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May 28, 2002

ATTN: Mr. John Morrall
Office of Information and Regulatory Affairs
Office of Management and Budget
New Executive Office Building, Room 10235
725 17th Street, N.W.
Washington, D.C. 20503

RE: Competitive Enterprise Institute Comments on the Draft Report to Congress on the Costs and Benefits of Federal Regulation, 67 Fed. Reg. 67, 15014 (March 28, 2002).

SUMMARY OF CEI COMMENTS: CEI's comments cover the following four areas.

Consumers' Right to Know: CEI has long advocated the consumer's "Regulatory Right to Know." Consumers benefit from information that helps them understand how regulations affect them personally. To that end, OIRA's report should provide cost information in a format that makes it comprehensible to consumers.

Department and Agency Assumptions: Congress mandated that OIRA provide an independent report on the costs and benefits of federal regulations. For this report, OIRA uses department/agency estimates, which contain department/agency biases and are not consistent between departments. In addition to working with agencies to standardize and improve procedures, OIRA's report should attempt to adjust figures to make them more suitable for cross-departmental comparisons.

Regulatory Impacts: One of CEI's key programs is our "Death by Regulation" project. With this project, we point out that, while a regulation may be designed to help people, it can also have adverse impacts. Currently agencies evaluate the cost to business for compliance, but they do not seem to make an effort to evaluate whether the regulations themselves might produce adverse consequences. Those consequences should be weighed against the benefits portion of the regulatory impact analysis along with other costs.

Recommendations for Review: Following the general comments offered in this letter, CEI analysts answer OIRA's call for suggestions on ways to improve existing agency regulations.

Consumers' Regulatory Right to Know

While most Americans understand the impact of tax policy on their income and eventually their quality of life, few understand the cost of regulation. The congressional mandate that OIRA produce a report on the costs and benefits of federal regulations should not only inform members of Congress, it should educate the public on the impacts of regulations. The most critical element of this task involves providing data in terms that the public understands. Instead of providing aggregate numbers alone, OIRA could also break those numbers down into more understandable terms. For example, it could identify:

Costs of federal regulation per household; including the total cost of regulation per household and the costs for various categories of regulation to each household.
Estimates on the cost of certain types of mandates, such as paperwork burdens.
Costs to small business.
Costs to state and local governments.

Department and Agency Assumptions

Various agencies do not use standard techniques for cost and benefit assessments, which begs the question as to which procedures are most accurate. Are some agencies employing procedures that exaggerate risks or are others underplaying risks? How can OIRA make cross comparisons between agencies when each employs different methodologies? In its draft report to Congress, OIRA relies mostly on department and agency estimates for costs and benefit estimates. However, OIRA has indicated that it recognizes the pitfalls with that approach and that it would like to improve department and agency estimates.

As OIRA reports on the costs of existing regulations, it should work to make some improvements that would at least inform the public of the limitations of existing estimates and the difficulty in comparing costs across agencies. In its 2001 comments to OMB, the Mercatus Center offered some constructive ways of addressing this dilemma. Mercatus recommended that OIRA offer some of its own best estimates employing standardized methodologies. OIRA would not be able to fully reassess all past regulations, but efforts to adjust some using standardized techniques would improve its analysis. The Mercatus Center also suggested that OIRA consider ranking agencies on their cost and benefit procedures to highlight which agencies use better analysis and which are weaker. Such an analysis would help consumers better understand the limitations of the estimates and it would encourage agencies to strive to meet a higher standard and comply more consistently with OMB guidelines (promoting better procedures as well as greater consistency among the departments).

When reviewing pending regulations (as well as existing regulations that OIRA is considering for reform), OIRA has much more leeway to improve benefit calculations and to demand the best science. In particular, OIRA should pay close attention to EPA benefit calculations. The EPA tends, perhaps more than any other agency, to overstate the risks, and

hence it produces higher benefits from regulating those risks. While each regulation may seem to make sense on its own, the questionable attributes of EPA benefit calculations become very apparent when EPA claims about "lives saved" or "cancers prevented" are viewed in the aggregate.

Scientist Michael Gough demonstrates that the total number of cancers that the EPA could possibly regulate is much smaller than the number of lives that EPA benefit calculations indicate that regulations save. Gough analyzed the data found in the landmark study of Sir Richard Doll and Richard Peto on the causes of cancer[1] along with EPA estimates of cancer risks estimated in EPA's report *Unfinished Business*.[2] Like Doll and Peto, Dr. Gough found that between 2 and 3 percent of all cancers could be associated with environmental pollution.

Accordingly, Gough reported that the EPA action can only address a very small percentage of cancers: "If the EPA risk assessment techniques are accurate, and all identified carcinogens amenable to EPA regulations were completely controlled, about 6,400 cancer deaths annually (about 1.3% of the current annual total of 435,000 cancer deaths) would be prevented. When cancer risks are estimated using a method like that employed by the Food and Drug Administration (FDA), the number of regulatable cancers is smaller, about 1,400 (about 0.25%)."

These findings raise serious doubts about EPA benefit estimates, which claim to reduce thousands of cancer deaths annually. For example, the upper-bound estimate for just one EPA regulation suggests that one drinking water contaminant alone — byproducts from chlorination — could prevent 2,040 annual cancer deaths. That number seems very unrealistic given that it is higher than the total number of EPA regulatable cancers that Gough found using FDA techniques for estimating such risks and that it is nearly one third of regulatable cancers using EPA risk assessment techniques.[3]

A key reason for EPA's inflated figures emanates from its reliance on questionable science. OMB has wisely called for reliance on the "best available, peer reviewed science" and for a strong scientific review process. Its desire for sound science is commendable, but it is reasonable to argue that the scientific process is broken and that it will take a great deal of effort to even begin repairs. For example, OMB identifies the process for reviewing the standard for arsenic in drinking water as a model of sound scientific review. But before following that model, OMB might want to reconsider whether the process is indeed sound. Some would argue that it exemplifies problems with a process more dominated by politics than science.

The scientific process for arsenic included two EPA-initiated National Research Council (NRC) reviews of the EPA risk assessment on arsenic. CEI provided comments to the NRC at a

[1] Richard Doll and Richard Peto, "The Causes of Cancer: Quantitative Estimates of Avoidable Risks of Cancer in the United States Today," *Journal of the National Cancer Institute* 66, no. 6 (June 1981): 1257.
[2] U.S. Environmental Protection Agency, *Unfinished Business: A Comparative Assessment of Environmental Problems*, Overview Report, February 1987.
[3] 63 Fed. Reg. 69439 (December 16, 1998), Table IV-reads that 17 percent of the 12,500 estimated bladder cancer deaths (2,040) are attributable to disinfection byproducts.

public meeting regarding problems with the NRC's first report.[4] For example, the first report called for a stronger standard (in the executive summary), yet that appears to be at odds with the report's scientific findings. Members of the first review committee expressed to EPA's Office of Congressional Intergovernmental Affairs that they felt pressured into calling for a more stringent standard. Several said that they did not agree a more stringent standard was necessary; none of these scientists were invited to return for the second panel. The report also included statistical risk analysis on data that the report authors said was of poor quality, and it noted that the analysis should not be used to support the regulation because it was for illustrative purposes only (to show how the models worked). But these analyses were used to back the regulation. In addition, without even running a model, the NRC speculated that risks could be as high as 1 in 100. Advocates of the regulation characterized that speculation as definitive NRC conclusion, which helped create political pressure for a higher standard.

The review and 2001 Update report did not shed new light onto the issue and many expressed concern that the agency did not consider the full range of information. In addition, the Small Business Administration pointed out serious flaws to the process, including the fact that the NRC does not follow the same transparency rules required by government agencies.[5] Members of the committee were largely selected in secret and deliberated in secret. To add insult to injury, the EPA announced that it would keep the more stringent standard on the day that public comments on the topic were due. Clearly, the agency did not even consider the information of those providing public comment. Ironically, one of the key reasons the agency had initiated the review was supposedly related to the fact that the public did not have enough time to comment on the Clinton Administration's midnight regulation.

While OIRA officials may disagree with the above analysis of the arsenic process, CEI does commend them for recognizing the need for better science at federal departments and agencies. Unfortunately, OIRA does have a small staff and a very large job. Hence, the agency's call for greater resources to hire more staff with various areas of technical expertise makes sense.

Regulatory Impacts

Many people consider the cost of regulation as the only trade-off. They assume that even if a regulation doesn't provide benefits, it's not likely to hurt much more than our pocketbooks. But it is critically important to assure that a regulation has a net benefit. That means in addition to assessing the costs of compliance, agencies need to consider whether the regulation will produce other costs to society.

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[4] Angela Logomasini, Comments to the Board of Environmental Studies and Toxicology, National Research Council Updating the 1999 Arsenic in Drinking Water Report, May 21, 2001, http://www.cei.org/gencon/003,02037.cfm.

[5] Testimony of Susan M. Walthall and Kevin L. Bromberg, Office of Advocacy, U.S. Small Business Administration, Review of Arsenic in Drinking Water September 2001 NRC Report, Before the Environment, Technology and Standards Committee, House Science Committee, October 4, 2001.

We can again use the EPA's arsenic standard for drinking water as an example. The agency assessed the costs of water facilities to treat water to remove arsenic. It did not assess whether those costs would encourage communities to disconnect water service, leaving consumers to access water from substandard sources. The agency's own Science Advisory Board (SAB) had advised the agency that such impacts were real possibilities.[6] The SAB also noted that there could be public health losses from a standard that raised costs so high that it would prevent families from putting food on the table or purchasing health insurance.

The AEI-Brookings Joint Center for Regulatory Studies further demonstrated this principle in its cost-benefit analysis of the arsenic standard. Considering the same factors that the SAB addressed, they estimated that the rule could lead to a net loss of 10 lives per year. [7]

During the past year, OIRA's reviews have demonstrated that it understands this principle. CEI applauds that approach and encourages OIRA to continue to apply and expand those efforts. As OIRA includes such considerations in its reviews, it should work to encourage agencies to promote this policy as well.

Thank you for taking the time to read these general comments. The next section provides some ideas of regulations that OIRA might want to consider reviewing.

Sincerely,
Angela Logomasini
Director of Risk and Environmental Policy

[6] EPA Science Advisory Board, *Arsenic Proposed Drinking Water Regulation* (Washington, D.C.: USEPA, December 2000), 18; EPA-SAB-DWC-01-001.
[7] Jason Burnett and Robert W. Hahn, *EPA's Arsenic Rule: The Benefits of the Standard Do Not Justify the Costs*, (Washington, D.C.: AEI-Bookings Joint Center for Regulatory Studies, 2001), Regulatory Analysis 01-02.

CEI Recommendations on Regulatory Review

ATF Restrictions On Alcoholic Beverage Health Claims

Proposed for Review: 64 Fed. Reg. 57,413 (October 25, 1999).

Recommended By: Ben Lieberman, Director of Clean Air Policy and Associate Counsel.

> **Recommendation:** Review Bureau of Tobacco and Firearms ban on labels that inform the public of the benefits of alcohol. The net benefits of allowing truthful health information on alcoholic beverage labels and advertisements are likely to be substantial

On October 25, 1999, the Bureau of Alcohol, Tobacco and Firearms (ATF) proposed a rule that would effectively codify its de facto ban on any mention of health benefits on alcoholic beverage labels and advertisements.[8] Beyond the First Amendment objections to this policy, ATF's proposed rule would deprive the public of potentially beneficial information, thus warranting close scrutiny by OMB.

As discussed in greater detail in the attached regulatory comments (Attachment A) filed with ATF, there is a strong medical consensus that moderate consumption of alcoholic beverages confers significant cardiovascular and other health benefits and reduces overall mortality for the adult population. Among the many published studies demonstrating this causal association are:

- a 1991 *Lancet* study stating that "moderate alcohol consumption reduces the risk of coronary artery disease."
- a 1992 *New England Journal of Medicine* review article on the major means of preventing myocardial infarction, which states that "there is a substantial body of observational epidemiologic evidence to suggest that moderate consumption of alcohol reduces the risk of heart disease."
- a 1994 *British Medical Journal* study concluding that "for most causes of death studied, the mortality was higher in non-drinkers than in light drinkers. . . ."
- a 1997 *New England Journal of Medicine* study concluding that "those who consumed up to one or two drinks of alcohol daily had lower overall mortality rates than nondrinkers."[9]

Even the 1995 edition of the *Federal Guidelines for Americans* stated that "current evidence suggests that moderate drinking is associated with a lower risk for coronary artery disease in some individuals."[10] These guidelines, published by the Departments of Agriculture

[8] 64 Fed. Reg. 57,413 (October 25, 1999).
[9] Michael Gough, "Beneficial Effects of Consumption of Low Levels of Alcohol." December 7, 1998.
[10] USDA and HHS, "Dietary Guidelines for Americans." 1995, at 40.

and Health and Human Services, constitute the government's foremost public statement on nutritional policy."[11]

Nonetheless, ATF, which has regulatory authority over alcoholic beverage labels and advertisements, does not allow the use of any summaries of this information. In a 1993 Industry Circular, the agency explained that it will forbid as misleading any health statements "unless they are properly qualified, present all sides of the issue, and outline the categories of individuals for whom any positive effects would be outweighed by numerous negative health effects."[12] The agency noted that its requirements probably made such claims impossible; in its words, "ATF considers it extremely unlikely that such a balanced claim would fit on a normal alcoholic beverage label."[13] Indeed, ATF presently does not allow any direct or indirect references to health on alcoholic beverage labels or advertisements, and has rejected a number of such statements over the past decade.[14] In its rulemaking, ATF now seeks to codify this restrictive policy.

Cardiovascular disease is the leading cause of death in adult men and women, and moderate drinking has been shown to reduce that risk by at least one third.[15] A *Journal of the American Medical Association* editorial estimated that a mean of 80,000 coronary heart disease deaths could be averted from universal moderate consumption.[16] However, a 1995 poll conducted by the Competitive Enterprise Institute found that the public was not well informed about the health benefits associated with moderate alcohol consumption. Further, studies conducted by the Federal Trade Commission have found that product labeling and advertising is an effective means of communicating health information. Thus, the potential public health benefits of allowing this information on labels and advertisement are significant.

On the other hand, the risks of this information appear to be negligible. Despite ATF's stated concerns that health messages would mislead pregnant women, recovering alcoholics and others into engaging in detrimental drinking behavior, or may confuse the public about the risks of excessive drinking, the evidence indicates otherwise. A 1998 study, conducted for ATF by the federal government's Center for Substance Abuse Prevention (CSAP), evaluated the

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[11] The Guidelines are publishes every five years under 7 U.S.C. Sec. 5341, which states that they "shall be promoted by each Federal agency in carrying out any Federal food, nutrition, or health program."
[12] ATF Industry Circular, "Health Claims In The Labeling And Advertising of Alcoholic Beverages," August 2, 1993, at 4.
[13] Id. at 4.
[14] Among the currently-restricted claims for which approval was sought are: "recent studies suggest that [redacted brand] wine may reduce the risk of heart disease;" "try [redacted brand] with a healthy meal;" "the proud people who made this wine encourage you to consult with your family doctor about the health benefits and risks of moderate wine consumption;" "several medical authorities say that a glass or two of wine enjoyed daily is not only a pleasant experience but can be beneficial to an adult's health;" and "there is significant evidence that moderate consumption of alcoholic beverages may reduce the risk of heart disease."
[15] New England Journal of Medicine, "The Primary Prevention of Myocardial Infarction," May 21, 1992, pp. 1406, 1412.
[16] Journal of the American Medical Association, "What to Advise Patients About Drinking Alcohol," September 28, 1994, at 967.

consumer response to two health statements.[17] It concluded that those exposed to the health claims still had a "[g]eneral understanding: there are risks of alcoholism, and certain conditions would counter indicate wine drinking." Further, in response to ATF concerns about pregnant women, the Director of CSAP stated that "the population studied overwhelmingly understands that drinking is counter-indicated during pregnancy."

Thus, the net benefits of allowing truthful health information on alcoholic beverage labels and advertisements are likely to be substantial. For the above reasons, we believe OMB should carefully review any regulatory attempt by ATF to restrict the flow of this information.

FDA Regulation of New Medical Drugs and Devices That Pose Minimal or No Added Risk

Proposed for review: Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355; 21 CFR Part 200; Medical Device Amendments of 1976, 21 U.S.C. § 360c; 21 CFR Ch. I, subchapter H.

Proposed By: Sam Kazman, General Counsel

> **Recommendation:** In practice, FDA often requires that new therapies be more effective than existing therapies in order to be approved. On occasion, FDA has denied approval to proposed therapies that hold substantial promise and that pose no new risks, due to disputes over whether these therapies were more effective than already-available therapies. In our view, in such cases individual doctors and hospitals should be able to make their own determination of whether to use these new therapies.

Background. The Food and Drug Administration requires that new medical drugs and devices be shown to be safe and effective in order to be approved by the agency.[18]

An Example: A case in point was the decision by FDA's Circulatory Systems Advisory Panel, at a meeting on June 29, 1998, against approval of a medical device known as the Ambu CardioPump. This is a handheld mechanical device used for CPR (cardiopulmonary resuscitation). The CardioPump has a rubber plunger-type device that enables the person administering CPR to actively decompress the patient's chest. By comparison, in conventional (manual) CPR, the patient's chest must decompress spontaneously before it can be compressed again. A number of researchers have found that active decompression via the CardioPump significantly improves certain survival criteria for those suffering out-of-hospital cardiac arrest. See, for example, Plaisance et al., *A Comparison of Standard Cardiopulmonary Resuscitation Versus Active Compression-Decompression For Out-of-Hospital Cardiac Arrest*, New England

[17] Department of Health And Human Services, Center for Substance Abuse Prevention, "The Effect of Wine Labels on Public Perception," January 1998.
[18] Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355; 21 CFR Part 200; Medical Device Amendments of 1976, 21 U.S.C § 360c; 21 CFR Ch. I, subchapter H.

Journal of Medicine 341:599-75 (Aug. 19, 1999); Plaisance et al., *Inspiratory Impedance During Active Compression-Decompression Cardiopulmonary Resuscitation*, Circulation 2000; 100:989 (March 7, 2000). The CardioPump has, in fact, become standard equipment in a number of European ambulance systems.

These findings of efficacy, however, have been disputed by other researchers who found no added benefit from use of the device. This dispute formed the basis for the FDA panel's decision not to approve the CardioPump. But what is not disputed is that the device creates no additional risk. As one critic of the CardioPump stated, "We do not yet know why it appeared to work in one study and not another. We do know that the device has shown no significant adverse effects." Dr. M. Callaham, Professor of Emergency Medicine, University of California at San Francisco, unpublished letter to *Time* Magazine, Dec. 13, 1994.

We submit that, in cases where a proposed therapy shows either no added risk or only minimal added risk, FDA approval should follow when the therapy is shown to be as effective as existing therapies. In such cases, FDA should require proof only of therapeutic equivalence, rather than therapeutic superiority. In the case of the CardioPump, such an approach would allow individual physicians, hospitals and ambulance systems to make their own evaluation of this device, rather than having its availability hinge on a ruling by one centralized decisionmaker.

The Energy Conservation Standard For Clothes Washers

Proposed for Review: 65 Fed. Reg. 59,550 (October 5, 2000); 66 Fed. Reg. 3,314 (January 12, 2001).

Recommended by: Ben Lieberman, Director of Clean Air Policy and Associate Counsel

Recommendation: Reconsider Department of Energy standards for clothes washers.

The 1987 Energy Policy and Conservation Act (the Act) set initial energy conservation standards and created procedures by which the Department of Energy (DOE) may promulgate amended standards for home appliances. The original requirements for clothes washers took effect in 1988, and amended standards took effect in 1994.

Towards the very end of the Clinton administration's second term, DOE hurriedly promulgated substantially tighter amended standards for clothes washers. The January 12, 2001 final rule mandates an additional 22 percent reduction in energy use by 2004 and a 35 percent reduction by 2007.[19] The 2007 standard is estimated by DOE to increase by $249 the average price of a new model, from $421 to $670.[20] Thus, this regulation will raise the cost of a clothes washer by 59 percent.

[19] 65 Fed. Reg. 59,550 (October 5, 2000); 66 Fed. Reg. 3,314 (January 12, 2001).
[20] 65 Fed. Reg. 3,315.

As discussed in the attached petition (Attachment B) for reconsideration filed with DOE, the agency did not adequately consider the costs of this standard, thereby violating several consumer protection provisions in the Act. These provisions require, among other things, that DOE balance the potential energy savings from an amended standard against such factors as "any increase in the price of, or in the initial charges for, or maintenance expenses of, the covered products which are likely to result from the imposition of the standard."[21] The 59 percent price increase, unprecedented in the nearly 15-year history of federal appliance standards, alone casts serious doubt on the economic justification of the new rule. In addition, DOE ignored several other factors, including concerns that the 2007 standard would increase maintenance costs for clothes washers.

The statute also forbids the Secretary of Energy from setting a standard that "is likely to result in the unavailability . . . of performance characteristics (including reliability), features, sizes, capacities, and volumes that are substantially the same as those generally available in the United States at the time of the Secretary's finding."[22] Here, DOE's own technical support documents concede that the 2007 standard would impinge upon clothes washer performance characteristics, but the agency nonetheless promulgated the rule.

The agency also failed to heed its own interpretive rules forbidding standards that would "have adverse impacts on a significant subgroup of consumers (including low income consumers). . . ."[23] Here, DOE did not adequately consider the disproportionate impact on low income households, many of which would have higher opportunity costs and less favorable financing options in paying the higher price of the new model. DOE similarly failed to adequately account for the impact on smaller and senior households, which likely do not do enough laundry loads to earn back the higher first cost in the form of energy savings over the life of the washer.

DOE also overstated the energy savings. Exaggerating the amount of laundry done in an average household, assuming an implausibly long average lifetime of a clothes washer, and using questionable assumptions about electricity costs led to unrealistic claims of net savings for the majority of households. Even so, the agency's admission that 19 percent of households will suffer net costs does hint at the significant anti-consumer potential of this rule.

Further, any claim of "benefits" by mandating ultra-efficient clothes washers should be viewed in light of the fact that several such models are already on the market for those who want them. Thus, the only consequence of the rule is to force high efficiency clothes washers on consumers who don't want them. The agency's interpretive rule obligates it to consider non-regulatory approaches "where it appears that highly efficient products can obtain a significant market share but less efficient products cannot be eliminated altogether because, for instance, of unacceptable adverse effects on a significant subgroup of consumers."[24] Although the facts here

[21] 42 U.S.C. Sec. 6295(o)(2)(B)(i)(II).
[22] 42 U.S.C. Sec. 6295(o)(4).
[23] 10 CFR, Part 430, Subpart C, Appendix A, Sec. 5(e)(3)(G).
[24] 10 CFR, Part 430, Subpart C, Appendix A, Sec. 12.

argue for such non-regulatory approaches (including existing federal appliance labeling programs that identify and promote high efficiency models), DOE did not seriously consider such approaches.

For the above-reasons, CEI believes that OMB should seriously consider the merits of the strict new clothes washer standards.

National Organic Program

Proposed for Review: U.S. Department of Agriculture's National Organic Program, 7 CFR 205

Proposed By: Gregory Conko, Director of Food Safety Policy

> **Recommendation:** USDA promulgated a single national standard for organic production in December 2000. This rule imposes a uniform, highly technical standard on an issue and an industry which are incapable of precise definition. It prohibits USDA-accredited certifiers from requiring practices that are greater, lesser, or in any way different from USDA's uniform standards. It also prohibits non-accredited entities from using the term "organic" to describe food production methods, a restriction on speech that may be unconstitutional. Consumers of organic products would benefit by being able to choose from an array of standards. CEI recommends replacing the USDA National Organic Program with a rule that allows for greater flexibility.

Background: In compliance with the Organic Foods Production Act of 1990, USDA promulgated a single national standard for organic food production in December 2000. The very attempt by USDA to promulgate a rule for the National Organic Program, however, spawned numerous, passionate disputes over the very nature of what the term "organic" actually means. There was no way for USDA to resolve those disputes in any rational manner, however, because they were purely ideological, involving attempts to define a vague concept encompassing issues of global and local ecology, a "holistic approach" to farming, and quality of life. It was as if USDA were attempting to define religious doctrine, a task not suitable for across-the-board determinations by a federal agency.

Furthermore, by prohibiting private parties from operating outside USDA's strictly defined standards, the rule restricts variability and flexibility, jeopardizes competitive forces that foster improvement and innovation, and directly harms consumer choice. Market forces are capable of meeting consumer information demands, as evidenced by the very existence of the organic food industry. USDA views the variety of organic certification schemes that pre-date the National Organic Program final rule as an indication that a uniform federal standard is the only solution.[25] However, CEI argues that this variety instead suggests that consumers actually want varying levels of "organicness." For example, the Demeter Association is a private organic certification agency that has long enforced its own standards for organic foods that are more

[25] 65 Fed. Reg. 13,512.

strict than those permitted under the USDA's National Organic Program. Some consumers seek out Demeter-certified foods for just this reason. But under the National Organic Program rule, the Demeter Association and other organizations are prohibited from meeting that consumer demand.

USDA has interpreted the Organic Foods Production Act as requiring a single, invariable definition of "organic" products, arguing that "[l]ack of a nationwide standard has also created confusion for consumers who may be uncertain what it really means when a food product is called 'organic.'"[26] But there does not appear to be any real evidence that deceptive labeling has been a problem. Gene Kahn, a charter member of the National Organic Standards Board, has said, "It's fair to say that the industry has been self-governing and has, by and large, done a good job."[27] Furthermore, it is not at all clear that the Act prohibits additional flexibly.

Rather than an outright prohibition, USDA could require that labels for foods that do not meet its standards carry a disclaimer, such as "This package does not comply with USDA standards for organic labeling." Similarly, organic certifying agencies that wish to enforce a more stringent standard – which, for example, meets all USDA standards as well as additional standards – might be permitted to carry a label such as "Exceeds all USDA standards for organic labeling." Another approach would be for USDA to establish several easily recognizable levels of organic "quality" or "strictness," such as "organic plus" and "super-organic." In short, USDA can fulfill its obligations under the OFPA while simultaneously permitting private parties to define the term "organic" more flexibly. This would provide consumers with greater choice and producers with greater flexibility.

Premarket Notice for Bioengineed Foods

Proposed for Review: U.S. Food and Drug Administration's Premarket Notice Concerning Bioengineered Foods (Proposed Rule), 66 Fed. Reg. 4706.

Proposed By: Gregory Conko, Director of Food Safety Policy

> **Recommendation:** The Food and Drug Administration published a proposed rule in January 2001 that would require plant breeders to submit data and other information to the agency prior to commercializing new bioengineered plant varieties. This requirement is not scientifically justified, as the risks inherent in bioengineering are the same in kind as the risks inherent in conventional breeding methods. The rule would, however, add needlessly to the cost of using bioengineering techniques to produce new plant varieties. It could also keep potentially beneficial products off the market and raise the price of those that do make it to market. CEI recommends that FDA either not require premarket notification or substantially

[26] See, 65 Fed. Reg. 13,513.
[27] Carole Sugarman, "Organic? Industry is Way ahead of Government," *The Washington Post* (December 31, 1997), p. E1.

revise the proposed rule so that regulatory oversight is focused only on identifiable high-risk products and that it not single out only bioengineered products for heightened scrutiny.

Background: In 1992, the Food and Drug Administration published in the Federal Register its "Statement of Policy: Foods Derived from New Plant Varieties," expanding the agency's interpretation of the Federal Food, Drug and Cosmetics Act with respect to foods derived from new plant varieties, including those developed with recombinant DNA techniques.[28] In this document, FDA acknowledged the broad consensus of numerous scientific bodies that foods derived from bioengineered plants do not pose risks that are in any way unique to the process of bioengineering (also known as rDNA technology). The agency further acknowledged that evaluations of the safety of bioengineered foods did not need to be different than evaluations of the safety of "conventional" foods. In both cases, evaluations were to be based on the "objective characteristics of the food product or its components rather than the fact that new development methods were used." The "Statement of Policy" also offered guidance to plant breeders regarding many of the scientific considerations for evaluating the safety and nutritional aspects of foods from new plant varieties, including those from traditional methods, tissue culture, and rDNA techniques, and it identified certain characteristics that would make any food products subject to heightened regulatory scrutiny.

Then, in January 2001, FDA published a proposed rule requiring producers of plant-derived bioengineered foods or animal feeds (and only bioengineered ones) to notify the agency at least 120 days prior to marketing. Each notification would have to include reams of information about the development and scientific testing of the bioengineered plants in question, and each notifier would be required to make available to FDA upon request any additional relevant data or information not included in the notice. Thus, the nature of this mandatory notification would be such that FDA could exercise a *de facto* premarket approval process solely for bioengineered plant varieties.

This decision runs counter to the scientific consensus that the risks of conventional and bioengineered plants are the same in kind, even though FDA acknowledged in its *Federal Register* notice that it had not identified "any new scientific information that raises questions about the safety of bioengineered foods currently being marketed."[29] More importantly, by focusing regulatory scrutiny on all bioengineered plants and on no conventional plants, it over-regulates many low-risk products and under-regulates some high-risk products.

The primary motivation for the proposed change seems to be that, "because breeders utilizing rDNA technology can introduce genetic material from a much wider ranger of sources than previously possible, there is a greater likelihood that the modified food will contain substances that are significantly different from, or are present in food at a significantly higher level than counterpart substances historically consumed in food. In such circumstances, the new substances may not be GRAS and may require regulation as food additives."[30] While this

[28] 57 Fed. Reg. 22,984 et seq.
[29] 66 Fed. Reg. 4708
[30] 66 Fed. Reg. 4709

theoretical proposition is true, it is not at all clear that this possibility alone merits heightened scrutiny for ***all*** new plant varieties developed with rDNA techniques. This proposal could only be justified if FDA expected all or most plants developed with rDNA to result in foods that present legal status questions, which is clearly not the case.

If FDA suspects that many, or even most, rDNA-manipulated plant varieties will in the future contain substances that present legal status questions, it need not create a one-size-fits-all regulatory scheme to deal with potential risks to consumers. The agency could incorporate such concerns into its documents providing guidance on characteristics that would require heightened scrutiny. There is no reason why FDA could not address rDNA-manipulated plants generally within its existing voluntary consultation process and require premarket notice only for those specific new plant varieties that raise risk-related concerns. The proposed premarket notice requirement is therefore unnecessary. It could serve to keep beneficial new products off the market and needlessly raise the price of those that are eventually commercialized. Finally, by focusing only on bioengineered plants, FDA mis-allocates scarce resources, over-regulating many low-risk products and under-regulating some high-risk products.

Risk Management Plans

Proposed for Review: 65 Fed. Reg. 48107. Regulations covering Section 112(r) of the Clean Air Act on risk management plans.

Recommended By: Angela Logomasini, Director of Risk and Environmental Policy.

> **Recommendation:** In 2000, the Department of Justice warned that the risk of a terrorist attack on a U.S. industrial facility was "both real and credible." After September 11, the federal government began removing information from its websites that terrorists might use in such attacks. Yet sensitive information about our nation's chemical facilities, infrastructure, and military installations remains available in federal libraries. OIRA should review the regulations that made this information available to ensure they do not continue to pose a public safety risk.

The legal authority of these regulations is a provision of the Clean Air Act Amendments of 1990 that requires facilities to develop "risk management plans" (RMPs), which are supposed to help plants prepare for accidental chemical releases. The law then directed the EPA to make these plans publicly available. Congress modified this provision in 2000 (discussed below), which led to the current regulations on the release of risk management plans.

Risk management plans include information that security officials from the FBI, CIA, International Association of Fire Chiefs and others say could assist terrorists in selecting targets and planning attacks on chemical facilities and infrastructure. According to a Department of Justice Report, risk management plans provide most (six out of nine pieces of information) of the information that the Department of Defense lists as critical for a terrorist to launch a successful terrorist attack on an industrial facility. Each plan states the chemicals and amounts stored at a

facility. One section covers the section on "offsite consequence analysis" (OCA), which details what would happen in the event of a catastrophic chemical release assuming the worse case scenario. This section includes the potentially exposed populations, the distance the release could travel under specified wind conditions, and related information. Plans also detail a plant's mitigation measures, which terrorists could use for developing an attack strategy.

Of particular concern among security experts is the ability of terrorists to use this information to rank facilities to select targets based on potentially exposed populations. They raised this concern when the deadline for plants to submit RMPs drew close in 1998. At that time, the EPA indicated that it would post the plans on the Internet after it had collected them from the regulated parties. Security experts expressed concern that such Internet posting would give terrorists easy access to an anonymous, searchable database of potential targets. The OCA data in particular would enable terrorists to rank facilities according to potentially exposed populations.

Congress reformed this law in 1999 with legislation requesting that the DOJ and the EPA issue a rule governing the process for releasing the data in a way that minimizes security risks. The new law included one key reform — it provided the EPA with a Freedom of Information Act exemption that prevented environmental groups from accessing the information in electronic form for easy Internet posting. Yet EPA opted to post the bulk of the information on the Internet in 2000 — including about 50 percent of the "worst case scenario" sections of the plans as well as full executive summaries.

The reformed law also mandated that EPA make the entire plans available in 50 federal "reading rooms" throughout the nation, which the agency did starting in January 2001. Individuals who show an identification card can view details on up to 10 facilities per month. The law does not bar anyone from collecting and posting all of this information online.

The Bush administration has already shown that it understands the sensitivity of this information and the need to ensure it is handled properly. In March 2001, the Bush administration wisely withdrew a last minute Clinton administration regulatory proposal that could have circumvented even the few security measures regarding distribution of the information that the agency had in place. The proposal would have released the information in the electronic format that security officials warned was the most dangerous.

Under the Clinton proposal, the public would have had access to the materials in a "read only" form at libraries, while "qualified researchers" would have been able to obtain both electronic and paper copies. The researchers would not be legally allowed to disseminate the information, but once it was provided to them, it would be impossible to prevent distribution.

In addition to that move, the administration also took action after September 11, pulling the risk management plans and their summaries off the EPA website. However, the federal government still makes the full information easily accessible at federal libraries, which is a policy that needs reconsideration.

We all know that after September 11, policymakers have had to reconsider all our security measures. Both Congress and the executive branch are looking into policies to help reduce vulnerabilities, particularly those related to the nation's basic infrastructure. In 2000, the DOJ noted that the types of facilities — such as infrastructure and military installations — that submit RMP data to the EPA are "preferred targets."

Fifteen percent of the facilities that produce RMPs fall into the category of basic infrastructure. About two thousand are water supply and irrigation facilities; 80 are military installations, 56 are related to electricity supply, transmission, and control; and 14 involve national gas distribution. "Disruption of even one of these facilities could wreak havoc on an entire region or locality," DOJ reported in 2000.

OMB should review this regulation to see if the administration can find an alternative to providing this information in federal libraries where potential terrorists can collect data. A better balance might include having emergency responders serve as the source of public information on potential risks, which is what John Eversole, chairman of the Hazardous Materials Task Force of the International Association of Fire Chiefs recommends.

Ban on Chromated Copper Arsenate (CCA)

Proposed for Review: EPA announcement that it is banning Chromated Copper Arsenate (CCA) used in pressure treated wood; http://www.epa.gov/pesticides/citizens/1file.htm.

Proposed by: Angela Logomasini, Director of Risk and Environmental Policy.

> **Recommendation:** Review EPA actions to ban CCA and demand that the agency follow proper scientific procedures before making a policy decision about the product.

CCA has been safely used on what most people know as pressure-treated wood for more than 60 years to prevent rotting and termite infestation of outdoor structures, such as decks, docks, fences, retaining walls and even some home foundations. Concerns about the wood's safety come from "studies" conducted by the Environmental Working Group (EWG) and the Healthy Building Network. EPA has conducted a risk assessment in the past, and the agency maintains that it "has not concluded that CCA-treated wood poses any unreasonable risk to the public or the environment." The agency was planning to do an updated risk assessment, but decided to ban the product a year before it is scheduled to be completed.

On February 12, the EPA announced it is banning CCA. According to EPA, the ban takes effect in 2003. But this decision is being pursued outside the usual regulatory procedures. After making its decision, the agency then opened a comment period and is working on a risk assessment that is not expected to be completed until well after the ban is in effect. There is an alternative product, but it is estimated that it will raise the cost of the wood by 20 percent or 30 percent, and may not be as effective in preventing deterioration of the wood.

The agency says it issued the ban simply because the producers of the chemical voluntarily agreed to phase it out. However, that should not preempt others from selling the product in the future and it does not take into consideration the concerns of consumers and the 350 wood treatment plants that use CCA. Those businesses will be forced to retool their facilities to switch to the new wood preservative. Estimated costs are $40,000 to $200,000 per facility of the $4 billion industry. Costs could escalate if hysteria created by such rulings causes people to dismantle pressure-treated wood structures. Florida has shut down an estimated 24 playgrounds because of unfounded fears raised about CCA.

If EPA wants to change the policy on CCA, it should follow traditional regulatory procedures. It should first complete its scientific assessment, have adequate time for public comment on that assessment, propose a rule, and allow comment on the proposal.

Regulation for Radon in Drinking Water

Proposed for Review: 64 Fed. Reg. 59246 (November 2, 1999). Radon in drinking water.

Recommended by: Angela Logomasini, Director of Risk and Environmental Policy

> **Recommendation:** Closely review agency science and cost calculations for its upcoming rule on radon in drinking water. Ensure that the agency sets a standard solely based on the radon risks related to drinking water, instead of other sources of radon exposure.

OIRA deserves praise because it appears to have returned the radon in drinking water rule to EPA, according to OIRA's web page. This regulation poses serious problems for rural communities and is not based on sound science. Costs to small communities may force them to make huge sacrifices. For example, public officials in Tustin, California noted in a Price Waterhouse Survey that the proposed 1991 rule (which is what EPA re-proposed in 1999) would cost them $4 million in capital costs and $30,000 in annual operating costs. Such costs would destroy that community, which only serves 180 homes. [31] The only solution for such communities might be to discontinue drinking water service, which can force residents to turn to dangerous sources such as untreated surface waters.

The EPA estimates that the radon rule will cost $407.6 million per year.[32] The agency claims that the rule would yield $362 million in benefits or $5.8 million per theoretical life saved and $538,000 per theoretical nonfatal cancer prevented.[33] The General Accounting Office, however, says that the agency has likely underestimated the costs significantly.[34]

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[31] Price Waterhouse, *Impact of Unfunded Mandates on U.S. Cities, A 314 City Survey*, (Washington D.C.: U.S. Conference of Mayors, October 26, 1993), D-7.
[32] Figures represent 1997 dollars; 64 Fed. Reg. 59269 (November 2, 1999).
[33] 64 Fed. Reg. 59269 (November 2, 1999).
[34] U.S. General Accounting Office, *Drinking Water: Revisions to EPA's Cost Analysis for the Radon Rule Would*

In 1998, the National Academy of Sciences issued its congressionally mandated risk assessment, which EPA and others hailed as a new definitive finding on radon. But the National Research Council (NRC) estimates are not based on new information, but on the same data that raised questions in the past among members of the agency's Science Advisory Board and others.[35]

The data show elevated cancer levels among miners who *smoked heavily* and were exposed to *very high* levels of radon *as well as nitrogen oxides and mineral dusts* in mines. The relevance of these studies to low-level residential exposures is unknown. Neither the NRC nor the EPA has been able to establish that low-level radiation in homes causes cancer to nonsmokers or even to smokers. Accordingly, the NRC risk assessment indicates that the risks from ingestion could be zero "depending on the validity of the linear no-threshold dose response hypothesis."[36] Despite these very serious weaknesses with the data, NRC claimed that radon in drinking water might cause as many as 180 deaths a year.[37] Based on the NRC estimates, the EPA claims that its 1999 proposal would save 62 lives.[38]

The EPA and the NRC report ignore the fact that radon may not only be safe under a given exposure level, but that low-level exposures might even be beneficial. Scientist Jay Lehr discusses such effects in a commentary addressing radiation exposure. Lehr notes: Studies have found instances where people exposed to low-levels of radiation actually experienced less incidence of leukemia than the general population, while highly exposed individuals experienced elevated rates of leukemia.[39] Another recent study, Lehr notes, found that increasing levels of low-level radon exposure is linked to *decreasing* cancer rates.[40]

Improve Its Credibility and Usefulness, February 2002, GAO-02-333.

[35] The original data is found in Lubin, J.H., et al, *Radon and Lung Cancer Risk: A Joint Analysis of 11 Underground Miners Studies* 94-3644 (Bethesda MD: National Institutes for Health, 1994); National Research Council, *Health Risks of Radon and Other Deposited Alpha-Emitters (BEIR IV)* (Washington DC: National Academy Press, 1988); National Research Council, *Health Effects of Exposures to Radon (BEIR VI)*, (Washington, DC: National Academy Press, 1999)]; for critiques of the data see: Richard Stone, "EPA Analysis of Radon in Water is Hard to Swallow," *Science* 261, (September 17, 1993), 1514.

[36] National Research Council, *Risk Assessment of Radon in Drinking Water* (Washington DC: National Academy Press, 1998).

[37] Ibid.

[38] 64 Fed. Reg. 59269.

[39] Jay Lehr, Ph.D., "Good News About Radon: The Linear Nonthreshold Model Is Wrong," May 1996, available on the Internet at: http://www.junkscience.com/news/lehr.html. Dr. Lehr cites the following studies: T.D. Luckey, "Radiation Hormesis, CRC Press, Boca Raton, FL, 1991; T. Sugahara, L.A. Sagan, and T. Aoyama, "Low Dose Irradiation and Biological Defense Mechanisms, Amsterdam: Exerpta Medica," 1992; and E.J. Calabrese, Biological Effects of Low-Level Exposures to Chemicals and Radiation; CRC Lewis Publishers, Boca Raton, FL 1994.

[40] B.L. Cohen, "Test of the Linear-no Threshold Theory of Radiation Carcinogenesis for Inhaled Radon Decay Products," *Health Physics* 68 no. 2, (1995): 157-174.

Nonetheless, even using its dubious science to exaggerate risks, the EPA's rule still promises more costs than benefits (EPA estimates annual costs at $407.6 million and benefits at $362 million).[41]

Having failed the cost benefit test, the EPA justified its rule based on a provision of the 1996 Safe Drinking Water Act that was an attempt to make the law flexible and "multimedia" oriented. It allows public water systems to meet a less stringent standard — which they call the alternative maximum contaminant level (AMCL) — if the state, locality, or public water system sets up a multimedia mitigation program (MMM). States must gain EPA approval of a MMM by outlining measures they will take to control radon in indoor air. If a state does not submit a plan, then localities and/or public water systems may propose plans to the EPA. Accordingly, in 1999, EPA proposed a radon rule that includes an MCL of 300 pCi/L, an AMCL of 4,000 pCi/L, and a set of requirements for MMMs. EPA estimated that if states chose that route, the regulation would only cost $80 million.[42]

However, rather than being more flexible, this provision of the 1996 law gives the EPA an excuse to enter into an entire new area of government regulation: control over levels of radon in indoor air. In fact, language in EPA's rule indicates that it set the MCL high to promote MMMs, not because the MCL was necessary to protect public health. The agency explained that it needed the higher MCL because "the equal or greater reduction required to be achieved through the AMCL/MMM option would be diminished as the MCL approaches the AMCL of 4000 pCi/L and that fewer states and CWS [community water systems] would select this option. Further, the AMCL/MMM would be eliminated entirely if the MCL were set at the AMCL."[43] In other words, EPA was setting a needlessly high standard so that it could regulate indoor air quality.

Moreover, this approach may not be any less expensive. In fact, attempts to control indoor radon in the air have been expensive and have produced mixed results in the past. Poorly designed or installed mitigation technology can increase radon levels and successful technology has cost thousands of dollars per home in the past. In addition, state-led programs implemented during the 1980s have proven costly. A New Jersey program during the 1980s proved disastrous, permanently displacing residents from their homes after the government removed soil from under the houses. The New Jersey government then spent years and millions of dollars trying to dispose of the soil as political debates raged over disposal sites.[44]

Disinfection Byproduct Rule

Proposed for Review: 63 Fed. Reg. 69390 (December 16, 1998); Rule regulating disinfection byproducts in drinking water.

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[41] 64 Fed. Reg. 59269.
[42] Ibid.
[43] 64 Fed. Reg. 59270 (November 2, 1999).
[44] For more information on disastrous radon policies see: Leonard A. Cole, *Element of Risk: The Politics of Radon*, (New York: Oxford University Press, 1993).

Recommended by: Angela Logomasini, Director of Risk and Environmental Policy.

> **Recommendation:** OIRA should review EPA's rule for disinfection byproducts, which a federal court ruled was not based on the "best available peer reviewed science," as required under the Safe Drinking Water Act.

For each regulated contaminant under the Safe Drinking Water Act (SDWA), the EPA usually specifies a "maximum contaminant level goal" (MCLG) which represents the level of a contaminant that the EPA would ideally want to allow in drinking water. The EPA uses the MCLG as a guide in setting the enforceable standard, the Maximum Contaminant Level (MCL). The MCL represents the amount of that contaminant that systems may legally allow in tap water. In 1998, controversy emerged when the EPA issued its first set of standards for disinfection byproducts. At issue was the standard for chloroform. The EPA set a zero MCLG and a 0.08 MCL for a group of disinfection byproducts called "total trihalomethanes" of which chloroform is one of four.[45] As discussed below, a federal court vacated the MCLG for chloroform.

After the passage of the 1996 SDWA amendments, the EPA set up an advisory committee on the rule and co-sponsored a study of disinfection byproducts with the International Life Sciences Institute Expert Panel. Consisting of 10 experts from government and industry, this panel concluded that cancer related to chloroform, "is expected to involve a dose response relationship, which is nonlinear and probably exhibits an exposure threshold."[46]

Based on those findings, the EPA indicated that it would set a standard higher than zero for chloroform.[47] Nine months later, the EPA reversed its position and set a zero MCLG for chloroform in the final rule.[48] The EPA had failed to use the "best available peer reviewed science," which the 1996 law demands it observe, and a federal court subsequently vacated the MCLG (but not the final MCL), calling the MCLG "arbitrary and capricious."[49] The EPA subsequently removed the zero goal.[50] While the EPA has not promulgated a new MCLG the enforceable MCL it set remains in effect.

Given the court ruling that the agency did not follow the best science as required by the law, OIRA should review this rule to see if the agency needs to change the goal rather than simply removing the goal all together. Setting a goal above zero may not affect the final

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[45] Under this standard, water providers must ensure that tap water contains no more than 0.08 mg/L of the combined concentration of these substances.
[46] 63 Fed. Reg. 15685 (March 31, 1998).
[47] 63 Fed. Reg. 15685 (March 31, 1998); The regulations for chloroform would not be affected by a zero Maximum Contaminant Level Goal (MCLG) because the enforceable Maximum Contaminant Level would not have changed. Also, the standard does not simply regulate chloroform. It regulates the level of "total trihalomethanes" of which chloroform is one of four contaminants.
[48] 63 Fed. Reg. 69390-69476. (December 16, 1998).
[49] Chlorine Chemistry Council v. Environmental Protection Agency, Nos. 98-1627, 99-1023 and 99-1056 (D.C. Cir. 3/31/00).
[50] 65 Fed. Reg. 34404-34405 (May 30, 2000).

standard, but it does set a precedent for following the best science that needs to be followed in subsequent regulations.

The 1997 EPA Standards for Ozone and Particulate Matter

Proposed for Review: 62 Fed. Reg. 38, 856 (July 18, 1997) and 62 Fed. Reg. 38,652 (July 18, 1997); Clean air standards for ozone and particulate matter.

Recommended By: Ben Lieberman, Director of Clean Air Policy and Associate Counsel

> **Recommendation:** OMB should assess problems with EPA science on ozone and particulate matter before the agency finalizes the rule.

New National Ambient Air Quality Standards (NAAQS) for ozone and particulate matter were proposed in 1996 and finalized in 1997.[51] At the time, a number of parties, including EPA's Clean Air Scientific Advisory Committee (CASAC), raised concerns about EPA's estimated costs and benefits of these rules, making them perhaps the most controversial ever promulgated under the 1970 Clean Air Act (CAA).

The new standards were immediately challenged in federal court on a variety of grounds. These challenges were largely unsuccessful, but have delayed implementation of the rules. During this interim, additional research has been conducted, which the agency asserts has vindicated their original analysis.

However, most of the initial concerns about the claimed net benefits of the new standards have not been adequately addressed, and two will be discussed here. With regard to the fine particulate (PM 2.5) standard, the evidence of health effects is based on two studies finding a weak statistical correlation between ambient concentrations and increased mortality. This evidence does not provide a sufficient factual basis for the claimed benefits. With regard to the ozone standard, EPA's attempt to downplay the evidence that the tightened standard would increase ground-level ultraviolet B (UVB) radiation and related health effects is in direct contradiction to its treatment of those same effects in the context of Title VI of the CAA dealing with stratospheric ozone depletion.

PM 2.5 Mortality Benefits Suspect. Prior to 1997, the NAAQS focused on PM 10, thus the new NAAQS represents the first-ever effort to regulate the smaller PM 2.5. Unlike PM 10, little is known about PM 2.5. Only two epidemiologic studies purport to show a positive correlation between PM 2.5 and mortality, the Harvard Six Cities study and the American Cancer Society study.[52] Beyond this rather modest base of epidemiologic evidence, there is no medical

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[51] 62 Fed. Reg. 38, 856 (July 18, 1997); 62 Fed. Reg. 38,652 (July 18, 1997).
[52] Douglas W. Dockery, et al., "An Association Between Air Pollution and Mortality in Six U.S. Cities," *New England Journal of Medicine*, vol. 329, pp. 1753-1759 (1993); C.A. Pope, et al., "Particulate Air Pollution as a Predictor of Mortality in a Prospective Study of U.S. Adults," *American Journal of Respiratory Critical Care Medicine*, vol. 151, pp. 669-674 (1995).

research establishing the suggested association between PM 2.5 and any adverse health outcomes. As discussed at length in the CEI monograph entitled *The Ongoing Clean-Air Debate: The Science Behind EPA's Rule on Soot, http://www.cei.org/gencon/025,02065.cfm*, this research, even after an extensive reanalysis by the Health Effects Institute, leaves considerable doubts as to whether the association is causal.

For example, the Harvard Six Cities Study found no significant association between PM 2.5 concentrations and mortality in four of the six cities studied. The American Cancer Society study found no significant association for persons with more than a high school education. Upon closer examination, both studies also indicated that other pollutants, particularly sulfates, may be more strongly linked to mortality than PM 2.5. Although the Health Effects Institute reanalysis of both studies was widely reported as confirmation of the EPA's new standard, the reanalysis actually concluded that the PM 2.5 evidence is "insufficient to identify causal relations with mortality."[53]

Nonetheless, the claimed benefits of the PM 2.5 rule (as well as other rules believed to reduce fine particulate matter emissions such as the recent diesel engine rule) are calculated by taking these suspect associations, extrapolating them over the percentage of the population living in areas not in attainment with the new NAAQS, and thereby deriving hypothetical lives saved numbering in the thousands per year. Though this leads to numerically high benefits estimates, the fact that the mortality figures are not based on a proven causal association casts serious doubt on their validity. For this reason, we believe that OMB scrutiny of the PM 2.5 NAAQS is still warranted.

The Disbenefits of the Ozone NAAQS Have Not Been Adequately Considered. Ozone is unusual among the pollutants addressed in that it has both harmful and beneficial effects on public health. Inhalation of ozone exacerbates respiratory conditions such as asthma, which was the primary focus of EPA's rulemaking. However, ozone also acts as a shield against potentially harmful UVB radiation from the sun, exposure of which has been linked to skin cancer. EPA based its ozone NAAQS on the former health effects, not the latter.

EPA argued that it is entitled to ignore the so-called ozone disbenefits, and that such effects are nonetheless too speculative and trivial to justify changing the standard to accommodate them. These arguments failed when the ozone rule was challenged in the United States Court of Appeals.[54] The court flatly rejected the assertion that the positive effects of ozone in blocking UVB should be ignored, noting that "it seems bizarre that a statute intended to improve public health would, as EPA claimed at argument, lock the agency into looking at only one half of a substance's health effects in determining the maximum level for that substance."[55]

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[53] Daniel Krewski et al., "Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality," Health Effects Institute, July 2000, p. 236.
[54] *American Trucking Associations, Inc. v. EPA*, 175 F.3d 1028 (D.C. Cir. 1999), *aff'd*, 195 F.3d 4 (D.C. Cir. 1999).
[55] *Id.* at 1052.

The court directed that "EPA must consider positive identifiable effects of a pollutant's presence in the ambient air in formulating [the NAAQS]."[56]

With regard to EPA's claim that the UVB effects are uncertain and trivial, the court observed that the CAA "does not rigorously or uniformly demand either quantifiability . . . or any specific level of significance."[57] The court also objected to EPA's double standard regarding the UVB effects and respiratory effects, particularly the agency's decision to ignore the former based on evidentiary concerns conceded to also be applicable to the latter. The court concluded that "we can see no reason for imposing a higher information threshold for beneficent effects than for maleficent ones. . . ."[58] The court remanded the ozone NAAQS to EPA to incorporate into its final standard the beneficial effects of ozone in shielding UVB. Although EPA appealed to the Supreme Court on other grounds, the agency did not challenge the Court of Appeals' holding regarding the UVB effects.

On November 14, 2001, EPA published its proposed response to remand.[59] While purporting to comply with the Court of Appeals' order, the agency decided not to change the ozone standard. The agency essentially repeated its earlier assertion that the UVB effects are too uncertain and too small to affect the NAAQS.

However, as was discussed in detail in the comments to EPA (available at: http://www.cei.org/gencon/027,02392.cfm), the agency's response is completely at odds with the evidence, and fails to comply with the requirements of the CAA.

In particular, EPA ignored the wealth of research, conducted by EPA and other American and international agencies, purporting to demonstrate a causal association between reduced atmospheric ozone and increased ground-level UVB and related health effects. This work was conducted in the context of stratospheric ozone depletion (Title VI of the CAA and the Montreal Protocol on Substances That Deplete the Ozone Layer), and has been extensively relied upon by EPA in promulgating numerous rules placing restrictions on ozone depleting substances. For example, a 1993 rule banning putative ozone-depleting compounds was promulgated because of "the agency's concern that significant ozone loss may occur over populated regions of the earth, exposing humans, plants, and animals to harmful levels of UV-B radiation. . . ."[60]

These concerns are equally relevant of the ozone NAAQS, which would reduce ozone in atmosphere as well. Nonetheless, EPA completely ignored its own evidence demonstrating these adverse effects when promulgating the new standard.

EPA's evidence also undercuts the agency's claims that these effects are insignificant. EPA estimated that the new NAAQS would result in a decline in total column ozone of

[56] *Id.* at 1052.
[57] *Id.* at 1053.
[58] *Id.* at 1053.
[59] 66 Fed. Reg. 57,268 (November 14, 2001).
[60] 58 Fed. Reg. 15,015 (March 18, 1993).

approximately 0.5 percent.[61] This equals 5 percent of the expected 10 percent ozone decline believed to be averted by the regulatory measures restricting the production and use of ozone depleting compounds. EPA's Regulatory Impact Analysis for the phase out of these compounds attributed health benefits ranging from 8 to 32 trillion dollars as a consequence of avoiding this 10 percent loss of ozone.[62] A simple extrapolation of these estimates to the approximately 0.5 percent ozone loss from the new NAAQS would yield costs far higher than EPA's initial estimate of the benefits from reduced respiratory problems, which range from zero to 1.5 billion dollars annually.[63]

In effect, EPA's assertion that the disbenefits of reducing atmospheric ozone are either too uncertain or too small is directly contradicted by the agency's own voluminous record in the context of regulating ozone-depleting compounds. These contradictions warrant OMB's attention as EPA finalizes its proposed response to remand.

[61] Larry T. Cupitt, "Calculations of the Impact of Tropospheric Ozone Changes on UV-B Flux and Potential Skin Cancers," AREAL, ORD, EPA (1994).
[62] EPA, "Regulatory Impact Analysis: Compliance With Section 604 of the Clean Air Act for the Phaseout of Ozone Depleting Chemicals," July 1992 and 1994 Addendum.
[63] 62 Fed. Reg. 65,746.