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To: John F. Morrall III/OMB/EOP@EOP

cc:
Subject: Comments on Draft Report to Congress

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Attached are CEI's Comments on the Draft Report to Congress on the Costs and Benefits of Regulation along with two attachments. Please let me know if you have trouble opening these word documents.

Thank you.

-- Angela

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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 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 effort 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' 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 prevenf 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

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[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 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 analysis were used to back the regulation. In addition, without even running a model, the NRC speculated in 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'smidnight 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:llwww.cei.orglgencod003,02037.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

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[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

[8] 64 Fed. Reg. 57,413 (October 25, 1999).
[9] Michael Gough, "Beneficial Effects of Consumption of Low Levels of Alcohol." December 7, 1998.

disease in some individuals."" These guidelines, published by the Departments of Agriculture and Health and Human Services, constitute the government's foremost public statement on nutritional policy.""

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 rulemalung, 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." A *Journal* d ***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

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[10] USDA and HHS, "Dietary Guidelines for Americans." 1995, at 40.
[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.

the federal government's Center for Substance Abuse Prevention (CSAP), evaluated the consumer response to two health statements." 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.''

**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*

[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.

*VersusActive* ***Compression-Decompression For*** *Out-of-Hospital Cardiac Arrest,* New England 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. 3,3**14** (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.

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[19] *65* Fed. Reg. 59,550 (October 5,2000); 66 Fed. Reg. 3,314 (January 12,2001).
[20] ***65*** Fed. Reg. 3,3 15.

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."" 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 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 is 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. 13,5 13.
[21] 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 20C1, 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 aff 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 terrorist 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 pew. law included one key reform — it provided the EPA with a Freedom of Information Act exemption that prevented environmental groups from accessing the infomation 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. 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 it 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) use 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 complete.

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 a **risk** assessment that is not expected to be complete 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 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]

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

[35] The original data is found in Lubin, JH, et al, ***Radon and Lung Cancer*** Risk: *A* Joint Analysis *of I I* 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 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).
[18] 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. 3/3 1/00).
[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." 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 is 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 on 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."" 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.orfi/fiencon/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

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[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.

# ATTACHEMENT A

## COMMENTS OF THE COMPETITIVE ENTERPRISE INSTITUTE AND CONSUMER ALERT ON THE BUREAU OF ALCOHOL, TOBACCO AND FIREARMS' PROPOSED RULE REGARDING HEALTH CLAIMS IN THE LABELING AND ADVERTISING OF ALCOHOL BEVERAGES

**64** Federal Register 57,413 (October *25,* 1999)

### SUMMARY

ATF's notice of proposed rulemaking seeks to prohibit what it deems misleading statements about the health benefits of alcohol consumption from appearing on alcoholic beverage labels and advertisements, but would in fact serve to suppress entirely truthful and non-misleading speech. The cardiovascular and overall health benefits associated with moderate alcohol consumption are amply supported by the medical evidence, and summary statements of these benefits **are** protected by the First Amendment. ATF's notice of proposed rulemaking should be withdrawn.

### INTRODUCTION

The Competitive Enterprise Institute (CEI) is a pro-market public interest group dedicated to advancing the principles of free markets and limited government. Consumer Alert (CA) is a free-market consumer advocacy group. Both organizations have a longstanding interest in the free flow of information between producers and consumers of alcoholic beverages. In 1995, CEI filed a petition for rulemaking with the Bureau of Alcohol, Tobacco and Firearms **(ATF)** regarding the use of health claims on alcoholic beverage labels and advertisements. Attachment 1. Despite a substantial body of evidence that moderate consumption reduces cardiovascular **risk** and overall mortality, and mounting legal precedent that such communications are protected by the First Amendment, the agency had in place a policy that effectively stopped all industry attempts to put health information on labels or ads.

Prior to our petition, industry had never been given any guidance by ATF to distinguish acceptable from unacceptable health claims language, other than a 1993 Industry Circular implying that all health claims are presumptively misleading and will be heavily scrutinized. Several industry attempts to communicate with consumers about the health benefits of moderate consumption were thwarted by ATF, in some instances by threats of administrative action against industry members. For this reason, CEI petitioned the agency to provide industry with an effective means for obtaining health claim approvals. CEI hoped that the rulemaking would result in several approved statements, such as the suggested "there is significant evidence that

moderate consumption of alcoholic beverages may reduce the risk of heart disease," or any variations acceptable to the agency.

After a year and a half of agency inaction in responding to our petition, CEI, along with CA, filed suit in 1996 challenging ATF's policy. *Competitive Enterprise Institute v. Robert E. Rubin, Civil Action No. 96-2476 (D.D.C., filed October 29, 1996)(CEI v. Rubin).*[1] Only after the suit was filed did ATF deny our petition for rulemaking. *CEI v. Rubin*, as amended, challenges the denial of our petition as well as the legality of ATF's ongoing policy, and is still pending.

Although ATF is finally engaging in a rulemaking on its health claims policy, CEI and CA are disappointed that, rather than opening the door to truthful statements about the health benefits associated with moderate consumption, the proposed rule is designed to shut that door, and essentially codify ATF's de facto ban on health information.

As will be discussed below, we believe this rulemaking should result in a policy allowing a wide range of accurate summary statements about moderate drinking and health to appear on alcoholic beverage labels and ads. Any other outcome would contradict the evidence as well as the First Amendment. For this reason, ATF's proposed change to its rules should not be promulgated.

## I
## ATF'S PROPOSED RULE WOULD RESTRICT TRUTHFUL AND NON-MISLEADING INFORMATION

ATF proposes to prohibit as misleading "any statement that makes a substantive claim regarding health benefits associated with the consumption of alcohol beverages unless such claim is properly qualified, balanced, sufficiently detailed and specific, and outlines the categories of individuals for whom any positive health effects would be outweighed by numerous negative health effects." 64 Fed. Reg. 57,413. This would include any statement referring to the cardiovascular and overall health benefits associated with moderate alcohol consumption. ATF then concedes, as it first did in its 1993 Industry Circular, that its proposed requirements amount to a de facto ban, because "it would be extremely unlikely that any such balanced claim would fit on a normal alcohol beverage label." 64 Fed. Reg. 57,415. This was the agency's rationale for rejecting the suggested health statement in CEI's petition for rulemaking, as well as several others submitted by industry members over the past decade. However, ATF's proposed requirements are completely unsupported by the evidence concerning health claims and their effect on consumers.

### A. The Medical Evidence Supports General Statements That Moderate Drinking is Beneficial For Adults.

[1] ATF has compiled an extensive administrative record in this case. The administrative record is also highly relevant to this notice of proposed rulemaking, and is therefore incorporated by reference into these comments.

There is a substantial body of evidence, far more than cited in the notice of proposed rulemaking, demonstrating that moderate consumption of alcoholic beverages confers significant cardiovascular and other health benefits and reduces overall mortality for the adult population. The attached summary of the evidence (with references), conducted for CEI and **CA** by Dr. Michael Gough in 1998, is particularly useful in light of the fact that ATF does not present an overview of net health effects associated with moderate drinking. Attachment 2. Additional studies, including some published subsequent to Dr. Gough's comments, are also attached. Attachment **3.** Instead of accurately summarizing this evidence, ATF devotes much of its time to identifying every conceivable category of individual who is not likely to benefit from moderate drinking. This includes adults too young to be at significant **risk** for cardiovascular disease, pregnant women, and recovering alcoholics. After identifying these and other groups, the agency essentially concludes that any summary of the effects of moderate drinking would be misleading unless accompanied by a lengthy discussion of each exception. In other words, the agency deems accurate summaries impossible.

ATF's review of the literature is highly misleading. In truth, the published research, including the studies selectively quoted by ATF, nearly unanimously concludes that moderate drinking reduces cardiovascular risk and overall mortality for the adult population. Regarding those not likely to obtain these net benefits, Dr. Gough concludes that "with the exception of these groups, who comprise a minority of the population, there does not appear to be a group of adults that does not benefit from moderate alcohol consumption." Attachment **2,** p. 17. Among the studies relied upon by Dr. Gough 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 1997 New England Journal of Medicine study concluding the "those who consumed up to one or two drinks of alcohol daily had lower overall mortality rates than nondrinkers."

- **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.. .

Indeed, virtually every scientific study in the medical literature supports the general thrust of ***the*** information the agency would prohibit – that moderate consumption of alcoholic beverages reduces cardiovascular risk and overall mortality. ATF's studied preoccupation with the exceptions to the general rule does not negate the truth of that rule.

In addition to overstating the proportion of the adult population that would not derive net benefits for moderate drinking, ATF has also overstated the degree of risk to such persons who do drink moderately. This is particularly true of the largest category of exceptions, adults too young to be at substantial risk of cardiovascular disease (especially younger women, whose cardiovascular risk is less than that for men). For example, ATF quotes one article claiming "an increase in all-cause mortality even in young women who are light drinkers ... compared with abstainers." 64 Fed. Reg. 57,414. However the underlying research paper on which this claim is based, a 1995 New England Journal of Medicine study entitled "Alcohol Consumption and Mortality Among Women," merely found a statistically insignificant mortality increase among such women aged 34-39. Attachment 4, p. 1,247. More importantly, this same study found statistically significant reductions in overall mortality among light and moderate drinking women aged 34-59, concluding that "these findings indicate that for women as a group light-to-moderate alcohol consumption confers a significant overall survival advantage." Attachment 4, p. 1,250. This conclusion is nearly identical to scores of others from studies of moderate drinking's net effects on adult men and women, but is precisely the kind of statement the agency now seeks to prohibit.

For these reasons, Dr. Gough states that "the available evidence contradicts ATF's statement that 'there is no significant scientific evidence to support an unqualified conclusion that moderate alcohol consumption has net health benefits for all or even most individuals."' Attachment 2. p. 19.

B. The Evidence Demonstrates That Health Claims Do Not Mislead The Public

There is another reason that ATF's overemphasis on the minority of adults who would not benefit from moderate drinking fails as justification for banning health claims - the individuals who comprise these categories know who they are and are unlikely to be misled. Indeed, completely absent from ATF's purely speculative assertion that health statements would have a misleading effect is any mention of the **only** evidence the agency has obtained regarding the consumer response to health statements. A 1998 study (excerpts attached), conducted for ATF by the federal government's Center for Substance Abuse Prevention **(CSAP),** evaluated the consumer response to the following two short statements on wine labels:

- to learn the health effects of moderate wine consumption, send for the Federal Government's "Dietary Guidelines for Americans."

- 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.

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Attachment 5, p. 1-2. The CSAP study's central conclusion is that "neither of the two labels ... would likely induce wine drinkers to alter their drinking pattern, quantitatively or otherwise." Attachment 5, p. 3. With regard to concerns about alcoholism and the existence of certain categories of individuals who should not drink, the study concluded that, even among those exposed to the health claims, there still is a "[g]eneral understanding: there are risks of

alcoholism, and certain conditions would counter indicate wine drinking." Attachment 5, p. 4. In fact, in a response to an ATF attempt to exaggerate the risk of health claims to pregnant women, the Director of CSAP stated in a letter that "the population studied overwhelmingly understands that drinking is
counter-indicated during pregnancy." Attachment 6.

C. Other Federal Agencies Have Approved Summary Health Statements Without The Extensive Qualifications Required By This Proposed Rule.

In its notice of proposed rulemaking, ATF defers to the expertise, and potential jurisdiction, of the Food and Drug Administration and Federal Trade Commission. 64 Fed. Reg. 57,415. However, ATF's proposed restrictions flatly contradict the practice of both FDA and FTC regarding summaries of nutritional research on product labels and ads.

Under the National Labeling and Education Act of 1990 (NLEA), Pub. L. No. 101-535, 104 Stat. 2353, FDA has conducted a series of rulemakings to approve more than 20 health claims, including several linking saturated fat and cholesterol and coronary heart disease, fiber-containing foods and coronary heart disease, calcium and osteoporosis, and sodium and hypertension. 21 CFR §§ 101.72-81.

For example, FDA has established the following "safe harbor" statements for appropriate food labels:

- "Whilemany factors affects heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease.'' 21 CFR § 101.75(e)(1)

- "Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors." 21 CFR §101.74(e)(1).

Similarly, FTC has allowed health claims in advertisements, including several statements that mention the link between high fiber foods and reduced **risk** for certain cancers.

In terms of both their generality and their lack of warnings for special groups of people, these approved claims are similar to CEI's suggested claim, yet under ATF's proposed approach they would all be supposedly misleading. For example, during FDA's rulemaking on the saturated fat claim (the first claim quoted above), the agency received comments that "questioned the applicability of a claim linking diets low in saturated fat and cholesterol to reduced risk of heart disease in the general U.S. population." **FDA,** *Final Rule – Health Claims: Dietary Saturated Fat and Cholesterol and Coronary Heart Disease, 58* Fed. Reg. 2,739, 2,745 (1993). FDA agreed that "the beneficial effects … are highly variable among individuals," but it nonetheless allowed the claims because there is "strong scientific agreement that the majority of persons in the U.S. will benefit…." *Id.* at 2,745-46. FDA expressly refused to require that this

health claim use the phrase "some persons, but not all,'' characterizing it as "too conservative." *Id.* at **2,746.** The agency took a similar approach in its low-sodium rulemaking, where it stated that despite the fact "that not all persons may be sensitive to salt," the "word 'some' may erroneously lead consumers to believe that only a small percentage of the population will benefit.. .." FDA, *Final Rule – Health Claims: Sodium and Hypertension,* 58 Fed. Reg. 2,820, 2,825 (1993). FDA pointed out that "the use of 'may' or 'might' …conveys the meaning that not all individuals respond to sodium restriction with lower blood pressure levels." 58 Fed. Reg. 2,825-26.

In contrast, ATF insists that the existence of exceptions to the general rule that moderate consumption reduces cardiovascular risk and overall mortality renders all summary health statements misleading, and therefore unallowable. Further unlike FDA and FTC, ATF shows absolutely no concern about requiring qualifying language that serves to misleadingly overstate these exceptions.

Measured by any standard – the strength of scientific support, the percentage of the population for whom the claim applies, the extent of the expected health benefit, the degree to which any exceptions are obvious and well-known – the health claims ATF seeks to prohibit are as justified, if not more so, than numerous health claims currently appearing on many product labels and advertisements. Under ATF's approach, none of these claims would have ever seen the light of day.

In sum, there is no basis for ATF's assertion that summaries of the net health benefits associated with moderate drinking are false or misleading, neither in terms of their scientific support nor in terms of the effect they have on consumers.[2]

## II ATF'S PROPOSED RULE VIOLATES THE FIRST AMENDMENT

Despite the obvious First Amendment concerns raised by ATF' proposal to severely restrict speech, the agency devotes only one paragraph to First Amendment issues, citing two cases in support of its assertion that its proposed rule is Constitutional. **57** Fed. Reg. **57,4** 16. Ironically, in both cases the Supreme Court struck down as unconstitutional government restrictions on speech, and in the most recent one the Court upheld the First Amendment rights of alcoholic beverage advertisers. ***44*** *Liquormart* v. *Rhode Island,* **517** U.S. **484** (1996). These and other Supreme Court cases have spawned many other successful challenges to federal and state restrictions on advertising and labeling, including some involving product health

2 Furthermore, any statement regarding the net health benefits of moderate drinking on an alcoholic beverages label would share space with the federally mandated statement: "Government Warning: (1) According to the Surgeon General, women should not *drink* alcoholic beverages during pregnancy because of the **risk** of birth defects. (2) Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery, and may cause health problems." 27 **U.S.C** 213 *et seq.* (1988). Thus ATF's insistence that summaries of benefits be "balanced" is already satisfied by a summary statement of the **risks** that appears on every alcohol product label.

statements. Indeed, virtually every argument made by ATF in support of its proposed speech limitations has repeatedly failed Constitutional scrutiny.3

## A. ATF Has Not Met Its Burden In Justifying A Restriction On Commercial

Speech.

The First Amendment applies to so-called commercial speech, protecting the labeling and advertising rights of both the speaker and the listener consumer. *See, Virginia State Bd. Of Pharmacy v. Virginia Consumer Council*, 425 U.S. 748 (1976) (drug price advertising); *Bates v. State Bar of Arizona*, 433 U.S. 350 (1977) (attorney advertising); *Central Hudson Gas v. Public Service Comm'n of N.Y.*, 447 U S . 557 (1980)(utility promotional advertising); *In Re RMJ*, 455 U.S. 191 (1982)(attorney advertising); *Zauderer v. Office of Disciplinary Council*, 471 U.S. 626 (1985)(attorney advertising); *Peel v. Attorney Reg. & Disciplinary Com'n*, 496 U.S. 91 (1990)(attorney advertising); *Edenfield v. Fane, 507* U.S. 761 (1993)(accountant in-person solicitations); *Ibanez v. Fla. Dept. of Bus. & Pro. Regulation*, 5 12 U.S. 136 (1994)(accountant advertising); Rubin *v. Coors*, 514 U.S. 476 (1995)(percent alcohol content on beer cans and labels). The state can place limited restrictions on commercial speech, but only if certain conditions are met. "It is well established that the party seeking to uphold a restriction on commercial speech carries the burden of justifying it." *Edenfield v. Fane*, 507 U.S 761,770 (1993)(internal quotations and citation omitted). Furthermore, "this burden is not satisfied by mere speculation or conjecture; rather, a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." *Edenfield*, at 770-771. For example, in *Rubin v. Coors*, ATF tried to justify its ban on percent alcohol content information on beer cans and labels by speculating that the restriction was necessary to prevent brewers from competing on the basis of alcoholic strength. The Supreme Court unanimously rejected as inadequate ATF's "anecdotal evidence and educated guesses to suggest that competition on the basis of alcohol content is occurring," and that the "ban has constrained strength wars that otherwise burst out of control." *Id.* 514 U.S., at 490.

Here, ATF has similarly failed to meet its burden. Rather than present evidence refuting the general assertion that moderate consumption reduces cardiovascular risk and overall mortality, the agency (albeit in a selective and misleading manner) cites medical evidence that actually supports this conclusion. In addition, the CSAP study, rather that confirming ATF's speculation that health claims would have misleading effects on consumers, demonstrates the precise opposite to be the case.

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3 Its should also be understood that ATF's proposed rule, in violating the First Amendment, also violates the Administrative Procedure Act (APA), §§ 5 U.S.C. 551 *et seq.* In addition, by restricting non-misleading therapeutic or curative claims, ATF's proposed rule violates the Federal Alcohol Administration Act (FAAA), 27 U.S.C. § 205(e) and (f).

Further, ATF's underlying assumption that health statements must be weighed down with extensive detail lest they be deemed misleading has often failed as a rationale for suppression. This is particularly true given ATF's highly paternalistic assumptions regarding easily-deceived consumers, and the agency's admission that its proposed disclosure requirements would serve to restrict the flow of information by making it nearly impossible to say anything at all about alcohol and health on product labels and ads. In *Bates,* the Supreme Court reviewed similar restrictions on attorney advertising, and concluded that:

> it seems peculiar to deny the consumer, on the ground that the infomation is incomplete, at least some of the relevant information needed to reach an informed decision. The alternative – the prohibition of advertising – serves only to restrict the information that flows to consumers. Moreover, the argument assumes that the public is not sophisticated enough to realize the limitations of advertising, and that the public is better kept in ignorance than trusted with correct but incomplete information. We suspect the argument rests on an underestimation of the public. In any event, we view as dubious any justification that is based on the benefits of public ignorance.

*Id.,* **433** U.S. at **374-375.** Some accurate information is always preferred to suppression. "Even when advertising communicates only an incomplete version of the relevant facts, the First Amendments presumes that some accurate information is better than no information at all." *Central Hudson*, **447** U.S., at **562.** With regard to the assumption that the public is better off if shielded from certain facts, the Court has stated that "the First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good." ***44*** *Liquormart,* 517 U.S. at 503. Disclaimers are preferred to outright suppression, but overly onerous and impractical disclaimer requirements may violate the First Amendment. "We recognize that unjustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected speech." *Zauderer,* **47** 1 **U.S.** at 651. ATF's attempt here to "protect" consumers from summaries of the health benefits of moderate consumption, by means of disclosure requirements so extensive as to make it unlikely that any such information will ever appear on a label or ad, is equally suspect.

Further, restrictions on commercial speech must be narrowly tailored to their end. "[W]e must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest." *Central Hudson,* **447** *U S .* at **566.** Broad restrictions on speech rarely pass muster, especially when more targeted restrictions or non-speech alternatives are not given adequate consideration. In *Rubin* ***v. Coors***, for example, the Court noted several means of combating alcoholic strength wars short of an all out ban on percent alcohol content information. The Court concluded that "the availability of these options, all of which could advance the Government's asserted interest in a manner less intrusive to respondent's First Amendment rights, indicates that [its ban] is more extensive than necessary." ***Id.*** at 491. Here, **ATF** is, by its own admission, attempting to effectively ban an entire category of speech, without contemplating more targeted measures. The notice of

proposed rulemaking does not even acknowledge the possibility that health summaries could be worded so as to satisfy ATF's stated concerns, and instead repeats the agency's assertion from its 1993 Industry Circular that any and all statements short enough to be of use are unacceptably misleading.

B. Recent Federal Cases Cast Further Doubt On the Constitutionality of ATF's Proposed Rule.

In addition to *44 Liquormart v. Rhode Island* and *Rubin v. Coors,* the two Supreme Court cases upholding the First Amendment against state attempts to restrict alcoholic beverage labels and advertisements, two recent federal cases dealing with health-related product information call into question the Constitutionality of ATF's proposed rule.

In 1999, an attempt by the Food and Drug Administration to ban certain health statements from dietary supplement labels was held unconstitutional. *Pearson v. Shalala,* 164 F.3d 650 (D.C. Cir. 1999), *rehearing denied,* 172 F.3d 72 (April 2, 1999). The court rejected as "almost frivolous" the FDA's contention that consumers are easily deceived by product health statements as if they "were asked to buy something while hypnotized." *Id.,* at 655.

In 1998, another FDA rule restricting manufacturer distribution of information regarding so-called off label uses of drugs was **struck** down as unconstitutional. *Washington Legal Foundation v. Friedman*, 13 F.Supp. 2d 51 (D.D.C. 1998). Again, regarding the government's asserted need to protect recipients of this information, the court concluded that "to endeavor to support a restriction upon speech by alleging that the recipient needs to be shielded from that speech for his or her own protection ... is practically an engraved invitation to have the restriction struck." *Id.,* at 70.

Here, the medical evidence is at least as strong, and ATF's speculation of an easily-misled populace is at least as weak, as in these two cases involving the **FDA.**

## CONCLUSION

ATF's proposed rule is both unsupported by the evidence and in violation of the First Amendment. For these reasons, the proposed rule should be withdrawn.

Ben Lieberman
Competitive Enterprise Institute

## Attachment B

March 13,2001

The Honorable Spencer Abraham
Secretary of Energy
Forrestal Building
1000 Independence Avenue
Washington, DC 20585-1000

**Re: Petition for Administrative Reconsideration of "Energy Conservation Program for Consumer Products: Clothes Washer Energy Conservation Standards; Final Rule"**

**66 Fed. Reg. 3,314 (January 12,2001)**
**Docket No. EE-RM-94-403**

Dear Secretary Abraham:

The undersigned organizations represent a broad cross-section of consumer advocacy and other public interest organizations, and respectfully petition the Department of Energy (DOE) to reconsider its new energy conservation standards for clothes washers.[1]

As will be discussed below, DOE's new standards conflict with several statutory criteria, including those designed to protect the interests of consumers. These concerns were raised during rulemaking proceedings, but have not been addressed by DOE. Furthermore, even if DOE does not believe that the law has been clearly violated, the new administration has the discretion to make changes to the standards. Therefore, we believe the Final Rule should be reopened for additional public comment and further agency consideration prior to its effective date.

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[1] This petition for reconsideration is to be distinguished from a petition for rulemaking. We are requesting that DOE consider modifying the Final Rule prior to its effective date, and not requesting that DOE promulgate a new standard to supersede the Final Rule. Indeed, DOE is not permitted to set an amended energy conservation standard less stringent than a previous one that has taken effect. 42 U.S.C. §6295(o)(1).

## I. BACKGROUND

The Energy Policy and Conservation Act, as amended (the Act), set initial energy conservation requirements and created a process by which DOE may promulgate amended standards, for clothes washers and 13 other energy-using home appliances.[2] The original requirements for clothes washers took effect in 1988, and mended standards took effect in 1994.

Soon thereafter, the agency began the process of promulgating a second round of amended standards. The agency published an Advance Notice of Proposed Rulemaking (ANOPR) in 1994, and, after numerous delays, a Supplemental ANOPR in 1998.[3]

On July 27,2000, all manufacturers of clothes washers sold in the United States joined several energy conservation advocacy organizations and utilities in submitting to DOE a Joint Stakeholders Comment (Joint Comment), endorsing new standards for clothes washers.[4] These standards would require a 22 percent increase in efficiency by 2004 and a 35 percent increase by 2007 above the standards currently in effect. The Joint Comment also endorsed substantial tax credits for manufacturers of energy efficient clothes washers and refrigerators.

No consumer organizations were a party to the Joint Comment, nor were any provisions made for public participation in its creation.[5] The Joint Comment does state that DOE endorsed this process, though the extent of any direct agency participation or support has not been disclosed.[6]

The Joint Comment was essentially adopted by DOE as its Notice of Proposed Rulemaking (NOPR), which was published on October 5, 2000.[7] Concurrent with the publication of the NOPR, DOE released its Technical Support Document (TSD), which contained more than 500 pages and cited numerous other materials, only some of which were included in the record.

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[2] 42 U.S.C. §§ 6291 to 6317.
[3] 59 Fed. Reg. 56,423 (November 14, 1994; 63 Fed. Reg. 64,344 (November 19,1998).
[4] Joint Stakeholders Comments on Energy Efficiency Standards for Clothes Washers, July 27,2000, No. 204.
[5] DOE's Interpretive Rule states that "joint recommendations will be of most value to the Department if the participants are reasonably representative of those interested in the outcome of the standards development process, including manufacturers, ***consumers,*** utilities, states and representatives of environmental or energy efficiency interest groups." 10 CFR, Part 430, Subpart C, Appendix A, §8(b) (emphasis added).
[6] Joint Comment, p. 3. It should be noted that DOE did not comply with the Federal Advisory Committee Act (FACA), though the agency's Interpretive Rule states that if the agency does participate in Joint stakeholder recommendations, "the procedural requirements of the Federal Advisory Committee Act may apply to such participation." 10 CFR, Part 430, Subpart C, Appendix A, §8(c). Specifically, FACA requires that applicable meetings be announced in the Federal Register, open to the public, and that all proceedings be documented for subsequent public inspection. DOE complied with none of FACA's requirements here.
[7] 65 Fed. Reg. 59,550 (October 5,2000).

The NOPR allowed only the statutory minimum 60 days for public comment, until December 4th. Despite the limited time span, DOE received several critical comments, including those from some of the undersigned organizations.[8] DOE submitted its draft final rule to the Office of Management and Budget on December 8th, only four days after the close of the comment period. The Final Rule, which DOE concedes is "based on the joint proposal submitted to the Department by clothes washer manufacturers and energy conservation advocates," was published in the Federal Register on January 12,2001, little more than a week before the change in Administration.[9] The brevity of the period that DOE considered comments is reflected in the Final Rule, which makes no substantive changes from the Joint Comment in response to comments from other parties. Furthermore, DOE's discussion of critical comments in the Final Rule was cursory and incomplete.[10]

## 11. THE FINAL RULE CONTRADICTS SEVERAL STATUTORY CRITERIA

The standards promulgated in the Final Rule are not economicallyjustified, will not result in significant energy savings, and threaten to compromise product choice and features. For these reasons, we believe the standards may violate the Act and warrant further consideration by the agency before taking effect. Though the following discussion is largely based on the 2007 standard, we are requesting agency reconsideration of both the 2004 and 2007 standards in the Final Rule.

### A. The Final Rule Is Not Economically Justified

Under the Act, amended standards must be economically justified, based on the following criteria:

- the economic impact on manufacturers and on consumers,
- the likely savings in operating costs compared to any increase in purchase price, initial charges or maintenance costs;
- the total projected amount of energy savings;
- any lessening of utility or performance;
- the impact of any lessening of competition, as determined by the Attorney General;
- the need for national energy conservation; and
- other factors the Secretary considers relevant.[11]

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[8] The comments of the undersigned Competitive Enterprise Institute, Mercatus Center, Consumer Alert, and Energy Market & Policy Analysis, Inc. are included in the rulemaking record, and are incorporated by reference in this petition.
[9] 66 Fed. Reg. 3,314, 3,320 (January 12,2001).
[10] 66 Fed. Reg. 3,320-25.
[11] 42 U.S.C. §6295(o)(2)(B)(i).

The 2007 standard fails several of these criteria.

DOE's analysis greatly overstates the net savings to consumers from purchasing a clothes washer that complies with the 2007 standard. Even so, the agency's own analysis of lifecycle costs concedes that 19 percent of consumers overall, and 28 percent of senior households, will actually suffer net costs.[12] However, the agency's analysis greatly understates the extent to which the standard is not economicallyjustified and will place an undue burden on consumers.

1. DOE Has Understated The Costs of Owning and Maintaining **A** 2007 Compliant Clothes Washer.

DOE estimates that the 2007 standard will add approximately $249 to the average purchase price of a new clothes washer, from $421 today to $670.[13] This 59 percent increase is unprecedented in the history of DOE's conservation standards program, and alone casts serious doubt on the economic justification of the standard. In addition, the actual ownership costs may be higher, as DOE has failed to meet its requirement in considering the likelihood of higher maintenance or warranty costs. The agency claims it has no data to that effect.[14] However, these costs may be substantial, as the 2007 standard will likely result in the demise of models that have been on the market for many years and that have established a strong track record for reliability. These models will be replaced by substantially new ones, many of which have yet to be introduced, and thus have no repair history to judge.

Any market shift from "tried and true" models to unproven ones is very likely to result in increased maintenance costs. For this reason, leading consumer publications recommend clothes washers of proven reliability.[15] To the limited extent repair histories of high efficiency front-loading washers are available, for at least one brand these new models are proving less reliable than their non-compliant top-loading counterparts.[16] Further, it was announced after the publication of the Final Rule that another brand's recently introduced high efficiency model was subject to a recall." The importance of

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[12] 66 Fed. Reg. 3,315-16.
[13] 66 Fed. Reg. 3,315.
[14] *65* Fed. Reg. 59,562. It appears that the agency made no attempt to study the possibility of higher maintenance and repair costs, and simply relied on submissions (or the lack thereof) from manufacturers. Not surprisingly, manufacturers declined to criticize their own future product lines as being less reliable and/or costlier to repair.
[15] Consumer Reports, "Spin City: Ratings of Washing Machines and Clothes Dryers," July 1999, pp. 30-33.
[16] Consumer Reports, "Product Updates," January 2001, p. 46("Maytag front-loaders were among the less reliable brands and less reliable than Maytag top-loaders.")
[17] Consumer Reports, "Sears Recalls Some Calypso Washers," March 2001, p. 55.

DOE taking into account the likelihood of increased repair or warranty costs is further underscored by the tendency for such costs to increase in high efficiency appliances.[18]

**2.** DOE Has Overstated the Likely Energy Savings From Its Standards."

There are several reasons to question DOE's poorly supported estimate of energy savings, but two agency assumptions deserve particular scrutiny – that the average clothes washer owner does 392 loads laundry per year and will own the same machine for over **14** years.

In its calculation of payback period and lifecycle costs, DOE has chosen to assume an average of 392 cycles per year.[20] As with many of DOE's assumptions, the agency does not provide enough information to independently determine the reliability of this estimate.[21] Since, energy savings correlate directly with usage, any household that does considerably less than 392 loads per year will save considerably less energy.

Fortunately, the absence in the record of verifiable data on clothes washer usage was remedied by a survey submitted by the Mercatus Center.[22] In contrast to DOE's assumption of 392 loads per year (more than 7 loads per week), the survey of nearly 2,000 households found that over **54.6** percent do *5* or fewer loads per week, while only 28.9 percent operate their clothes washer *6* or more times per week.[23] In addition to casting serious doubt on DOE's assumed average, these results indicate that a majority of households will not operate their 2007 compliant clothes washer frequently enough to earn back the higher purchase price.[24] DOE declined to discuss this survey in its response to comments.

Even if no other adjustment is made to DOE's analysis, simply replacing DOE's assumption of 392 loads per year with more accurate estimates (which could take the form of a range rather than a single average) would greatly weaken the agency's assertion that the rules are economicallyjustified.

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[18] See, Consumer Reports,-"Way Cool: **A** Guide To Buying Air Conditioning," June 1998, p. 37 ("Mid-efficiency models ... may be the least expensive to own overall because they're cheaper **to buy** and less likely to need repair.")

[19] DOE also takes water savings into account, though the statute clearly limits the consideration for clothes washers to energy savings. 42 U.S.C. §6295(o)(2)(A).

[20] 66 Fed. Reg. 3,315.

[21] DOE states that the number comes from a Proctor and Gamble survey, as adjusted by the agency using Residential Energy Consumption Survey data on household sizes. The Proctor and Gamble survey is not provided, and no other estimates are discussed. DOE further concedes that "in actuality, the number of loads of laundry washed per household per year depends on the number of persons in the household, and probably on other factors." TSD, p. 10-6.

[22] Mercatus Center Regulatory Studies Program, Addendum to Public Interest Comment on the Department of Energy's Proposed Clothes Washer Efficiency Standards, No. 224, pp. 4-5.

[23] **Id.,** pp. **4-5.**

[24] Elsewhere in its analysis, the Mercatus Center calculates that a clothes washer meeting the 2007 standard must be used 300 times a year, or 5.8 times per week, to recover the higher purchase price over its useful life. Based on this estimate and the survey results of actual usage rates, the Mercatus Center concludes that more than two-thirds of households would not recoup the higher purchase price of the mandated washing machines. Id., p. **5.**

Nearly as dubious **as** the assumption of 392 loads per year is the assumption that the initial purchaser of a clothes washer will own it throughout its useful life of 14 years. In reality, most people will change residences (and leave their clothes washer behind) before that time, and indeed a substantial number will change residences before the payback period (the time it takes to earn back the higher purchase price in the form of energy savings) has elapsed. According to the U.S. Bureau of the Census, the average median duration in one's current residence is 5.2 years overall, 8.2 years for owner-occupied housing units.[25]

In its NOPR, DOE argued that that it is obligated by statute to calculate the energy savings over the entire expected lifetime of a clothes washer.[26] However, the agency cannot logically attribute all of these energy savings to the original owner, irrespective of the actual period of ownership and use. Indeed, the Act directs the agency to consider "the economic impact of the standard ... on the consumers of the products subject to such standards."[27] Thus, DOE cannot ignore the likelihood that most consumers will not operate the same clothes washer for 14 years, and indeed that many won't own a 2007 compliant washer long enough to earn back the higher purchase price. Data on the actual period of clothes washer ownership should be a part of the analysis.

Compounding the overstatement of the amount of energy saved are exaggerations of the cost of that energy. **As** several commenters noted, DOE uses highly problematic forecasts of energy prices extending decades into the future, though such forecasts have a track record for unreliability. In particular, the US Energy Information Administration electricity forecasts over the past twenty years have often overstated what proved to be the actual electricity costs. In addition, DOE has used an inexplicably low discount rate, rather than more plausible but higher alternatives such as average credit card or consumer loan rates.[28] Given the long period of clothes washer ownership assumed by DOE, the agency's use of a low discount rate significantly overstates the present value of the hypothetical stream of future energy savings.

3. DOE's Consumer Subgroup Analysis Greatly Understates the Disproportionately Adverse Impacts on Low Income and Senior Households.

In its NOPR, DOE analyzed the effect of the rule on low income and senior households, but made no attempt to directly study these subgroups. Instead, DOE used simple mathematical adjustments to its estimate of **392** loads per year for the average household, based entirely on average sizes of low income and senior households. By DOE's reckoning, since low income households have slightly higher numbers of persons per household, DOE calculated that they average 410 loads per year (nearly 8 loads per week), and thus benefit slightly more than the average household by owning an energy

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[25] U.S. Bureau of the Census, Seasonality *of* Moves and Duration of Residence, October 1, 1998.
[26] 65 Fed. Reg. 59,562.
[27] 42 §6295(o)(2)(B)(i)(I).
[28] TSD, 7-22.

efficient clothes washer.[29] Similarly, DOE estimates that senior households, with fewer persons, average 299 loads per year (nearly 6 loads per week), less than the overall average of 392 but enough so that only 28 percent of such households suffer net lifecycle costs.[30]

In contrast to DOE's speculative and inferential approach, the Mercatus Center actually asked persons with low incomes and senior citizens how much laundry they do. The survey results indicate that both subgroups do substantially less laundry than the average household, and far less than DOE's calculations indicate.[31] Of households with incomes under $20,000 per year, 66.6 percent do 5 or fewer loads per week, and only 9.8 percent do as much or more as DOE estimates.[32] For persons 65 years of age or older, 65.7 percent do 5 or fewer loads per week, and only 11.3 percent do as much or more as DOE estimates.[33] Based on these usage rates, a substantial and disproportionately high majority of low income and senior households would not recoup the higher purchase price of a 2007-compliant clothes washer.

Beyond net costs, there are other reasons low income and senior households would suffer disproportionately from these standards. For example, low income households would need to make greater sacrifices in order to come up with the additional $249 for a 2007-compliant clothes washer, and would face less favorable financing options and interest rates as compared to the average household.[34] Senior households disproportionately object to the inconvenience of front loading washers, which (as will be discussed in a subsequent section) may become the predominant type once the 2007 standard takes effect.[35]

4. The Attorney General's Letter Failed To Consider the Anti-Competitive Effects.

The Attorney General is required to make a determination in writing of the impact energy conservation standards would have on competition.[36] The letter from the Acting Assistant Attorney General, included with the Final Rule, states that the clothes washer standards would not adversely affect competition.[37] In concluding *so,* the Acting Assistant Attorney General cites as primary support the Joint Comment, and in particular the fact that "virtually all manufacturers of clothes washers who sell in the United States participated in arriving at the recommendation...."[38] Apparently, the Acting Assistant

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[29] 65 Fed. Reg. 59,573.
[30] Id.
[31] No. 224, Addendum, pp. 8, 10.
[32] Id. at 10.
[33] Id. at 8.
[34] Indeed, DOE's analysis assumes that the majority of low income households would have to forego purchasing a new high efficiency washer. TSD, Appendix 5-27.
[35] No. 224, Addendum, p. 5.
[36] 42 U.S.C. §6295(o)(2)(B)(ii).
[37] 66 Fed. Reg. **3,333.**
[38] Id.

Attorney General believes there can be no concerns about competition as long as all the manufacturers of a product are working in unison. In contrast, we believe that this apparent cooperation only heightens such concerns.

It should be noted that, through the Joint Comment, representatives of the entire United States clothes washer market agreed to a future limitation of production to models estimated to cost 59 percent more than the current average. If such an agreement were made and implemented outside of any federal regulatory context, the Department of Justice would almost certainly initiate antitrust proceedings under Sherman Act.[39] The fact that the manufacturers here used DOE's rulemaking process to achieve the same result hardly eliminates the competitiveness concerns.

Competition must be preserved, not just between independent manufacturers, but also among product types and price ranges – indeed it is the latter form of competition that most directly affects consumers.[40] For this reason, we respectfully request further input from the Attorney General's office regarding the impact on competition of the new standards.

5. DOE Has Not Established The Need For National Energy Conservation

DOE's primary stated need for the energy savings is the "cumulative greenhouse gas emission reductions of 95.1 million metric tons (Mt) of carbon dioxide equivalent," the agency attributes to reduced electricity generation from 2004 to 2030.[41] This estimate, even if it proves accurate, is too trivial to be of consequence. Based on the US Energy Information Administration's most recent forecast, carbon emissions associated with energy consumption will total approximately 53,000 million metric tons during this period.[42] Thus, the estimated reductions of carbon dioxide equivalent represent only 0.18 percent of this total.[43]

Furthermore, it is not clear if DOE is allowed to consider greenhouse gas emissions reductions. DOE is specifically forbidden from promulgating rules that implement or give effect to the Kyoto Protocol, the as yet unratified treaty obligating the

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[39] See, Federal Trade Commission and U.S. Department of Justice, "Antitrust Guidelines for Collaborations Among Competitors," April 2000, p. 6 ("Competitor collaborations may harm competition and consumers by increasing the ability or incentive profitably to raise price above or reduce, output, quality, service, or innovation below what likely would prevail in the absence of the relevant agreement.").

[40] In a January 22,2001 energy conservation standard for air conditioners and heat pumps, the Acting Assistant Attorney General did raise competition concerns, in part because the standard could disadvantage some product types relative to others. 66 Fed. Reg. 7,170, 7,200 (January 22,2000).

[41] 66 Fed. Reg. 3,319.

[42] US Energy Information Administration, Annual Energy Outlook 2001, December 2000, Table A-19.

[43] DOE's estimated reductions in nitrogen oxides and sulfur dioxide are similarly trivial, and are largely unnecessary because ambient concentrations of these pollutants are already declining substantially under the Clean Air Act. See, Environmental Protection Agency, "Latest Findings on National Air Quality: 1999 Status and Trends," August 2000.

US and other nations to reductions in carbon dioxide and other greenhouse gas emissions.[44] DOE declined to comment on this possible statutory violation.

The above discussion highlights several reasons why the Final Rule is not economicallyjustified. Given the inadequate support in the rulemaking record, DOE should reconsider its initial determination as to economic justification.

## B. The Energy Savings Are Insignificant

DOE may not prescribe a standard that "will not result in significant conservation of energy...."[45] This is a separate requirement from the determination of economic justification described above. Indeed, "even an efficiency standard with no technical or economic drawbacks whatever – one that offers a completely painless way to energy conservation – will be discarded if its fails to achieve 'significant' conservation."[46] DOE states that the energy savings here are significant, equating the term with "non-trivial."[47] The agency did not articulate a threshold below which energy savings would be not be considered significant.

Here, however, the energy savings are so small (especially in relation to the costs to achieve them) that allowing the standards to go into effect would render this requirement meaningless. DOE estimates that the standards would result in savings of 5.52 quadrillion Btu (quads) of energy over the period 2004 to 2030.[48] As discussed previously, this estimate is likely exaggerated, but even if accurate would likely fail any reasonabletest of significance. Based on the US Energy Information Administration's forecast of energy consumption, the nation will use approximately 3,400 quads of energy during this period.[49] Thus, the estimated energy savings 5.52 quads from the new standards are 0.16 percent of total energy use.

We request DOE to reconsider its determination that the expected energy savings are significant. If DOE does determine that 0.16 percent energy savings are significant, the agency should at least explain where it believes the threshold for insignificance lies.

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[44] Department of the Interior and Related Agencies Appropriations Act, 2001, Public Law No. 106-291, §329.

[45] 42 U.S.C§ 6295(o)(3)(B).

[46] ***Natural Resources Defense Council v. Herrington,*** 768 F.2d 1355, 1373 (D.C. Cir. 1985) ***(Herrington).***

[47] DOE relies on ***Herrington*** for the proposition that "significant" is synonymous with "non-trivial". 66 Fed. Reg. at 3,318. This conclusion both misinterprets ***Herrington*** and overstates its relevance to the standards at issue here. In ***Herrington,*** the court did not equate significance with non-triviality, and indeed declined to impose any specific definition of significance on the agency. Id. at 1382. The court merely rejected DOE's working definition of significance, which was so high at the time that the agency literally refused to set any energy conservation standards whatsoever. Here, in contrast, clothes washer standards are already in place, and DOE seeks to amend them for the second time, despite the questionable significance of the marginal energy savings in doing so.

[48] ***66*** Fed. Reg. 3,316.

[49] US Energy Information Administration, Annual Energy Outlook 2001, December 2000, Table A2.

## C. The New Standards Are Likely To Impermissibly Restrict Choice and Features

In perhaps the strongest consumer protection provision in the Act, DOE is restricted from prescribing a standard if interested persons establish by a preponderance of evidence that the standard is likely to result in the unavailability "in any covered product type (or class) 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."[50] This requirement ensures that product performance and features will not be sacrificed for the sake of energy conservation.

The 2007 standard threatens to restrict product quality and choice to an extent unprecedented for energy conservation standards. Here, the preponderance of evidence standard can be easily met, since DOE's own TSD concludes that the 2007 standard will likely violate this provision. The agency readily concedes that that full feature, vertical axis top loading clothes washers (which currently dominate in the market) would no longer be available once the 2007 standard takes effect." DOE's record also establishes that door placement is an important feature for consumers and that top loading models are the preferred choice.[52]

In the Final Rule, DOE conceded that "the original manufacturer data assumed that all clothes washers at and above a 35 percent improvement [the 2007 standard] would be horizontal-axis machines," but added that progress has been made in the past few years and that "manufacturers have already begun offering top-loading, vertical-axis clothes washers that would meet the 2007 standard."[53] However, DOE provides no documentary support for this change in position, such as evidence that these new ultra-efficient top-loading models provide all the performance characteristics consumers demand.

Further, new evidence has emerged that these 2007 compliant top-loading clothes washers are not problem-free. The recently recalled washer is one such model; nonetheless, it is highlighted in some of DOE's materials as proof that high efficiency top loading washers are currently available.[54] Another 2007 compliant top-loader was previously criticized in ***Consumer Reports*** for saving energy by not heating the water sufficiently.[55]

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[50] 42 U.S.C. §6295(o)(4).
[51] For example, on page **J-3** of the Technical Support Documents, DOE discusses compliant washers as being "either front loading machines with hot water wash capability or top loading machines with no hot water capability." Further, in Tables 11.12 and 11.13, DOE assumes that top loaders will no longer be sold once the 2007 standard takes effect.
[52] TSD, 3-18 and 19, I-19.
[53] 66 Fed. Reg. 3,325.
[54] Consumer Reports, "Sears Recalls Some Calypso Washers," March 2001, p. 55. The model in question, the Kenmore Elite Calypso, was specifically cited by DOE to refute the charge that its new standards will eliminate top-loading washing machines.
www.eren.doe.gov/buildings/consumer_information/clotheswashers/clonew.html
[55] ConsumerReports, "Who Gets An Energy Star?" July 1999, p. 31.

Thus, DOE's original concerns about the effect of the 2007 standard on top-loading models have been confirmed by difficulties with the first of these models to reach the market. Clearly, there is substantial evidence that this standard will compromise product choice and features.

## III. EVEN IF DOE VIEWS ITS FINAL RULE AS COMPLYING WITH THE STATUTORY CRITERIA, IT SHOULD NONETHELESS EXERCISE ITS DISCRETION AND RECONSIDER THE RULE

Even if DOE rejects the position that its Final Rule fails to meet the statutory criteria for clothes washer standards, it should still exercise its discretion to reopen this proceeding. "An agency's view of what is in the public interest may change, either with or without a change in circumstances." *Greater Boston Television Corp. v. FCC,* 444 F.2d 841, 852 (D.C. Cir. 1971). This is especially true with a change in administration, because:

> the responsible members of one administration may consider public resistance and uncertainties to be more important than do their counterparts in a previous administration. A change in administration brought about by the people casting their votes is a perfectly reasonable basis for an executive agency's reappraisal of the costs and benefits of its programs and regulations. As long as the agency remains within the bounds established by Congress, it is entitled to assess administrative records and evaluate priorities in light of the philosophy of the administration.

*Motor Vehicle Mfrs. Ass'n. v. State Farm Mutual Life Ins. Co.,* 463 U.S. 29, 59 (1983) (Rehnquist, Berger, Powell, and O'Connor concurring in part and dissenting in part.) Further, "an agency to which Congress has delegated policymaking responsibilities may, within the limits of that delegation, properly rely upon the incumbent administration's views of wise policy to inform its judgments." *Chevron v. Natural Resources Defense Council,* 467 U.S. 837, 865 (1984). Given the questions described above concerning the previous administration's handling of such issues as economic impacts and the uncertain reliability of new technology, DOE clearly has the power to reopen this matter. All that is required under the law is that, if DOE does proceed to change this rule, it "supply a reasoned analysis" for why it has done so. *Greater Boston,* at 852. The reasons set forth in this petition, we submit, are the basis for such a change.

## IV. CONCLUSION

For the reasons discussed above, we respectfully request DOE to reconsider its Final Rule on clothes washers. In light of the inadequate discussion of critical comments in the rulemaking record, we also request that the reconsideration process be fully open to input from all interested parties.