Informing Regulatory Decisions: 2004 Draft Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities

EXECUTIVE SUMMARY

This Draft Report to Congress on regulatory policy was prepared pursuant to the Regulatory Right-to-Know Act. It provides a statement of the costs and benefits of Federal regulations and recommendations for regulatory reforms. The report will be published in its final form later this year, after revisions to this draft are made based on public comment, external peer review, and interagency review.

A major feature of this report is the estimates of the total costs and benefits of regulations reviewed by OMB. Major Federal regulations cleared by OMB from October 1, 1993, to September 30, 2003, were examined to determine their quantifiable benefits and costs. The estimated annual benefits range from $62 billion to $168 billion, while the estimated annual costs range from $34 billion to $39 billion. A substantial portion of both benefits and costs is attributable to a handful of EPA clean-air rules that reduce public exposure to fine particulate matter.

During the past year, 6 "major" final rules with quantified and monetized benefits and costs were adopted. These rules added $1.6 to $4.5 billion in annual benefits compared to $1.9 billion in annual costs. There were an additional 8 final "major" rules that did not have quantified and monetized estimates of both benefits and costs.

The Report also reviews the international literature on the effects of regulation on national economic growth and performance. Based on a comparison of 130 countries, the ten least regulated economies are Hong Kong, Singapore, the United States, New Zealand, the United Kingdom, Canada, Switzerland, Ireland, Australia and the Netherlands. These same economies have experienced relatively good economic performance measured by economic growth, per capita income and life expectancy. The adverse impacts of regulation may be mediated through factors such as the number of procedures required to start a new business, the time and costs of registering a new business, and the enforceability of contracts. More research is needed to determine the precise causal relationships between regulation and economic growth and performance.

In light of recent concerns about the health of manufacturing in the U.S., the Report reviews the economics literature on the impacts of regulation on manufacturing enterprises. The cumulative costs of regulation on the manufacturing sector are large compared to other sectors of the economy. In response to the large impact of regulation on manufacturing, OMB requests public nominations of promising regulatory reforms relevant to this sector. In particular, commenters are requested to suggest specific reforms to rules, guidance documents or paperwork requirements that would improve manufacturing regulation by reducing unnecessary costs, increasing effectiveness, enhancing competitiveness, reducing uncertainty and increasing flexibility.

CHAPTER I: THE COSTS AND BENEFITS OF FEDERAL REGULATIONS

Section 624 of the FY 2001 Treasury and General Government Appropriations Act, the "Regulatory Right-to-Know Act," requires OMB to submit "an accounting statement and associated report" including:

(A) an estimate of the total annual costs and benefits (including quantifiable and nonquantifiable effects) of Federal rules and paperwork, to the extent feasible:

(1) in the aggregate;
(2) by agency and agency program; and
(3) by major rule;

(B) an analysis of impacts of Federal regulation on State, local, and tribal government, small business, wages, and economic growth; and

(C) recommendations for reform.

This chapter consists of two parts: part A presents the accounting statement, and part B presents a brief report on regulatory impacts on State, local, and tribal governments, small business, wages, and economic growth. We recently reported on regulatory reform progress in our 2003 final report published in September, 2003, and we will update this progress in the 2004 final report.

Part A revises the benefit-cost estimates in last year's report by updating the estimates to the end of fiscal year 2003 (September 30, 2003). Like the 2003 report, this chapter uses a 10-year look-back: estimates are based on the major regulations reviewed by OMB from October 1, 1993 to September 30, 2003. This means that 32 rules reviewed from October 1, 1992 to September 30, 1993, were included in the totals from last year's report but are not included here. A list of these rules can be found in Appendix B. All of the estimates presented in this chapter are based on agency information or transparent modifications of agency information performed by OMB.

We also include in this chapter a discussion of major rules issued by independent regulatory agencies, although OMB does not review these rules under Executive Order 12866. This discussion is based on data provided by these agencies to the General Accounting Office (GAO) under the Congressional Review Act.

A. Estimates of the Total Benefits and Costs of Regulations Reviewed by OMB[1]

Table 1 presents estimates by agency of the benefits and costs[2] of major rules[3] reviewed by OMB over the past year (October 1, 2002 to September 30, 2003). OMB reviewed 37 final major rules over that period.[4] These 37 rules represent approximately 11 percent of the 349 final rules reviewed by OMB during this 12-month period, and less than 1 percent of the 4,312 final rules published in the Federal Register during this 12-month period. OMB believes, however, that the costs and benefits of major rules capture the vast majority of the total costs and benefits of all rules subject to OMB review.

Of the 37 rules, 25 implemented Federal budgetary programs, which caused income transfers, usually from taxpayers to another group. Rules that transfer Federal dollars among parties are not included in the benefit-cost totals because transfers are not social costs or benefits. If included, they would add equal amounts to benefits and costs. The remaining 12 regulations were "social regulations," which may require substantial additional private expenditures as well as provide new social benefits.

Of the 12 "social regulations," we are able to present estimates of both monetized costs and benefits for 6 rules. OMB used agency estimates where available. If an agency quantified estimates but did not monetize, standard assumptions were used to monetize, as explained in Appendix A. The 6 other final rules did not include monetized estimates for either costs or benefits, so we did not include these rules in the totals in tables 1-3. We attempt to summarize the available information on the impact of these rules in the "other information" column of Table 4.

---

[1] OMB discusses, in this report and in previous reports available at http://www.whitehouse.gov/omb/inforeg/regpol.html, the difficulty of estimating and aggregating the costs and benefits of different regulations over long time periods and across many agencies using different methodologies. Any aggregation involves the assemblage of benefit and cost estimates that are not strictly comparable. In part to address this issue, the 2003 report included OMB's new regulatory analysis guidance, also released as OMB Circular A-4, which took effect on January 1, 2004, for proposed rules, and will take effect in January 1, 2005, for final rules. The guidance recommends what OMB considers to be "best practice" in regulatory analysis, with a goal of strengthening the role of science, engineering, and economics in rulemaking. The overall goal of this guidance is a more competent and credible regulatory process and a more consistent regulatory environment. OMB expects that as more agencies adopt our recommended best practices, the costs and benefits we present in future reports will become more comparable across agencies and programs. OMB will work with the agencies to ensure that their impact analyses follow the new guidance.

[2] In many instances, agencies were unable to quantify all benefits and costs. We attempted to capture the essence of these effects on a rule-by-rule basis in the columns titled "Other Information" in the various tables reporting agency estimates. The monetized estimates we present necessarily exclude these unquantified effects.

[3] The Federal Register citations for these major rules are found in Table 4.

[4] This draft report does not contain information on EPA's Prevention of Significant Deterioration and Nonattainment New Source Review: Routine Maintenance and Repair Final Rule (68 FR 61247). OMB completed review of this rule on August 27, 2003 and EPA published the rule on October 27, 2003. On December 24, 2003, however, the Court of Appeals for the District of Columbia Circuit stayed the effective date of the rule. As a result, the rule did not become effective on December 26, 2003, as originally intended by the Agency.

Table 1: Estimates of the Annual Benefits and Costs of Major Federal Rules October 01, 2002 to September 30, 2003 (millions of 2001 dollars)		
Agency	**Benefits**	**Costs**
Agriculture	43-152	17
Health and Human Services	457-3,065	19-35
Transportation	945	1,538
Environmental Protection Agency	204-355	335
Total	**1,649-4,517**	**1,908-1,925**

Table 2 presents an estimate of the total costs and benefits of 85 regulations reviewed by OMB over the ten-year period from October 1, 1993 to September 30, 2003 that met two conditions. Each rule generated costs or benefits of at least $100 million annually, and a substantial portion of its costs and benefits were quantified and monetized by the agency or, in some cases, monetized by OMB. The estimates are therefore not a complete accounting of all the costs and benefits of all regulations issued by the Federal government during this period. As discussed in the 2003 Report, OMB has chosen a 10-year period for aggregation because pre-regulation estimates prepared for rules adopted more than ten years ago are of questionable relevance today. The estimates of the costs and benefits of Federal regulations over the period October 1, 1993 to September 30, 2003 are based on agency analyses subject to public notice and comments and OMB review under E.O. 12866.

Table 2: Estimates of the Total Annual Benefits and Costs of Major Federal Rules, October 1, 1993 to September 30, 2003 (millions of 2001 dollars)		
Agency	**Benefits**	**Costs**
Agriculture	2,933-6,123	1,634-1,656
Education	655-813	361-610
Energy[5]	3,990-4,058	1,836
Health &Human Services	8,742-12,138	3,025-3,121
Dept. of Homeland Security*	62	899
Housing & Urban Development	190	150
Labor	1,264-3,645	806
Transportation	6,608-9,386	3,814-5,854
Environmental Protection Agency	37,647-131,682	21,629-24,024
Total	**62,091-168,098**	**34,156-38,958**
*As of this draft , the Homeland Security column includes only Coast Guard rules, formerly part of Transportation		

The aggregate benefits reported in Table 2 are substantially smaller than the aggregate benefits presented in the 2003 Report. This is due to one EPA rule implementing the sulfur dioxide limits of the acid rain provisions in the 1990 Amendments to the Clean Air Act. This rule fell in the time period of 1992 to 1993 and therefore is not included in this report's totals. This rule's estimated benefits of nearly $80 billion per year represented roughly one-third to one-half of the total benefits from the 10-year aggregation. Regardless, as can be seen in Tables 2 and 3, EPA rules continue to be responsible for the majority of costs and benefits generated by Federal regulation during this time period.

Table 3 provides additional information on aggregate benefits and costs for specific agency programs. In order for a program to be included in Table 3, the program needed to have finalized 3 or more rules in the last 10 years with both monetized or monetizable costs and benefits. These criteria account for the major difference between Table 3 in the 2003 report and Table 3 of the 2004 report: the Coast Guard is no longer included as a program, since one of their Vessel Response Plans fell out of the 10-year range. OMB did review three major Coast Guard rules this year (see Table 4), but the benefits of a reduced risk of terrorism have proven very difficult to quantify and monetize. See Chapter 4 in the 2003 Report for a more detailed discussion of this issue.

The ranges of costs and benefits presented in Tables 1-3 are not necessarily correlated. In other words, when interpreting the meaning of these ranges, the reader

[5] On January 13, 2004, the United States Court of Appeals for the Second Circuit struck down a 2001 Department of Energy rule setting energy efficiency standards for central air conditioners. Because of this ruling, we removed this rule from our totals for the Department of Energy in Tables 2 and 3. We will reconsider the treatment of this rule in the final version of the report.

should not assume that low benefits are associated with low costs and that high benefits are associated with high costs. Thus, for example, it is possible that the net benefits of EPA's water programs taken together could range from negative $2.2 billion to positive $5.7 billion per year.

Based on the information contained in this and previous reports, the total costs and benefits of all Federal rules now in effect (major and non-major, including those adopted more than 10 years ago) could easily be a factor of ten or more larger than the sum of the costs and benefits reported in Table 2. More research is necessary to provide a stronger analytic foundation for comprehensive estimates of total costs and benefits by agency and program.

In order for comparisons or aggregation to be meaningful, benefit and cost estimates should correctly account for all substantial effects of regulatory actions, not all of which may or may not be reflected in the available data. OMB has not made any changes to monetized agency estimates other than converting them to annual equivalents. Any comparison or aggregation across rules should also consider a number of factors that our presentation does not address. To the extent that agencies have adopted different methodologies —for example, different monetized values for effects, different baselines in terms of the regulations and controls already in place, different treatments of uncertainty—these differences remain embedded in Tables 1-3. While we have relied in many instances on agency practices in monetizing costs and benefits, our citation of, or reliance on, agency data in this report should not be taken as an OMB endorsement of all the varied methodologies used to derive benefits and cost estimates.

Many of these major rules have important non-quantified benefits and costs. These qualitative issues are discussed in the agency rulemaking documents, in previous versions of this Report, and in Table 4 of this Report.

Table 3: Estimates of Annual Benefits and Costs of Major Federal Rules: Selected Programs and Agencies October 1, 1993-September 30, 2003 (millions of 2001 dollars)		
Agency	**Benefits**	**Costs**
Energy		
Energy Efficiency and Renewable Energy	3,990-4,058	1,836
Health & Human Services		
Food and Drug Administration	1,911-4,754	283-301
Labor		
Occupational Safety and Health Administration	1,264-3,645	806
Transportation		
National Highway Traffic Safety Administration	4,227-7,005	2,300-4,340
Environmental Protection Agency		
Office of Air	34,596-115,494	15,796-17,647
Office of Water	1,095-8,431	2,753-3,266

The majority of the large estimated benefit of EPA rules is attributable to reduction in public exposure to a single air pollutant: fine particulate matter. Thus, the favorable benefit-cost results for EPA regulation should not be generalized to all types of EPA rules or to all types of clean-air rules. EPA has two rulemakings underway —a rule to reduce emissions from off-road diesel engines and a rule to reduce interstate transport of pollution— which should achieve substantial, additional benefits in the reduction of fine particles.

As Table 3 indicates, the degree of uncertainty in benefit estimates for clean air rules is large. In addition, the wide range of benefits for particle control does not capture the full extent of the scientific uncertainty. The five key assumptions in the benefits estimates are as follows:

- Inhalation of fine particles is causally associated with a risk of premature death at concentrations near those experienced by most Americans on a daily basis. While no definitive studies have yet established any of several potential biological mechanisms for such effects, the weight of the available epidemiological evidence supports an assumption of causality.
- All fine particles, regardless of their chemical composition, are equally potent in causing premature mortality. This is an important assumption, because fine particles formed from power plant SO_2 and NO_x emissions are chemically different from directly emitted fine particles from both mobile sources and other industrial facilities, but no clear scientific grounds exist for supporting differential effects estimates by particle type.
- The concentration-response function for fine particles is approximately linear within the range of outdoor concentrations under policy consideration. Thus, the

estimates include health benefits from reducing fine particles in both attainment and non-attainment regions.

- The forecasts for future emissions and associated air quality modeling are valid.
- The valuation of the estimated reduction in mortality risk is largely taken from studies of the tradeoff associated with the willingness to accept risk in the labor market.

In response to recent recommendations from a committee of the National Research Council/National Academy of Sciences, EPA is working with OMB to improve methods to convey the degree of technical uncertainty in benefits estimates.[6]

[6] For more information on this study, please see *Estimating the Public Health Benefits of Proposed Air Pollution Regulations*, National Academy of Sciences, 2003. Available at http://books.nap.edu/catalog/10511.html

B. Estimates of the Benefits and Costs of This Year's Major Rules

In this section, we examine in detail the benefits and costs of each major rule, as required by section 624(a)(1)(C), for which OMB concluded review during the 12-month period beginning October 1, 2002, and ending September 30, 2003.

The statutory language that categorizes the rules we consider for this report differs from the definition of "economically significant" in Executive Order 12866. It also differs from similar statutory definitions in the Unfunded Mandates Reform Act and subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996: Congressional Review of Agency Rulemaking. Given these varying definitions, we interpreted section 624(a)(1)(C) broadly to include all final rules promulgated by an Executive branch agency that meet any one of the following three measures:

- Rules designated as "economically significant" under section 3(f)(1) of Executive Order 12866;
- Rules designated as "major" under 5 U.S.C. ' 804(2) (Congressional Review Act); and
- Rules designated as meeting the threshold under Title II of the Unfunded Mandates Reform Act (2 U.S.C. ' 1531 - 1538)

Social Regulation

Of the 37 economically significant rules reviewed by OMB, Table 4 lists 12 regulations requiring substantial private expenditures or providing new social benefits. The Table summarizes the costs and benefits of these rules, as reported by the agencies, and provides other descriptive information taken from rule preambles and Regulatory Impact Analyses (RIAs). The totals are: the Department of Homeland Security's (DHS) United States Coast Guard (USCG), 3 rules; the Department of Health and Human Services' (HHS) Food and Drug Administration (FDA), 2 rules; the Department of Interior (DOI), 2 rules; and 1 rule each for the Environmental Protection Agency (EPA), the HHS Center for Medicare and Medicaid Services (CMS), the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS), and the Department of Transportation's (DOT) National Highway Traffic Safety Administration (NHTSA), and Federal Motor Carrier Safety Administration (FMCSA).

The Table also includes 2 rules that were considered major under the Congressional Review Act (CRA) that were not otherwise included: a USDA Agricultural Marketing Service (AMS) rule, exempt from E.O. 12866 review, revising milk product-price formulas applicable to all Federal milk-marketing orders, and an EPA rule revising regional haze requirements for nine western states and eligible Indian tribes, which was not economically significant but was classified as a major rule under CRA.

Table 4. Summary of Agency Estimates for Final Rules October 1, 2002 to September 30, 2003 (As of Date of Completion of OMB Review)					
Rule	**Agency**	**FR Cite**	**Benefits**	**Costs**	**Other Information**
Early-Season Migratory Bird Hunting Regulations	DOI	See "Other Information"	$50 million to $192 million per year	Not Estimated	DOI finalized a total of three Early Season regulations, the Final Framework (68 FR 51658), the Bag and Possession Limits (68 FR 51832), and the Regulations on Certain Federal Indian Reservations and Ceded Lands (68 FR 51919). The analysis, which jointly estimated the impact of all Early and Late Season Regulations, was based on the 1996 National Hunting and Fishing Survey and the U.S. Department of Commerce's County Business Patterns, from which it was estimated that migratory bird hunters would spend between $429 million and $1,084 million at small businesses in 2003. The listed benefits represent estimated consumer surplus.
Late-Season Migratory Bird Hunting Regulations	DOI	See "Other Information"	$50 million to $192 million per year	Not Estimated	DOI finalized a total of three Late Season regulations, the Final Frameworks (68 FR 55784), the Bag and Possession Limits (68 FR 56048), and the Regulations on Certain Federal Indian Reservations and Ceded Lands (68 FR 56102). The analysis, which jointly estimated the impact of all Early and Late Season Regulations, was based on the 1996 National Hunting and Fishing Survey and the U.S. Department of Commerce's County Business Patterns, from which it was estimated that migratory bird hunters would spend between $429 million and $1,084 million at small businesses in 2003. The listed benefits represent estimated consumer surplus.

Table 4. Summary of Agency Estimates for Final Rules October 1, 2002 to September 30, 2003 (As of Date of Completion of OMB Review)					
Rule	**Agency**	**FR Cite**	**Benefits**	**Costs**	**Other Information**
Area Maritime Security	DHS/USCG	68 FR 39284	Reduced risk from a transportation security incident	$477 million (present value) for the period 2003 to 2012	The Coast Guard published a series of six temporary Interim Final Rules, three of which were economically significant and are listed here, in order to promulgate requirements mandated by the Maritime Transportation Security Act (MTSA) of 2002 (Public Law 107-295). These were effective from July 1, 2003, until November 25, 2003. This unusual rulemaking procedure was necessitated by specific language contained in the MTSA, which stated the Secretary shall issue an interim final rule implementing these security requirements as soon as practicable after the date of enactment of the law. The MTSA further stated any of the temporary regulations that are not superseded by final regulations shall expire not later than 1 year after the date of enactment, or November 25, 2003. A final rule superseding the area maritime security interim rule was published on October 22, 2003 (68 FR 60472). The impact analysis accompanying these rules assumed they would be in place for the foreseeable future. Costs include committee meetings, travel, and security drilling (68 FR 39287). Benefits are estimated in "risk points reduced," a qualitative measure designed to help estimate the overall increase in security many different activities would produce. The area maritime security rule had an estimated cost per risk point reduced of $469 (present value, 2003–2012) (68 FR 39288).

Table 4. Summary of Agency Estimates for Final Rules October 1, 2002 to September 30, 2003 (As of Date of Completion of OMB Review)					
Rule	**Agency**	**FR Cite**	**Benefits**	**Costs**	**Other Information**
Vessel Security	DHS/USCG	68 FR 39292	Reduced risk from a transportation security incident	$1.368 billion (present value) for the period 2003 to 2012	See first USCG Table entry for an explanation of the rulemaking process. A final rule superseding the vessel security interim rule was published on October 22, 2003 (68 FR 60483). The impact analysis accompanying these rules assumed they would be in place for the foreseeable future. Costs include purchasing, installing, and maintaining security-related equipment; hiring security officers, and preparing paperwork (68 FR 29298). Benefits are estimated in "risk points reduced," a qualitative measure designed to help estimate the overall increase in security many different activities would produce. The vessel security rule had an estimated cost per risk point reduced of $233 (present value, 2003–2012) (68 FR 39299).
Facility Security	DHS/USCG	68 FR 39315	Reduced risk from a transportation security incident	$5.399 billion (present value) for the period 2003 to 2012	See first USCG Table entry for an explanation of the rulemaking process. A final rule superseding the facility security interim rule was published on October 22, 2003 (68 FR 60515). The impact analysis accompanying these rules assumed they would be in place for the foreseeable future. Costs include purchasing, installing, and maintaining security-related equipment; hiring security officers, and preparing paperwork (68 FR 39319). Benefits are estimated in "risk points reduced," a qualitative measure designed to help estimate the overall increase in security many different activities would produce. The facility security rule had an estimated cost per risk point reduced of $1,517 (present value, 2003–2012) (68 FR 39319).

Table 4. Summary of Agency Estimates for Final Rules October 1, 2002 to September 30, 2003 (As of Date of Completion of OMB Review)					
Rule	**Agency**	**FR Cite**	**Benefits**	**Costs**	**Other Information**
Truck Driver Hours of Service	DOT/FMCSA	68 FR 22456	$671 million per year (status quo baseline) $228 million per year (full compliance baseline)	$1,282 million per year (status quo baseline) Negative $905 million (full compliance baseline)	Because of widespread noncompliance with the current regulations, FMCSA estimated benefits and costs against two baselines: full compliance with current rules, and the status quo. Note that negative cost means a net cost-savings.
Light Truck CAFE for Model Years 2005-2007	DOT/NHTSA	68 FR 16867	$218 million (05) $645 million (06) $955 million (07)	$170 million (05) $537 million (06) $862 million (07)	The benefits are derived mainly from fuel savings over the lifetime of the vehicle, although they include other effects such as emissions reductions. Costs estimates are based on the specific technologies that manufacturers would need to apply to improve fuel economy up to the level of the final rule. All cost and benefit figures are net present values over the lifetime of each model year. The benefit and cost estimates are estimated from a baseline of each manufacturer's production plans for a single model year. It is likely that CAFE standards for prior model years (or anticipation of more stringent future standards) cause a given single model year's production plans to incorporate greater fuel economy than they otherwise would. NHTSA did not attempt to factor this effect into its baseline estimates, as this exercise would become increasingly speculative. To the extent that this is the case, the "true" baseline fuel economy is lower than that reflected in the product plans and, as estimated by NHTSA, both the cost and benefit estimates of a given standard will be underestimated.

Table 4. Summary of Agency Estimates for Final Rules October 1, 2002 to September 30, 2003 (As of Date of Completion of OMB Review)					
Rule	**Agency**	**FR Cite**	**Benefits**	**Costs**	**Other Information**
Revisions to Regional Haze Regulations for Nine Western States and Eligible Indian Tribes	EPA	68 FR 33764	Not Estimated	$72 million per year	EPA performed a cost-benefit analysis in connection with the Regional Haze Regulations that it published as a final rule on July 1, 1999 (64 FR 35714). EPA finds that the costs and benefits associated with the Western Regional Air Partnership's program have been captured in the 1999 analysis. That analysis concluded that the planning, analysis, and Best Available Retrofit Technology control elements would result in $72 million in incremental annualized costs. If States all choose to establish the same illustrative progress goal, the incremental costs range from $1 billion to $4 billion with associated benefits of $1 billion to $19 billion.

Table 4. Summary of Agency Estimates for Final Rules October 1, 2002 to September 30, 2003 (As of Date of Completion of OMB Review)					
Rule	**Agency**	**FR Cite**	**Benefits**	**Costs**	**Other Information**
National Pollutant Discharge Permits and Standards for Concentrated Animal Feeding Operations (CAFOs)	EPA	68 FR 7175	$204 million to $355 million per year.	$335 million per year.	Monetized benefits are based on both health and environmental impacts. The rule also identifies several benefit categories that have not been monetized. These include reduced eutrophication and pathogen contamination of coastal and estuarine waters, reduced pathogen contamination of groundwater, reduced human and ecological risks from antibiotics, hormones, metals and salts, improved soil properties, and reduced costs of commercial fertilizers for non-CAFO operations. Only the first of these would likely significantly affect the benefits estimates if monetized. Costs are based on CAFO compliance costs and State and Federal government implementation costs. CAFO compliance costs are primarily associated with new restrictions on land application of manure, and coverage of dry poultry operations that were not previously covered by the regulations. Costs for land application include preparation of a Nutrient Management Plan, and transportation costs for sale or disposal of excess manure that can no longer be applied to the facility's own fields. Costs for dry poultry include, in addition to land application, capital and operation and maintenance costs for new technology.

Table 4. Summary of Agency Estimates for Final Rules October 1, 2002 to September 30, 2003 (As of Date of Completion of OMB Review)					
Rule	**Agency**	**FR Cite**	**Benefits**	**Costs**	**Other Information**
Health Insurance Reform: Security Standards Implementing HIPAA	HHS/CMS	68 FR 8333	Not Estimated	Not Estimated	This final rule adopts standards for the security of electronic protected health information to be implemented by health plans, health care clearinghouses, and certain health care providers. CMS stated that, although they could not determine the specific economic impact of the standards in this final rule (and individually each standard may not have a significant impact), the overall impact analysis makes clear that, collectively, all the standards will have a significant impact of over $100 million on the economy.

Table 4. Summary of Agency Estimates for Final Rules October 1, 2002 to September 30, 2003 (As of Date of Completion of OMB Review)					
Rule	**Agency**	**FR Cite**	**Benefits**	**Costs**	**Other Information**
Trans fat Labeling	HHS/FDA	68 FR 41433	$234 million to $2,884 million per year.	$139 million to $275 million incurred in the first two years after rule finalized.	FDA estimates the benefits of this rule using two approaches that reflect different methods. First, it calculates benefits as the value of life-years gained from preventing a fatal case of heart disease, plus the value of quality adjusted life years (QALYs) gained from preventing a non-fatal case of CHD. Its second calculation values reductions in mortality risk as the number of statistical deaths prevented multiplied by the willingness to pay to reduce the risk of death, and values reductions in morbidity risk as simply the medical cost savings. The range of benefits is also based on two different estimates of the effect of trans fat on CHD risk (one method leads to approximately twice the impact as the other method); adopting different valuations for QALYs, life years and lives saved; and applying the 3% and 7% discount rates. Cost estimates include direct labeling and other compliance costs, and reformulation costs and subsequent market impacts for firms that choose to reformulate. The range of costs is derived from the 3% and 7% discount rates, and model uncertainties in the labeling cost estimate.

Table 4. Summary of Agency Estimates for Final Rules October 1, 2002 to September 30, 2003 (As of Date of Completion of OMB Review)					
Rule	**Agency**	**FR Cite**	**Benefits**	**Costs**	**Other Information**
Patent Listing Requirements and Application of 30 Month Stays of Abbreviated New Drug Applications (Generics)	HHS/FDA	68 FR 36675	$230 million per year	Less than $10 million per year.	FDA estimates the largest impact will be a transfer of resources from current patent holders to generic drug manufacturers and consumers. FDA estimates patent holders will suffer approximately a $4.8 billion revenue loss per year. Consumers will save approximately $3.3 billion per year, and generic manufacturers will gain approximately $1.8 billion per year. The benefit is the efficiency gain from this market entry. Direct costs are derived from the increase in burden of additional applications and modifications to analytical requirements. The benefits and costs are annualized at a 7% discount rate over 10 years.
Milk in the Northeast and Other Marketing Areas	USDA/AMS*	68 FR 7063	Not Estimated	Not Estimated	The Agricultural Marketing Service performed a cost analysis and summarized the average of the price changes from a model baseline using a 5-year period (2003-2007). The formula changes increase the protein prices and reduce the prices for butterfat and nonfat solids. The results are higher Class III prices, lower Class IV and Class II prices, and lower Class I prices. The advanced Class I base price is the higher of the Class III or Class IV advance pricing factors. The Class I base price is the Class IV price in all years of the analytical period for the baseline, while Class III becomes the Class I price in 2003 through 2005 under this decision. The Class I price falls in 2003, 2006, and 2007. The resulting increases in Class I and Class II demand for nonfat and fat solids sufficiently absorbs production increases to very slightly increase cheese and butter prices and only slightly decrease nonfat dry milk prices.

Table 4. Summary of Agency Estimates for Final Rules October 1, 2002 to September 30, 2003 (As of Date of Completion of OMB Review)					
Rule	**Agency**	**FR Cite**	**Benefits**	**Costs**	**Other Information**
Control of Listeria monocytogenes in Ready-to-Eat Meat and Poultry Products	USDA/FSIS	68 FR 34207	$44 million per year to $154 million per year	$16.6 million per year	The benefits are derived from avoided illnesses and death. Estimated costs are implementation costs. USDA also presents a range of benefits estimates, based on model uncertainty and statistical variability, and presents an alternative benefits estimate, based on a reduction in effectiveness, which is approximately 50% lower than the benefits presented here. Both benefits and costs are annualized at a 7% discount rate over 10 years, the assumed useful life of the necessary firm investments.
*OMB is statutorily prohibited from reviewing marketing orders. Information presented in this table is based on the GAO report.					

Regulations Implementing Federal Budgetary Programs

Of the 37 economically significant rules reviewed by OMB, Table 5 lists the 25 that implement Federal budgetary programs. The budget outlays associated with these rules are "transfers" from taxpayers to program beneficiaries, therefore in past reports OMB has referred to these rules as "transfer" rules. The totals are: HHS/CMS, 11 rules; USDA, 6 rules; the Department of Veterans Affairs (VA), 2 rules; the Department of Labor (DOL), 1 rule; DOT, 1 rule; DOI, 1 rule; the DHS Federal Emergency Management Agency (FEMA), 1 rule; the Office of Personnel Management (OPM), 1 rule; and the Small Business Administration (SBA), 1 rule.

Here, we highlight two of the rules presented below. First, OPM issued a rule to allow Federal employees to pay for their health benefits with pre-tax dollars. This change is estimated to save Federal employees $848 million in taxes in fiscal year 2003. Unlike other rules listed here, this rule does not implement any particular spending program. This rule, however, has almost an identical effect as rules that implement other spending programs; by lowering the total taxes taken in, the effect is to transfer general tax revenue to a specific group.

Second, DOT's NHTSA issued a rule implementing a statute which requires the withholding of fiscal year 2004 Federal-aid highway funds from any State that has not enacted a driving while intoxicated law that provides for a blood or breath alcohol (BAC) limit of 0.08 percent. Although a major impact of this rule would be to Federal budgetary programs, the clear goal is to inspire State-level laws and regulations with public health and safety goals similar to the Federal rules reported in the other sections of this chapter.

Table 5: Agency Rules Implementing Federal Budgetary Programs (October 1, 2002 to September 30, 2003)
Department of Agriculture (USDA)
2002 Farm Bill: Cooperatives, Cotton, Dairy and Honey Price Support; Dairy and Apple Market Loss
2002 Farm Bill: Loans and Deficiency Payments for Peanuts, Pulse Crops, Wheat, Feed Grains, and Minor Oilseeds
2002 Farm Bill: Direct and Counter Cyclical Payments and Peanut Quota Buy-Out
2002 Farm Bill: Conservation Reserve Program
2003 Agricultural Assistance Act: Crop Disaster Program, Livestock Assistance Program, and Weather-Related Losses
Environmental Quality Incentives Program
Department of Health and Human Services (HHS)
Changes to the Hospital Outpatient Prospective Payment System and CY 2003 Payment Rates
Medicare Program: Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for 2003
Medicare Program: Application of Inherent Reasonableness of All Medicare Part B Services Other than Physician Services
Medicare Program: Monthly Actuarial Rates and Monthly Supplementary Medical Insurance Premium Rate Beginning January 1, 2003
Medicare Program: Physician Fee Schedule Update for CY 2003.
Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2003 and Inclusion of Registered Nurses in the Personnel Provision of the Critical Access Hospital Emergency Services Requirement for Frontier Areas and Remote Locations

Medicare Program: Time Limitation on Price Recalculations and Recordkeeping Requirements Under the Drug Rebate Program
Medicare Program: Change in Methodology for Determining Extraordinarily High (Outlier) Payment in Acute Care and Long-Term Care Hospitals
Medicare Program: Changes to the Inpatient Rehabilitation Facility Prospective Payment System and FY 2004 Rates
Medicare Program: Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2004 Rates
Medicare Program: Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities Update for FY 2004.
Veterans Administration
Payment or Reimbursement for Emergency Treatment Furnished at Non-VA Facilities
Enrollment; Provision of Hospital and Outpatient Care to Veterans; Subpriorities of Priority Categories 7 and 8 Annual Enrollment
Department of Labor
Claims for Compensation Under the Energy Employees Occupational Illness Compensation Program Act of 2000
Department of the Interior
Bureau of Indian Affairs: Distribution of Fiscal Year 2003 Indian Reservation Roads Funds
Department of Transportation
Operation of Motor Vehicles by Intoxicated Persons
Federal Emergency Management Administration
Assistance to Firefighters Grant Program
Office of Personnel Management
Health Insurance Premium Conversion
Small Business Administration
Small Business Size Regulations: Government Contracting Programs; HUBZone Program

Major Rules for Independent Agencies

The congressional review provisions of the Small Business Regulatory Enforcement Fairness Act (SBREFA) require the GAO to submit reports on major rules to the committees of jurisdiction, including rules issued by agencies not subject to Executive Order 12866 (the "independent" agencies). We reviewed the information on the costs and benefits of major rules contained in GAO reports for the period of October 1, 2002 to September 30, 2003. GAO reported that 3 independent agencies issued 7 major rules during this period. Two agencies, the Federal Reserve System and the Nuclear Regulatory Commission (NRC), did not conduct benefit-cost analyses, although the NRC did calculate the expected dollar amount of fee recovery from their program, which can be considered a cost of the rulemaking. One agency, the Securities and Exchange Commission (SEC), did consider the benefits and costs of its rules. OMB lists the agencies and the type of information provided by them (as summarized by GAO) in Table 6.

In comparison to the agencies subject to E.O. 12866, the independent agencies provided in their analyses relatively little quantitative information on the benefits of major rules; half of the economically significant rules reviewed by OMB reported monetized benefits, whereas only 1 of the 7 rules finalized by independent agencies reported monetized benefits. As Table 6 indicates, most of the rules included some

discussion of benefits and costs, and reported monetized costs. OMB does not know whether the rigor and the extent of the analyses conducted by the independent agencies are similar to those of the analyses performed by agencies subject to the Executive Order, since OMB does not review rules from independent agencies.

Table 6: Rules for Independent Agencies
(October 1, 2002 to September 30, 2003)

Agency	Rule	FR Cite	Information on Benefits or Costs	Monetized Benefits	Monetized Costs
Federal Reserve	Transactions Between Member Banks and Their Affiliates	67 FR 76560	No	No	No
NRC	Revision of Fee Schedules; Fee Recovery for FY 2003	68 FR 36714	Yes	No	Yes
SEC	Disclosure in Management's Discussion and Analysis About Off-Balance Sheet Arrangements and Aggregate Contractual Obligations, GAO-03-463R, February 19, 2003 IND	68 FR 5982	Yes	No	Yes
SEC	Strengthening the Commission's Requirements Regarding Auditor Independence	68 FR 6006	Yes	No	No
SEC	Disclosure of Proxy Voting Policies and Proxy Voting Records by Registered Management Investment Companies	68 FR 6564	Yes	No	Yes
SEC	Management's Report on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports	68 FR 36636	Yes	No	Yes
SEC	Certain Research and Development Companies	68 FR 37046	Yes	Yes	Yes

B. The Impact of Federal regulation on State, local, and tribal government, small business, wages, and economic growth

Sec. 638 (a)(2) of the Regulatory Right-to-Know Act calls on OMB to present an analysis of the impacts of Federal regulation on State, local, and tribal governments, small business, wages, and economic growth.

Impacts on State, Local, and Tribal Governments

Over the past 8 years, 7 rules have imposed costs of more than $100 million per year on State, local, and tribal governments (and thus have been classified as public sector mandates under the Unfunded Mandates Act of 1995).[7] The Environmental Protection Agency issued all 7 of these rules, which are described in some detail below.

- *EPA's Rule on Standards of Performance for Municipal Waste Combustors and Emissions Guidelines* (1995): This rule set standards of performance for new municipal waste combustor (MWC) units and emission guidelines for existing MWCs under sections 111 and 129 of the Clean Air Act [42 U.S.C. 7411, 42 U.S.C. 7429]. The standards and guidelines apply to MWC units at plants with combustion capacities greater than 35 mega grams per day (Mg/day) (approximately 40 tons per day) of municipal solid waste (MSW). The EPA standards require sources to achieve the maximum degree of reduction in emissions of air pollutants that the Administrator determined is achievable, taking into consideration the cost of achieving such emissions reduction, and any non-air quality health and environmental impacts and energy requirements.

  EPA estimated the annualized costs of the emissions standards and guidelines to be $320 million per year (in constant 1990 dollars) over existing regulations. While EPA estimated the cost of such standards for new sources to be $43 million per year, the cost for existing sources was $277 million per year. The annual emissions reductions achieved through this regulatory action include, for example, 21,000 Mg. of sulfur dioxide; 2,800 Mg. of particulate matter (PM); 19,200 Mg of nitrogen oxides; 54 Mg. of mercury; and 41 Kg. of dioxins/furans.

- *EPA's Standards of Performance for New Stationary Sources and Guidelines for Control of Existing Sources: Municipal Solid Waste Landfills (1996):* This rule set performance standards for new municipal solid waste landfills and emission guidelines for existing municipal solid waste landfills under section 111 of the Clean Air Act. The rule addressed non-methane organic compounds (NMOC)

[7] EPA's proposed rules setting air quality standards for ozone and particulate matter may ultimately lead to expenditures by State, local or tribal governments of $100 million or more. However, Title II of the Unfunded Mandates Reform Act provides that agency statements of compliance with Section 202 must be conducted "unless otherwise prohibited by law." The conference report to this legislation indicates that this language means that the section "does not require the preparation of any estimate or analysis if the agency is prohibited by law from considering the estimate or analysis in adopting the rule." EPA has stated, and the courts have affirmed, that under the Clean Air Act, the primary air quality standards are health-based and EPA is not to consider costs.

and methane emissions. NMOC include volatile organic compounds (VOC), hazardous air pollutants (HAPs), and odorous compounds. Of the landfills required to install controls, about 30 percent of the existing landfills and 20 percent of the new landfills are privately owned. The remaining landfills are publicly owned. The total annualized costs for collection and control of air emissions from new and existing MSW landfills are estimated to be $100.

- *EPA's National Primary Drinking Water Regulations: Disinfectants and Disinfection Byproducts (1998):* This rule promulgates health-based maximum contaminant level goals (MCLGs) and enforceable maximum contaminant levels (MCLs) for about a dozen disinfectants and byproducts that result from the interaction of these disinfectants with organic compounds in drinking water. The rule will require additional treatment at about 14,000 of the estimated 75,000 covered water systems nationwide. The costs of the rule are estimated at $700 million annually. The quantified benefits estimates range from zero to 9,300 avoided bladder cancer cases annually, with an estimated monetized value of $0 to $4 billion per year. Possible reductions in rectal and colon cancer and adverse reproductive and developmental effects were not quantified.

- *EPA's National Primary Drinking Water Regulations: Interim Enhanced Surface Water Treatment* (1998): This rule establishes new treatment and monitoring requirements (primarily related to filtration) for drinking water systems that use surface water as their source and serve more than 10,000 people. The purpose of the rule is to enhance health protection against potentially harmful microbial contaminants. EPA estimated that the rule will impose total annual costs of $300 million per year. The rule is expected to require treatment changes at about half of the 1,400 large surface water systems, at an annual cost of $190 million. Monitoring requirements add $96 million per year in additional costs. All systems will also have to perform enhanced monitoring of filter performance. The estimated benefits include average reductions of 110,000 to 338,000 cases of cryptosporidiosis annually, with an estimated monetized value of $0.5 to $1.5 billion, and possible reductions in the incidence of other waterborne diseases.

- *EPA's National Pollutant Discharge Elimination: System B Regulations for Revision of the Water Pollution Control Program Addressing Storm Water Discharges* (1999): This rule expands the existing National Pollutant Discharge Elimination System program for storm water control. It covers smaller municipal storm sewer systems and construction sites that disturb one to five acres. The rule allows for the exclusion of certain sources from the program based on a demonstration of the lack of impact on water quality. EPA estimates that the total cost of the rule on Federal and State levels of government, and on the private sector, is $803.1 million annually. EPA considered alternatives to the rule, including the option of not regulating, but found that the rule was the option that was "most cost effective or least burdensome, but also protective of the water quality."

- *EPA's National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring* (2001): This rule reduces the amount of arsenic that is allowed to be in drinking water from 50 ppb to 10 ppb. It also revises current monitoring requirements and requires non-transient, non-community water systems to come into compliance with the standard. This rule may affect either State, local or tribal governments or the private sector at an approximate annualized cost of $206 million. The monetized benefits of the rule range from $140 to $198 million per year. The EPA selected a standard of 10 ppb because it determined that this was the level that best maximizes health risk reduction benefits at a cost that is justified by the benefits, as required by the Safe Drinking Water Act.

- *EPA's Effluent Limitation Guidelines and New Source Performance Standards for the Construction and Development Category* (2002): This rule proposed three options to address storm water discharges from construction sites. Option one proposed technology-based effluent limitation guidelines and standards (ELGs) for storm water discharges from construction sites required to obtain National Pollutant Discharge Elimination System (NPDES) permits. Option two proposed not to establish ELGs for storm water discharges from those sites, but to allow technology-based permit requirements to continue to be established based upon the best professional judgment of the permit authority. Option three would establish inspection and certification requirements that would be incorporated into the storm water permits issued by EPA and States, with other permit requirements based on the best professional judgment of the permit authority. EPA is considering all options, and did not state a preferred option in the proposed rule. Options one and two would impose a mandate on the States, local, or Tribal governments, in the aggregate, or private sector that would exceed $100 million per year. Option 3 would not impose a mandate with costs that exceed $100 million per year for the public or private sectors.

Although these 7 EPA rules were the only ones over the past 8 years to require expenditures by State, local and Tribal governments exceeding $100 million, they were not the only rules with impacts on other levels of governments. For example, 14 percent, 9 percent, and 6 percent of rules listed in the April 2001 Unified Regulatory Agenda cited some impact on State, local or tribal governments, respectively.

In the final version of this report, we will present a full discussion of agency compliance with the Unfunded Mandates Reform Act.

Impact on Small Business

The need to be sensitive to the impact of regulations and paperwork on small business was recognized in Executive Order 12866, "Regulatory Planning and Review." The Executive Order calls on the agencies to tailor their regulations by business size in order to impose the least burden on society, consistent with obtaining the regulatory objectives. It also calls for the development of short forms and other efficient regulatory

approaches for small businesses and other entities. Moreover, in the findings section of the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Congress stated that "... small businesses bear a disproportionate share of regulatory costs and burdens." This is largely attributable to fixed costs—costs that all firms must bear regardless of size. Each firm has to determine whether a regulation applies, how to comply, and whether it is in compliance. As firms increase in size, fixed costs are spread over a larger revenue and employee base resulting in lower unit costs.

The Office of Advocacy of the Small Business Administration (Advocacy) recently sponsored a study (Crain and Hopkins 2001) that estimated the burden of regulation on small businesses. That study found that regulatory costs per employee decline as firm size—as measured by the number of employees per firm—increases. Crain and Hopkins estimate that the total cost of Federal regulation (environmental, workplace, economic, and tax compliance regulation) was 60 percent greater per employee for firms with under 20 employees compared to firms with over 500 employees. The average per employee regulatory costs were $6,975 for firms with fewer than 20 employees compared to $4,463 for firms with over 500 employees. These findings are based on their overall estimate of the cost of Federal regulation for 2000 of $843 billion. These results do not indicate whether reducing regulatory requirements on small firms would produce net positive benefits.

Because of this relatively large impact of regulations on small businesses, this Administration's E.O. 13272 reiterates the need for agencies to assess the impact of regulations on small businesses under the Regulatory Flexibility Act (RFA). Under the RFA, whenever an agency comes to the conclusion that a particular regulation will have a significant impact on a substantial number of small entities, the agency must conduct both an initial and final regulatory flexibility analysis. This analysis must include an assessment of the likely burden of the rule on small entities, and an analysis of alternatives that may afford relief to small entities while still accomplishing the regulatory goals. OIRA has a Memorandum of Understanding with Advocacy that supports our review of these analyses. Please visit OMB's website at http://www.whitehouse.gov/omb/inforeg/regpol.html for a copy of this Memorandum.

Advocacy recently released two studies (CONSAD 2002, Advocacy 2004) exploring how well agencies work with Advocacy and OMB in estimating small business impacts and considering regulatory relief. The CONSAD report found that some agencies made significant improvements in determining small business impacts in their rulemaking, while others continued noncompliance. The study concluded that in 1995, about 39 percent of final rule notices did not certify or explain the small business economic impacts of the regulation; by 1999, the rate of RFA noncompliance fell to 32 percent.

The Advocacy report summarizes the overall performance of agency compliance with the RFA and Executive Order 13272, and Advocacy efforts to improve the analysis of small business impacts and to persuade agencies to afford relief to small businesses. This comprehensive report contains four main sections. Section one provides a brief

overview of the RFA, as amended SBREFA. Section two details the role of the Advocacy. This section also shows breakdowns of Advocacy activities in Fiscal Year 2003, many of which were facilitated by the Memorandum of Understanding between Advocacy and OMB. Section three provides a snapshot of several of the rulemakings in which Advocacy effectively represented the interests of small entities. Section four of this annual report provides a brief overview and update on the report submitted to OMB on agency compliance with E.O. 13272 for Fiscal Year 2003. Please visit Advocacy's website at http://www.sba.gov/advo to learn more about Advocacy, review regulatory comment letters, and obtain useful research relevant to small entities.

In previous reports, OMB has requested public nomination of promising regulatory reforms. Agencies have adopted or are continuing to follow up on many suggestions relevant to small business, including recommendations from Advocacy, and OMB will continue to seek information from agencies on how they plan to address their candidates for reform. In addition, OMB will continue to provide status reports to Congress on agency progress. In this report, OMB requests public nominations of promising regulatory reforms relevant to the manufacturing sector, particularly those relevant to the welfare of small and medium-sized enterprises. In particular, because the Crain and Hopkins (2001) study found that tax compliance was particularly burdensome for small businesses, OMB is especially interested in suggestions to simplify IRS paperwork requirements.

Impact on Wages

The impact of Federal regulations on wages depends upon how "wages" are defined and on the types of regulations involved. If we define "wages" narrowly as workers' take-home pay, social regulation usually decreases average wage rates, while economic regulation often increases them, especially for specific groups of workers. If we define "wages" more broadly as the real value or utility of workers' income, the directions of the effects of the two types of regulation can be reversed.

1. Social Regulation

By broad measures of welfare, social regulation—defined as rules designed to improve health, safety, and the environment—create benefits for workers and consumers. Compliance costs, however, must be paid for by some combination of workers, business owners, and/or consumers through adjustments in wages, profits, and/or prices. This effect is most clearly recognized for occupational health and safety standards. As one leading textbook in labor economics suggests: "Thus, whether in the form of smaller wage increases, more difficult working conditions, or inability to obtain or retain one's first choice in a job, the costs of compliance with health standards will fall on employees."[8]

Viewed in terms of overall welfare, the regulatory benefits of health, safety, and environmental improvements for workers can outweigh their costs, assuming the

[8]From Ehrenberg and Smith's *Modern Labor Economics*, p. 279.

regulation produces net benefits. In the occupational health standards case, where the benefits of regulation accrue mostly to workers, workers are likely to be better off if health benefits exceed compliance costs and such costs are not borne primarily by workers.[9] Although wages may reflect the cost of compliance with health and safety rules, the job safety and other benefits of such regulation can compensate for the monetary loss. Workers, as consumers benefiting from safer products and a cleaner environment, may also come out ahead if regulation produces significant net benefits for society.

2. Economic Regulation

For economic regulation, defined as rules designed to set prices or conditions of entry for specific sectors, the effects on wages may be positive or negative. Economic regulation can result in increases in income (narrowly defined) for workers in the industries targeted by the regulation, but decreases in broader measures of income based on utility or overall welfare, especially for workers in general. Economic regulation is often used to protect industries and their workers from competition. These wage gains come at a cost in inefficiency from reduced competition, however, which consumers must bear. Moreover, growth in real wages, which are limited generally by productivity increases, will not grow as fast without the stimulation of outside competition.[10]

These statements are generalizations of the impact of regulation in the aggregate or by broad categories. Specific regulations can increase or decrease the overall level of benefits accruing to workers depending upon the actual circumstances and whether net benefits are produced.

Economic Growth and Related Macroeconomic Indicators

The strongest evidence of the impact of regulation on economic growth is the differences in per capita income growth experienced by countries under different regulatory systems. A well-known example is the comparison of the growth experience of the formerly Communist state-controlled economies with the more market-oriented economies of the West and Pacific Rim. Although state-controlled economies initially appeared to have growth advantages because of their emphasis on investment in capital and infrastructure, as technology became more complex and innovation a more important driver of growth, the state-directed economies fell farther behind the more dynamic and flexible market-oriented economies. Less well known is that significant differences in growth rates, perhaps for the same reasons, are also seen among economies with smaller differences in the degree of government control and regulation.

[9]Based on a cost benefit analysis of OSHA's 1972 Asbestos regulation by Settle (1975), which found large net benefits, Ehrenberg and Smith cite this regulation as a case where workers' wages were reduced, but they were made better off because of improved health (p. 281).

[10]Winston (1998) estimates that real operating costs declined 25 to 75 percent in the sectors that were deregulated over the last 20 years—transportation, energy, and telecommunications.

Several institutions have attempted to develop indicators of economic freedom to rank countries and compare their economic performance. Since 1995, the Heritage Foundation and the *Wall Street Journal* have collaborated to publish a yearly index for 161 countries that finds a very strong relationship between the index and per capita GDP.[11] The index, based mostly on subjective assessments of in-house experts, is composed of 50 independent variables divided into 10 broad factors that attempt to measure different aspects of economic freedom: trade policy, fiscal burden, government intervention, property rights, banking and finance, wages and prices, regulation, and informal market activity. Since a correlation between economic freedom and per capita GDP cannot prove that economic freedom causes economic growth, the authors also examine the relationship between the change in the index since 1995 and the average GDP growth rate growth over seven years. After dividing the 142 countries (for which they had complete) data into quintiles, they find a very strong association between improvement in the index and growth rates. The first quintile of countries grew at a rate of 4.9% per year, almost twice the 2.5 % growth rate of the fifth quintile.

Since 1997, the Fraser Institute of Vancouver, B.C. has published the Economic Freedom of the World index for 123 countries.[12] The report finds that the index is highly correlated with per capita income, economic growth, and life expectancy. The index, which is based on 38 variables, many of them from surveys published by other institutions, measures five major areas: size of government, legal structure and security of property rights, access to sound money, freedom of exchange with foreigners, and regulation of credit, labor, and business. The top ten economies in order are Hong Kong, Singapore, the United States, New Zealand, the United Kingdom, Canada, Switzerland, Ireland, Australia, and the Netherlands.

Although these studies provide broad support for the claim that regulation reduces economic growth, they have several drawbacks that weaken the strength of their findings. First, they are largely based on subjective assessments and survey results. In addition, they include non-regulatory indicators as well as indicators of direct regulatory interventions, such as measures of fiscal burden and the openness of trade policies.

In an attempt to correct for some of these shortcomings, the World Bank has recently begun a multi-year project to catalogue the differences in the scope and manner of regulations among over 130 countries based on measures of actual regulations – such as the number of procedures required to register a new business and the time and costs of registering a new business, enforce a contract, or go through bankruptcy. The first volume of the annual series examines five of the fundamental regulatory aspects of a firm's life cycle: starting a business, hiring and firing workers, enforcing contracts, getting credit, and closing a business. Other types of regulation will be examined in future years. Entitled *Doing Business in 2004, Understanding Regulation* the study reached three major conclusions:

---

[11] Marc A. Miles, Edwin J. Feulner, Jr., Mary Anastasia O'Grady, and Ana I. Eiras. *2004 Index of Economic Freedom.* Heritage Foundation/WallSteet Journal.

[12] James Gwartney and Robert Lawson, *Economic Freedom of the World: 2003 Annual Report*. Fraser Institute, Vancouver, BC.

- Regulation varies widely around the world.
- Heavier regulation of business activity generally brings bad outcomes, while clearly defined and well-protected property rights enhance prosperity.
- Rich countries regulate business in a consistent manner. Poor countries do not.[13]

The study finds that rich countries regulate less in all aspects of regulation covered in the report. Combining all indicators, Australia, Canada, Denmark, the Netherlands, New Zealand, Norway, Singapore, Sweden, the United Kingdom, and the United States, among the richest countries in the world, are the least regulated. The study also finds that common law and Nordic countries regulate less than countries whose legal systems are based on French, German, and socialist origins.

Second, as with the studies based on broader and more subjective indicators, the World Bank study finds that both labor productivity and employment are positively correlated with less regulation. The World Bank study also finds that heavier regulation is associated with greater inefficiency of public institutions and more corruption. The result is that regulation often has a perverse effect on the people it is meant to protect. Overly stringent regulation of business creates strong incentives for businesses to operate in the underground or informal economy. The study cites the example of Bolivia, one of the most heavily regulated economies in the world, where an estimated 82% of business activity takes place in the informal sector.

Third, the study finds that rich countries tend to regulate consistently across the five indicators, as measured by the statistical significance of their 15 cross correlations compared to the cross correlations of poor countries. The World Bank suggests that this indicates that poor countries have made some progress in some reform areas but not others and that this finding suggests some optimism that these reforms may spread.

Based on its analysis of the impact of regulation on economic performance, the World Bank concludes that countries that have performed well have five common elements to their approach to regulation:

1. Simplify and deregulate in competitive markets.
2. Focus on enhancing property rights.
3. Expand the use of technology.
4. Reduce court involvement in business matters.
5. Make reform a continuous process.

It is interesting to note that these principles correspond fairly closely to the principles that characterize the U.S.'s program of "Smarter Regulation."[14]

---

[13] World Bank. 2004. *Doing Business in 2004: Understanding Regulation*. Oxford Press. Washington DC.

The strong relationship between excessive regulation and economic performance persists even when the sample of countries is confined to the 30 mostly high-income democracies in the Organization for Economic Cooperation and Development (OECD). A recent report by Giuseppe Nicoletti summarizes the findings of the OECD work in this area as follows:

> The empirical results suggest that regulatory reforms have positive effects not only in product markets, where they tend to increase investment, innovation and productivity, but also for employment rates.[15]

According to the OECD's regulatory index for seven key industries, the five countries with least regulation in order are: the United Kingdom, the United States, New Zealand, Australia, and Sweden. The five with the most regulation in order are: Greece, Italy, Portugal, Ireland, and France. One of the most interesting findings of the OECD study is that the least regulated countries tended to show the greatest improvement in their rates of multifactor productivity growth over the 1990s compared to the 1980s and that those countries also tended to show both the largest increase in the number of new small and medium-sized firms and in the rate of investment in research and development in manufacturing. Both of these factors are thought to be important in increasing the growth rate of productivity and per capita income.

These four major efforts to determine the effect of regulatory policies on economic performance described use quite different indicators of regulatory quality, yet reach very similar conclusions. This pattern of findings provides strong support for policies that pursue smarter regulation. These results are also consistent with economic theory, which predicts that economic growth is enhanced by regulatory policies that promote competitive markets, secure property rights, and intervene to correct market failures rather than to increase state influence.

---

[14] For a description of the Administration's regulatory reform program see, in particular, Chapter 1 of *Stimulating Smarter Regulation:2002 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local, and Tribal Entities*. Office of Management and Budget.

[15] Giuseppe Nicoletti, "the Economy-Wide Effects of Product Market Reform". OECD. Paris, December 2002.

APPENDIX A: CALCULATION OF BENEFITS AND COSTS

Chapter I presents estimates of the annual costs and benefits of selected final major regulations reviewed by OMB between October 1, 1993 and September 30, 2003. OMB presents more detailed explanation of these regulations in several documents. The explanation of the calculations for the major rules reviewed by OMB between April 1, 1995 and March 31, 1999 can be found in Chapter IV of our 2000 report. Table 19, Appendix E, of the 2002 Report presents OMB=s estimates of the benefits and costs of the 20 individual rules reviewed between April 1, 1999 and September 30, 2001. Tables 18 and 19 in Appendix A in the 2003 report present the results for October 1, 1993 to March 31, 1995 (Table 18), and October 1, 2001 to September 30, 2002 (Table 19). Table 7 in this appendix presents the newly added rules from October 1, 2002 to September 30, 2003. All benefit and cost estimates were adjusted to 2001 dollars.

In assembling estimates of benefits and costs, OMB has:

(1) applied a uniform format for the presentation of benefit and cost estimates in order to make agency estimates more closely comparable with each other (for example, annualizing benefit and cost estimates); and
(2) monetized quantitative estimates where the agency has not done so (for example, converting Agency projections of quantified benefits, such as, estimated injuries avoided per year or tons of pollutant reductions per year to dollars using the valuation estimates discussed below).

The adoption of a uniform format for annualizing agency estimates allows, at least for purposes of illustration, the aggregation of benefit and cost estimates across rules. All inflation adjustments are performed using the latest CPI-U numbers from the Bureau of Labor Statistics. In instances where the nominal dollar values the agencies use for their benefits and costs is unclear, we assume the benefits and costs are presented in nominal dollar values of the year before the rule is finalized. In periods of low inflation such as the past few years, this assumption does not impact the overall totals. All amortizations are performed using a discount rate of 7%, unless the agency has already presented annualized, monetized results using a different explicit discount rate.

OMB discusses, in this report and in previous reports, the difficulty of estimating and aggregating the costs and benefits of different regulations over long time periods and across many agencies. In addition, where OMB has monetized quantitative estimates where the agency has not done so, we have attempted to be faithful to the respective agency approaches. The adoption of a uniform format for annualizing agency estimates allows, at least for purposes of illustration, the aggregation of benefit and cost estimates across rules; however, the agencies have used different methodologies and valuations in quantifying and monetizing effects. Thus, an aggregation involves the assemblage of benefit and cost estimates that are not strictly comparable.

In part to address this issue, the 2003 report included OMB's new regulatory analysis guidance, also released as OMB Circular A-4, which took effect on January 1,

2004, for proposed rules, and will take effect in January 1, 2005, for final rules. The guidance recommends what OMB considers to be "best practice" in regulatory analysis, with a goal of strengthening the role of science, engineering, and economics in rulemaking. The overall goal of this guidance is a more competent and credible regulatory process and a more consistent regulatory environment. OMB expects that as more agencies adopt our recommended best practices, the costs and benefits we present in future reports will become more comparable across agencies and programs. OMB will work with the agencies to ensure that their impact analyses follow the new guidance.

Table 7. Estimates of Annual Benefits and Costs of 6 Major Rules
October 1, 2002 to September 30, 2003
(millions of 2001 dollars per year)

Rule	Agency	Benefits	Costs	Explanation
Truck Driver Hours of Service	DOT	690	1,318	Impacts are relative to the status quo baseline. Year 2000 wages are the basis of analysis, so we inflated estimates to 2001 dollars.
Light Truck CAFE for Model Years 2005-2007	DOT	255	220	We amortized the sum of all three model years of the agency's present value estimates over 10 years, the assumed lifespan of a vehicle.
National Pollutant Discharge Permits and Standards for Concentrated Animal Feeding Operations (CAFOs)	EPA	204-355	335	
Patent Listing Requirements and Application of 30 Month Stays of Abbreviated New Drug Applications (Generics)	FDA	226	10	
Trans fat Labeling	FDA	230-2839	9-26	
Control of Listeria monocytogenes in Ready-to-Eat Meat and Poultry Products	USDA	43-152	17	
Total		**1649-4517**	**1908-1925**	

A. Valuation Estimates for Regulatory Consequences[16]

Agencies continue to take different approaches to monetizing benefits for rules that affect small risks of premature death. As a general matter, we continue to defer to the individual agencies' judgment in this area. Except where noted, in cases where the agency both quantified and monetized fatality risks, we have made no adjustments to the agency's estimate. In cases where the agency provided a quantified estimate of fatality risk, but did not monetize it, we have monetized these estimates in order to convert these effects into a common unit.

The following is a brief discussion of OMB's valuation estimates for other types of effects which agencies identified and quantified, but did not monetize. As a practical matter, the aggregate benefit and cost estimates are relatively insensitive to the values we have assigned for these rules because the aggregate benefit estimates are dominated by those rules where EPA provided quantified and monetized benefit and cost estimates.

Injury. For NHTSA's rules, we adopted NHTSA's approach of converting nonfatal injuries to "equivalent fatalities." These ratios are based on NHTSA's estimates of the value individuals place on reducing the risk of injury of varying severity relative to that of reducing risk of death.[17] Note that the light truck average fuel economy rule NHTSA finalized in 2003 did present quantified and monetized costs and benefits, which we did not adjust. For the OSHA rules, we monetized only lost workday injuries using a value of $50,000 per injury averted.

1. Change in Gasoline Fuel Consumption. We valued reduced gasoline consumption at $0.80 per gallon pre-tax. This equates to retail (at-the-pump) prices in the $1.10 - $1.30 per gallon range.
2. Reduction in Barrels of Crude Oil Spilled. OMB valued each barrel prevented from being spilled at $2,000. This is double the sum of the most likely estimates of environmental damages plus cleanup costs contained in a published journal article (Brown and Savage, "The Economics of Double-Hulled Tankers," *Maritime Policy and Management*, Volume 23(2), 1996, pages 167-175.)
3. Change in Emissions of Air Pollutants. Please see the following paragraphs for an explanation of the derivation of these values. All values are in 2001 dollars.

Hydrocarbon:	$600 to $2,700 per ton
Nitrogen Oxide (stationary):	$400 to $2,500 per ton
Nitrogen Oxide (mobile):	$1,400 to $8,800 per ton
Sulfur Dioxide:	$2,100 to $14,000 per ton
Particulate Matter:	$10,000 to $100,000 per ton

[16] The following discussion updates the monetization approach used in previous reports and draws on examples from this and previous years.

[17] National Highway Traffic Safety Administration, The Economic Cost of Motor Vehicle Crashes, 1994, Table A-1. http://www.nhtsa.dot.gov/people/economic/ecomvc1994.html

The estimates for reductions in hydrocarbon emissions were obtained from EPA's RIA for the 1997 rule revising the primary National Ambient Air Quality Standards (NAAQS) for ozone and fine particulate matter (PM). OMB has revised the estimates for reductions in NO_x emissions to reflect a range of estimates from recent EPA analyses for several rules and for proposed legislation. In particular, OMB has adopted different benefit transfer estimates for NO_x reductions from stationary sources (e.g., electric utilities) and from mobile sources. EPA believes that there are a number of reasons to expect that reductions in NO_x emissions from utility sources achieve different air quality improvements relative to reductions from ground-level mobile sources. For example, mobile source tailpipe emissions are located in urban areas at ground level (with limited dispersal) while electric utilities emit NO_x from "tall stacks" located in rural (remote) locations with substantial geographic dispersal (Letter to Don Arbuckle, Deputy Administrator, OIRA from Tom Gibson, Associate Administrator, Office of Policy, Economics and Innovation, EPA, May 16, 2002). There remain considerable uncertainties with the development of these estimates. The discussion below outlines the various EPA analyses serving as the basis for the NO_x benefit transfer values presented above and discusses the uncertainties that attend these estimates.

Analysis of recent EPA rules yield several estimates for the NO_x benefits per ton from electric utility sources. (See the Regulatory Impact Analyses for the "NO_x SIP Call" and the Section 126 rules, available on the web at http://www.epa.gov/ttn/ecas/econguid.html. In addition, see Memo to NSR Docket from Bryan Hubbell, Senior Economist, Innovative Strategies and Economics Group, EPA.) Based on these studies, EPA estimates the mortality-based benefits of NO_x reductions from stationary sources (electric utilities) is $1,300 (1999$) per ton.

For mobile sources, EPA recently published the final Tier 2/Gasoline Sulfur rule RIA (EPA, 1999) and Heavy Duty Engine/Diesel Fuel RIA (EPA, 2000). For the Tier 2 rule, which affects light-duty vehicles, NO_x reductions account for around 90 percent of PM precursor emissions and 86 percent of ozone precursor emissions. Based on the final Tier 2/Gasoline Sulfur RIA, EPA estimates that NO_x reductions will yield benefits of $4,900 (1999$) per ton. EPA believes this analysis provides a more appropriate source for the NO_x benefit transfer value for mobile sources than available estimates for stationary sources (Letter from Tom Gibson, pp. B2 and B3, May 16, 2002). Additional details on the Tier 2 benefits analysis are available in the Tier 2/Sulfur Final Rulemaking RIA, available on the web at http://www.epa.gov/oms/fuels.htm.

The Heavy Duty Engine/Diesel Fuel benefits analysis examined the impacts in 2030 of reducing SO_2 emissions by 141,000 tons and NO_x emissions by 2,750 thousand tons, as well as a 109,000 ton reduction in direct PM emissions. Based on this analysis, EPA estimates a value for NO_x reductions of $10,200/ton in 2030 (Letter from Tom Gibson, p.B3, May 16, 2002). Complete details of the emissions, air quality, and benefits modeling conducted for the HD Engine/Diesel Fuel Rule can be found at http://www.epa.gov/otaq/diesel.htm and http://www.epa.gov/ttn/ecas/regdata/tsdhddv8.pdf. Because the Heavy Duty

Engine/Diesel Fuel estimate includes an adjustment for income growth out to 2030 and involves reductions in several PM-related pollutants, OMB has adopted a value of $4,900 (1999$) per ton from EPA's analysis of the Tier 2 rule as a benefits transfer value for reductions in NO_x emissions from mobile sources.

Reductions in the risk of premature mortality dominate the benefits estimates in all of these analyses. The size of the mortality risk estimates from the underlying epidemiological studies, the serious nature of the effect itself, and the high monetary value ascribed to prolonging life make mortality risk reduction the most important health endpoint quantified in these analyses.[18] Because of the importance of this endpoint and the considerable uncertainty among economists and policymakers as to the appropriate way to value reductions in mortality risk, OMB has adjusted these benefits per ton estimates to reflect the substantial range in the estimated values (VSL) for reductions in mortality risk. In its recent rulemakings setting SO_2, NO_x and mercury emissions standards for electric utilities, EPA adopted a confidence interval for VSL estimates ranging from $1 million to $10 million based on two meta-analyses of the wage-risk VSL literature. The $1 million lower end estimate represents the lower end of the interquartile range from the Mrozek and Taylor (2002) meta-analysis. The $10 million upper end estimate represents the upper end of the interquartile range from the Viscusi and Aldy (2003) meta-analysis. Using this VSL range, the estimated benefits for reductions in NO_x emissions range from $400 to $2,500 per ton and for mobile sources range from $1,400 to $8,800 per ton.

EPA also developed estimates for the benefits associated with reductions in SO_2 from electric utilities. Based on an analysis outlined in a June 20, 2001 EPA memo to the file, "Benefits Associated with Electricity Generating Emissions Reductions Realized Under the NSR program," we used $7,300 per ton. Using the VSL range, the estimated benefits for reductions in SO_2 range from $2,100 to $14,000 per ton.

As mentioned above, OMB only monetized benefits estimates for rules that were not otherwise monetized by the agencies. Therefore, these per ton benefits estimates

[18] There are several key assumptions underlying the benefit estimates for reductions in NO_x emissions, including:

1. Inhalation of fine particles is causally associated with premature death at concentrations near those experienced by most Americans on a daily basis. While no definitive studies have yet established any of several potential biological mechanisms for such effects, the weight of the available epidemiological evidence supports an assumption of causality.
2. All fine particles, regardless of their chemical composition, are equally potent in causing premature mortality. This is an important assumption, because fine particles formed from power plant SO_2 and NO_x emissions are chemically different from directly emitted fine particles from both mobile sources and other industrial facilities, but no clear scientific grounds exist for supporting differential effects estimates by particle type.
3. The concentration-response function for fine particles is approximately linear within the range of outdoor concentrations under policy consideration. Thus, the estimates include health benefits from reducing fine particles in both attainment and non-attainment regions.
4. The forecasts for future emissions and associated air quality modeling are valid.
5. The valuation of the estimated reduction in mortality risk is largely taken from studies of the tradeoff associated with the willingness to accept risk in the labor market.

were only applied to EPA rules in which emission impacts were quantified but not monetized by EPA.

We applied these values to several rules regulating mobile sources of emissions. These rule are: Reformulated Gasoline and Non-Road Diesel Engines (1993-1994); Deposit Control Gasoline, Federal Test Procedures, and Marine Engines (1996-1997); New Locomotives (1996-1997); Non-Road Diesel Engines II and Non-Handheld Engines (1998-1999); Hand-Held Engines Phase II (1999-2000); and 2004 Heavy Duty Engines (2000-2001).

In addition, we applied these values to several rules regulating stationary sources of emissions. These rules are: Acid Rain NO_x and Hazardous Organic NESHAP (1993-1994); Municipal Waste Combustors (1995-1996); Acid Rain NO_x Phase II (1996-1997); and Steam Generating Units (1998-1999).

B. Adjustment for Differences in Time Frame across These Analyses

Agency estimates of benefits and costs cover widely varying time periods. The differences in the time frames used for the various rules evaluated generally reflect the specific characteristics of individual rules, such as expected capital depreciation periods or time to full realization of benefits. In order to allow us to provide an aggregate estimate of benefits and costs, we developed benefit and cost time streams for each of the rules. Where agency analyses provide annual or annualized estimates of benefits and costs, we used these estimates in developing streams of benefits and costs over time. Where the agency estimate provided only annual benefits and costs for specific years, we used a linear interpolation to represent benefits and costs in the intervening years.[19]

C. Further Caveats

In order for comparisons or aggregation to be meaningful, benefit and cost estimates should correctly account for all substantial effects of regulatory actions, including potentially offsetting effects, which may or may not be reflected in the available data. OMB has not made any changes to agency monetized estimates. To the extent that agencies have adopted different monetized values for effects—for example, different values for a statistical life or different discounting methods—these differences remain embedded in the tables. Any comparison or aggregation across rules should also consider a number of factors which our presentation does not address. For example,

[19] The adjustment to reflect the range in VSL estimates was developed as follows: The mortality-related benefits associated with NO_x reductions typically account for 90 percent or more of total monetized benefits. Starting with the estimate of $1,300 per ton for the mortality-related benefits associated with a reduction in NO_x emissions, and assuming that this represents 90 percent of total benefits, a reduction in NOx emission would yield total benefits of $1,450 per ton - $1,300 per ton in mortality-related benefits and $150 per ton in other monetized benefits. Since the mortality-related benefits are proportional to VSL and the $1,300 per ton is based on a VSL of $6 million, the VSL range of $1 to $10 million yields mortality-related benefits of $217 to $2,167 per ton (1999$) and total benefits of $400 to $2,300 per ton for reductions in NO_x emissions from stationary sources. A similar calculation yields a total benefits estimate for reductions in NO_x emissions from mobile sources ranging from $1,238 to $7,965 per ton (1997$).

these analyses may adopt different baselines in terms of the regulations and controls already in place. In addition, the analyses for these rules may well treat uncertainty in different ways. In some cases, agencies may have developed alternative estimates reflecting upper- and lower-bound estimates. In other cases, the agencies may offer a midpoint estimate of benefits and costs. In still other cases the agency estimates may reflect only upper-bound estimates of the likely benefits and costs. While OMB has relied in many instances on agency practices in monetizing costs and benefits, citation of, or reliance on, agency data in this report should not be taken as an OMB endorsement of all the varied methodologies used to derive benefits and cost estimates.

APPENDIX B: THE BENEFITS AND COSTS OF MAJOR RULES: OCTOBER 1, 1992 TO SEPTEMBER 30, 1993.

Tables 8 and 9 list the rules that were reported in Chapter 1 of the 2003 report as part of the 10-year totals of costs and benefits, but are not included in Chapter 1 of the 2004 report. Table 8 presents only the rules that had annualized, monetized costs and benefits used for the purposes of calculating the totals in previous reports. Table 9 presents the unmodified details of all major rules from this time period, including rules that did not have monetized costs or benefits and were therefore not included in the totals in previous reports. FDA published a single analysis as a basis for the costs and benefits of 23 individual rules regarding food labeling as one rulemaking. If considered separate rulemakings in this accounting, the total number of rules that drop out of the analysis is 32. If considered one rulemaking, the total number of rules that drop out of the analysis is 10.

Table 8. Estimate of Annual Benefits and Costs of 10 Major Rules October 1, 1992 to March September 30, 1993
(millions of 2001 dollars per year)

REGULATION	AGENCY	BENEFITS	COSTS	EXPLANATION
Nutrition Labeling of Meat and Poultry Products	USDA/FSIS	205	25-32	We amortized the agency's present value estimates over 20 years.
Food Labeling (combined analysis of 23 individual rules)	HHS/FDA	438-2,637	159-249	We amortized the agency's present value estimates over 20 years.
Real Estate Settlement Procedures	HUD	258-332	135	
Manufactured Housing Wind Standards	HUD	103	63	
Permit Required Confined Spaces	DOL/OSHA	540	250	We valued each fatality at $5 million and each lost-workday injury at $50,000. We did not value non-lost-workday injuries.
Vessel Response Plans	DHS/USCG	9	295	We amortized the agency's present value estimates over 30 years. We valued each barrel of oil not spilled at $2,000.
Acid Rain Permits Regulations	EPA	78,454-78,806	1,109-1,871	We valued SO_2 reductions at $7,800 per ton.

Table 8. Estimate of Annual Benefits and Costs of 10 Major Rules
October 1, 1992 to March September 30, 1993
(millions of 2001 dollars per year)

REGULATION	AGENCY	BENEFITS	COSTS	EXPLANATION
Vehicle Inspection and Maintenance (I/M)	EPA	247-1,120	671	We used the estimates of cost and emission reductions of the new I/M program compared to the baseline of no I/M program. We valued VOC reductions at $600-$2,700 per ton. We did not assign a value to CO reductions.
Evaporative Emissions from Light-Duty Vehicles, Light-Duty Trucks, and Heavy-Duty Vehicles.	EPA	274-1,246	161-248	We assumed the VOC emission reductions began in 1995 and rise linearly until 2020, after which point they remain at the 2020 level. Annualizing this stream results in an average of 468,000 tons per year. We valued these tons at $600-$2,700 per ton.
Onboard Diagnostic Systems	EPA	702-3,423	226	We amortized the agency's emission reduction and cost estimates over 15 years. We valued VOC reductions at $600-$2,700 per ton and NO_x reductions at $1,100-$5,500 per ton.

Table 9. Agency Estimates of Benefits and Costs of Major Rules October 1, 1992 to September 30, 1993				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
Nutrition labeling of meat and poultry products	USDA/ FSIS	$1.75 billion (NPV)	$218-272 million (NPV)	NPV of benefits and costs discounted over 20 years at 7%
Food Labeling (combined analysis of 23 individual rules)	HHS/FDA	$4.4-$26.5 billion	$1.4-$2.3 billion plus $163 million in costs to Federal government	HHS-FDA performed one analysis for the food labeling requirements imposed by 23 HHS-FDA rules put in place as a result of the Nutrition Labeling and Education Act.
Real Estate Settlement Procedures Act (Regulation X), FR-1942	HUD	$119,014,950 annually in greater competition in title insurance business $89.1-148.5 million net benefit annually in reducing transaction costs by packaging services with affiliated services	Cost of duplicate good-faith-estimates: $56,824,627 per year Cost of new disclosure for controlled business arrangements: $48,147,000 per year Cost of computerized loan originations: $3,607,890 per year Cost of two additional years for storage (discount rate=6%): 24,305	
Manufactured Housing Construction and Safety Standards	HUD	$103 million	$63 million	

Table 9. Agency Estimates of Benefits and Costs of Major Rules October 1, 1992 to September 30, 1993				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
Final frameworks for early-season migratory bird hunting regulations	DOI	Not Estimated	Not Estimated	
Migratory bird hunting, final frameworks for late-season migratory bird hunting regulations	DOI	Not Estimated	Not Estimated	
The Family and Medical Leave Act of 1993	DOL/ESA	Not Estimated	$674 million annually	Estimate provided by U.S. General Accounting Office (Parental Leave: Estimated Costs of H.R. 925, the Family and Medical Leave Act of 1987—GAO/HRD-88-34, Nov. 10, 1987)
Permit Required Confined Spaces	DOL/OSHA	Reduced annually: 54 fatalities; 5,931 lost-workday injury and illness cases; 5,908 non-lost-workday cases	$202.4 million annually	"OSHA anticipates that improved worker productivity as a result of the standard will help to lower production costs and contribute to higher quality output. Although OSHA did not quantify these cost offsets, the Agency believes they will be substantial" (RIA, pp. I-10, I-13). "OSHA anticipates that greater use of mechanical ventilation to reduce atmospheric hazard in permit spaces may result in additional release of hazardous substances to the air. Incremental release quantities related to the permit space standard are not determinable at present, but are expected to be minor relative to current overall releases" (RIA, pp. I-17 – I-18).

Table 9. Agency Estimates of Benefits and Costs of Major Rules October 1, 1992 to September 30, 1993				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
Lead Exposure in Construction	DOL/OSHA	Near-term avoided annual health effects Reduced nerve conduction velocity: 16,199-22,831 cases; Reduced blood ALA-D levels: 130,056-164,044 cases; Increased urinary ALA: 60,389-78,676 cases; Gastrointestinal disturbances: 1,135-4,413 cases; Detected blood-lead levels above MRP trigger: 24,262-35,163 cases Long-term avoided health effects over 10 years Fatal/nonfatal infractions: 2,164-2,322 cases; Fatal/nonfatal stroke: 644-698 cases; Renal disease: 1,258-2,157 cases	$365-445 million annually plus one-time start-up costs of $150-$183 million.	

Table 9. Agency Estimates of Benefits and Costs of Major Rules October 1, 1992 to September 30, 1993				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
Response Plans for Marine Transportation-Related Facilities	DHS/USCG	58,838 barrels of oil not spilled (NPV)	$176,105,666 (NPV)	Timeline of the analysis: 1996-2025 Discount Rate: 7%; $1996
Vessel Response Plans	DHS/USCG	50,312 barrels of oil not spilled (NPV)	$3,245,869,985 (NPV)	Timeline of the analysis: 1996-2025 Discount Rate: 7%; $1996
Light Truck Average Fuel Economy Standard for Model Year 1995	DOT/NHTSA	Not Estimated	Not Estimated	

Table 9. Agency Estimates of Benefits and Costs of Major Rules October 1, 1992 to September 30, 1993				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
Water quality standards regulation: Compliance with CWA Section 303(C)(2)(B) Amendments	EPA	Not Estimated	Not Estimated	"The analysis performed was limited to assessing only the potential reduction in cancer risk; no assessment of potential reductions in risks due to reproductive, developmental, or other chronic and subchronic toxic effects was conducted. However, given the number of pollutants, there could be: (1) Decreased incidence of systemic toxicity to vital organs such as liver and kidney; (2) decreased extent of learning disability and intellectual impairment due to the exposure to such pollutants as lead; and (3) decreased risk of adverse reproductive effects and genotoxicity." (57 FR 60848-) "The ecological benefits that can be expected from today's rule include protection of both fresh and salt water organisms, as well as wildlife that consume aquatic organisms…In addition, the rule would result in the propagation and productivity of fish and other organisms, maintaining fisheries for both commercial and recreational purposes. Recreational activities such as boating, water skiing, and swimming would also be preserved along with he maintenance of an aesthetically pleasing environment" (57 FR 60848-) "EPA acknowledges that there will be a cost to some dischargers for complying with new water quality standards as those standards are translated into specific NPDES permit limits…Revised wasteload allocations may result in adjustments to individual NPDES permit limits for point source dischargers, and these adjustments could result in increased wastewater treatment costs or other pollution control activities such as recycling or process changes. The magnitude of these costs depends on the types of treatment or other pollution control, the number and type of pollutants being treated, and the level of control that can be achieved by technology-based effluent limits for each industry. Similar sources of costs and the variables affecting costs may also apply to indirect industrial dischargers to the extent that the industrial discharger is a source of toxic pollutants discharged by the POTW…Nonpoint sources of toxic pollutants may also incur increased costs to the extent that best management practices need to be modified or applied to more sources to reflect the revised water quality standards. Although there is no Federal permit program for nonpoint sources comparable to that for point sources, there are State regulatory programs to control nonpoint source discharges. Monitoring programs are another source of potential incremental costs to dischargers and States." (57 FR 60848-)

Table 9. Agency Estimates of Benefits and Costs of Major Rules October 1, 1992 to September 30, 1993				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
Coastal nonpoint pollution control program development and approval guidance (EPA, NOAA), guidance specifying management measures for sources of nonpoint… Section 6217	EPA	Not estimated	$389,940,000-$590,640,000 (annualized)	The RIA identified generally the types of "off-site benefits" that could be related to water quality improvements, including 4 use benefits (in-stream, near stream, option value, and diversionary) and 3 non-use (intrinsic) benefits (aesthetic, bequest, and existence).
Oil and Gas Extraction Point Source Category, Offershore Subcategory, Effluent Limitations Guidelines and New Source Performance Standards (Final Rule)	EPA	$28.2-103.9 million per year	Total annualized BAT and NSPS costs: 1st year=$122 million, 15th year=$32 million	"Other benefits that are quantified, to the extent possible, but not monetized due to lack of appropriate data, include: (1) Human health risk reductions associated with systemics other than lead, pH-dependent leach rates, carcinogens for which there are no risk factors available, exposure to pollutants via sediment or food chair; (2) ecological risk reductions; (3) fishery benefits; and (4) intrinsic benefits…The non-quantified, non-monetized benefits assessed in this RIA include increased recreational fishing, increased commercial fishing, improved aesthetic quality of waters near the platform, and benefits to threatened or endangered species [the Kemp's Ridley Turtle and the Brown Pelican] in the Gulf of Mexico." (58 FR 12454-)

Table 9. Agency Estimates of Benefits and Costs of Major Rules October 1, 1992 to September 30, 1993				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
Acid Rain Permits, Allowance System, Emissions Monitoring, Excess Emissions and Appeals Regulations Under Title IV of the Clean Air Act Amendments of 1990	EPA	10 million tons/year reduction in SO_2 emission (mandated by Title IV) Cost savings: $689-973 million (annualized)	$894-1,509 million (annualized)	SO_2 emission reductions are expected to : (1) reduce acidification of surface waters, thereby increasing the presence an diversity of aquatic species; (2) improve visibility by reducing haze; (3) may improve human health as lower SO_2 emissions reduce air concentrations of acid sulfate aerosols and thus acute and chronic exposure to the acid aerosols that adversely affect human health may even affect even mortality; (4) eliminate damage to forest soils and foliage, especially of high-elevation spruce trees in the eastern U.S. and allow recovery of previously damaged tree populations; (5) may reduce damage to auto paint, reduce soiling of buildings and monuments, and thus the life of some materials and structures may be extended and the costs of maintenance or repair reduced (RIA, pp. 1-5 to 1-6, and 6-1 to 6-3) Engineering costs associated with CEM retrofit were not analyzed (RIA, pp. 4-18) "The annualized costs of the implementation regulations are estimated to increase the annual costs of generating electricity by 0.5 to 1.2 percent." (58 FR 3590-)

Table 9. Agency Estimates of Benefits and Costs of Major Rules October 1, 1992 to September 30, 1993				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
Vehicle Inspection and Maintenance Requirements for State Implementation Plan (Final Rule)	EPA	Emission reductions from continuing current I/M program unchanged (baseline=no I/M program)in 2000: 116016 tons VOC, 1566395 tons CO (annual tons in 2000) Emission reductions from new I/M program in 2000 (baseline=no I/M program): 420415 tons VOC, 2845754 tons CO (annual tons in 2000)	Continuing current I/M program: NET COST=$894 million ($2000) New I/M program: NET COST=$541 million ($2000)	"These repairs have been found to produce fuel economy benefits that will at least partially offset the cost of repairs. Fuel economy improvements of 6.1% for repair of pressure test failures and 5.7% for repair of purge test failures were observed. Vehicles that failed the transient short test at the established cutpoints were found to enjoy a fuel economy improvement of 12.6% as a result of repairs." (57 FR 52950-) "In conclusion, today's action may cause significant shifts in business opportunities. Small businesses that currently do both inspections and repairs in decentralized I/M programs may have to choose between the two. Significant new opportunities will exist in these areas for small businesses to continue to participate in the inspection and repair industry. This will mean shifts in jobs but an overall increase in jobs in the repair sector and a small to potentially large increase in the inspection sector, depending on state choices." (57 FR 52950-)
Evaporative emission regulations for gasoline-fueled and methanol-fueled light duty vehicles, light-duty trucks, and heavy-duty vehicles —SAN 2969	EPA	Total VOC Reduction in 2020: 1,120,000 metric tons	Annual total program cost without fuel savings: $130-200 million ($1992, NPV to the year of the sale)	"[Emission] projections are made for the year 2020 in order to provide benefit predictions for a fully turned-over fleet and to factor in other known trends, such as the effects of other new Clean Air Act programs. These new programs include high-technology inspection and maintenance and reformulated gasoline. Reformulated gasoline achieving a 25 percent overall VOC emission reduction standard is assumed to be used in 40 percent of the nation." (58 FR 16002-) "[The cost] estimate does not include the offsetting fuel savings." (58 FR 16002-)

Table 9. Agency Estimates of Benefits and Costs of Major Rules October 1, 1992 to September 30, 1993				
RULE	**AGENCY**	**BENEFITS**	**COSTS**	**OTHER INFORMATION**
Control of air pollution from new motor vehicles and new motor vehicle engines, regulations requiring on-board diagnostic systems on 1994 and later model year light-duty vehicles	EPA	4.0 million tons HC, 30.8 million tons CO, 2.5 million tons NO_x (NPV)	$16.6 billion (NPV) ($1993)	Discount rate: 7% (58 FR 9468-) Timeline: 2005-2020 (58 FR 9468-) "EPA has not been able to adequately quantify some potential cost savings not included in these estimates. Potential cost savings can accrue due to early repairs of malfunction which, if left undetected and unrepaired, could result in the need for even more costly repairs in the future. Also, improved repair effectiveness should reduce the potential for a part to be unnecessarily replaced in attempting to fix a problem. Repair facilities should also benefit from the availability of generic tools for accessing and using the OBD system in problem diagnosis and repair. These service facility benefits could be passed along to the consumer in the form of lower repair costs." (58 FR 9468-)

CHAPTER II: REGULATIONS AND MANUFACTURING

Introduction

Manufacturing is a substantial and vital part of the U.S. economy; the manufacturing sector accounted for approximately 14% of Gross Domestic Product (GDP) in 2002 (Yuskavage and Strassner 2003). Regulatory compliance costs impose a burden on manufacturers that has the potential to lower the viability of U.S. manufacturers and the competitiveness of U.S. manufacturing relative to our international trading partners.[20] Regardless of the health of manufacturing in the United States, when assessing whether or not to impose a regulation on the manufacturing sector, the government should strive to accurately estimate the cost of the regulatory intervention, make sure that benefits justify costs, and adopt least-cost alternatives that meet statutory objectives.

Regulatory reform of the manufacturing sector needs to be approached with analytic care because many rules governing this sector may produce substantial benefits for workers, consumers and the environment. For example, this Report has discussed the billions of dollars of public health benefits associated with selected rules adopted pursuant to the 1990 Amendments to the Clean Air Act, and some of these rules cover the manufacturing sector. Even where the benefits of rules are substantial, it makes sense to search for more cost-effective ways of achieving those benefits (e.g., market-based policy instruments). Whenever the costs of rules are substantial, the search for cost-effective reforms is critical.

Definition of the Manufacturing Sector

The U.S. Census bureau (2003) defines manufacturers as "establishments engaged in the mechanical, physical, or chemical transformation of materials, substances, or components into new products." This includes such activities as electronic equipment, transportation equipment, printing and publishing, rubber and plastic products, and textile mills. The indirect effects of impacts to this sector can be more widespread, including impacts to consumers or suppliers in the form of higher or lower prices, and impacts to employment trends to the extent that manufacturing employment experiences relative productivity gains when compared to other sectors (Economic Report of the President 2004).

This review provides background on two questions. What is the overall burden of regulatory requirements on manufacturers, and what could be the direct and indirect effects of this burden on the economy?

Overall Burden

History of New Regulatory Costs: 1987 - 2003.

[20] In this review, we do not discuss the structural or cyclical health of the manufacturing sector; please see the 2004 Economic Report of the President for a discussion of overall manufacturing trends.

Regulatory analysts have developed a variety of ways to measure the growth of the Federal regulatory burden over time: the number of new Federal rules, the number of pages in the Federal Register devoted to new Federal rules, the number of new "economically significant" rules and the number of full-time equivalent staff at regulatory agencies. Although each of these measures offers some insight, they share the important limitation that they do not measure a key quantity of interest: the overall economic cost to society of new Federal rules. In order to develop such a measure, OIRA has assembled for this draft Report a time series of new Federal regulatory costs for the 1987-2003 period.

Each year since 1987 OIRA has collected estimates of the new regulatory costs imposed on the economy due to actions by Cabinet agencies and EPA that were reviewed by OIRA (under E.O. 12291 prior to September 1993 and under E.O. 12866 after 1993). These actions are primarily "social regulations" which expend capital and labor resources in an effort to improve public health, safety, and the environment. A substantial number of these rules affect the manufacturing sector, particularly labor and environmental rules. During this period there were few new "economic regulations" reviewed by OIRA. The analysis reported below excludes the economic impacts of new rules that are included in the Federal budget, since most of these rules represent transfers from one group in society to another and thus do not necessarily incur societal cost. Cost estimates for each of the new rules are based on agency estimates prepared in the pre-regulation period, prior to the promulgation of the rule.

Over this 17-year period, these new rules added a total of $95 billion in regulatory cost burden, which amounts to an average incremental burden of $5.6 billion per year. The additional costs of new regulation are not spread evenly over the 17-year period. The added costs were largest in the early part of the period, plus the large increase in the last year of the Clinton Administration. During the first 32 months of this Administration, the average annual increase in regulatory costs has been about $1.6 billion, approximately 80% smaller than the average for the previous 14 years.

An even better measure of new regulatory performance would be net benefits (new benefits to society minus new costs to society), a measure of overall economic efficiency. We do not yet have comparable measures of new regulatory benefits for the 1987-2003 period, although we are in the process of preparing such information for the 2005 Report to Congress. That analysis will necessarily be incomplete, since many rules that impose significant cost do not have any corresponding numeric estimate of benefit. Nonetheless, the quality of benefit information is improving and thus we intend to report whatever information is available, with appropriate qualifications.

With regard to the quality of regulatory cost information, we highlight here some of the important technical limitations of the available estimates. First, these cost estimates are generated by the regulatory agency prior to a rule's promulgation and have not been validated by post-regulation cost measurement. Although many of these cost estimates may be accurate, the regulatory analysis literature suggests, based on limited

validation studies, that the actual costs of rules can be significantly different -- larger or smaller -- than the pre-regulation estimates of costs. Second, these cost estimates typically address only the direct costs of rules (e.g., compliance expenditures made by regulated businesses). However, the full social cost of regulation would include any declines in product quality or price-induced changes in consumption that are caused by regulation. The magnitude of the resulting error in regulatory cost estimation is unknown but could be significant. Third, there are intangible costs of rules -- for example, losses of freedom, privacy and innovation -- that are difficult to measure in monetary terms. Thus, the intangible costs of regulation need to be considered in conjunction with the tangible resource costs associated with regulation. Finally, the estimates reported here are only for "economically significant" Federal rules, which account for a small percentage of the total number of Federal rulemaking actions. However, OIRA believes that these "economically significant" actions, because they have impacts greater than $100 million per year, are likely to account for the vast majority of new regulatory costs.

The Regulatory Burden on Manufacturing.

Among the more recent and comprehensive sources of estimates of the overall burden of regulation on specific economic sectors is the Crain and Hopkins 2001 study performed for the SBA Office of Advocacy, which depended in part on overall totals from previous versions of this report. Crain and Hopkins estimated the impact of four types of regulations —social regulation, which they separate into environmental and workplace rules; economic regulation; and tax compliance— on different sectors of the economy. These sectors are manufacturing, trade, services, and "other",[21] and the study used three metrics to estimate regulatory burden: the overall burden per sector, the burden per firm in each sector, and the burden per employee in each sector. By comparing across sectors, this study came to the conclusion that the manufacturing sector bears the highest total regulatory burden of any sector and the highest burden per firm of any sector, followed in order by "other", trade, and services. In terms of regulatory costs per employee, the manufacturing sector was a close second to "other", followed in order by trade and services. According to the study, environmental regulations are the highest source of burden on manufacturing, at approximately $206,000 per firm and $3,700 per employee in annual cost, followed by economic regulations, tax compliance, and workplace rules, which include categories such as employee benefits, occupational safety and health, and labor standards.

Several studies have focused on whether traditional measures of the "cost" of regulatory activity in manufacturing, such as compliance cost reports or regulatory impact statements, systematically under or overestimate the true burden of regulation.[22] Most of this literature focuses on environmental regulation, the largest component of regulatory burden. Morgenstern, Pizer, and Shih (2001) frame the issue well in their

[21] These sectors are defined using codes from the U.S. Census Bureau's "Statistics of U.S. Businesses." The trade sector includes both wholesale and retail trade. The "other" sector consists of the residual of businesses in this dataset that do not fall under the other three categories.

[22] Studies have also found that benefits can be under or overestimated, a subject we will expand on in more detail in next year's report.

study of the accuracy of the primary source of environmental burden estimates, the Pollution Abatement Costs and Expenditures (PACE) surveys. Most researchers agree that this data is the best available source for environmental expenditures by industry; however, theory suggests several reasons why these expenditures may over or understate the true burden of regulation. Costs could be understated because 1) environmental investments crowd out other productive investment, 2) many rules contain a new source bias that may discourage investment in new more efficient facilities, or 3) pollution control may reduce operational flexibility. Costs could be overstated because 1) complementarities in production may exist, or the cost of jointly producing output and an environmental "good" may be less expensive than producing each one separately, 2) the direct value of effluents that rules may require firms to recycle may not be counted as an offset to expenditures, or 3) "harvesting:" firms may be able to coordinate the timing of other efficiency-enhancing investments with required environmental investments in order to lower their cost. For example, if a firm must shut down a line to install environmental equipment, they could use that opportunity to also install other equipment and avoid another line shutdown.

Porter and Van de Linde (1995) make a more provocative claim: well designed environmental regulations can actually improve competitiveness. By stimulating innovation and causing more productive use of resources, regulations can actually yield net cost savings to industries. The authors rightfully point out that most economists are resistant to this idea, since it implies that firms are not pursuing profitable activities without the help of government intervention. The Morgenstern, Pizer, and Shih (2001) study tested for both systematic under and overstatement, and did include a direct test of the Porter hypothesis. They found no evidence of understatement of costs, and some evidence of overstatement. The paper found no empirical support for the claim that environmental regulation is overall cost saving.

Other studies in this field suggest that costs, if reported as expenditures, substantially underestimate regulatory burden. James (1998) suggests that reported compliance costs substantially underestimate the burden of OSHA regulations. Specifically, the total annual cost of OSHA regulations in 1993 are estimated at approximately $33 billion. This cost estimate is approximately three times the highest figure estimated in previous studies of OSHA. Joshi, Krishnan, and Lave (2001) used plant level data from steel mills to conclude, in that industry, that a $1 increase in environmental compliance costs is associated with $9 - $10, at the margin, in additional costs. These costs are in areas such as labor, materials, and energy, and arise primarily due to increased constraints introduced into the production process that are not captured in direct compliance cost measurements. The authors point out that the average total cost of environmental regulations is probably less than 10 times the average direct cost. It should be relatively easy to reduce emissions as controls are first introduced, but as stringency increases, the marginal cost of further reductions is likely non-linear and rising. They state this result may be more applicable to newly-introduced regulations that impose costs over and above existing regulatory requirements.

In perhaps the most global estimate of the impact to the economy of regulations, Jorgenson and Wilcoxen (1990) simulate the growth of the U.S. economy with and without the regulatory burden associated with environmental regulation, in contrast to other estimates that tend to be based on static compliance costs. Note that this is a relatively old study that does not include rules issued over the period from 1992 to 2003. They conclude that the annual growth rate of the economy between 1973 and 1985 fell by .191% due to environmental regulations. This result implies that Gross National Product (GNP) in 1985 was approximately $140 billion (1996$) lower than it would have been in the absence of environmental regulation; this is several times the reduction in growth estimated in previous studies.

Trade and Competitiveness Implications

In addition to the direct impact of raising the cost of manufacturing, a significant economic literature has been dedicated to the theory and estimation of the relative impact of regulatory burden on the competitiveness of U.S. manufacturing firms both within the United States and internationally.

Large Versus Small Firms. Some studies conclude that regulatory burdens favor large firms relative to small firms. Since most new firms start as small firms, a regulatory burden favoring large firms can be considered a barrier to entry. Crain and Hopkins (2001) estimated that firms employing fewer than 20 employees face an annual regulatory burden per employee nearly 60 percent above that facing a firm with over 500 employees. Dean, Brown, and Stango (2000) estimate the effects of environmental regulations on the formation of small manufacturing establishments. By estimating the effect of size and environmental regulatory burden on new firm formation across manufacturing industries, they conclude that environmental regulation appears to act as a barrier to entry for small manufacturing firms, while the regulations appear not to have deterred market entry by large manufacturing firms. They found this effect persistent across the study time period of 1977, 1982, and 1987.

Plant Location Decisions. Some literature is dedicated to the "pollution haven" hypothesis, that is industries in countries with less stringent regulation out-compete industries in countries with stringent regulation, therefore causing manufacturing to shift to low standard countries. Much of this literature also concentrates on factory location decisions within the United States. Among the first studies to explore this question was Walter (1982). A related concept is the "race to the bottom" hypothesis, where competition to lure and keep manufacturers has an adverse impact on the standards themselves. Seminal work in this area includes studies collected in Anderson and Blackhurst (1992) and Bhagwati and Hudec (1996). Almost all studies of this type concentrate on the question of environmental regulation; however, nothing in theory restricts this effect to environmental rules. Other imposed regulatory burdens on the manufacturing process will adversely affect firms in a similar way.

Studies within the United States have found that differing environmental stringency across areas affects firm investment and location decisions, though that

finding is not universal. Becker and Henderson (2000) use county level air quality attainment status and plant data from 1963-1992, and find a substantial relocation of polluting industries from more to less polluted areas to avoid stricter regulation, a relative proliferation of small-scale enterprises (which enjoy less strict regulation in this case), and a substantial effect on the timing of new plant investments (polluted area plants start off significantly larger, with more up front investment). McConnell and Schwab (1990) studied the location decisions of motor vehicle plants based on Volatile Organic Compounds regulation. In their more refined measure of the degree to which counties were out of attainment, they found that firms were deterred from locating plants in the most polluted non-attainment areas. On the other hand, Levinson (1996a), examines the effect of differences in state environmental regulations on location choice, and finds no evidence that environmental regulations systematically affect location choices in most manufacturing industries. This study looked at a broad range of manufacturing industries; however, because it used state-level measures of activity, as opposed to county-level activity measures used in the other mentioned studies, this study may fail to capture the effect of regulatory stringency on location decisions. On the other hand, differences in regulatory stringency may only be a secondary factor affecting location decisions within a state.

The other major theme of this literature is the impact of differences in international regulatory regimes on trade and competitiveness. These studies depend on complicated trade flow models, which are well summarized in Van Beers and Van Den Bergh (1996), which focuses on environmental regulatory impact; and Brown, Deardorff, and Stern (1996), which concentrates on labor standards and other workplace regulation.

Jaffe et al. (1995) characterizes the concerns well: if international regulatory differences lead to a decrease in net exports, this impact could manifest itself in several ways. In the short run, a reduction in net exports in manufacturing would raise the current account deficit, which would eventually require a decline in the value of the dollar to return toward balance in the long run. Under such an effect, imported goods would become more expensive, thus reducing U.S. living standards. Second, if industries most affected by regulation employ less flexible workers, those workers displaced may have an especially hard time finding new jobs at comparable wages. Third, a diminishing U.S. share of world capacity in particular industries, such as steel, petroleum refining, and autos, may endanger economic security. Finally, the rearrangement toward other non-pollution intensive industries may create a broader set of social costs associated with a transitioning economy.

Most empirical studies, however, have not concluded that the relative stringency of environmental requirements give rise to international pollution havens. Several reviews (Dean 1992, Jaffee et al 1995 and Levinson 1996b) have summarized literature on this issue. Dean (1992) concludes that the many empirical studies developed to test the hypothesis have failed to show any evidence in support of it. Levinson (1996b) comes to much the same conclusion, stating that "the literature surveyed is almost unanimous in its conclusion that environmental regulations have not affected interjurisdictional trade or the location decisions of manufacturers." Jaffee et al (1995)

reports pollution abatement and control expenditures as a percent of GDP for several OECD countries, and shows that the U.S. is roughly comparable up to 1990.

Studies that have also come to this conclusion include the seminal work of Walter (1982), which looked at aggregate foreign investment flows and surveys of international firms. While a significant amount of production by pollution-intensive, multi-national firms occurred in developing countries, the study found little evidence that these investments were seriously influenced by environmental considerations. Xu (1999) uses a later time series accounting for almost 80% of world exports of environmentally sensitive goods from 1965-1995, and finds that the pattern of export performance for these goods did not undergo systematic changes between the 1960s and 1990s, a period of the introduction of significantly more stringent environmental standards in most developed countries.

These reviews generally cover the period before the many large regulations covered in Chapter 1 became effective. More recent preliminary work suggests that the relative impact of regulation across countries may be becoming more pronounced, which could cause an effect not yet found in the literature. A recent National Association of Manufacturers report by Leonard (2003) concludes that the contribution of regulatory compliance cost relative to unit labor costs in U.S. manufacturing has grown and is now the highest of any major trading partner for which measurements are available. On the other hand, the European Commission just adopted a major new requirement for the Registration, Evaluation, and Authorization of Chemicals (REACH) on October 29, 2003. The EC estimated the cost of this system at approximately $370-$700 million per year, while using a 7% discount rate required of U.S. regulatory agencies would increase their estimated impact to $1.7 billion -2.4 billion per year. These trends, which are generally not yet captured in the literature, may warrant a reassessment of the international impact of regulatory burden.

Request for Regulatory Reform Recommendations

In light of the relatively large impact of regulation on the manufacturing sector of the economy, OMB requests public nomination of promising regulatory reforms relevant to this sector. In particular, commenters are requested to suggest specific reforms to regulations, guidance documents or paperwork requirements that would improve manufacturing regulation by reducing unnecessary costs, increasing effectiveness, enhancing competitiveness, reducing uncertainty and increasing flexibility. OIRA is particularly interested in reforms that address burdens on small and medium-sized small manufacturers, where burdens tend to be relatively large, though any promising reform ideas relevant to the manufacturing sector are encouraged. In addition, because the Crain and Hopkins (2001) study found that tax compliance was particularly burdensome for small businesses, OMB is especially interested in suggestions to simplify IRS paperwork requirements.

OMB requests that commenters, in the selection of which reform ideas to submit, consider the extent to which (1) a benefit-cost case (quantitative and/or qualitative) can

be made for the reform, (2) the agency or multiple agencies have statutory authority to make the suggested change, (3) the reform recommendation gives due consideration to fair and open trade policy objectives, and (4) the rule or program is important. The reforms may include modifying, extending or rescinding regulatory programs, guidance documents or paperwork requirements. OMB requests that nominations be submitted electronically to OMB within 90 days from the date of notice publication in the Federal Register. OMB will then assemble and evaluate the reform nominations and discuss each of them with the relevant federal agencies. Final decisions about each nomination will be made by the agency, taking account of statutory, economic, and budgetary considerations.

BIBLIOGRAPHY

Anderson, K. and Blackhurst, R. 1992. *The Greening of World Trade Issues.* University of Michigan Press, Ann Arbor.

Becker, R. and Henderson, V. 2000. "Effects of Air Quality Regulations on Polluting Industries." *Journal of Political Economy* 108(2): 379-421.

Bhagwati, J., and Hudec, R. 1996. *Fair Trade and Harmonization: Prerequisites for Free Trade?* MIT Press, Cambridge and London.

Brown, D.K., A.V. Deardorff, and R.M. Stern 1996. "International Labor Standards and Trade: A Theoretical Analysis." In *Fair Trade and Harmonization: Prerequisites for Free Trade?* MIT Press, Cambridge and London, 227-280.

CONSAD Research Corporation 2002. "An Evaluation of Compliance with the Regulatory Flexibility Act by Federal Agencies." Report prepared for the Office of Advocacy, U.S. Small Business Administration. Available at http://www.sba.gov.

Council of Economic Advisors 2004. *Economic Report of the President*. Available at http://www.gpoaccess.gov/eop/index.html

Crain, W.M. and Hopkins, T.D. 2001. "The Impact of Regulatory Costs on Small Firms." Report prepared for the Office of Advocacy, U.S. Small Business Administration. Available at http://www.sba.gov.

Dean, J.M. 1992, "Trade and the Environment: A Survey of the Literature," in *International Trade and the Environment,* (P.Low, editor) pp 15-28, World Bank Discussion Papers, no. 159, World Bank, Washington, D.C.

Dean, T. J., R. L. Brown, and Stango V. 2000. "Environmental Regulation as a Barrier to the Formation of Small Manufacturing Establishments: A Longitudinal Analysis," *Journal of Environmental Economics and Management* 40: 56-75.

Ehrenberg, R. and R. Smith 1991. *Modern Labor Economics, 4th Edition*. HarperCollins, p. 279.

The European Commission, 2003. "The New EU Chemicals Legislation – REACH." Available at europa.eu.int/comm/enterprise/chemicals/chempol/whitepaper/reach.htm, accessed December 2, 2003.

Gwartney, J. and R. Lawson 2003. *Economic Freedom of the World: 2003 Annual Report.* Fraser Institute, Vancouver, BC

James, H.S. 1998. "Estimating OSHA Compliance Costs," *Policy Sciences* 31: 321-341.

Jorgenson, Dale W. and Peter J. Wilcoxen 1990. "Environmental Regulation and U.S. Economic Growth," *Rand Journal of Economics* 21(2): 314-40.

Jaffee, Adam B., Steven R. Peterson, Paul R. Portney, and Robert N. Stavins 1995. "Environmental Regulation and the Competitiveness of U.S. Manufacturing: What Does the Evidence Tell Us?" *Journal of Economic Literature* 33: 132-163.

Joshi, S., L. Lave, J.-S. Shih, and F. McMichael 1997. "Impact of Environmental Regulations on the U.S. Steel Industry," Carnegie Mellon University mimeograph.

Leonard, J. 2003. "How Structural Costs Imposed on U.S. Manufacturers Harm Workers and Threaten Competitiveness," Report Prepared for the National Association of Manufacturers and the Manufacturers Alliance/MAPI. Available at http://www.nam.org.

Levinson, A. 1996a. "Environmental Regulations and Manufacturers' Location Choices: Evidence from the Census of Manufacturers." *Journal of Public Economics* 62: 5-29.

Levinson, A. 1996b. "Environmental Regulations and Industry Location: International and Domestic Evidence." In *Fair Trade and Harmonization: Prerequisites for Free Trade?* MIT Press, Cambridge and London, 429-457.

McConnell, Virginia D., and Schwab, Robert M. 1990. "The Impact of Environmental Regulation on Industry Location Decisions: The Motor Vehicle Industry." *Land Economics* 66: 67-81.

Miles, M., E.J. Feulner, Jr., M.A. O'Grady, and A.I. Eiras 2004. *2004 Index of Economic Freedom.* Heritage Foundation/WallSteet Journal.

Morgenstern, R. D., W. Pizer and J.-S. Shih 2001 "The Cost of Environmental Protection." *Review of Economics and Statistics* 83(4): 732-738.

Mrozek, J.R. and L.O. Taylor 2002. "What Determines the Value of Life? A Meta-Analysis." *Journal of Policy Analysis and Management* 21(2), 253-270.

National Academy of Sciences 2003. "Estimating the Public Health Benefits of Proposed Air Pollution Regulations," Available at http://books.nap.edu/catalog/10511.html

National Highway Traffic Safety Administration 1994. *The Economic Cost of Motor Vehicle Crashes, 1994.* Available at http://www.nhtsa.dot.gov/people/economic/ecomvc1994.html

National Academy of Sciences 2003. *Estimating the Public Health Benefits of Proposed Air Pollution Regulations.* Available at http://books.nap.edu/catalog/10511.html

Nicoletti, G. 2002. "The Economy-Wide Effects of Product Market Reform." OECD. Paris.

Office of Advocacy, U.S. Small Business Administration 2004. *Report on the Regulatory Flexibility Act, FY 2003: The Annual Report of the Chief Counsel for Advocacy on Implementation of the Regulatory Flexibility Act and Executive Order 13272*. Available at http://www.sba.gov.

Porter, M.E. 1991. "America's Green Strategy." *Scientific* American: 168.

Porter, M.E. and C. Van de Linde 1995. "Toward a New Conception of the Environment-Competitiveness Relationship." *Journal of Economic Perspectives* 9(4): 97-118.

Settle, R. 1975. "Benefits and Costs of the Federal Asbestos Standard," Paper delivered at the Department of Labor Conference on Evaluating the Effects of the OSHA Program, March 18-19, 1975.

U.S. Census Bureau, 2003. *Economic Census Reports*, available at www.census.gov/epcd/www/97EC31.HTM, accessed November 04, 2003.

Van Beers, C., and J. C.J.M van den Bergh. 1996. "An Overview of Methodological Approaches in the Analysis of Trade and Environment," *Journal of World Trade* 30(1): 143-167.

Viscusi, W.K., and J. Aldy 2003. "The Value of a Statistical Life: A Critical Review of Market Estimates Throughout the World." *Journal of Risk and Uncertainty* 27(1): 5-76.

Walter, I. 1982. "Environmentally Induced Industrial Relocation in Developing Countries," in *Environment and Trade* (editors, J. Seymour, J. Rubin, and T.R. Graham), 67-101, Allanheld, Osmun, and Co., Totowa, N.J.

Walter I. And Ugelow, J. 1979. "Environmental Policies in Developing Countries, *Ambio* 8(2,3): 102-109.

Winston, Clifford (1998), "U.S. Industry Adjustment to Economic Deregulation", *Journal of Economic Perspectives* 12(3): 89-110.

World Bank 2004. *Doing Business in 2004: Understanding Regulation.* Oxford Press. Washington DC.

Xu, Xinpeng 1999. "Do Stringent Environmental Regulations Reduce the International Competitiveness of Environmentally Sensitive Goods? A Global Perspective," *World Development* 27(7): 1215-1226.

Yuskavage, R.E. and E.H. Strassner 2003. "Gross Domestic Product by Industry for 2002." *Survey of Current Business*, Bureau of Economic Analysis, May, 2003: 7-14.