



June 16, 2023

The Honorable Richard L. Revesz
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
The White House
Washington DC 20503

Re: Comments on proposed Circular A–4 “Regulatory Analysis”¹
Document ID: OMB-2022-0014-0001; Federal Register Number: 2023-07364

Dear Administrator Revesz:

The American Lung Association appreciates the Office of Management and Budget’s work to enhance the federal regulatory process and the opportunity to comment on the draft Circular A-4. Our organization’s mission is to save lives by improving lung health and preventing lung disease, including by advocating for federal rules to reduce threats to lung health from tobacco, air pollution and climate change and to expand prevention and treatment. Decades of research shows that the benefits of these types of policies dramatically outweigh their costs, and we strongly support the many ways that the draft could result in better accounting of health benefits when conducting regulatory analysis for proposed regulations.

Below we offer general comments followed by specific comments addressing different sections of the draft.

The American Lung Association strongly supports engaging the broader public from the outset – those affected by the regulation and those unaffected but with expertise, special knowledge, or insight into the regulatory issues under consideration. Continued consultations will allow for more comprehensive analyses. For example, many communities experience disproportionate exposure to harmful emissions from nearby air pollution sources such as power plants and industrial facilities. Because these communities are also often underserved, they may lack access to air monitoring to quantify the scope of the problem. Similar communities are disproportionately targeted by tobacco companies, and the death and disease ripple across their communities. In cases such as these, members of the affected communities themselves have

¹ Proposed Circular: <https://www.whitehouse.gov/wp-content/uploads/2023/04/DraftCircularA-4.pdf>; preamble to the proposed Circular: <https://www.whitehouse.gov/wp-content/uploads/2023/04/DraftCircularA-4Preamble.pdf>;

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irreplaceable knowledge of local impacts that can and should inform OMB review.

Early engagement is also important when viewed in the context of OMB and OIRA's broader effort to increase transparency in the rulemaking process, because these efforts support one another. Engaging members of the public at the analysis stage can then help ensure broader participation in 12866 meetings.

We appreciated that the proposed changes offer agencies flexibility in approaches to adequately account for socio-temporal impacts of regulations under consideration, but they must also ensure consistency across agencies in the approaches they adopt. Agencies must also ensure transparency at all stages in conducting regulatory analyses and in developing proposed and alternative regulations (while adequately ensuring patient privacy when working with studies that deal with confidential patient information.) For health-related regulations, the agencies should provide clear and substantiated rationale and justification for preferring and proposing specific aspects of a regulation when the alternatives analyzed clearly show greater net benefits.

We note, as does the draft A-4, that the OMB requirement of a regulatory analysis with benefit-cost analysis (BCA) as the primary analytical tool contrasts with statutory requirements in some cases. For example, in the setting of the National Ambient Air Quality Standards (NAAQS) under the Clean Air Act, the U.S. Environmental Protection Agency (EPA) cannot use economic impacts to determine the health- or welfare-based standards. The Family Smoking and Tobacco Control Act requires the Food and Drug Administration to make determinations based on what is "appropriate for the protection of the public health." In such instances, the regulatory analyses required by OMB must not supersede the statutory requirements or lead to delaying or weakening of regulations under consideration.

The Lung Association also advises that OMB and regulatory agencies take care when doing regulatory and benefit-cost analysis on addictive products like tobacco products to avoid problematic concepts that might add to the cost, like lost smoking pleasure from stopping smoking or use of tobacco products. Being addicted to a product overrides a consumer's ability to make a rational choice, and any pleasure derived could be due to the physical addiction. Ultimately, the death and disease caused by tobacco use and protecting the public health must be the guiding principle to FDA's decisions.

Specific comments on key sections of the draft A-4 follow:

2. Analytical Approaches

The guidance advises that "agencies should select those alternative regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity.)" We appreciate the draft's consideration that not all benefits are quantifiable or can be

monetized, and that accounting for these benefits cannot be achieved with a "one size fits all" process. Examples of benefits that are difficult to quantify or monetize abound with regard to clean air regulations: EPA's models typically monetize only a subset of air pollutants from the power, industrial and transportation sectors, with other impacts – such as brain damage from mercury exposure in utero, for instance, or new cancer cases from some airborne toxics – clearly worth factoring into OMB analysis despite the fact that they are not currently monetized.

We also strongly support the continued practice of ensuring that all benefits including so-called "co-benefits" are considered among benefits. Federal rules that make multiple improvements at once, or whose benefits extend beyond the immediate problem regulated while still remaining in the boundaries of the statute governing them, are a success story.

Some benefits can accrue over time that is beyond regulatory consideration or show additionality that may not be accounted for in the analysis (for example, more stringent National Ambient Air Quality Air Standards leading to better air quality leading to better health outcomes during unexpected events like the Covid pandemic). These should be factored into estimating public health benefits in BCAs. We further note that in addition to many benefits being difficult to quantify leading to likely underestimations of benefits, estimated compliance costs are often much lower than initially projected.

3. Scope of Analysis

With regard to Temporal Scope of Analysis, the draft notes, "The time frame for your analysis should include a period before and after the date of compliance that is long enough to encompass all the important benefits and costs likely to result from the regulation." Some regulations, e.g. NAAQS revisions (review, revision, and implementation of updated standards) involve very long timeframes of many years. Even with full compliance and robust enforcement, the benefits of the new regulation may not be fully realized across all parts of the country for more than a decade. The timeline of analysis should account for this. Given such durations, regulatory impact analyses including BCAs and Cost-Effectiveness Analyses (CEAs) are fraught with uncertainties and have to rely on multiple assumptions. These uncertainties and assumptions must be clearly specified in the Regulatory Impact Analyses (RIAs).

Impacts of climate change and other externalities must also be incorporated in analyses to the extent possible. For example, warming temperatures impose a "climate penalty" that drives higher levels of ground-level ozone air pollution than would have occurred in the absence of climate change, an important consideration when calculating benefits of reducing greenhouse gases.

7. Developing Benefit and Cost Estimates

The draft circular notes that agencies should "propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs." Net benefits do not need to equal or exceed costs in the preferred alternative regulation. When net benefits of proposed and alternative standards/provisions of a proposed regulation are tabulated, those standards/provisions that offer the most benefits in the BCA are expected to be proposed in the published rule and adopted in the final rule. If the regulatory agency does not do so, then it must offer detailed justification and rationale in its less beneficial rulemaking among the alternatives considered.

10. Distributional Effects

The draft notes, "agencies may choose to conduct a benefit-cost analysis that applies weights to the benefits and costs accruing to different groups to account for the diminishing marginal utility of goods when aggregating those benefits and costs." We strongly support this proposed option. Benefits of an environmental or health regulation are not uniformly distributed across different demographics, even if costs are. Because of the diminishing marginal utility of income/wealth where gains in utility taper off with rising income, using income-weighted or wealth-weighted measures of benefits and costs can help address socioeconomic inequities and disparities. Conducting BCAs with such weighted distributions could address environmental injustice and/or health inequities by ensuring an equitable realization of all benefits of these regulations across marginalized subpopulations and would also help assess the effectiveness of other related policies and programs among such populations.

With this change, for example, a proposal could significantly reduce out-of-pocket costs for patients with chronic conditions that disproportionately impact certain demographic groups but slightly increase premiums for higher income individuals.

12. Discount Rates

We acknowledge the value of using discount rates to compare contemporaneous costs to future benefits. We support updating the social discount rate from the current 3% to the proposed 1.7% based on updated data from the most recent 30 years, although we note as the draft notes that this measure is less reflective of the impacts of climate change on future generations. We therefore support the approach of incorporating a declining discount rate schedule explicitly in the circular to better account for these long-reaching impacts. Individual investment decisions may well not adequately account for the farther-reaching impacts of climate change (although many impacts are not a generation in the future but happening now.) For both immediate term impacts and on a declining basis for long term impacts, a lower discount rate will significantly improve the accuracy of the Social Cost of Carbon to adequately account for climate impacts in federal rulemaking.

We also note that they are *ex ante* estimates based on forecasts rather than factual or measured data.

Regarding accounting for effects on capital, we support the use of the “analytically preferred” method of “shadow price of capital.” This approach accounts for the higher investment rate of return where costs displacing capital investments are converted to consumption-equivalent values. It also allows for consistent measurement of impacts on households in terms of their consumption over time so that all costs and benefits are appropriately discounted at the consumption discount rate.²

For example, investments in preventive care like vaccinations, cancer screenings, and tobacco cessation will result in savings many years in the future. The proposed changes to the discount rate will help to ensure that the benefits of proposed policy changes that improve access to and utilization of preventive care are more fully included in regulatory analyses.

Thank you for the opportunity to comment on these important reforms. We urge you to finalize an updated Circular A-4 that helps ensure agencies better account for the health benefits of regulations.

² Newell, R. G., Pizer, W. A. & Prest, B. C. (Nov, 2022). The Shadow Price of Capital: Accounting for Capital Displacement in Benefit-Cost Analysis. *Resources for the Future*, Issue Brief 22-08.