marie_cayco@dc.kirkland.com
05/05/2003 06:55:50 PM

Record Type: Record

To: Lorraine D. Hunt OIRA BC RPT/OMB/EOP@EOP

cc:
Subject: Comments on 2003 Draft Report

---------- Forwarded by Marie Cayco/Washington DC/Kirkland-Ellis on 05/05/2003 07:02 PM ----------

Marie Cayco
05/05/2003 03:09 PM

To: OIRA_BC_RPT@omb.eop.gov
cc:

Subject: Comments on 2003 Draft Report

May 5, 2003

Ms. Lorraine Hunt
Office of Information and Regulatory Affairs
Office of Management and Budget
NEOB
Room 10202
725 17th Street, N.W.
Washington, D.C. 20503

Re: Comments on Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations

Dear Ms. Hunt:

Attached please find General Motors Corporation's comments on the the Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations.

If you have any questions, please call me at (202) 879-5126.

Sincerely,

Marie Cayco
Legal Secretary

(See attached file: GM Comments_OMB 2003 Benefit-Cost Analysis_05-05-03.pdf)

Marie V. Cayco
Kirkland & Ellis
Phone: (202) 879-5126
Fax: (202) 879-5200
655 Fifteenth Street, N.W.
Washington, DC 20005

- GM Comments_OMB 2003 Benefit-Cost Analysis_05-05-03.pdf

OFFICE OF MANAGEMENT AND BUDGET
EXECUTIVE OFFICE OF THE PRESIDENT

Comments of

GENERAL MOTORS CORPORATION

Responding to the Notice and
Request for Comments On the Draft **2003** Report to
Congress on the Costs and Benefits of Federal Regulations

May **5,2003**

For further information contact:

Michael J. Whinihan, PhD.
Senior Economist
Public Policy Center
GENERAL MOTORS CORPORATION
300 Renaissance Center
P.O. Box **300**
Detroit, MI **48265-3000**

TABLE OF CONTENTS

COMMENTS OF GENERAL MOTORS CORPORATION

General Motors Corporation ("General Motors") respectfully submits these comments in response to the invitation in the Office of Management and Budget's ("OMB") February 3,2002 Notice seeking comments on its Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations. *See* **68** Fed. Reg. 5492 (Feb. 3,2003); *see also* **68** Fed. Reg. 15772 (Apr. 1, 2003) (extending deadline for comments).

These comments are divided into five parts. Part I focuses on the importance of benefit and cost analysis as a tool for forming regulatory policy, and recommends that such analysis be required for all major rulemakings. Part II explains why OMB should declare that the value of a statistical life year ("VSLY") methodology is preferred to the value of a statistical life ("VSL") methodology as a metric for valuing reduced mortality risks. Part III discusses recent scholarship on the issue of discount rates, and recommends that OMB make clear that discount rates used in regulatory analysis should normally equal the opportunity cost of capital. Part IV addresses the NPRM's recommendation that benefit transfer methods be a "last resort option," and suggests that OMB consider centralizing investigation of willingness-to-pay issues in the Office of Information and Regulatory Affairs ("OIRA"). Part V explains why state regulation should be preempted anytime that it stands as an obstacle to the achievement of a federal agency's full regulatory objectives.

ANALYSIS

I. OMB SHOULD CLARIFY THAT BENEFIT AND COST ANALYSIS IS NEEDED FOR ALL MAJOR RULEMAKINGS

General Motors commends OMB for its continued efforts to improve the regulatory analyses prepared by federal agencies. Like OMB, General Motors believes that it is important to improve how federal agencies use economic analysis in forming regulatory policy. As OMB is well-aware, existing federal regulations have often been questioned for relying on shaky science, for adopting inefficient command-and-control mechanisms, and for failing to achieve a complete or reliable accounting of the benefits of mortality risk reductions. *See, e.g.*, ECONOMIC **ANALYSES AT** EPA (Richard D. Morgenstern ed. 1997); Cass R. Sunstein, *Paradoxes of the Regulatory State,* 57 U. Chi. L. Rev. 407 (1990) (discussing the causes of regulatory failure).

OMB's proposed guidelines represent two important steps in the direction of improved analytical rigor in the decisionmaking of federal agencies. ***First,*** the guidelines require that federal agencies "provide a benefit and cost analysis of major health and safety rulemakings" in addition to a cost-effectiveness analysis. **68** Fed. Reg. at 5520. This statement apparently requires agencies to furnish a benefit and cost analysis for all "health and safety" rules with costs or benefits in excess of $100 million. ***Second,*** for major rules "involving threshold costs of $1 billion" or more, the guidelines require federal agencies to "present a formal quantitative analysis of the relevant uncertainties." **68** Fed. Reg. at 5523.

General Motors commends OMB for incorporating these important requirements into its guidelines, but recommends that they be further clarified. In particular, General Motors

recommends clarifying that benefit and cost analysis is required for ***all*** rulemakings imposing costs of at least $100 million on entities outside the federal government (including the private sector, state, and local governments and tribes). Analysts agree that benefit and cost analysis helps promote better regulatory decisionmaking, as it can identify trade-offs among alternatives and improve the chance that regulations will be designed to achieve particular policy goals at a lower cost. When practiced artfully, careful benefit and cost analysis is a useful tool that regulators should employ in many different contexts to improve the quality of agency decisionmaking. *See, e.g.*, Richard D. Morgenstern, *Conducting An Economic Analysis — Rationale, Issues, and Requirements*, in ECONOMIC **ANALYSES AT** EPA, at 25 (Richard D. Morgenstern ed. 1997).

The NPRM, however, appears to limit the benefit and cost analysis requirement to only "health and safety" regulations. This limitation is potentially disadvantageous because it could be taken by some agencies to exclude regulatory actions aimed at protecting aesthetic, cultural, or "option" values. Regulation of private land in order to guard against visibility impairment, extinction of species, or degradation of historic settings are examples of these types of regulatory action. Clarifying the broad applicability of the benefit and cost analysis requirement is therefore important because it is precisely in the context of non-traditional health and safety regulation that the insights provided by proper benefit and cost analysis will often be most revealing. *See* Robert W. Hahn & Cass R. Sunstein, *A New Executive Order for Improving Federal Regulation? Deeper and Wider Cost Benefit Analysis,* 150 U. Pa. L. Rev. 1489 (2002).

11. OMB SHOULD CLARIFY THAT THE VALUE OF A STATISTICAL LIFE YEAR ("VSLY") IS THE PREFERRED METRIC FOR VALUING REDUCED MORTALITY RISKS

In the real-world practice of applying economic analysis to regulatory issues, choosing the correct methodological approach for measuring risk is fundamental. OMB's guidelines should therefore make clear that the value of a statistical life year ("VSLY") is the ***preferred*** metric for analysis and, in particular, that it is preferable (and not just an alternative) to the monetary value of saving a statistical life ("VSL"). At present, the NPRM's discussion on this point is somewhat confusing and may lead to the misimpression that VSLY and VSL are to be regarded as equally appropriate metrics for valuing reduced mortality risks.

There is a broad consensus within the economic literature on the advantages of using VSLY over VSL as a measure of mortality risks. Indeed, for many years now, most academic authors and analysts have stressed the importance of taking into account the expected duration of lost lives instead of mortality. *See, e.g.*, Richard Zeckhauser & Donald Shepard, *Where Now for Saving Lives?*, 40 Contemporary Problems 5-45 (1976); W. Kip Viscusi, *Risk By Choice: Regulating Health and Safety in the Workplace,* Harv. U. Press (1983); Sherwin Rosen, *The Value of Life Expectancy,* 1 J. of Risk and Uncertainty 285-304 (1988); W. Kip Viscusi & Michael J. Moore, *Rates of Time Preference and Valuations of the Duration of Life,* 38 J. of Public Econ. 297-317 (1989); Cass R. Sunstein, *Health-Health Tradeoffs*, 42 U. Chi. L. Rev. 15 (1996) (suggesting that it would be better to focus on statistical years rather than statistical lives). As this literature almost universally recognizes, the VSLY approach improves upon the VSL approach by recognizing that timing matters: A rule giving 50 years of extra life is, all other things being equal, superior to a rule giving only 5 extra years. Because the VSL approach

ignores this timing issue, it is inherently inferior to VSLY approaches and can substantially overstate the expected benefits of regulation. *See generally* COST-EFFECTIVENESS IN HEALTH AND MEDICINE (Marthe R. Gold *et al.* eds. 1996).

Accordingly, as the NPRM appears to acknowledge, the VSL approach as a measure of regulatory benefits is often inappropriate. *See* 68 Fed. Reg. at 5521 (noting that "VSL values for middle-aged populations are not necessarily applicable to rules that address lifesaving among children or the elderly"). While VSL values typically assume that the lives saved by any particular regulation will be healthy ones, for many regulations that assumption does not hold true. Likewise, while VSL values implicitly assume that the lives saved by any particular regulation are all of equal age, in many areas (especially, for example, in the air pollution context), the populations at risk vary greatly with age.

The NPRM is therefore close to the mark with the observation that "since everyone is expected to die sooner or later," it has been suggested that VSL be replaced with VSLY. 68 Fed. Reg. at 5521. This insight is key to proper analysis: No regulatory action can save human lives indefinitely, as a species or cultural treasure might be indefinitely saved through wise regulation. *See* Richard Zeckhauser and Donald Shepard, *Where Now for Saving Lives?*, *40* L. & Contemp. Probs. 5 (1976) (noting that regulatory policies cannot confer immorality, but simply extend lifetimes). Instead, the best that regulation can ever hope to do is delay death, and usually the longer death is delayed the better.

The NPRM seems to appreciate this fact, but then confuses it with a critical misstatement: "A key assumption implicit in [the VSLY] approach is that public willingness to pay for risk reduction is strictly proportional to the number of years at risk.'' ***Id.*** The NPRM then goes on to state that this may not always be the case, and that elderly, for example, "may have substantial willingness to pay for reductions in their mortality risk precisely because they have relatively few life years remaining." ***Id.***

In fact, nothing in the use of the VSLY metric implies that "public willingness to pay for risk reduction is strictly proportional to the number of life years at risk" regardless of age. The point of using VSLY is not to discriminate either in favor of or against the aged, or to assume simplistically that they have the same attitudes toward prolonged life as the young. Rather, it is to distinguish between different regulatory benefits. The problem with the VSL method is that it cannot distinguish, as the VSLY method can, between a one-year life extension for a cohort of 65-year-olds and a five-year life extension for that same cohort. The NPRM's criticisms of the VSLY methodology might be construed as an argument for declining to assume simplistically that willingness to pay for longer life is invariant with age; but it is certainly no reason to refuse to adopt VSLY as the preferred metric.

Moreover, there may well be even more fundamental problems with the suggestion that the proper metric for valuing mortality risks should depend on "willingness to pay" criteria. At the outset, valuing statistical lives (or even statistical life years) by "willingness to pay" criteria implicitly places different values on a person's life year depending on that person's age, wealth, and possibly even gender, race, or religion. Tellingly, the World Health Organization rejects this questionable approach and instead measures results only in increases in statistical life years (or

Quality Adjusted Life Years), regardless of age or wealth. *See* Remarks of David B. Evans at the Resources for the Future "Valuing Health Outcomes" Conference (Feb. 2003).

As James K. Hammit has recently explained, there are sensible reasons why an additional year of health life should be valued the same, regardless of an individual's willingness to pay:

> Under this [VSLY or QALY] perspective, one year of health life is the standard, and an additional year of health life counts the same, regardless of who receives it. This standard might be motivated by a theoretical social contract, in which individuals in what the late philosopher John Rawls described as an 'original position' behind a 'veil of ignorance,' not knowing their future wealth, health, and other characteristics, might agree to a system in which public policies are designed in order to maximize the number of QALY's produced in the population. Some survey evidence suggest that people's preferences for allocating lifesaving efforts are at least roughly consistent with this perspective — it is often viewed as more important to save the life of a younger than an older person.

James K. Hammit, *Valuing Health: Quality Adjusted Life Years* ***Or*** *Willingness to Pay?*, RISK IN PERSPECTIVE, at 5 (Harvard Center for Risk Analysis, March 2003). Indeed, in a country founded on the principle of equality, federally agencies should not be encouraged to discriminate by assuming that some life years are worth more than others.

Yet another reason for using the VSLY approach instead of "willingness to pay'' criteria for valuing regulatory benefits is that "willingness to pay" and other conjoint valuations are always subject to biases, most of them upward with respect to health and safety. *See, e.g.*, W. Kip Viscusi, *Regulating the Regulators,* 63 U. Chi. L. Rev. 1423, 1445-1447 (1996) (discussing the problem of "conservatism" bias); William H. Desvousges & Janet C. Lutz, *Compensatory Restoration: Economic Principles and Practice,* 42 Ariz. L. Rev. 411, 423 (2000) (because stated preference analysis "is based on hypothetical choices, not real behavior," it is subject to bias). For example, most companies have products that consumers claim they would buy in "willingness to pay" and conjoint studies, but did not buy when actually asked to reach for their wallets.

Finally, regardless of whether certain groups may be more willing to pay for additional years of healthy life, using the VSL approach instead of the VSLY approach is unwise because it sometimes results in choosing options that sacrifice life years compared to other options. For example, if two policies have the same costs and would help an equal number of citizens, under the VSL approach, the policy that offers a 60 percent chance of extending life by one year would be preferred to a policy that offers a 50 percent chance of extending life by ten years.

For these reasons, among others, OMB should eliminate any ambiguity in its guidelines that might allow agencies to continue to use the VSL approach, when the VSLY approach is preferred. This clarification is especially important because many agencies remain committed to the outdated VSL approach, notwithstanding the substantial and well-known barriers to further progress with that methodology.

111. OMB SHOULD MAKE CLEAR THAT DISCOUNT RATES SHOULD NORMALLY EQUAL THE OPPORTUNITY COST OF CAPITAL

The NPRM suggests that discount rates of seven, three, and even one percent are the proper rates to use for regulatory analysis. *See* 68 Fed. Reg. at *5522-5523.* In particular, the NPRM suggests that lower rates — "including rates as low as 1 percent per annum" — might be used for intergenerational analysis. ***Id.*** at *5523.* Although it may be advisable, as the NPRM suggests, to use various discount rates for any given regulatory problem to "show the sensitivity of the estimates to the discount rate assumption," ***id.*** at *5522,* General Motors recommends that the proposed guidelines be revised to give agencies greater direction regarding what discount rates should normally be used when conducting regulatory analysis.

At the outset, General Motors recommends that the NPRM be revised to emphasize that OMB discourages agencies from using interest rates lower than the opportunity cost of capital, at least for projects with a 40 year or less time frame. In 1999, Resources for the Future and the Stanford Energy Modeling Forum held a conference on the subject of discounting and published a book, DISCOUNTING IN INTERGENERATIONAL EQUITY, that includes a number of articles on discounting by leading experts in the field. As the editors of that book, Paul R. Portney and John P. Weyant, note, there is near consensus among experts that all projects with a time frame of 40 years or less should be discounted at the opportunity cost of capital. *See* DISCOUNTING AND INTERGENERATIONAL EQUITY, at 7 (Paul R. Portney & John P. Weyant, eds. 1999). Using a discount rate lower than the opportunity cost of capital will nearly always mis-state regulatory benefits and costs and, therefore, should normally be avoided.

As noted in the NPRM, the cost of capital will normally be 7 percent. The guidelines should make clear, however, that some projects can impose even higher capital costs on industry. Under those circumstances, when industry's cost of capital exceeds 7 percent, agencies should consider using a higher interest rate.

General Motors also recommends that OMB prohibit agencies from using a zero discount rate when conducting serious regulatory analysis. Portney and Weyant report in DISCOUNTING IN INTERGENERATIONAL EQUITY that there is near consensus among experts that all projects, no matter how long the time frame, must be discounted at a positive discount rate. *See* ***id.*** at ***6.*** Accordingly, as the NPRM correctly notes, because benefits and associated costs do not always take place in the same time period, it is incorrect simply to "add up expected benefits and costs without taking account of when they actually occur." **68** Fed. Reg. at *5523.*

Finally, OMB should make clear that, except in unusual circumstances, agencies should use discount rates based on the opportunity cost of capital, even for longer-term projects. Indeed, at the very least, agencies should be required to discount at the 7 percent rate, in addition to some proposed lower rate, and then leave the decision whether the lower rate is justified to the experts at OMB. While there admittedly is diverse opinion about whether interest rates should be lower for projects with longer time horizons, there are several reasons to believe that the proper discount rate is the opportunity cost of capital, even for those projects.

At the outset, using an interest rate lower than the opportunity cost of capital will often skew the analysis and create perverse regulatory incentives. No matter what year the agency

decides to start a project at a low interest rate, it will likely regret that it did not postpone the project for at least one year. For instance, consider investing $1 billion in year 2003 at 3 percent interest in a project with benefits expected to occur in 100 years. In the year 2004, the agency will inevitably regret not having postponed the project for at least one more year. Assuming the opportunity cost of capital is 7 percent, had it not invested in 2003, the agency would have $1.07 billion available in 2004, and would only need to invest $1.03 billion in order to obtain the same benefits. (And, of course, the same reasoning would apply every year to postpone the project still another year.)

Moreover, most economic models forecast growth in per capital real income over the next century. As the NPRM correctly notes, "future generations are likely to be wealthier than those currently living." 68 Fed. Reg. at 5522. It therefore raises ethical concerns to require the relatively poor (current generation) to sacrifice for the benefit of the relatively wealthy (future generation).

Finally, OMB should acknowledge that there is a substantial scientific and technological risk in forecasting benefits over long-term time horizons. For instance, were science to discover that the greatest threat to the environment in 2100 is the onset of another Ice Age, any investment made today to reduce global warming would produce environmental harm instead of benefit from the perspective of scientists in 2100. Similarly, were regulators, for example, to start a project to curtail global warming by reducing C02 emissions with benefits expected to occur in the next century, such a project would be wasteful if technological advances resulted in cheap fusion power, cheap hydrogen sources, or cheap C02 sequestration. The risks of scientific and technological uncertainty thus make estimating future benefits over the long-term inherently difficult. The usual way to incorporate these risks into a project evaluation is to *increase* discount rates, not lower them.

IV. INSTEAD OF MAKING BENEFITS TRANSFER METHODS "A LAST RESORT OPTION," OMB SHOULD CONSIDER CENTRALIZING INVESTIGATION OF WILLINGNESS-TO-PAY IN THE OFFICE OF INFORMATION AND REGULATORY AFFAIRS

The NPRM suggests that, in many cases, "conducting an original study" of willingness to pay "may not be possible due to time and expense involved." 68 Fed. Reg. at 5519. The NPRM then points to several studies that "have documented the difficulties in applying benefit transfer methods." *Id*. The NPRM concludes that benefit transfer methods should be regarded as "a last resort option." *Id*.

A better approach would be simply to centralize the investigation of willingness-to-pay in the Office of Information and Regulatory Affairs ("OIRA"), perhaps in conjunction with the Council of Economic Advisors ("CEA"). *Cf.* Stephen Breyer, Breaking the Vicious Circle: Toward Effective Risk Regulation, at 59-63 (1993) (recommending an elite core of well-trained and experienced public servants to rationalize risk regulation and establish a sensible system of regulatory priorities); *see also* Richard H. Pildes and Cass R. Sunstein, *Reinventing the Regulatory State*, 62 U. Chi. L. Rev. 1 (1995). The regulatory experts at OIRA and CEA could then decide whether an existing revealed-preference or stated-preference study could be used to value benefits or, alternatively, whether a new investigation is needed. Because the monetization

of benefits will always have large impacts on the results of an analysis, and because agencies have no particular expertise in the proper design of "willingness-to-pay" studies, OIRA and CEA should choose the appropriate study in all cases of major rulemakings for which benefit and cost analysis is required.

V. OMB SHOULD MAKE CLEAR THAT STATE REGULATION SHOULD BE PREEMPTED WHEN IT STANDS AS *AN* OBSTACLE TO THE ACHIEVEMENT OF A FEDERAL AGENCY'S FULL OBJECTIVES

The NPRM states that "[w]here federal regulation is clearly appropriate, for example, to address interstate commerce issues," regulators "should try to examine whether it would be more efficient to reduce State and local regulation." 68 Fed. Reg. at 5515. In particular, the NPRM suggests that regulators should "consider the possibility of reducing as well as expanding State and local rulemaking," including, for example, when "the burdens on interstate commerce arising from different State and local regulations such as compliance costs for firms operating in several States, may exceed any advantages associated with the diversity of State and local regulation." *Id.*

This statement in the NPRM refers to federal preemption. As the NPRM rightly acknowledges, there are times when federal regulation should be exclusive and, as a general matter, should not be supplemented by the states. In particular, when a federal agency creates a finely tuned regulatory scheme that carefully balances the risks of over- and under-regulation, state regulation that upsets that balance is an obstacle to the achievement of the federal agency's full objectives and should be preempted.

A. The Supreme Court Has Approved The Use Of Preemption As An Appropriate Antidote On Regulatory Excursions

It is a familiar and well-established principle that the Supremacy Clause of the United States Constitution invalidates state laws that "interfere with, or [are] contrary to," federal law. *Gibbons v. Ogden,* 9 Wheat 1,211 (1824). State law is impliedly preempted if federal regulation is sufficiently comprehensive that no room is left for state regulation. *See Hillsborough County v. Automated Medical Labs., Inc.,* 471 U.S. 707, 713-14 (1985) (discussing the different ways that federal law may supersede state law). Moreover, it is settled that state laws can be preempted by federal regulations as well as by federal statutes. *See id.*

The legitimacy of applying federal preemption in regulatory contexts has been recognized by the U.S. Supreme Court, which has made clear that, when a federal agency has created a comprehensive scheme of regulation, federal policy choices must be protected from state second-guessing. As the Supreme Court has explained, "[d]eciding what competing values will or will not be sacrificed to the achievement of a particular objective is the very essence of legislative choice." *Rodriguez v. United States,* 480 U.S. *522,* 526 (1987). Indeed, it "frustrates rather than effectuates legislative intent simplistically to assume" that added layers of state regulation will necessarily complement the federal regulatory scheme.

In *Buckman Company v. Plaintiffs' Legal Committee,* 531 U.S. 341 (2000), for example, the Supreme Court held that federal law impliedly preempts state-law tort claims alleging fraud

on the Food & Drug Administration ("FDA") during the regulatory process for obtaining FDA clearance prior to the marketing of certain medical devices. The Court explained that "the federal regulatory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives." *Id.* at 348. The Court then concluded that this delicate federal balance of "difficult (and often competing) objectives" could "be skewed by allowing" the federal scheme to be supplemented by state law. *Id.* at 348-49.

Buckman's rationale employs the same essential reasoning previously set forth in *Geier v. American Honda Motor Co.*, 529 **U.S.** 861 (2000). In *Geier*, the Court held that Department of Transportation airbag regulations preempted a state-law tort suit accusing Honda of negligently failing to design an airbag into a 1987 Honda Accord. The Court noted that there are sound reasons why a federal agency responsible for public health and safety might want to regulate only so far and no further. It then held that state tort law claims were preempted because otherwise additional layers of state law would serve as an obstacle to federal regulatory goals. *See id.* at 883. As it did in *Buckman*, the *Geier* Court refused to assume that more regulation is always better. Rather, the Court emphasized that because the federal regulatory scheme was detailed and finely tuned, state tort laws would necessarily interfere with the tradeoffs that federal regulators had carefully made among alternative goals and objectives.

The NPRM is therefore right to suggest that, when federal agencies set careful balances between too much and too little regulation, states lack authority to impose additional regulatory requirements. In fact, OMB should stand ready to clarify for affected agencies that there should be a very strong presumption that all federal regulatory agency policies are exclusive in their own spheres of operation, and ***not*** subject to supplementation by states. If federal agencies wish to delegate regulatory authority to states (such as authority to fill gaps in a federal regulatory regime), they certainly may do so expressly. But absent express authorization of state supplementation of federal rules, agencies should assume that federal regulations are intended as exclusive.

B. OMB Should Recognize That States Can Use Common Law Doctrines, Like Breach Of Contract And Fraud, To Achieve Ends Similar To Those Traditionally Achieved Through State Rulemaking

OMB should also make clear that, in considering the preemptive effect of federal regulations, agencies should be particularly attuned to the pervasive problem of regulation through litigation, especially litigation in state courts. Scholars increasingly recognize the threat that regulation through litigation poses for regulatory agencies. Harvard Economics Professor W. Kip Vicusi notes, for example, that class action litigation in particular often leads to the undesirable consequence of usurping the traditional regulatory authority of governmental agencies. *See* W. Kip Viscusi, *The Regulation-Litigation Interaction*, Working Paper 01-13, at 20 (AEI-Brookings Joint Center for Regulatory Studies, Oct. 2001). When federal regulatory agencies, especially those involved in regulating health and safety, attempt to achieve optimal levels of regulation, they strike delicate balances between the costs and benefits of regulation to society at large. Significant rulings in judicial proceedings addressing the same private conduct necessarily upset these carefully calibrated balances. The inevitable result is the imposition of state legal requirements that contradict the supposedly uniform requirements of federal law.

The Supreme Court too has repeatedly recognized that state common law rulings by state courts are tantamount to the types of state regulations and orders that are typically promulgated through state administrative processes. *See, e.g.*, *Medtronic*, 518 U.S. at 504 (Breyer, J., concurring); *id.* at 510 (O'Connor, J., concurring in part and dissenting in part); *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993); *Cippollone v. Liggett Group, Inc.*, 505 U.S. 504, 520-24 (1992) (Stevens, J., plurality opinion); *id.* at 548-49 (Scalia, J., concurring in part and dissenting in part). In *Cipollone*, for example, the Supreme Court held that express preemption provisions contained in the Public Health Cigarette Smoking Act of 1969 made no distinction between state common law and state positive law. Even though there was some evidence in the legislative history suggesting that Congress "was primarily concerned with positive enactments by States and localities," the Court was emphatic that "the language of the Act ***plainly*** reaches beyond such enactments." *Cippollone*, 505 U.S. at 520-24 (emphasis added).

The Court reached the same conclusion in the *CSX* and *Medtronic* cases. In *CSX*, the Court considered the preemptive effect of the Federal Railroad Safety Act of 1970, which contained a preemption clause providing that applicable federal regulations preempted any state "law, rule, regulation, order, or standard relating to railroad safety." 45 U.S.C. § 434. The Court easily dispatched any suggestion that common law actions are somehow different for preemption purposes from state positive law. *See CSX Transp., Inc.*, 507 U.S. at 664 (stating that "[l]egal duties imposed on railroads by the common law fall within the scope" of the Act's preemption clause). Likewise, in *Medtronic*, a majority of the Court rejected the argument that "common law duties" were not requirements within the meaning of the preemption clause contained in the Medical Device Amendments of 1976. As Justice Breyer, in a separate concurrence, observed: "The effects of state agency regulation and the state tort suit are identical. To distinguish them for pre-emption purposes would grant greater power . . . to a single state jury than to state officials acting through stat administrative or legislative lawmaking processes.'' *Medtronic*, 518 U.S. at 504.

These cases should be followed with special care by agencies engaged in federal rulemaking. Because state-imposed supplemental requirements necessarily impose risks for the delicate balances that federal agencies set between the benefits and costs of federal regulation, agencies should take care to ensure that the balance is not skewed by supplemental state laws.

CONCLUSION

OMB should be applauded for its ongoing efforts to improve the regulatory analyses prepared by federal agencies. Additional improvements, as described above, should nonetheless be made in order to ensure that agencies are better able to develop effective regulation.