from quantified benefits implicitly assumes that there is zero probability of the effect occurring and that exposed populations do not have any willingness-to-pay to avoid an effect where the evidence is uncertain. The consequence is an underestimate of expected benefits, and in some instances (for example, cardiovascular disease mortality from arsenic in drinking water), the excluded benefits can be substantial.⁵⁸ Effects with suggestive evidence may often correspond to those for which important health disparities exist, and thus excluding these effects from the quantified benefits narrows the potential opportunities to evaluate and address inequities. The revised Circular A-4 should specifically state that health effects with ambiguous evidence should be included in benefits analysis instead of being disregarded.

c. Circular A-4 should direct agencies to use systematic review methods for identifying and evaluating valuation studies.

Systematic review methods adapted from clinical medicine are increasingly being used by federal agencies for assessment of health and safety risks, following important recommendations from the National Academies, as they have been shown to provide a less biased, more comprehensive and transparent evaluation of the evidence.^{59,60,61,62,63,64} Key elements of systematic review methods include: pre-specifying methods in a published protocol; a comprehensive search of the literature for relevant evidence; assessing risk of bias (also referred to as internal validity) in the relevant studies; and procedures for synthesizing and integrating evidence from multiple studies. Systematic review does not eliminate the need for professional judgment, but it provides a framework to minimize bias and to provide clear documentation and rationales for key decisions. Revised Circular A-4 should direct agencies to adopt systematic review methods for relevant elements of benefits analysis, after allowing some period of time (perhaps up to 18 months) for development and training. To promote timely and consistent implementation, it may be useful for OMB to convene workshops on application of systematic methods to benefit-cost analysis, with an initial focus on preparing protocols and planning risk of bias assessments of valuation studies.

Systematic review procedures would represent a significant improvement to current practices outlined in the draft revised Circular for identifying and evaluating studies that may be used for monetizing benefits. A particularly needed development offered by systematic review is the pre-specification of methods for

⁵⁶ McGartland A, Revesz R, Axelrad DA, Dockins C, Sutton P, Woodruff TJ. [Estimating the health benefits of environmental regulations](#). *Science*, 2017 August 4;357(6350):457-458. doi:10.1126/science.aam8204.

⁵⁷ U.S. EPA. Control of Air Pollution from Motor Vehicles: Tier 3 Motor Vehicle Emission and Fuel Standards Final Rule. Regulatory Impact Analysis. EPA-420-R-14-005, 2014, Table 8-5.

⁵⁸ Clewell HJ, Crump KS. Quantitative Estimates of Risk for Noncancer Endpoints. *Risk Analysis*, April 2005, 25(2):285-289. <https://doi.org/10.1111/j.1539-6924.2005.00589.x>

⁵⁹ National Academies of Sciences Engineering, and Medicine. (2017). Application of Systematic Review Methods in an Overall Strategy for Evaluating Low-Dose Toxicity from Endocrine Active Chemicals. Washington, D.C.: The National Academies Press

⁶⁰ National Research Council. (2014). Review of EPA's Integrated Risk Information System (IRIS) Process. Washington, DC: The National Academies Press; 2014.

⁶¹ Institute of Medicine. (2011). Finding what works in health care: Standards for systematic reviews. <https://www.ncbi.nlm.nih.gov/books/NBK209518/>

⁶² National Academies of Sciences Engineering, and Medicine. (2018). Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation. Washington, DC: The National Academies Press; 2018.

⁶³ U.S. EPA. ORD Staff Handbook for Developing IRIS Assessments (2022). U.S. EPA Office of Research and Development, Washington, DC, EPA/600/R-22/268, 2022.

⁶⁴ National Toxicology Program Office of Health Assessment and Translation. Handbook for Conducting a Literature-Based Health Assessment Using OHAT Approach for Systematic Review and Evidence Integration. National Institute of Environmental Health Sciences; 2015.

evaluating valuation studies, as a more formal, consistent, and transparent approach would increase clarity regarding the selection of studies and their strengths and limitations. The revised Circular A-4 should re-work the current lists of principles for evaluating valuation studies into recommended domains for risk of bias assessment and should direct agencies to specify their methods for evaluating studies before searching the literature to identify candidate studies. These revisions should be applied in the Circular's sections on *Appropriate Use of Revealed Preference Methods*, *Appropriate Use of Stated Preference Methods*, and *Benefit Transfer Methods*, as well as in new text that should be added to Circular A-4 regarding the use of cost-of-illness studies for monetizing benefits.

3. Circular A-4 should incorporate expanded discussion of how considerations like imperfect information and advancing equity can justify the need for federal regulatory action.

Circular A-4 discusses several considerations that may be used to justify regulatory action in Section 5, *Identifying the Need for Federal Regulatory Action*. The identified considerations appropriately include "correcting market failure...promoting distributional fairness and advancing equity; and protecting civil rights and civil liberties or advancing democratic values."⁶⁵ Several enhancements would improve this important section of the Circular, particularly concerning treatment of imperfect information and advancing equity.

This section of Circular A-4 should incorporate the principles stated in the Presidential Memorandum on Regulatory Review that regulations are intended to "promote public health and safety, economic growth, social welfare, racial justice, environmental stewardship, human dignity, equity, and the interests of future generations."⁶⁶

a. Revised Circular A-4 should expand its discussion of imperfect information to recognize the limitations of information strategies for addressing toxic chemicals.

Imperfect information is an important externality in many circumstances warranting regulation to protect health and safety, but the draft Circular does not address this issue in sufficient detail. An early passage in Section 5, *Identifying the Need for Federal Regulatory Action* presents the standard theoretical economics concept of addressing externalities through bargaining:

In theory, if bargaining were costless and all property rights were well defined, fully informed people could eliminate externalities through bargaining without the need for government regulation. From this perspective, externalities can arise from high transaction costs or poorly defined/costly to enforce property rights that prevent people from reaching efficient outcomes through market transactions.⁶⁷

This text briefly touches on the issue of imperfect information by referencing "fully informed people," but the following sentences that point out how the bargaining concept frames the identification of externalities makes no mention of the issue. This paragraph should be revised to highlight how

⁶⁵ Office of Management and Budget. Circular A-4, Regulatory Analysis. Draft for Public Review, April 6, 2023. <https://www.whitehouse.gov/wp-content/uploads/2023/04/DraftCircularA-4.pdf>.

⁶⁶ Presidential Memorandum of January 20, 2021 (Modernizing Regulatory Review). Sec. 2. Implementation.

⁶⁷ Office of Management and Budget. Circular A-4, Regulatory Analysis. Draft for Public Review, p. 16, April 6, 2023. <https://www.whitehouse.gov/wp-content/uploads/2023/04/DraftCircularA-4.pdf>.

imperfect information (e.g., regarding health risks from chemical exposures) creates an externality that cannot be appropriately addressed by bargaining or other market transactions.

Section 5.a.iii. of the draft revised Circular on *Asymmetric or Imperfect Information* should be expanded to address critical issues regarding chemical exposures and other health and safety risks where market transactions are subject to information externalities. For example, individual purchasing decisions by consumers who wish to avoid products containing hazardous chemicals do not provide sufficient protection of consumers from health risks. A consumer with concerns about chemicals in a single product category does not have sufficient ability to make informed purchasing decisions given the complexity of assessing and quantifying health risks and the lack of information regarding product formulations. Given the thousands of chemicals contained in thousands of consumer products, even full disclosure of product formulations (which is not the current situation) would not be sufficient to overcome the imperfect information externality created by the complexity of risk estimation and the many purchasing decisions made by each household; the burden on consumers to read, understand, and act on risk information for every product they buy would be overwhelming and places an undue burden on the consumer. It is therefore unrealistic to expect that consumer purchasing decisions can appropriately reduce health and safety risks, and the Circular should recognize this aspect of imperfect information as an important justification for regulatory action. These issues are touched on later in the draft Circular (*Benefits and Costs Arising from Imperfect or Asymmetric Information*, p. 56) with a discussion of “information overload,” but should also be included in the earlier section on *Identifying the Need for Federal Regulatory Action* (p. 15).

The 2003 Circular A-4 includes this language regarding complex information:

When it is time-consuming or costly for consumers to evaluate complex information about products or services (e.g., medical therapies), they may expect government to ensure that minimum quality standards are met.⁶⁸

This language does not appear in the draft revised Circular, but it is pertinent to health risks from toxic chemicals. Consumers often assume that products on the market have been tested and reviewed for safety⁶⁹ – expecting that if it is a product they can buy, it must be safe. This amplifies the asymmetric or imperfect information externality and should be included in the revised Circular.

b. The draft Circular A-4 section on promoting distributional fairness and advancing equity as a justification for regulations is inadequate.

The draft Circular recognizes “Promoting Distributional Fairness and Advancing Equity” as a justification for regulatory action, but the section on this topic consists of only the following brief paragraph:

Regulations can play a key role in promoting distributional fairness and advancing equity. Such regulations are sometimes issued pursuant to statutes that reflect congressional determinations that advancing these goals serves a compelling public need. For example, some statutes create social welfare programs, such as Medicaid, Medicare, and the Supplemental Nutrition

⁶⁸ Office of Management and Budget. Circular A-4, Regulatory Analysis. *Inadequate or Asymmetric Information*, p. 5. September 17, 2003

⁶⁹ Ian M. Urbina, “Think Those Chemicals Have Been Tested?” New York Times, April 13, 2013. <https://www.nytimes.com/2013/04/14/sunday-review/think-those-chemicals-have-been-tested.html>

Assistance Program. Congress has enlisted agencies to implement these programs, including through agency regulations that help determine who is eligible for program benefits and what sorts of benefits they may receive under which circumstances.⁷⁰

This paragraph fails to recognize the role of environmental regulations in promoting distributional fairness and advancing equity by ameliorating the contribution of chemicals and pollutants to health inequities. As noted above, the Presidential Memorandum on Modernizing Regulatory Review of January 20, 2021, identified equity as an objective of regulatory policy, calling on OMB

to ensure that regulatory initiatives appropriately benefit and do not inappropriately burden disadvantaged, vulnerable, or marginalized communities.⁷¹

E.O. 14096 directs agencies to use their statutory authorities to address environmental justice and disparities in health risks:

Each agency shall... evaluate relevant legal authorities and, as available and appropriate, take steps to address disproportionate and adverse human health and environmental effects (including risks) and hazards...including those related to climate change and cumulative impacts of environmental and other burdens on communities with environmental justice concerns.⁷²

E.O. 14096 directs the EPA Administrator to

provide recommendations on legislative, regulatory, or policy options to advance environmental justice in Federal decisionmaking.⁷³

Use of the relevant legal authorities to address environmental justice, as envisioned by the Executive Order, will necessarily include regulatory authorities. As discussed above, health disparities in the U.S. are extensive and well-documented, and many health and safety regulations provide meaningful opportunities to address and reduce these inequities. Several environmental statutes direct or allow the U.S. EPA to take health equity into account in assessment and managing health risks; for example, the Toxic Substances Control Act requires protection of susceptible subpopulations.⁷⁴ The important role of environmental regulations in promoting fairness and equity and in responding to E.O. 14096 should be incorporated into this section of the revised Circular.

⁷⁰ Office of Management and Budget. Circular A-4, Regulatory Analysis. Draft for Public Review, p. 19, April 6, 2023. <https://www.whitehouse.gov/wp-content/uploads/2023/04/DraftCircularA-4.pdf>

⁷¹ Presidential Memorandum of January 20, 2021 (Modernizing Regulatory Review). Sec. 2. Implementation.

⁷² Executive Order 14096. Revitalizing Our Nation's Commitment to Environmental Justice for All. Sec. 3. Government-Wide Approach to Environmental Justice. 88 FR 25251, April 26, 2023.

⁷³ Executive Order 14096. Revitalizing Our Nation's Commitment to Environmental Justice for All. Sec. 3. Government-Wide Approach to Environmental Justice. 88 FR 25251, April 26, 2023.

⁷⁴ U.S. Environmental Protection Agency, EPA Legal Tools to Advance Environmental Justice, May 2022.