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Comments to the Draft 2005 Report to Congress
On the Costs and Benefits
Of Federal Regulations

Public Citizen is a national public interest organization with 150,000 members that represents consumer interests through lobbying, litigation, regulatory oversight, research and public education. For 34 years, Public Citizen has had direct, practical involvement with a wide variety of federal health and safety protections and has represented consumer groups, labor unions, and public health organizations in standard-setting proceedings involving the Occupational Safety and Health Administration (OSHA), the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the Consumer Product Safety Commission (CPSC), the U.S. Department of Agriculture (USDA), the National Highway Traffic Safety Administration (NHTSA), the Federal Motor Carrier Safety Administration (FMCSA) and other health and safety agencies.

We are writing in response to the March 23, 2005 notice in the Federal Register requesting comments on the Draft 2005 Report to Congress on the Costs and Benefits of Federal Regulations (hereinafter 2005 Draft Report). Business, of course, would prefer not to be regulated. The question is whether this dislike for rules is justified because, as has been asserted, regulation imposes some economic costs to business. Public Citizen recognizes the significant difficulties industry faces, but compromising the public good by rolling back or failing to issue important regulations that prevent environmental degradation, death, injury, and disease is not the answer. Studies have thoroughly debunked anti-regulatory claims that regulations negatively impact economic strength, and some document that well-crafted regulation stimulates industry competitiveness and the economy. Additionally, regulations provide the public with critical protections, helping to secure health, safety, and civil rights for the American people, and preserve the environment. Such fundamental liberties must be cherished, and only in the direst of circumstances considered for sacrifice.

Our comments make the following points:

I. Well-designed health, safety and environmental protections stimulate the economy, result in better products and improve the overall quality of life.

II. OMB’s draft report ignores cogent critiques and fails to address flaws.
III. OMB’s “hit list” serves as a conduit for business opposition to needed regulations and is an inappropriate interference in agency functions.

IV. OMB’s draft report should include balanced, scholarly look-back studies and exclude flawed studies.

V. Regulatory actions are needed to protect the public

I. **Well-Designed Health, Safety and Environmental Protections Stimulate the Economy, Result in Better Products and Improve the Overall Quality of Life.**

While it may seem intuitive that regulations cost businesses and jobs, there is little actual research to suggest that this claim is true. There is in fact strong scholarship and empirical evidence to the contrary.

Business mainly cites badly inflated and repackaged data from the flawed study by Crain and Hopkins, in which the data dates from 1990 and 1991. Public Citizen provided an extensive critique of the Crain and Hopkins report in comments to OMB’s 2004 draft report.\(^2\) Also, OMB has been very critical of this study in appearances before Congress.\(^3\) OMB also cites a study by the World Bank and an economist from the Organization for Economic Co-operation and Development (OECD) that dealt with constraints on capital under regulated economies – including constraints on property and contractual rights.\(^4\) Yet the U.S. is already the least restrictively regulated industrial country in the world.\(^5\) The OMB-cited studies do not address the economic consequences that might arise from rollbacks of our existing, relatively robust and well-justified health, safety and environmental rules or the cost of failing to update and improve these rules.

Nor is there any evidence that rollbacks would benefit industry. In fact, most of the evidence on environmental and safety protections points in the opposite direction. Just as pollution wastes resources, unchecked harm to society is very costly and a squandered opportunity to prevent injury or save lives. We all pay, in terms of higher insurance and medical costs, in lost worker productivity and illness, and even in traffic delays. As just one example, the annual cost of all traffic crashes in the U.S., which take more than 42,500 lives and inflict more than 3 million injuries every year, is more than $230 billion in 2000 dollars, or $800 for every man, woman and child in the U.S.

It is not mere conjecture that well-crafted and well-justified regulation spurs innovation and growth – it is fact. Regulation also enhances competitiveness and helps to ensure that industries are shielded from the often dire consequences of short-term, profit-driven decision making. For example, fuel economy standards put in place while I was Administrator of NHTSA helped to shield the domestic auto industry from a disaster during the late 1970s domestic oil crisis, created jobs in more sustainable technologies, insulated fuel costs from inflation-inducing spikes, reduced harmful pollution, and lowered fuel demand so substantially that the Organization of the Petroleum Exporting Countries (OPEC) for some years could not set oil prices.
The literature on manufacturing competitiveness and regulation, and core insights from Public Citizen’s nearly 35 years in the regulatory process, shows that well-designed rules can improve economic well-being in the following ways:

- **It is far cheaper to prevent harm than to clean up afterwards.** Regulation that corrects market failures connects cause with effect, focuses attention on mitigation at the source, and generates useful information about inefficiencies. Innovation forged by regulation can result in cleaner, higher quality products with more consumer appeal and export value, and create new industries and jobs (*i.e.*, in recycling, manufacturing pollution abatement technologies, antilock brakes, or air bags).

- **Stimulating investment in sustainable practices is a core government function that also benefits industry.** According to the “Porter hypothesis,” a theory authored by Michael Porter of Harvard’s Kennedy School of Government which posits that well-crafted regulations lead to economic growth, the stimulation effect is far greater when regulations are more rather than less stringent. This is because growth from such “innovation offsets” can encourage true progress: extraordinarily creative measures which leap-frog industrial practices to new levels of quality, utility, environmental responsibility and societal well-being. To the extent that OMB’s meddling introduces unjustified uncertainty or potential rollbacks in the regulatory process, its actions can incur additional delay and unwarranted costs in the form of investment insecurity, undermining these benefits.

- **Regulation levels the playing field and reduces total societal costs for beneficial innovations.** Rolling back regulations, or not implementing appropriate regulations, unfairly imposes costs on the public. In contrast, rules that set minimum motor vehicle safety standards, for example, assure that the safety investment will be made by every manufacturer, and that suppliers will compete to bring down costs over time. These cost reductions can happen quickly and be quite dramatic. In the case of air bags, according to testimony by Fred Webber of the Alliance of Automobile Manufacturers at a June 2005 hearing in the House Energy and Commerce Committee, the cost of frontal air bags fell from $500 in the early 1990s to “well below $100” today. The public and industry both benefit from far greater economies of scale when optional equipment becomes standard. For example, while side impact air bags can cost as much $500 today, government estimates for side impact air bags as standard equipment in the near future are in the $120 per vehicle range, including automaker and dealer profit.

- **As OMB concludes, health, safety and environmental rules are highly beneficial on balance.** While much of industry’s complaints focus on costs alone, every accounting report by OMB has found that regulations on the whole produce benefits that exceed costs most recently by over threefold. This is remarkable, as OMB’s accounting of benefits ignore many unmonetized and qualitative benefits,
and the cost information, which is primarily supplied by industry, is usually exaggerated.

The assault on regulation is a convenient lobbying strategy: it is far easier to blame the rules than deal with the truth. A wealth of research shows that direct labor costs, such as the wages for comparably skilled workers, are the major driver for industrial decisions to relocate jobs, not regulatory costs, which are less than one percent of the cost of shipped goods. A closer look at recent history tells us there is little merit to industry’s claims that manufacturing rules are the cause of recent job losses in the manufacturing sector.

While these losses are both devastating and pervasive, very few new major regulatory burdens have been added to the manufacturing sector since 2000. In fact, according to OMB, between October 1, 2003 and September 30, 2004, only 26 social regulations required “substantial private expenditures.” In short, job losses have skyrocketed while the level of regulatory compliance has remained essentially unchanged since the mid-1990s, which was a time of record economic gains. It thus makes no sense to blame regulatory burdens for changes more likely attributable to fundamental shifts in the U.S. and global economy since 2000.

The literature and recent events that free trade agreements and tax loopholes encouraging foreign investment are the major cause of industry job flight, as corporations seek out countries offering the lowest wages for workers and tax advantages. For example, a major study by the Economic Policy Institute shows that between 1993 and 2002, the North American Free Trade Agreement (NAFTA) resulted in a net loss of 879,280 American jobs.

II. OMB’s Draft Report Ignores Cogent Critiques and Fails to Address Flaws

OMB claims that it strives to neutrally separate good regulations from bad regulations, and adheres to neither a pro- nor anti-regulation bias. However, OMB has more than earned the skepticism and antipathy of the public interest community by repeatedly publishing drafts and final reports that make no mention of the serious objections submitted in comments to it. It is frustrating for regulatory experts who raise principled, well-documented critiques, to receive no response, or even acknowledgment, from OMB regarding their potent analyses.

This is in sharp contrast to the regulatory agencies, which must, and usually do, respond to comments under the Administrative Procedures Act in regulatory preambles. It is a miscarriage of OMB’s assignment to conduct only a sham notice and comment process on the draft versions of its report, because it never actually responds to the arguments and facts presented. The outcome is a sloppy report, developed in a self-imposed vacuum, that provides little meaningful insight into crucial questions about regulatory needs.
Apparently uninterested in addressing the deep flaws of its reports to Congress, OMB has condemned itself to repeat the errors that have riddled its past reports. Following is a list of the errors Public Citizen and other commenters identified in last year’s draft report that appear again in this year’s report.

- **Some rules in, some out.** The report’s accounting omits all homeland security rules, as well as those OMB nonsensically designates as “transfer rules.” Also, OMB’s 10-year analysis is marred by a methodological flaw that contributes to inaccurate, misleading estimates of the costs and benefits of regulations. OMB excludes the costs and benefits of regulations issued prior to the 10-year timeframe. For example, a range in benefits from $433 million to $4.4 billion with costs of $297 million flowing from an EPA rule on acid rain (NOx) reductions was excluded from the 2005 draft for falling outside OMB’s 10-year analysis. A regulation does not arbitrarily stop producing costs and benefits when it falls out of the temporal scope of OMB’s analysis.

- **Difficulties monetizing costs and benefits.** As in the 2004 report, monetized costs and benefits could not be provided for many of the regulations. Last year, OMB could provide estimates for only six of the twelve “social rules” to which it limited its report. This year, OMB was able to present monetized costs and benefits for only 11 of the 26 “social regulations.” Also, in many cases, agencies again were unable to quantify all costs and benefits, and OMB again admitted that it was difficult to aggregate the cost and benefit estimates acquired from different agencies and over different time periods. This recognition of the impossibility of monetizing many regulations underscores the fundamental failing of OMB’s annual report to Congress.

- **Scholarly literature ignored.** In comments to the 2004 draft report, Public Citizen listed recent publications and studies that detail the use of cost-benefit analysis as an anti-regulatory weapon, as well as serious flaws in estimates and presentation of cost and benefit information. The 2005 draft report fails to address the points raised in these works, which Public Citizen last year included in comments to OMB. Points raised in these publications and studies include:

  - Costs estimates are usually inflated, as they often rely on information provided by the regulated industries, which have strong incentives to skew the cost-benefit analysis with exaggerated cost information. Moreover, industry sources are often confidential.
  - Agencies tend to use inappropriate assumptions in determining costs.
  - Agencies apply only static-market analysis to cost estimates, which can yield inaccurate estimates, as costs often decline over time following initial compliance costs and use of innovations that reduce compliance costs, when industry actually wishes to comply with a rule. Cost estimates also fail to factor off-setting economic gains resulting from regulation.
  - In depth analysis of past cost-benefit studies shows numerous errors and inherent flaws.
The Bush administration has suppressed and distorted scientific results, and censored government employees to push policy.

- Costs and benefits of deregulatory actions utterly omitted. OMB’s single-edged sword fails to count lost benefits suffered by the public when safeguards are weakened or blocked, such as the Environmental Protection Agency’s crippling of the New Source Review program under the Clean Air Act. The neglect of these costs to the public in OMB’s report misrepresents the true costs of the failure to regulate effectively.

- Glaring uncertainties in cost and benefit estimates. CPR’s comments to the 2005 draft report highlight the uncertainties behind the false appearance of scientific accuracy and objectivity that OMB’s figures project. CPR details the staggering uncertainties of cost-benefit analysis, in which a reasonable analysis could yield benefits estimates ranging from $13 million to $3.4 billion, and uncertainties related to the dose-response curve, discounting, the value of life, and ecological benefits. Despite the astounding inaccuracy of cost-benefit analysis, OMB presents hard numbers, neglecting even range estimates for several of its analyses.

- Ethical problems invalidate attempts to monetize the value of human life. OMB’s random assignment of a $6.1 million value to a human life is grounded in dubious and totally discredited research on willingness-to-pay for risk reductions by outdated studies of workers in high-risk jobs. This habit, and the discounting of life that accompanies it, is morally offensive and intellectually bankrupt.

- Information gaps and uncertainties are compounded by macro-level attempts to compute overall costs and benefits. Without answering the criticism already addressed to OMB’s overly simplistic accounting methods, the 2005 draft report solicits comments on a “net benefits” approach which would conceal lost opportunities to significantly increase benefits for a minimal increase in costs and would even further diminish the already questionable value of OMB’s conclusions.

- OMB’s role conflicts with agencies’ authorizing mandates. Finally, OMB’s role directly conflicts, in many cases, with authorizing mandates agencies receive from Congress. For many workplace health, safety and environmental protections, as the Supreme Court has recognized, cost-benefit analysis in standard-setting is forbidden or is not an authorized basis for a standard.

OMB’s drive to impose cost-benefit analysis may stem from a confusion about the difference between decisions about means and decisions about ends. Cost-benefit analysis may be helpful in order to develop the most cost-effective means for carrying out a policy. In contrast, it is unethical to set the ends or goals for safeguards based upon factors other than their impact on human health and well-being.
OMB’s failure to address the cogent points of commenters undermines the commenting process, and condemns the report to replicate past errors. Clearly, the report is not the presentation of a scientific analysis of the costs and benefits of regulations—scientific studies are subjected to intense scrutiny, and errors are addressed prior to publication. OMB apparently has no interest in pursuing the scientific objectivity and accuracy to which it purportedly subscribes and demands of the government agencies that it oversees.

III. OMB’s “Hit List” Serves as a Conduit for Business Opposition to Needed Regulations and is an Inappropriate Interference in Agency Functions

There are two fundamental hypocrisies in OMB’s interference in agency activities in the form of the “hit list,” a process initiated by Office of Information and Regulatory Affairs (OIRA) Administrator John Graham that would irrationally discard those rules most disliked by industry:

1) The nomination and selection process for OMB’s hit list lacks the minimum indicia of accountability and transparency that it would reasonably expect of any U.S. government agency process, but especially a White House office that is pushing peer review of even everyday research; and

2) Its unwarranted and unauthorized interference in agency and Congressional priorities is unsupported by any analysis of the costs and benefits of the regulatory rollback it recommends or of the harm caused by delay in agency issuance of important new health, safety, environment and consumer protection rules.

The consequence of these two flaws is that OMB’s list is intellectually incoherent. OMB’s choices for the hit list remain unexplained and unjustified. When OMB summarized the original 189 submissions in December 2004, it stated that it would instruct agencies to review the suggestions and respond. OMB then summarily announced the 76 hit list endorsements, without revealing any of the rationales for the presence of those on or off the list or the responses of the relevant agencies. OMB merely repeated the reasons offered by nominators in the first instance. The public deserves to be informed of the reasons for prioritizing these suggested rollbacks of their safeguards.

OMB also must justify the need for this process in view of the many other ways in which special interests can and do affect regulatory policy. These include petitions for rulemaking, comments to regulatory dockets, lobbying Congress, litigation and the direct lobbying of agencies. Instead, the hit list process lacks any disclosure where it counts most – OMB’s substantive decision making about priorities.

While OMB may attempt to cast this process as a method for unearthing long-neglected and commonsense regulatory “fixes,” at least two of the endorsements on the final hit list, the hours-of-service rule and the hexavalent chromium rule, in fact, are the
subject of ongoing agency rulemakings that have been pending for more than a few years. OMB does not explain why the rulemaking processes of agencies, as well as, in the case of hexavalent chromium, a review process initiated by the Small Business Administration, are insufficient to address industry’s concerns.

Moreover, OMB must provide a good reason for its provision of yet another special access porthole in view of the tremendous and uneven power that regulated interests already have to weaken and derail regulation. The public, with only a relatively diffuse interest in the outcome of particular rules, is systematically disadvantaged by high-level attempts to highjack public priorities. OMB’s dabbling only exacerbates this profound inequality.

Leaving agenda-setting to Congress and the agencies makes much more sense. Congress is available to identify emerging public policy issues and to direct agencies to act, while the agencies know their issues with a depth and breadth that a handful of economists and a scientist or two at OMB cannot match. The courts also play a constitutionally assigned oversight role in safeguarding Congressional intent and assuring that evidence presented in the regulatory docket drives agency action.

While regulations may end up being far from perfect, the point is that the process involves a carefully designed balance, embedded in the separation of powers, and that OMB’s interference has no place in this purposeful architecture. OMB’s sole appropriate function is to assist in the coordination of delegated authorities among the agencies. It should not be a political gatekeeper or provide an appeal of last resort to derail rules for corporate interests.

Public Citizen’s 2004 comments called OMB to task for focusing on creation of a hit list rather than on unmet health safety and environmental needs. To that end, we submitted recommendations for affirmative action on 32 pressing social problems. OMB’s misappropriation of two of our nominations for its hit list does not alleviate the deficiencies outlined above. While both of our rulemaking actions now on its hit list are legitimate areas for action by NHTSA, OMB fails to explain its rejection of our 30 other nominations, all of which were highly deserving of attention by NHTSA or another agency. OMB needs to explain its reasons for rejecting or accepting candidates for its hit list and to publicly share agency responses.

We were somewhat surprised to note that OMB appears to agree with our assessment that a motor vehicle compatibility standard is needed, and that voluntary manufacturer activity to address vehicle mismatch in crashes is insufficient. Vehicle compatibility is a long-neglected area. The design of light trucks — and large SUVs and pickup trucks in particular — with a high center of gravity, high bumpers, and steel bars and frame-on-rail construction, makes these vehicles highly aggressive in crashes.

A car driver is twice as likely to die if their vehicle is struck on the driver’s side by an SUV rather than by a car. A vehicle compatibility standard is needed to mitigate harm done by aggressive vehicle designs. In addition, a consumer information program
for an incompatibility rating would allow consumers to make more ethical decisions about the likely harm inflicted on others when purchasing a vehicle. Rather than pushing for these needed items, OMB appears content with NHTSA’s promise to publish a report on this issue. This certainly ranks among the most tepid responses by any agency to a hit list prompt, and is far from good enough, particularly given the deadly problem of vehicle aggressivity.

A requirement for an occupant ejection safety standard is pending in the Senate version of H.R. 3, the highway reauthorization bill and has received widespread bipartisan support. More than 13,000 highway fatalities, and many more serious injuries, involve ejection each year, and occur in both side impact rollover crashes. Government estimates are that advanced glazing in side windows would save between 500 and 1,300 people each year, while stronger door locks and latches would prevent hundreds of deaths annually. Especially troubling is the fact that safety belts are not designed to protect occupants in rollovers, and more than 400 belted occupants are killed annually in rollover ejections.

We strongly support Congressional enactment of a requirement for a new ejection prevention safety standard, particularly when combined, as it is in H.R. 3 and should be at NHTSA, with a new standard for roof crush. A strong roof crush rule could dramatically reduce ejections by closing the ejection portals caused by roof deformation and broken side window glass. But OMB has ignored Public Citizen’s request for priority action on roof crush.

Following is a discussion of two hit list nominations of particular note that fall more squarely into OMB’s typical anti-regulatory approach. In the case of both the hours-of-service and hexavalent chromium rules, court involvement initiated by Public Citizen was required to assure that the federal agencies act according to their statutory mandate. Also in both cases, Public Citizen’s litigation was founded on a science-based challenge, and our claims were upheld by the reviewing court, U.S. Courts of Appeal, in unanimous rulings by a three-judge panel.

**HOS rollback would jeopardize truck drivers and the driving public.**

In 2003, Public Citizen sued the FMCSA over a final rule extending allowable driver time from 10 to 11 hours and for other serious flaws that diminished safety. The overall impact of the various parts of the overturned rule was to increase total work time by nearly 40 percent and total driving time by 20 percent.

A U.S. Court of Appeals for the District of Columbia Circuit overturned the rule, harshly criticizing FMCSA for failing to consider the effect of the rule on the health of truck drivers as well as other challenged aspects of the rule. The Court strongly suggested that the agency’s rule was not founded in science, which shows an increase in risk every hour of driving beyond eight hours on the road. The agency is now in rulemaking to respond to the court’s decision.
Truck drivers are currently exempt from the Fair Labor Standards Act, and receive no overtime pay despite having to work 14-hour shifts – nearly double the daily hours of the average American. Truck driving is very strenuous work, involving operating a heavy vehicle for long periods of time with intense concentration, as well as unloading and loading shipments. Motor vehicle crashes involving commercial trucks kill nearly 5,000 Americans each year, and many of these crashes are fatigue-related.

OMB’s endorsement of a nomination to extend maximum driving beyond 11 hours for local or any other category of drivers is entirely without basis in science and would greatly jeopardize the safety of both the public and commercial drivers. As FMCSA acknowledges in its rulemaking, performance degrades geometrically after eight hours, and in fact, the risk of a crash doubles between the 10th and 11th hours of consecutive driving.

The local or short-haul drivers that are the focus of OMB’s hit list item are not exempt from the cumulative fatigue of these long work shifts. Although fatigue effects for these workers may be relatively less severe when compared to long-haul drivers, long on-duty hours, regardless of driving time, still degrade performance and increase risk. One major study by FMCSA of short-haul drivers found that fatigue was a factor in 20 percent of the 77 critical incidents over a two week period where the driver was deemed at fault. Studies show that the overall impact of long work shifts negatively impacts safety, with risk approximately doubling after 12 hours of work. Long work days are exhausting, in and of themselves, and allowing drivers to continue driving at the tail-end of these long shifts would substantially exacerbate risks to others on the road.

Endorsement of hexavalent chromium complaint is unjustified

OMB’s inclusion of OSHA’s hexavalent chromium rulemaking on its list is similarly completely unjustified and misleading. All reputable scientists agree that hexavalent chromium is a lung carcinogen. The National Institute for Occupational Safety and Health in 1975, the National Toxicology Program in 1980, the Environmental Protection Agency in 1984, the International Agency for Research on Cancer in 1990 and the Agency for Toxic Substances and Disease Registry in 2000 have all reached this conclusion. So has OSHA itself. In 1994, in response to a petition from Public Citizen and a union now allied with the United Steelworkers to reduce occupational hexavalent chromium exposure levels, Joseph Dear, then Assistant Secretary of Labor for Occupational Safety and Health, stated that there is “clear evidence that exposure ... at the current [Permissible Exposure Limit] PEL ... can result in an excess risk of lung cancer.”

Because of OSHA’s failure to act on this conclusion, we sued the agency in 1997 and again in 2002. We prevailed in the second case, resulting in a court order from the U.S. Court of Appeals for the Third Circuit requiring OSHA to produce a final rule by January 18, 2006. The court decried OSHA’s “indefinite delay and recalcitrance in the face of an admittedly grave risk to public health” and held that “OSHA’s delay in promulgating a lower permissible exposure limit for hexavalent chromium has exceeded the bounds of reasonableness.”
On October 4, 2004, OSHA produced its court-ordered proposed rule, reducing the PEL from the current 52 micrograms to 1 microgram per cubic meter. In general, this rule is thoughtfully assembled, and comprehensively analyzes all data available to the agency. OSHA acknowledges that its new PEL leaves “clearly significant” health risks, and we believe that it is economically and technologically feasible to lower the PEL further to reduce these risks. Based on the leading epidemiological study in the field (the Gibb study), exposure to hexavalent chromium at the current PEL of 52 micrograms per cubic meter for a working lifetime (the required assessment under the Occupational Safety and Health Act) would result in 351 excess lung cancer deaths per 1,000 workers. Even at the proposed new PEL, nine excess lung cancer deaths per 1,000 workers would occur, well in excess of the standard set in the Supreme Court’s 1980 Benzene decision. At present, the agency estimates that over 85,000 unfortunate workers (22.4 percent of chromium-exposed workers) exceed the proposed PEL.

The industry has already made full use of its numerous opportunities to influence this rulemaking. Through individual chromium-using companies, industry associations and the so-called Chrome Coalition, the industry intervened in both Public Citizen lawsuits, provided written comments during the three stages of the rulemaking, testified and cross-examined witnesses at a ten-day OSHA public hearing, participated in the Small Business Regulatory Enforcement Fairness Act (SBREFA) process, and held at least two meetings with the OMB. The chromium industry testimony at a recent hearing before the House Subcommittee on Regulatory Affairs is simply the latest round in an effort, stretching back over a decade, to undermine a proposed rule that could save hundreds of lives.

It is not as if OSHA has been too busy to regulate hexavalent chromium. The agency has not completed a single safety standard on an occupational chemical since 1997 and, except for this court-ordered proposal, has not proposed any such regulation since at least the beginning of the Clinton administration. There is little else of substance on the agency’s regulatory agenda at present.

IV. Draft Report Should Include Balanced, Scholarly Look-Back Studies, Exclude Flawed Studies

OMB neglects many important look-back studies from its list of ex post analyses. One glaring omission is Ruth Ruttenberg’s Not Too Costly, After All, which Public Citizen submitted to OMB last year with comments to the 2004 draft report. OMB’s list also neglects a number of other studies, which OMB Watch lists in its comments to the 2005 draft report. Without these important studies, OMB cannot accurately compare ex ante and ex post costs. We request that OMB reference all these studies in the final report.

Two seriously flawed look-back studies in OMB’s list should be removed. One is the AEI-Brookings study. OMB Watch provides analysis of the study showing reason
for removal in comments to the draft report.\textsuperscript{33} The other study is the Thompson/Graham evaluation of airbag cost-effectiveness, which relies upon data from a 1997 study by Graham that Public Citizen criticized in detail in the 2001 report “Safeguards at Risk.”\textsuperscript{34} The Thompson/Graham study failed to distinguish between different models of air bags and types of air bag release systems – a failing which invalidates the results because, for example, top-mounted vertically deploying air bags installed in a number of models hit the windshield before impacting with occupants and had not caused any fatalities at the time the study was completed.

Based on the analysis of the flawed \textit{JAMA} study, the Thompson/Graham study concludes that the “large amount of uncertainty associated with airbag-effectiveness estimates did not appear to be fully appreciated,” which may have resulted in overlooked opportunities to conduct further research on the effectiveness of airbags.\textsuperscript{35}

However, as OMB Watch details in comments to the report, uncertainty has many different meanings. In its scientific definition, uncertainty is present in any study. For example, uncertainty exists in extrapolating from the reaction of laboratory studies to administered drugs to the likely effect those drugs will have on humans.\textsuperscript{36} Anti-regulatory rhetoric, however, often misapplies “uncertainty,” inappropriately casting doubt on even the soundest scientific studies in order to further an anti-regulatory agenda.

As demonstrated in an analysis of environmental regulations conducted by Frank Ackerman, Lisa Heinzerling, and Rachel Massey, degrees of uncertainty were present in important regulation decisions in the past. For instance, regulations removing lead from gasoline were adopted on a precautionary basis. Despite EPA’s inability to precisely quantify the adverse health effects caused by lead, the agency established regulations that reduced the amount of lead allowed in gasoline, which protected the public, and particularly vulnerable children, from lead exposure, and returned enormous benefits.\textsuperscript{37}

The Administration, however, has repeatedly misused uncertainty as a tool to push a policy of regulatory inaction, delay, and rollback. FMCSA’s recent notice of proposed rulemaking (NPRM) on rules governing the hours-of-service (HOS) of motor carrier drivers is an example of how the Administration is using the rulemaking process to generate uncertainty regarding a large, well-established body of scientific evidence.\textsuperscript{38}

In April 2003, FMCSA issued a final rule on HOS that failed to consider the effect of the new rules on the health of truck drivers — as the agency is required to do under law. Moreover, the rule increased both the consecutive hours and the weekly hours that truck drivers are permitted to drive without rest. A coalition of safety groups filed suit challenging the rule, and in July 2004 a panel of the U. S. Court of Appeals for the District of Columbia Circuit issued a unanimous decision that vacated the rule in its entirety for ignoring driver health. In addition, the three-judge panel also expressed grave doubt that any of the challenged aspects of the agency’s regulation could survive scrutiny. The court ordered the agency to revise its safety standard in a manner consistent with the court’s opinion. In response to the Court decision, FMCSA issued a new HOS NPRM in January 2005.\textsuperscript{39}
However, the notice simply re-proposes the 2003 HOS final rule. In again proposing an HOS rule that was recently found by the Court to be grossly flawed, FMCSA demonstrates a shocking disregard both for the Court and for its mandate to protect health and safety. The Court vacated FMCSA’s final rule because the agency ignored the well documented effects of driving time on driver health. Moreover, the Court severely chastised FMCSA for extending driving time in the face overwhelming scientific evidence to the contrary.

FMCSA’s January 2005 request for comments fails to reflect a sincere interest in gathering nonbiased information and instead demonstrates a clear attempt to “fish” for evidence or junk science to prop up aspects of the NPRM that the agency cannot justify. For example, the agency asks “To what extent does a reduction of the ‘daily’ duty-period from 15 non-consecutive hours to 14 consecutive hours, and the increase in minimum off-duty time from 8 hours to 10 hours, offset the increase in allowable driving time from 10 hours to 11 hours in terms of driver health, the safe operation of the CMVs, and economic factors in the CMV industry?” The request baldly and self-servingly states the conclusion that FMCSA wishes to reach. Moreover, it is requesting precisely the supporting information that the agency itself should be providing to justify its HOS proposal in the first place. It is entirely unacceptable that FMCSA propose HOS regulations that are arbitrary and unsupported by objective, scientific evidence.

Industry also has employed manufactured uncertainty and junk science to squash critical public protections. For example, Ford has used junk science to undermine and delay the issuance of a roof strength standard that will adequately protect occupants in rollover crashes. Ford has argued for decades that roof crush does not cause injury in rollover crashes. To back this counterintuitive claim, Ford created junk science that blames neck and head injuries in rollovers on occupants diving into the roofs of vehicles, not on the roof crushing down on them.

A recent report written by Martha Bidez, Ph.D., of Bidez Associates, and a professor of biomedical engineering at the University of Alabama at Birmingham, however, debunks this claim with scientific evidence. Bidez’s report, “Roof Crush as a Source of Injury in Rollover Crashes,” analyzes Ford’s own tests to show that roof crush does, in fact, occur prior to injurious neck loads during rollovers. Thus, improving a vehicle’s resistance to roof crush would, in fact, prevent catastrophic head and spinal cord injuries and deaths. In addition, there is no safety standard for belt performance in rollovers, and many belts fail to adequately restrain occupants in such crashes. Ford ignores this performance failure in its arguments.

Further, new industry documents made public only recently show that while Ford has denied a link between roof strength and rollover crash injuries, its subsidiary, Volvo, has recognized that strengthening roofs and installing side head air bags and pre-tensioned belts in rollover crashes will save lives. Volvo produces the XC-90, a vehicle with a roof that does not crush in during rollover tests.
Strengthening roofs and installing other basic safety devices, such as side head air bags, safety glass and pre-tensioned belts, is the only way to save lives in rollover crashes. Also, strong roofs and pillars are crucial for the effective performance of belts, side head airbags, and to prevent windows from shattering, opening portals for ejection. For automakers to claim that head injuries are the fault of people ‘diving’ into the roofs of their cars is ludicrous. If the roofs don’t collapse in a rollover crash, the people in the vehicle have a far better chance of surviving. One of the basic tenets of auto safety is that to prevent injuries, there can be little or no intrusion. It is essential to prevent parts of the vehicle from closing in and coming into contact with occupants in the vehicle.

Ford has used the “diving” claim that argue against government requirements for stronger roofs on vehicles and to shield themselves from liability in lawsuits brought by families of rollover crash victims. Improvements to the roof crush standard have languished, and to this day, NHTSA has not updated the 1971 standard that has proven completely inadequate. Every year, almost 10,000 people are killed in rollover crashes, and 6,000 to 7,000 deaths a year are related to roof crush and its consequences for other vehicle components such as windows, doors, and restraints.

The current roof crush standard was enacted in 1971 and took effect in 1973. The one-sided static test requires one section of a vehicle’s roof to withstand 1.5 times the vehicle’s weight. The test assumes the windshield remains intact throughout the crash, despite the fact that in virtually all rollover crashes, the windshield is usually gone by the first quarter turn. Once gone, the roof loses a third of its strength, making it far more likely that the roof will crush in and making it easier for people to be ejected. Occupants sitting on the far side of the vehicle from the direction of the roll are particularly vulnerable.

Over the years, NHTSA officials have promised many times to upgrade the standard and require automakers to make stronger roofs. But the agency has dragged its feet and has not issued a rule. The agency is expected to propose a minor upgrade – a placebo – to respond to demands for stronger vehicle roofs.

Look-back studies must be conducted by independent and disinterested scholars. As OMB Watch details in comments to the report, certain groups do not meet these criteria, and OMB should avoid studies from these sources.

V. Regulatory Actions are Needed to Protect the Public

Agency resources are limited, and while OMB whisks corporate interests to the head of the line for agency attention, many public needs go unmet. Without adequate safety standards to meet these needs, the public will continue to suffer. Following is a list of unmet needs and critical measures to protect the public that the relevant government agencies should make priorities.

Auto and Highway Safety
Key measures to improve auto and highway safety include:

- A rollover crashworthiness safety standard, including a dynamic roof strength standard, that requires improved seat structure and safety belt design (including belt rollover pretensioners), side impact head protection airbags, roof injury prevention padding, and laminated side-window glazing.
- A rollover prevention safety standard to increase vehicle resistance to rollover consistent with electronic stability technology.
- The coverage of all passenger vehicles up to 10,000 pounds, including 15-passenger vans, by all NHTSA safety standards, as appropriate, applicable to light trucks, SUVs or cars, and inclusion in the New Car Assessment Program.
- A rule to require NCAP ratings or industry results of equally or more stringent tests at point-of-sale.
- Completion of the rule to upgrade the side impact safety standards and set better baselines for side impact protection.
- A rule to require a reminder system when the ignition is in the off position and occupants remain in the rear seats of a vehicle.
- A rule establishing a rearward visibility standard.
- A rule setting new safety belt reminder systems that are more effective than the current 8-second reminder. NHTSA should conduct a study of the effectiveness of safety belt reminder systems and consider methods of increasing safety belt use.
- A rule to eliminate rocker window switches, and require pull-up or pull-out switches and an automatic reverse mechanism on power windows.
- NHTSA should also establish and maintain a database on non-traffic, non-crash incidents involving vehicles less than 10,000 pounds. All such information should be readily available to the public.
- Completion of an HOS rule that promotes driver health and protects the driving public.
- A rule requiring compatibility between trucks, cars, and SUVs in front, side, and rear impact crashes.
- A rule including all passenger vehicles in frontal impact crash tests.

Drug and Supplement Safety

Key loopholes abound in the area regulated by the Food and Drug Administration, including:

- Compounded drugs can be sold without FDA approval.
- Unregulated dietary supplements can interfere with the effectiveness of medications, affect blood pressure, and pose even greater risks when used by pregnant women.
• Off-label promotion of drugs has lead to such disastrous results as the widespread heart valve damage caused by use of “fen/phen” as a diet drug.

Needed measures to increase drug and supplement safety include:

• Authority to treat compounded drugs as unapproved new drugs;
• Mandatory reporting by pharmacists of adverse effects from compounded drugs;
• Authority to regulate off-label promotion;
• Mandatory pre-market studies and post-marketing adverse reports for dietary supplements.

Food Safety

In many areas, food safety regulations have not kept pace with critical needs or have been undermined:

• The potential effects of Bovine Spongiform Encephalopathy (BSE) are devastating, yet USDA has failed to mandate known safety measures to protect against human exposure.
• Many of the largest ground beef plants in the United States have been allowed to continue to send ground beef stamped USDA-approved to market after tests repeatedly showed the presence of Salmonella.
• USDA has issued directives constraining inspectors’ ability to implement the “zero tolerance” policy for fecal contamination.
• Although no long-term studies have been done of the effect of eating irradiated food and it is known that irradiation produces new chemical compounds that have been found to cause cellular damage, USDA has approved irradiated beef for the school lunch program.
• The weakened listeria monocytogenes rule allows companies not to tell USDA inspectors if they discover listeria on premises, requiring, instead, that inspectors request test results.

Sorely needed measures to increase food safety include:

• A total ban on the use of Advanced Meat Recovery;
• A ban on the sale of all brains, spinal cords, and other significant risk materials from cows of any age;
• Continuation of the bar against imports from Canada, for both live animals and meat products;
• A BSE testing program that ensures that appropriate animals are tested at an adequate rate and includes testing of all non-ambulatory, disabled animals and testing of all cattle 20 months or older;
• A ban on feeding of mammalian parts to other animals and poultry;
• Daily microbial tests for *Salmonella* and appropriate government action as soon as plants fail the tests;
• Enforcement of “zero tolerance” for fecal contamination under any and all circumstances and withdrawal of directives that weaken enforcement;
• Withdrawal of the approval of irradiated meat for the school lunch program;
• Compulsory disclosure of supermarkets involved in meat, egg, or poultry products recalls;
• Authority to ensure the enforceability of microbial testing performance standards and standard sanitation operating procedures.

**Workplace Safety**

Needed measures to increase workplace safety include:

• A rule to prevent ergonomic injuries;
• Amendment of the Process Safety Management Standards to achieve more comprehensive control of reactive hazards;
• A rule to protect workers who handle metalworking fluids;
• A rule to protect workers who are at risk of exposure to TB infection;
• A requirement that employers pay for all required personal protective equipment;
• A revised beryllium standard that is adequate to protect workers, together with medical surveillance and engineering controls to reduce exposure.
• Completion of the court-ordered hexavalent chromium standard.

**VI. Conclusion:**

Regulations are a modern form of the social contract. They embody a fundamentally democratic idea about the exchange of responsibilities among participants in a society. The expression of values and moral judgments enacted by government safeguards are completely neglected in OMB’s econometric accounting of what government is or does.

To illustrate the depth of commitment and salience of the common sentiments captured in government standards, we would like to suggest the following five principles for understanding the purposes of government regulation. These are our own version of the ideals at stake in debates over the nature of the regulatory process and decisions about whether and how to regulate:

1) Corporations, like people, should clean up after themselves and be required to prevent the foreseeable harm of actions and choices.
2) Government action should correct social and political wrongs, set out fair rules for participation, distribute resources fairly and preserve and protect shared resources and the public commons.
3) Government activity both reflects and enacts moral values and collective goals – clarifying who we are and what matters to us.
4) People have a responsibility to actively respect the lives and health of people we do not know, as well as the natural environment and its limitations and gifts.
5) Voluntary risks are morally distinct from risks imposed upon the public without their knowledge or consent.

The principles encapsulate some of what is systematically disregarded by OMB’s cynical view of both government and the people whom government protects under the constitutional prescription that it “promote the general Welfare.”

Because much government activity is motivated by equitable concerns for others, rather than narrow self-interest, OMB’s basic framework excludes a real understanding of its subject. OMB’s analytical tools and worldview suffer crippling limitations, and therefore should be abandoned.

Sincerely,

Joan Claybrook
President
Public Citizen

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3 In a hearing in 2003, Graham thoroughly dismissed the Crain and Hopkins study regularly cited by industry, stating:
   “The fact that attempts to estimate the aggregate costs of regulations have been made in the past, such as the Crain and Hopkins estimate of $843 billion mentioned in Finding 5, is not an indication that such estimates are appropriate or accurate enough for regulatory accounting. Although the Crain and Hopkins estimate is the best available for its purpose, it is a rough indicator of regulatory activity, best viewed as an overall measure of the magnitude of the overall impact of regulatory activity on the macro economy. The estimate, which was produced in 2001 under contract for the Office of Advocacy of the Small Business Administration, is based on a previous estimate by Hopkins done in 1995, which itself was based on summary estimates done in 1991 and earlier, as far back as the 1970s. The underlying studies were mainly done by academics using a variety of techniques, some peer reviewed and some not. Most importantly, they were based on data collected ten, twenty, and even thirty years ago. Much has changed in those years and those estimates may no longer be sufficiently accurate or appropriate for an official accounting statement. Moreover, the cost estimates used in these aggregate estimates combine diverse types of regulations, including financial, communications, and environmental, some of which impose real costs and others that cause mainly transfers of income from one group to another. Information by agency and by program is spotty and benefit information is nonexistent. These estimates might not pass OMB’s information quality guidelines.”
The Center for Progressive Reform (CPR) highlighted in comments last year to the 2004 draft report that OMB relied upon flawed and inapposite studies to support its claim of a regulation-economic strength trade-off. See Heinzerling, Lisa and Frank Ackerman, Letter to Lorraine Hunt, OIRA, May 20, 2004, at 4. OMB repeats this mistake in this year’s draft report, citing the same flawed and inapposite studies, such as the Heritage Foundation index. OMB states that “[s]ince 1995, the Heritage Foundation and the Wall Street Journal have published jointly a yearly index of economic freedom for 161 countries. They find a very strong relationship between the index and per capita GDP.” OMB Draft report, at 30. OMB uses the Heritage Foundation index in support of the “impact of smart regulation on economic growth,” even while acknowledging that a “correlation between degrees of economic freedom and per capita GDP does not prove that economic freedom causes economic growth.” Id. OMB also cites an index published by the Fraser Institute, which CPR also criticized in comments to the 2004 draft report. OMB uses both the Heritage Institute and the Fraser Institute indexes, even though, according to OMB, both “have several drawbacks,” such as “the data are based largely on subjective assessments and survey results” and “include non-regulatory indicators.” Additionally, OMB cites a World Bank study despite an extensive critique of OMB’s use of the report last year by CPR that showed the report’s conclusion to be inapplicable to OMB’s purposes.

See generally Kevin Gallagher, Trade Liberalization and Industrial Pollution in Mexico: Lessons for the FTAA (Global Dev. & Envt. Inst. Working Paper, Oct. 2000) (finding that labor costs rather than pollution abatement regulation drive overseas relocation of industries); Eban Goodstein, A New Look at Environmental Protection and Competitiveness (Econ. Pol. Inst. Briefing Paper, 1997) (concluding that industries that spent more on regulatory compliance between 1979-1989 exhibited superior performance to foreign competitors); Eban Goodstein, Jobs and the Environment: The Myth of a National Trade-Off 19 (1994) (“Highly polluting industries are relocating to poor countries; but the reason, overwhelmingly, is low wages.”); Jaffe et al., Environmental Regulation and the Competitiveness of U.S. Manufacturing: What Does the Evidence Tell Us?, 33 J. Econ. Lit. 132 (1995) (finding that “overall, there is relatively little evidence to support the hypothesis that environmental regulations have had a large adverse effect on competitiveness”). See also Testimony of Sidney A. Shapiro, before the Subcommittee on Regulatory Affairs Committee on Government Reform, U.S. House of Representatives, April 12, 2005.


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For just one example of its imperviousness, OMB claimed in the 2005 draft report that the costs associated with regulations is borne by workers, providing no support for this strong claim except for a citation to a single economics textbook. In its 2004 comments, CPR excoriated OMB for this thinly veiled and inaccurate attack on regulation, stating: “Textbooks, of course, do not all agree with each other, and they do not represent peer-reviewed literature, the standard of proof that OMB requires in other areas. OMB cites no empirical evidence for its claim. OMB should exclude this claim from the Report unless it produces evidence for it. Moreover, if OMB does produce evidence for this claim, it should address the significant evidence that exists on the other side of the issue. For example, University of California-Berkeley economist David Card and Princeton University economist Alan Krueger have written widely on empirical studies of minimum wage laws, finding that – contrary to assumptions in many textbooks – moderate increases in the minimum wage have a zero to slightly positive effect on employment. Their work has appeared twice in the prestigious American Economic Review, and the book-length version has been published by Princeton University Press.” Heinzerling, Lisa and Frank Ackerman, Letter to Lorraine Hunt, OIRA, May 20, 2004, at 3. Regardless of this well-reasoned objection, OMB’s 2005 draft report repeated the assertion verbatim and without noting CPR’s critique.

As CPR pointed out in 2004 comments in a critique which went unanswered by OMB, the designation by OMB of some rules as transfer rules makes little sense. One so-called “transfer rule” is of particular interest, as it concerns a rule currently being challenged in court by Public Citizen. The rule allocates credits under the Corporate Average Fuel Economy (CAFE) program to automakers for the production of vehicles with a “dual-fuel” capacity. Because these vehicles actually use alternative fuel less than 1 percent of the time, according to the government’s own published estimates, the rule permits overall fuel economy standards to be considerably lower than those set under CAFE. There are few clearly quantifiable public benefits and no monetizable benefits, according to NHTSA’s regulatory impact analysis (RIA) on the subject, which also provides a cost estimate range for the rule as between 2.6 billion and 3.2 billion gallons of gasoline, at a corresponding discounted value of between $1.9 billion and $2.2 billion. See “Final Economic Assessment, Alternative Fuel ed Vehicles, Extension of CAFE Option, Part 538,” Feb. 2004, Docket No. NHTSA-2001-10774-37. OMB has therefore designated a “transfer rule” a rule that has nothing to do with the budget, that NHTSA clearly thought required preparation of an RIA, and for which NHTSA estimated massive costs and only highly contingent, and possibly nonexistent, benefits.


See Lisa Heinzerling and Frank Ackerman, Priceless: On Knowing the Price of Everything and the Value of Nothing, New Press (2004) at 75-6 (providing ample discussion of the grave deficiencies in willingness-to-pay calculations, including its basis in studies rife with methodological problems); see also Heinzerling, Lisa and Frank Ackerman, Letter to Lorraine Hunt, OIRA, May 20, 2004.


The National Transportation Safety Board has estimated driver fatigue as a probable cause in 58 percent of single-vehicle large truck crashes it investigated and 30 to 40 percent of all large truck crashes. See National Transportation Safety Board, “Factors That Affect Fatigue in Heavy Truck Accidents,” Washington, D.C.: NTSB, 1995, at v.

The study involved 42 drivers only and classified 77 of the total 249 critical incidents recorded as the fault of the driver. See Impact of Local/Short Haul Operations on Driver Fatigue, U.S. Department of Transportation, Federal Motor Carrier Safety Administration, Report No. DOT-MC-00-203, Sept. 200, at ix.

The timeline for efforts to establish rules for hexavalent chromium exposure is as follows:

- **July 1993** - Public Citizen files a petition for a rulemaking for an occupational health standard for hexavalent chromium.
- **Feb. 1994** - OSHA agrees there is clear evidence of an excess risk of lung cancer with exposure at the existing standard, and states that it will publish a notice of proposed rulemaking no later than March 1995.
- **Aug. 1997** - After repeated delay in issuance of a notice (accompanied by repeated acknowledgments that the existing standard was inadequate and should be lowered by a factor of 10 to 100), OSHA denies Public Citizen’s request for a rulemaking schedule but says it will move as quickly as possible.
- **Oct. 1997** - Public Citizen brings an action in the Third Circuit claiming unreasonable delay and seeking to compel action. OSHA tells the court that the agency expects to issue a notice of proposed rulemaking (NPRM) by Sept. 1999.
- **March 1998** – The court denies the Public Citizen petition to compel agency action, holding that agency delay is not yet extreme enough to warrant action and emphasizing the agency’s intention to act in 1999.
- **August 2000** - The Gibb study is published and confirms that hexavalent chromium causes lung cancer at exposure levels far below those permitted by the existing standard.
- **Dec 2001** - OSHA’s regulatory agenda demotes revision of hexavalent chromium to a “long-term action” with a timetable “to be determined.”
- **March 2002** - Public Citizen files another action in court, claiming unlawful delay.
- **December 2002** – The court finds that the agency has engaged in unlawful delay and orders the parties to mediate over a possible remedy.
- **Feb. 2003** - In mediation, OSHA proposes to take over four more years to issue a final rule; Public Citizen proposes a two-year schedule. The mediator recommends a three-year schedule.
- **March 2003** - The court accepts the mediator’s proposed schedule, calling for issuance of the NPRM by October 2004, and a final rule by January 2006.
**Oct. 2004** - OSHA issues the NPRM on schedule. The proposal calls for a 50-fold reduction in the exposure standard for hexavalent chromium, although OSHA acknowledges that significant risks will remain at that level. OSHA’s cited rationale for not lowering the standard further is a concern about the technological feasibility of a lower standard for only two industries, out of dozens, in which workers are exposed.

**Feb. 2005** - OSHA holds two weeks of hearings on the proposed rule. Public Citizen, the National Institute for Occupational Safety and Health (NIOSH), and labor groups testify that OSHA should reduce the exposure level still further to eliminate the significant risks that remain at the proposed exposure levels. Industry comes out in force to claim the proposed rule will be economically infeasible and to ask for a much more permissive standard.

**April 2005** - Industry groups present a new study to OSHA in post-hearing comments, claiming that it shows that low levels of exposure do not elevate cancer risks. Public Citizen points out that the study is underpowered to support any such conclusions.

38 See also OMB Watch, Comments on 2005 Draft Report, at 48 – 49.
39 70 FR 3339.
41 70 FR 3347.