ORAL ARGUMENT NOT YET SCHEDULED

Nos. 11-1483 & 15-1027

In The United States Court of Appeals for the District of Columbia Circuit

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INDEPENDENT PILOTS ASSOCIATION,
Petitioner,

v.

FEDERAL AVIATION ADMINISTRATION,
Respondent.

ON PETITION FOR REVIEW FROM A RULE OF THE FEDERAL AVIATION ADMINISTRATION

FINAL BRIEF OF RESPONDENT

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. Parties and Amici

The petitioner is the Independent Pilots Association. The Respondent is the Federal Aviation Administration. The Intervenor is the Cargo Airline Association. There are no amici.

B. Rulings Under Review

At issue are regulations issued by the Federal Aviation Administration at 77 Fed. Reg. 330-01, 2012 WL 10131 (January 4, 2012), and at 79 Fed. Reg. 72970-01, 2014 WL 6879528 (Dec. 9, 2014).

C. Related Cases

This case has not been previously before this Court. Undersigned counsel is not aware of any related cases pending in this Court.

/s/ Mark W. Pennak
Mark W. Pennak, Counsel for Respondent

TABLE OF CONTENTS

TABLE OF AUTHORITIES*

CASES:

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* Authorities chiefly relied upon are marked with an asterisk

STATUTES:

REGULATIONS:

OTHER AUTHORITIES:

GLOSSARY OF ABBREVIATIONS

1.	**The Act**	Airline Safety and Federal Aviation Administration Extension Act of 2010, P.L. 111-216, 124 Stat. 2348
2.	**BTS**	Bureau of Transportation Statistics
3.	**FAA**	Respondent, the Federal Aviation Administration
4.	**IPA**	Petitioner, the Independent Pilots Association
5.	**NTSB**	National Transportation Safety Board
6.	**OMB**	Office of Management and Budget
7.	**Part 121**	Part 121 of Title 14 of the Code of Federal Regulations
8.	**RIA**	Regulatory Impact Analysis
9.	**Rule or Part 117**	Flight Crew Member Duty and Rest Requirements, 77 Fed. Reg. 330-01, 2012 WL 10131 (Jan. 4, 2012)
10.	**Supplemental RIA or SRIA**	Supplemental Regulatory Impact Analysis

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STATEMENT OF JURISDICTION

The Respondent, the Federal Aviation Administration, issued its initial final Rule in this matter on December 21, 2011. See *Flight Crew Member Duty and Rest Requirements*, 77 Fed. Reg. 330-01, 2012 WL 10131 (Jan. 4, 2012) (JA 1). Petitioner, the Independent Pilots Association ("IPA"), filed a timely petition for review on December 22, 2011, pursuant to 49 U.S.C. §46110(a), and that petition was docketed in this Court as No. 11-1483. At the FAA's request, this Court remanded the record to the FAA for additional findings, which were subsequently published on December 9, 2014, 79 Fed. Reg. 72970-01, 2014 WL 6879528 (Dec. 9, 2014)(JA 3308). On February 5, 2015, petitioner filed a new petition for review,

which was docketed in this Court as No. 15-1027. That petition was consolidated with IPA's prior petition docketed as No. 11-1483. This Court has jurisdiction over both petitions under 49 U.S.C. §46110(c).

QUESTIONS PRESENTED

1. Whether the Airline Safety and Federal Aviation Administration Extension Act of 2010, P.L. 111-216, 124 Stat. 2348 ("the Act"), which authorizes the FAA to consider "any other matters" that the FAA considers to be "appropriate" in addressing "problems" of pilot fatigue, allows the FAA to conduct a cost-benefit analysis concerning whether to exclude all-cargo operations from new regulations governing flightcrew duty and rest rules.

2. Whether the FAA's findings and conclusions concerning the costs and benefits associated with its new regulations are supported by "substantial evidence" and are thus "conclusive" under the judicial review provisions of 49 U.S.C. §46110(c).

STATUTES AND REGULATIONS

Relevant statutory and regulatory provisions are reproduced in the statutory addendum accompanying petitioner's brief. A copy of Airline Safety and Federal Aviation Administration Extension Act of 2010, P.L. 111-216, 124 Stat. 2348, and a copy of the Office of Management & Budget Circular A-4, 2003 WL 24011971 (O.M.B. 2003), are set forth in the attached statutory addendum.

STATEMENT OF THE CASE

A. Nature of the Case

Section 212(a)(1) of the Airline Safety and Federal Aviation Administration Extension Act of 2010, P.L. 111-216, 124 Stat. 2348, 2362 (2010), requires the FAA to issue regulations "to specify limitations on the hours of flight and duty time allowed for pilots to address problems relating to pilot fatigue." In 2012, that Rule was published in Part 117 of Title 14 of the Code of Federal Regulations. *Flight Crew Member Duty and Rest Requirements*, 77 Fed. Reg. 330-01, 2012 WL 10131 (Jan. 4, 2012) ("the Rule" or "Part 117")(JA 1).

As thus issued, the Rule establishes new standards for flight crew member duty and rest with respect to passenger operations subject to FAA authority under Part 121. The FAA, however, initially elected to retain existing rules in place for all-cargo operations on grounds that such application would be "either overly costly or impractical to implement." 77 Fed. Reg. at 330-01 (JA 1-2). In a Supplemental Regulatory Impact Analysis issued on December 9, 2014, after a voluntary remand of the record, the FAA adhered to that conclusion. See 79 Fed. Reg. 72970-01, 2014 WL 6879528 (Dec. 9, 2014) (JA 3308). Petitioner, the IPA, challenges that exclusion of all-cargo operations.

B. The Statutory Scheme

In relevant part, Section 212 of the Act, 49 U.S.C. §47701 note, provides:

> SEC. 212. PILOT FATIGUE.
>
> (a) FLIGHT AND DUTY TIME REGULATIONS.
>
> (1) IN GENERAL. In accordance with paragraph (3), the Administrator of the Federal Aviation Administration shall issue regulations, based on the best available scientific information, to specify limitations on the hours of flight and duty time allowed for pilots to address problems relating to pilot fatigue.
>
> (2) MATTERS TO BE ADDRESSED. In conducting the rulemaking proceeding under this subsection, the Administrator shall consider and review the following:
> (A) Time of day of flights in a duty period.
> (B) Number of takeoff and landings in a duty period.
> (C) Number of time zones crossed in a duty period.
> (D) The impact of functioning in multiple time zones or on different daily schedules.
> (E) Research conducted on fatigue, sleep, and circadian rhythms.
> (F) Sleep and rest requirements recommended by the National Transportation Safety Board and the National Aeronautics and Space Administration.
> (G) International standards regarding flight schedules and duty periods.
> (H) Alternative procedures to facilitate alertness in the cockpit.
> (I) Scheduling and attendance policies and practices, including sick leave.
> (J) The effects of commuting, the means of commuting, and the length of the commute.
> (K) Medical screening and treatment.
> (L) Rest environments.
> (M) Any other matters the Administrator considers appropriate.

> (3) RULEMAKING. The Administrator shall issue
> (A) not later than 180 days after the date of enactment of this Act, a notice of proposed rulemaking under paragraph (1); and not later than one year after the date of enactment of this Act, a final rule under paragraph (1);
> (B) not later than one year after the enactment of this Act, a final rule under paragraph (1).

Pursuant to Section 212, the FAA duly published a Notice of Proposed Rulemaking on September 14, 2010. 75 Fed. Reg. 55852 (Sept. 14, 2010) (JA 557). That Notice of Proposed Rulemaking invited comments on a set of proposed rules which, at that time, included all Part 121 carriers, including both passenger operations and all-cargo operations.[1]

C. The Rule

In issuing its initial Notice of Proposed Rulemaking, the FAA also issued a regulatory impact analysis estimating the costs and benefits of the proposal. That analysis indicated that the costs of applying the proposed rule to cargo operations would greatly exceed the benefits for the cargo operations. The FAA sought comments on the methodology, data, and assumptions employed in that analysis to help inform its decision making at the final rule stage.

The FAA received thousands of comments in response to the Notice, including comments from the petitioner. Petitioner's comments did not analyze the

[1] Part 121 carriers are those domestic air carriers regulated by the FAA under 14 C.F.R. Part 121. See 14 C.F.R. 121.1(a).

cost-benefit analysis set forth in the Regulatory Impact Analysis, and did not respond to any of the requests for comments posed in the Regulatory Impact Analysis. In contrast, other commenters, such as United Parcel Service (FAA-2009-1093-1898)(JA 1898) and the Cargo Airline Association (FAA-2009-1093-2221)(JA 1058), criticized the agency for proposing to apply the same flight, duty, and rest regulations to both all-cargo operations and passenger operations, given the cost of compliance for the cargo industry.

After review of the comments and further revision of the Regulatory Impact Analysis, on December 21, 2011, the FAA issued a final Rule that was published in the Federal Register on January 4, 2012. See 77 Fed. Reg. 330 (JA 1). The FAA determined that the amended flight, duty, and rest rules would apply only to flight crews conducting passenger-carrying operations under Part 121 and would exclude flight crews conducting cargo-only operations under Part 121 from complying with the revised requirements because the costs of the final Rule significantly outweighed the benefits of the rule for cargo-only operations. While cargo operators are not required to comply with the revised rules, the Rule permits all-cargo operators to opt into the Rule if they so choose.

The IPA challenged that Rule with a petition for review on December 22, 2011. While that petition was pending, the FAA discovered errors in the Regula-

tory Impact Analysis[2] issued with the final Rule. The errors were associated with the scope of the costs related to the implementation of the regulations for cargo-only operations. These errors appeared to be of a sufficient amount that the FAA concluded it was prudent to review the portion of the cost-benefit analysis related to cargo-only operations and allow interested parties an opportunity to provide comment on the corrected analysis. Thus, by motion filed May 17, 2012, the FAA requested a remand of the record, which this Court granted by order issued June 8, 2012.

On December 12, 2012, the FAA reopened the record and published an Initial Supplemental Regulatory Impact Analysis ("Supplemental RIA" or "SRIA"), reached as a matter of the FAA's reexamination of the record and its correction of errors. See *Flightcrew Member Duty and Rest Requirements*, 77 Fed. Reg. 73911 (Dec. 12, 2012) (JA 3509). In that notice, the FAA specifically sought comment on whether the FAA was statutorily foreclosed from considering costs and benefits as part of the flight, duty, and rest rulemaking, as well as any other aspect of the Initial Supplemental Regulatory Impact Analysis.

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[2] Agencies must issue a "Regulatory Impact Analysis" for any regulations that have a significant effect on the economy, defined as "major rules" in Executive Order 12,291, 46 Fed. Reg. 13,193 (1981). See generally *Meyer v. Bush*, 981 F.2d 1288, 1290 (D.C. Cir. 1993).

In a decision issued December 9, 2014, the FAA adhered to its prior decision to exclude all-cargo operations, issuing its Final Supplemental Regulatory Impact Analysis on that date. See 79 Fed. Reg. 72970-01, 2014 WL 6879528 (Dec. 9, 2014)(JA 3308). In that Analysis, the FAA responded to comments submitted by petitioner and others, made "adjustments to the methodology used to estimate the costs and benefits of applying the final flight, duty, and rest rule to cargo-only operations, and include[d] additional sensitivity analyses." (Id.). The FAA stated:

> The results of the Final SRIA [Supplemental Regulatory Impact Analysis] concludes that the base-case benefits of applying the flight, duty, and rest rule to cargo-only operations would be *about $3 million*, and the high-case benefits of doing so would be *about $10 million*. Conversely, the costs of applying the flight, duty, and rest rule to cargo-only operations would be *about $452 million*. Because the results of the analysis continue to indicate that the costs of mandating all-cargo operation compliance with the new flight, duty, and rest rule significantly outweigh the benefits, the FAA has determined that no revisions to the final rule are warranted.
> (79 Fed. Reg. at 72970-71) (emphasis added) (JA 3308-09).

In essence, FAA excluded the cargo operations based upon a determination that the costs of including all-cargo operations were huge and vastly exceeded any realistic assessment of benefits. As stated in the Notice of Proposed Rulemaking Regulatory Impact Analysis, the FAA arrived at this conclusion by identifying the expected costs and benefits of the rule with respect to cargo operations as well as passenger operations and, in doing so, applied the best available fatigue science to

maximize the benefits relative to costs. Notice of Proposed Rulemaking Regulatory Impact Analysis, FAA-2009-1093-0019 at 1 (JA 413).

As explained in the final Rule Regulatory Impact Analysis and in the Initial Supplemental Regulatory Impact Analysis, after remand, the FAA applied the more traditional, well-accepted historical accident review methodology of assessing risk. The FAA found that this more traditional approach was consistent with National Transportation Safety Board ("NTSB") findings, was recognized by industry, and was easily reproducible and thus consistent with the requirements set forth in Office of Management & Budget ("OMB") Circular A-4, 2003 WL 24011971 (O.M.B. 2003). See Initial Supplemental Regulatory Impact Analysis, 2009-1093-2523 at 5 (JA 2725); see also Final Supplemental Regulatory Impact Analysis, FAA-2009-1093-2541 (disclosing costs and projected benefits to both cargo and passenger-carrying operators) (JA 3314).[3]

While the final Rule provides that operators and flightcrews that conduct passenger-carrying operations are subject to the flight, duty, and rest rules set forth in 14 C.F.R. Part 117, cargo-only operations remain subject to the extensive pre-existing requirements set forth for supplemental operations in subpart S of Part

[3] The Administrative Record, as amended, can be found at FAA Docket FAA-2009-1093, available on-line at http://www.regulations.gov/#!searchResults;rpp=25;po=0;s=faa-2009-1093;fp=true;ns=true.

121.[4] For example, for a two pilot crew, subpart S provides that a pilot who is scheduled to fly more than 8 hours in a 24-hour period must be provided with an intervening rest period at or before the end of the flight duty. The rest period must be the greater of either: (1) 8 hours, or (2) twice the number of hours flown since the lastrest period. 14 C.F.R. 121.505(a). Similarly, a pilot who has flown for more than 8 hours during a 24-hour period (regardless of whether he was scheduled to do so) must be provided with 16 hours of rest before being assigned to further duty. 14 C.F.R. 121.503(b).

In addition, a pilot in a two pilot crew cannot be on duty for more than 16 hours in a 24-hour period, 14 C.F.R. 121.505(b), and must be provided with at least 24 hours of consecutive rest at least once in a seven consecutive day period. 14 C.F.R. 121.503(c). Subpart S also imposes cumulative limits, *viz.*, a pilot may

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[4] Prior to the adoption of the final Rule currently under review, the regulatory scheme for flight, duty, and rest for Part 121 operations was split into three different categories: (1) domestic (Subpart Q of Part 121), (2) flag (Subpart R of part 121),and (3) supplemental (Subpart S of Part 121). Under this framework, all-cargo operations were carved out and categorized as supplemental operations subject to the flight time and duty rules under Subpart S. In addition to all-cargo operations, subpart S also applied to a small subset of passenger-carrying operations: (1) passenger-carrying operations for which the departure time, departure location, and arrival location are negotiated with the customer; and (2) public charter operations. See 14 C.F.R. 110.2 (definition of "supplemental operation"). This small subset of passenger-carrying operations are now subject to the requirements of Part 117 while all-cargo operations remain subject to the requirements in subpart S.

not fly as a crewmember for more than 100 hours during 30 consecutive days, 14 C.F.R. 121.503(d), and may not fly as a crewmember for more than 1,000 hours during any calendar year. 14 C.F.R. 121.503(e). See generally, 75 Fed. Reg. 55852, 2010 WL 3536229 at 3 (summarizing pre-existing Part 121 requirements and comparing those to the requirements in the proposed rule) (JA 559).

SUMMARY OF ARGUMENT

1. The IPA's principal argument on this appeal is that Section 212 of the Act impliedly forbids the FAA from conducting any cost-benefits analysis at all and that, therefore, the hundreds of millions of dollars in costs associated with applying the Rule to all-cargo operations are completely irrelevant. That contention does not survive scrutiny. First, as a general principle, well recognized by this Court and by the Supreme Court, cost of compliance is always a relevant consideration in rulemaking and thus must be taken into account under *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983), unless Congress has forbidden any such a consideration.

Congress has not done so here. There is nothing in Section 212 of the Act that purports to bar the FAA from taking costs into account. Section 212 authorizes regulations for the purpose of "addressing" the "problem" of "pilot fatigue." There is nothing in Section 212 that is remotely incompatible with the

Administrator's consideration of costs in determining the scope or nature of the "problem" of pilot fatigue. The IPA's assertion that the Administrator is required to impose rules on "all pilots," regardless of the scope of the problem and regardless of costs, cannot be accepted.

Moreover, Congress expressly provided in Section 212(a)(2)(M) of the Act that the Administrator may consider "[a]ny other matters the Administrator considers appropriate" in regulating under Section 212. The Supreme Court most recently held in *Michigan v. EPA*, 135 S.Ct. 2699 (2015), that an agency **must** consider costs under a statute authorizing regulations where "appropriate." As defined by the Court in *Michigan*, "appropriate" means merely "relevant" under *State Farm*, and, as the Court expressly held in *Michigan*, cost considerations are *always* relevant under *State Farm*. The FAA did not err in considering costs as an "appropriate" "matter" under Section 212(a)(2)(M).

2. The IPA also argues that the FAA erred in its calculation of costs and benefits. Yet, the FAA's calculation of costs and benefits is set forth in exacting detail in this record and this Court owes great deference to that calculation. The IPA simply fails to carry the high burden it must demonstrate in order to overcome that deference. At any rate, IPA's attempt to undermine that calculation fails because it never comes to grips with the stark reality of the actual numbers. Those

numbers make plain that the Rule is only cost-effective if it is limited to passenger operations, which comprise roughly 94% of Part 121 operations subject to the Rule. Indeed, the Rule becomes cost-prohibitive by $147 million if the Rule is extended to the relatively small part of Part 121 operations represented by cargo-only operations. IPA never demonstrates that any of its arguments, if accepted, would make any difference in this ultimate bottom line. That failure is fatal to their substantial evidence argument here.

Specifically, the FAA found that net benefits (over costs) of applying the Rule *only* to passenger operations in the "high case" scenario is $295 million, while the "high case" net cost of applying the Rule to all-cargo operations is a *minus* $442 million for all-cargo operations. The difference is a $147 million more in costs over benefits if the Rule were to be applied to both passenger and all-cargo operations. And that result obtains in the "high case" scenario in which the estimated benefits are calculated to be at their highest level. In the "base case" scenario, the Rule is estimated to result in a net *minus* $61 million in costs for passenger operations and a net *minus* $449 million for all-cargo operations for a net of $510 million in costs over benefits. (Id.). The Administrator acted reasonably in taking these realities into account in differentiating between passenger operations and cargo-only operations.

ARGUMENT

I. THE STANDARD OF REVIEW

This Court has jurisdiction over this appeal under 49 U.S.C. §46110(c), which provides:

> Authority of court.--When the petition is sent to the Secretary, Under Secretary, or Administrator, the court has exclusive jurisdiction to affirm, amend, modify, or set aside any part of the order and may order the Secretary, Under Secretary, or Administrator to conduct further proceedings. After reasonable notice to the Secretary, Under Secretary, or Administrator, the court may grant interim relief by staying the order or taking other appropriate action when good cause for its action exists. Findings of fact by the Secretary, Under Secretary, or Administrator, if supported by substantial evidence, are conclusive.

In applying Section 46110(c), the Court looks first to the substantial evidence standard articulated in Section 46110(c) on questions of fact and applies, "by default," the standard of review set forth in the Administrative Procedure Act, 5 U.S.C. §706. *Wilson Air Ctr., LLC v. FAA*, 372 F.3d 807, 812 (6th Cir. 2004). However, the Court may "apply the standards articulated in the Administrative Procedure Act only where the Federal Aviation Act does not provide the appropriate standard." *Flamingo Exp., Inc. v. FAA*, 536 F.3d 561, 567 (6th Cir. 2008). See also *Aviators for Safe and Fairer Regulation, Inc. v. FAA*, 221 F.3d 222, 228 (1st Cir. 2000) ("And absent a mistake of law, the standard of review is whether the agency's actions are arbitrary or capricious, 5 U.S.C. §706(2)(a)

(1994), and whether any fact findings it made rest on substantial evidence, 49 U.S.C. §46110(c) (1994)"); *J. Andrew Lange, Inc. v. FAA*, 208 F.3d 389, 391 (2nd Cir. 2000) (same).

"The substantial evidence standard 'requires more than a scintilla, but can be satisfied by something less than a preponderance of the evidence.'" *Town of Barnstable, Mass. v. FAA*, 740 F.3d 681, 687 (D.C. Cir. 2014), *quoting Fla. Gas Transmission Co. v. FERC*, 604 F.3d 636, 645 (D.C. Cir. 2010) (citation omitted). Stated differently, substantial evidence is simply "'such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'" *Consumers Union of U.S., Inc. v. FTC*, 801 F.2d 417, 422 (D.C. Cir. 1986) (citation omitted); *Kornman v. SEC*, 592 F.3d 173, 184 (D.C. Cir. 2010) (same). See also *North America Freight Car Ass'n v. Surface Transp. Bd.*, 529 F.3d 1166, 1170-71 (D.C. Cir. 2008). Viewed differently, a regulation unsupported by "substantial evidence" in this context "is only that not substantial in the APA sense- *i.e.*, not 'enough to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn ... is one of fact for the jury.'" *Association of Data Processing Service Org., Inc. v. Board of Governors*, 745 F.2d 677, 684 (D.C. Cir. 1984) (citations omitted). See also *South Carolina Public Service Authority v. FERC*, 762 F.3d 41, 65 (D.C. Cir. 2014) (noting that "court has long held [that substantial

evidence] does not necessarily mean empirical evidence" and noting further that "as long as a prediction is 'at least likely enough to be within the Commission's authority' and it is based on reasonable economic propositions, the court will uphold it") (citation omitted).

Similarly, under the APA, 5 U.S.C. §706(2)(A), "[a] party challenging an agency's rulemaking has the burden of showing that the agency action was "'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *Advocates for Highway and Auto Safety v. FMCSA*, 492 F3d 1136, 1144-45 (D.C. Cir. 2005), quoting 5 U.S.C. §706(2)(A). Under this standard, "[a]n agency's rule will be found arbitrary 'if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to difference in view or the product of agency expertise.'" (*Id*., quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)).

This APA standard of review is applied with the "'utmost deference in view of administrative expertise.'" *Public Citizen, Inc. v. FAA*, 988 F.2d 186, 196-97 (D.C. Cir. 1993), quoting *Pillai v. Civil Aeronautics Bd.*, 485 F.2d 1018, 1027 (D.C. Cir. 1973). See also *Pharmaceutical Research and Mfrs. of America v. FTC*,

--- F.3d ----, 2015 WL 3556040 at *12 (D.C. Cir. 2015) ("The FTC's cumulative experience with filings and fielding informal requests for guidance was a valid basis for its decision to promulgate a rule focused on the pharmaceutical industry."); *Nat'l Classification Comm. v. United States*, 779 F.2d 687, 695 (D.C. Cir. 1985) ("It is beyond dispute that an agency may provide the factual predicate for a finding by taking 'official notice' ... of matters known to the agency through its cumulative experience and consequent expertise."). (Citations omitted).

Finally, under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), a reviewing court must give deference to the agency's implementation of a statutory scheme where Congress has delegated that authority to the agency. Under the first step of the familiar two-step analysis of *Chevron,* "[i]If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.' Id. at 842–43. Under the second step, "if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." Id. at 843. See *Helicopter Ass'n Intern., Inc. v. FAA*, 722 F.3d 430, 433 (D.C. Cir. 2013). Under *Chevron*, "the question in every case is, simply, whether the statutory text forecloses the agency's assertion of authority, or not." *City of*

Arlington v. FCC, 133 S.Ct. 1863, 1871 (2013). See also *City of Olmstead Falls v. FAA*, 292 F.3d 261, 269 (D.C. Cir. 2002). If Congress has not "foreclose[d]" the agency's interpretation, then a reviewing court "'may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency.'" *Grunewald v. Jarvis*, 776 F.3d 893, 900 (D.C. Cir. 2015), quoting *Chevron*, 467 U.S. at 844.

Chevron indisputably applies to the regulations at issue here. Under *United States v. Mead Corp*., 533 U.S. 218, 226-27 (2001), an agency may claim *Chevron* deference "when it appears [1] that Congress delegated authority to the agency generally to make rules carrying the force of law, and [2] that the agency interpretation claiming deference was promulgated in the exercise of that authority." Both elements are satisfied here as Section 212(a) of the Act expressly directs the Administrator to "issue regulations" and the regulations were issued under that grant of authority. Petitioner here does not contend that the FAA lacked the authority to issue the regulations.

Finally, the Court's jurisdiction and scope of review is also confined by 49 U.S.C. §46110(d), which provides that the Court may consider an objection to an order of the Administrator "only if the objection was made in the proceeding conducted by the * * * Administrator or if there was a reasonable ground for not

making the objection in the proceeding." Arguments not advanced by a petitioner in the administrative proceeding below are deemed waived under Section 46110(d). See, e.g., *Wilson Air Center, LLC v. FAA*, 372 F.3d 807, 813 (6th Cir. 2004); *City of New York v. Minetta*, 262 F.3d 169, 179 (2nd Cir. 2001).

II. THE ACT PERMITS THE ADMINISTRATOR TO CONSIDER THE COMPLIANCE COSTS OF SUBJECTING AIR CARGO OPERATIONS TO THE RULE

Petitioner's principal contention is that Section 212 precludes the Secretary from considering costs at all in deciding whether to impose the Rule on the all-cargo operations. Indeed, petitioner contends that the FAA was affirmatively obligated to regulate all-cargo operations regardless of the costs associated with that regulation. As demonstrated below, the FAA's consideration of costs and benefits was reasonable, consistent with Executive Orders, rational decision making mandated by the APA and common sense. See 79 Fed. Reg. 782971-74 (JA 3308-12). Consideration of costs is thus the default, not the exception. Nothing in Section 212 can be reasonably read as barring the Administrator from such consideration of costs.

A. Consideration of Costs Is Required By Executive Orders

Every presidential administration for more than three decades has made analysis of costs an integral part of the internal Executive Branch regulatory process. See Executive Order 12,291, 46 Fed. Reg. 13193 (Pres. 1981), Executive Order 12,866, 58 Fed. Reg. 51735, 1993 WL 13149641 (Pres. 1993), and Executive Order 13,563, 76 Fed. Reg. 3821, 2011 WL 176023 (Pres. 2011).

These orders specifically mandate consideration of costs and benefits in deciding whether to regulate at all. Section 1(a) of Executive Order 12,866 specifies that "[i]n deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, *including the alternative of not regulating*." (Emphasis added). The Order thus directs that an agency must "assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs." Id. Sec.1(b)(1)-1(b)(3). Similarly, Executive Order 13563 states that each agency must "propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify)." Executive Order 13,563, Sec. 1(b).

The FAA's longstanding practice has been in accordance with these Executive Orders and over the last three decades, the agency has considered costs as a "central feature of agency rulemaking." 79 Fed. Reg. at 72972 and n.19-20 (JA 3310).[5] This includes the 1985 promulgation of the last flight, duty, and rest rule, in which the agency considered costs and benefits as part of the rulemaking process. (Id. at 72972).

B. Under The APA, Costs Must Be Considered In The Absence Of Express Direction To The Contrary By Congress

The APA authorizes reviewing courts to set aside agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. §706(2)(A). In *Motor Vehicles Manufacturers Ass'n* v. *State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29 (1983), the Supreme Court made clear that, while an agency decision would be upheld provided that the agency had taken into "consideration…the relevant factors," the agency's decisionmaking

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[5] *See, e.g., Commuter Operations and General Certification and Operations Requirements*, 60 Fed. Reg. 65,832, 65,911-12 (Dec. 20, 1995) (conducting a cost-benefit analysis); *Reduction of Fuel Tank Flammability in Transport Category Airplanes*, 73 Fed. Reg. 42,444, 42,486-88 (July 21, 2008) (same); *Safety Management Systems for Part 121 Certificate Holders Notice of Proposed Rulemaking*, 75 Fed. Reg. 68224 (Nov. 5, 2010); s*ee also Pilot Certification and Qualification Requirements Final Rule*, 78 Fed. Reg. 42,324 (July 15, 2013); *Qualification, Service, and Use of Crewmembers and Aircraft Dispatchers Final Rule*, 78 Feg. Reg. 67,800 (Nov. 12, 2013). See 79 Fed. Reg. at 72,972 n.18.

would be found unreasonable where the agency had "entirely *failed to consider* an important aspect of the problem." (463 U.S. at 42-43) (emphasis added).

Since *State Farm*, the Supreme Court has repeatedly admonished that agencies must consider costs in establishing standards regulating conduct. In the Court's most recent decision on this point in *Michigan v. EPA*,135 S.Ct. 2699 (2015), the Court relied expressly on *State Farm* in reversing the EPA's refusal to consider costs at the outset of the rulemaking proceeding under the Clean Air Act. As the Court explained:

> Consideration of cost reflects the understanding that reasonable regulation ordinarily requires paying attention to the advantages and the disadvantages of agency decisions. It also reflects the reality that "too much wasteful expenditure devoted to one problem may well mean considerably fewer resources available to deal effectively with other (perhaps more serious) problems."

(135 S.Ct. at 2707-08), quoting *Entergy Corp. v. Riverkeeper, Inc.*, 556 U.S. 208, 233 (2009) (BREYER, J., concurring in part and dissenting in part).

This reasoning makes eminent sense. See Cass R. Sunstein, *Interpreting Statutes in the Regulatory State*, 103 Harv. L. Rev. 405, 493 (1989) ("A rational system of regulation looks not at the magnitude of the risk alone, but assesses the risk in comparison to the costs."); Richard L. Revese & Michael A. Livermore, *Retaking Rationality* 12 (2008) ("For certain kinds of governmental programs, the use of cost benefit analysis is a requirement of basic rationality."). As Justice

Powell stated in concurring in *Industrial Union Dept., AFL-CIO v. American Petroleum Institute*, 448 U.S. 607, 669 (1980), "a standard-setting process that ignored economic considerations would result in a serious misallocation of resources and a lower effective level of safety than could be achieved under standards set with reference to the comparative benefits available at a lower cost."

This Court's case law is in full accord. As explained in *United Auto Workers v. OSHA*, 938 F.2d 1310, 1321 (D.C. Cir. 1991), "cost-benefit analysis entails only a systematic weighing of pros and cons, or what Benjamin Franklin referred to as a 'moral or prudential algebra.'" Similarly, in *Competitive Enter. Inst. v. NHTSA*, 956 F.2d 321, 323 (D.C. Cir. 1992), this Court held that the National Highway Traffic Safety Administration's automobile fuel efficiency rulemaking was not "reasoned" when the agency focused on the environmental risks of excessive fuel use, but failed to consider the countervailing risks posed by smaller and less crash-worthy vehicles.

C. Congress Did Not Forbid The FAA From Considering Costs

Given that reasoned rulemaking always requires a consideration of costs any congressional intent to forbid an agency from considering costs must be clear and definitive. See *Chemical Mfrs. Ass'n v. NRDC*, 470 U.S. 116, 134 (1985) (relevant issue is whether there is a "clear congressional intent to forbid" the challenged

agency action); *City of Arlington*, 133 S.Ct. at 1868 ("Statutory ambiguities will be resolved, within the bounds of reasonable interpretation, not by the courts but by the administering agency."). There is no such definitive indication here.

1. IPA's reliance on *Whitman* is misplaced

IPA relies heavily on the Supreme Court's decision in *Whitman v. American Trucking Associations*, 531 U.S. 457 (2001), in which the Court held that costs could not be considered in applying a statutory provision in the Clean Air Act, 42 U.S.C. §7409(b), that required that ambient air quality standards be set at levels "requisite to protect the public health" with an "adequate margin of safety." IPA argues that pilot fatigue, addressed by Section 212, is akin to such air quality standards as both relate to public health. (P. Br. 35-37). IPA's reliance on *Whitman* is misplaced.

In *Michigan*, the Supreme Court rejected the EPA's reliance on *Whitman* as controlling, stating that this "discrete criterion does not encompass cost; it encompasses health and safety." (135 S.Ct. at 2709). In contrast to "health and safety," the Court reasoned, the statutory provision at issue in *Michigan* was whether regulation was "appropriate and necessary," which the Court stated "is a far more comprehensive criterion than 'requisite to protect the public health'" (Id.). The Court concluded that when "read fairly and in context . . . the term

plainly subsumes consideration of cost." (Id.). Also critical to the Court's decision in *Whitman* was that statutory scheme referenced costs in other portions of the statute but did not include any reference to costs in the section of the statute at issue. See *Whitman*, 531 U.S. at 467 ("We have therefore refused to find implicit in ambiguous sections of the [Clean Air Act] an authorization to consider costs that has elsewhere, and so often, been expressly granted."). Thus, in *Entergy*, the Court distinguished *Whitman* on grounds that "[t]he relevant 'statutory context' [in *Whitman*] included other provisions in the Clean Air Act that expressly authorized consideration of costs, whereas § 109 did not"). (556 U.S. at 223). *Whitman* thus merely stands for the principle that costs cannot be considered under a statutory term that would not otherwise encompass costs, where other provisions of the same statute expressly reference costs.

This case is controlled by *Michigan*, not *Whitman*. The Act bears no resemblance to the *Whitman* statutory provision, *viz*., a provision that required regulatory levels "requisite to protect the public health" with an "adequate margin of safety." Rather, the Act is closely similar to the *Michigan* statutory provision, which authorized regulations that were "appropriate and necessary." Indeed, as explained in detail below, Congress has removed all reasonable doubt on this question with its enactment of Section 212(a)(2)(M), which authorizes the Administrator to consider "any other matters" that the Administrator may find

"appropriate." As *Michigan* holds, costs are always an "appropriate" consideration.

Stated differently, this is *not* a case where Congress enumerated the list of considerations set forth in Section 212(a)(A)-(L) and ordered the agency to use *only* those considerations in issuing a rule. Unlike *Whitman*, Congress did not limit the agency's discretion to matters of "public health" and, unlike *Whitman*, the Act does not expressly permit consideration of costs in other sections, but omit any such reference to costs in Section 212.[6] Rather, Congress identified a list of factors to consider in subsections (A) through (L) *and then* expressly afforded the Administrator broad discretion under subsection (M) to consider "any other matters the Administrator considers appropriate." No such provision was at issue in *Whitman*. Petitioner's reliance on *Whitman* (P. Br. at 29) thus fails.

[6] The Act contains seven other mandates for rulemaking. See Sections 203(b)(2); Section 206(b)(1)-(2); Section 209(a); Section 215(a); Section 216(a)(1); and Section 217(a). None of those sections purports to address costs or change the FAA's longstanding practice of considering costs. See 79 Fed. Reg. at 72973 (explaining the FAA's consideration of the rulemaking mandates specified in the Act) (JA 3311).

2. Under Subsection (M), costs are an "appropriate" "matter" for the Administrator's consideration

In subsections (A) through (L), Congress listed a series of factors for the Administrator consider, but in subsection (M) of Section 212(a)(2), Congress included an additional provision, stating that Administrator may "consider and review" . . . "*[a]ny other matters the Administrator considers appropriate.*" (Emphasis added). Again, that provision plainly allows the consideration of costs no less than the term "appropriate," at issue in *Michigan*, mandated consideration of costs. *Michigan*, 135 S.Ct. at 2707. Indeed, the Court in *Michigan* viewed the issue as plain, stating:

> One does not need to open up a dictionary in order to realize the capaciousness of this phrase. *In particular, "appropriate" is "the classic broad and all encompassing term that naturally and traditionally includes consideration of all the relevant factors*."

135 S.Ct. at 2707, quoting *White Stallion Energy Center, LLC v. EPA*, 748 F.3d 1222, 1266 (D.C. Cir. 2014) (Kavanaugh, J., dissenting), *reversed Michigan v. EPA*, 135 S.Ct. 2699 (2015). (Emphasis added). In short, "appropriate" means merely that which is "relevant."

Whether a factor is "relevant," the *Michigan* Court also explained, is assessed by reference to the principles set forth in *State Farm*, under which "an agency may not 'entirely fai[l] to consider an important aspect of the problem' when deciding whether regulation is appropriate." (Id. quoting *State Farm*, 463

U.S. 43, bracket the Court's). The Court concluded that "[r]ead naturally in the present context, the phrase "appropriate and necessary" requires at least some attention to cost." (Id.). As the Court explained, "[o]ne would not say that it is even rational, never mind 'appropriate,' to impose billions of dollars in economic costs in return for a few dollars in health or environmental benefits." (Id.). Costs are thus always "relevant" under *State Farm*. *Michigan*, 135 S.Ct. at 2707.

The broad nature of the term "appropriate" in the context of the Act is confirmed by the rest of subsection (M). As noted, subsection (M) is phrased very broadly to authorize the Administrator to consider "[a]ny other matters" that the Administrator "considers appropriate." The term "any other matters" is not limited or defined. On its face, the term is as broad and as all-encompassing as the term "appropriate." For example, the dictionary definition of "matter" is simply "a subject under consideration." See http://www.merriam-webster.com/dictionary/matter. Subsection (M) thus allows the Administrator to include "any" such "subject" that the Administrator may find "appropriate" in the Administrator's judgment. If anything, this delegation of discretion is even broader than the term "appropriate and necessary" at issue in *Michigan*.

D. The FAA's Application Of Section 212(a) Is Entitled To *Chevron* Deference

At a minimum, the Administrator's interpretation of "any other matters" and "appropriate" to permit a consideration of costs is entitled to *Chevron* deference. In *Michigan*, the Court held that agency is entitled to *Chevron* deference with respect to its construction of a statute entrusted to its administration, but only so long as the agency "'operate[s] within the bounds of reasonable interpretation.'" (135 S.Ct. at 2707, quoting *Utility Air Regulatory Group v. EPA*, 134 S.Ct. 2427, 2442 (2014)). Stated simply, if (as the Supreme Court holds) costs *must* be considered under the term "appropriate," then the FAA is certainly *permitted* to construe Section 212(a)(2)(M) as *allowing it* to consider costs as falling within the phrase "any other matters" that the Administrator may consider to be "appropriate." Indeed, the air cargo operators argued in these administrative proceedings that the FAA was *obligated* to consider costs.[7]

1. The statutory text supports the FAA's approach

IPA disputes this analysis, contending that the terms "any other matters" and "appropriate" are limited to other matters that are akin or alike to those factors set forth in Section 212(a)(2)(A)-(L), which IPA characterizes as "scientific" inquiries. (P. Br. at 36-37). In essence, IPA contends that the term "any other matters" must

[7] See, e.g., Comments of the Cargo Airline Association to the Initial Supplemental Regulatory Impact Analysis, FAA-2009-1093-2529 at 4 (JA 2878).

be read as if the phrase read "any other **such scientific** matters." (Id.). Yet, the statute simply does not say that. See *Water Quality Ass'n Employees' Benefit Corp. v. United States*, 795 F.2d 1303, 138 (7th Cir. 1986) ("It is a basic principle of statutory construction that courts have no right first to determine the legislative intent of a statute and then, under the guise of its interpretation, proceed to either add words to or eliminate other words from the statute's language."); *United States v. Sonmez*, 777 F.3d 684, 688 (4th Cir. 2015) ("we are required to interpret statutory language as written and are not permitted to add words of our own choosing"). See also 2A Sutherland Statutory Construction § 47.38 (4th ed. 1984). Here, Section 212(a) lists some factors (A)-(L), but subsection (M) then adds the phrase "any other matters." That phrase must be given its plain meaning as the rule is clear that "general phrases cannot be so narrowly construed that they become meaningless." *United States v. EME Homer City Generation, L.P.*, 727 F.3d 274, 293 (3d Cir. 2013), citing *Christopher v. SmithKline Beecham* Corp., 132 S.Ct. 2156 (2012).

This principle that the courts should not add words has particularly strong application here. The use of the modifier "other" suggests as a matter of usage that the "any other matters" extend beyond those factors already separately enumerated in subsections (A)-(L). Similarly, the modifier "any" in this context is best read "naturally" to mean "'one or some indiscriminately of whatever kind.'" *United*

States v. Gonzales, 520 U.S. 1, 5 (1997), quoting Webster's Third New International Dictionary 97 (1976). See also *Harrison v. PPg. Industries, Inc.*, 446 U.S. 578, 587 (1980) (broadly construing "any"). Congress did not purport to confine the Administrator's discretion with respect to "other matters." The only "limitation" on that discretion is that the matter be "appropriate" and Congress assigned that assessment to the Administrator's discretion. The only limitation on that discretion is that the "matter" be relevant. As noted above, that is the test articulated in *State Farm* and *Michigan* makes clear that costs are *always* relevant under *State Farm*.

These considerations dispose of IPA's suggestion (P.Br. at 37) that the Administrator's interpretation of subsection (M) fails under *Chevron* step one. Under step one, "[w]e first ask whether Congress 'has directly spoken to the precise question at issue.'" *National Asss'n of Broadcasters v. FCC* ,--- F.3d ----, 2015 WL 3634693 (D.C. Cir. 2015), quoting *Chevron*, 467 U.S. at 842. Yet, IPA has pointed to nothing (P. Br. at 33) in either the statutory text or its legislative history that shows that Congress has "directly spoken to the precise question" of whether the Administrator may consider costs.[8] Likewise, we have found nothing

[8] The exceptionally sparse legislative history indicates that Congress was motivated by the crash of passenger jet, Colgan Air Inc. Bombardier Dash 8–Q400, Flight 3407, that crashed during an instrument approach to the Buffalo-Niagara International Airport in Buffalo, New York. That crash killed four crew members and 45 passengers. H.R. Rep. 111-284, 111th Cong., 1st Sess. 2009, 2009 WL

in the legislative history on this point. In these circumstances, the rule is simple: where "'the statute is silent or ambiguous with respect to the specific issue,'" we do not conclude, at *Chevron* step one, that "'Congress has directly spoken to the precise question.'" *Natural Resources Defense Council v. EPA*, 777 F.3d 456, 465 (D.C. Cir. 2014), quoting *City of Arlington*, 133 S.Ct. at 1868, quoting *Chevron*, 467 U.S. at 842–43. At a minimum, Section 212 is "silent or ambiguous" with respect to the consideration of costs. IPA's *Chevron* step one argument thus fails.

2. IPA's reliance on canons of construction is misplaced

Similarly without merit is IPA's reliance (P. Br. at 38) on the canon "*ejusdem generis*" as applied in *Cement Kiln Recycling Coalition v. EPA*, 493 F.3d 207 (D.C. Cir. 2007). First, it is doubtful that the canons, standing alone, are sufficient to resolve Congress' clear intent at step one in the absence of supporting statutory language and/or legislative history on the "precise question."[9]

3190666 at 1 (Oct. 6, 2009).

[9] See *Association of Private Sector Colleges and Universities v. Duncan*, 681 F.3d 426, 443-44 (D.C. Cir. 2012), in which this Court observed:

> This court's decisions discussing the application of these canons at *Chevron* step one are not entirely consistent. Compare *Indep. Ins. Agents of Am., Inc. v. Hawke*, 211 F.3d 638, 644-45 (D.C. Cir. 2000) (rejecting agency's interpretation at step one based on the tandem canons "of avoiding surplusage and expressio unius "),with *Mobile Commc'ns Corp. of Am. v. FCC*, 77 F.3d 1399, 1405 (D.C. Cir.1996) (" Expressio unius 'is simply too thin a reed to support the conclusion that Congress has clearly resolved [an] issue.' " (alteration in original)

Certainly nothing in *Cement Kiln* sheds light on that particular question. There, this Court applied the canon to *sustain* an agency interpretation of its own *regulation*. Analytically, that situation presents a question under *Auer v. Robbins*, 519 U.S. 452 (1997), not a *Chevron* step one inquiry. The analytical framework obviously matters. See *Perez v. Mortgage Bankers Ass'n*, 135 S.Ct. 1199, 1208 n.4 (2015) (noting that under *Auer* "it is the court that ultimately decides whether a given regulation means what the agency says").

In any event, the Court in *Cement Kiln* merely held that a regulation's reference to "other factors as may be appropriate" in defining what information the agency may request was not "standardless" because that facially broad regulatory subsection took a more limited meaning from the introductory requirements applicable to each of the subsections under which information could be demanded by the agency under that regulation. *Cement Kiln*, 493 F.3d at 221. No such question or situation is presented here by the structure of Section 212.

Moreover, it is well-established that "a court need not follow these canons, when they do 'not hold up in the statutory context.'" *Association of Private Sector Colleges and Universities v. Duncan*, 681 F.3d 427, 444 (D.C. Cir. 2012), quoting

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(citations omitted)), and *Tex. Rural Legal Aid, Inc. v. Legal Servs. Corp.*, 940 F.2d 685, 694 (D.C. Cir.1991) ("[A] congressional prohibition of particular conduct may actually support the view that the administrative entity can exercise its authority to eliminate a similar danger." (citation omitted)).

Indep. Ins. Agents of Am., Inc. v. Hawke, 211 F.3d 638, 644-45 (D.C. Cir. 2000). See also *United States v. Alpers*, 338 U.S. 680, 682 (1950) (instructing that rule of *ejusdem generis* cannot be employed to "obscure and defeat the intent and purpose of Congress" or "render general words meaningless"); *Christopher v. SmithKline Beecham Corp*., 132 S.Ct. 2156, 2171 (2012) (quoting *Alpers*); *CSX Transp., Inc. v. Alabama Dept. of Revenue*, 562 U.S. 277, 295 (2011) (declining to apply *ejusdem generis* on ground that "[w]e typically use *ejusdem generis* to ensure that a general word will not render specific words meaningless"); *Watt v. W. Nuclear, Inc*., 462 U.S. 36, 44 n.5 (1983) (declining to apply *ejusdem generis* to the phrase "coal and other minerals"); *Harrison*, 486 U.S. at 588 (noting that *ejusdem generis* is applied only in cases of "uncertainty" and "we discern no uncertainty in the meaning of the phrase, 'any other final action'").

The *ejusdem generis* canon does not "hold up" in the particular statutory context of Section 212 of the Act. Section 212(a)(1) sets forth the duty to regulate in broad terms, *viz*., "to address limitations on the hours of flight and duty time allowed for pilots to address problems relating to pilot fatigue." This language requires the regulations to "address" hours of flight and duty time, but only where necessary "to address problems" with respect to "pilot fatigue." Nothing in that language purports to constrict the Administrator's discretion in defining the scope of the "problems," much less constrain the Administrator in choosing the manner

by which any problems are to be addressed. Any doubt on that point is erased by Subsection (M) which accords the Administrator discretion to take into account "any other matters" that the Administrator may deem to be "appropriate."

3. The IPA's remaining arguments are without merit

The statutory framework also effectively refutes IPA's simplistic notion that the term "pilots" as used in Section 212 necessarily includes "*all* pilots" (P. Br. at 27) (emphasis IPA's). That argument proves too much. All pilots can experience fatigue and it is certainly possible that any fatigued pilot may have an accident. Yet, there is no serious argument that the Administrator was *obligated* to apply Section 212 of the Act, without regard to costs, to general aviation pilots, student instructor pilots, tour operator pilots, agricultural pilots and commuter pilots, all of whom are regulated under different Parts of the FAA regulatory framework.[10] Plainly, IPA's "one size fits all" approach to pilot fatigue cannot possibly take into account the reality that the nature of the "problem" may be different with respect to different segments of the aviation industry. See, e.g., 77 Fed. Reg. at 336 (accep-

[10] For example, commuter air carriers are regulated under Part 135. See 14 C.F.R. 119.21(a)(4). Operators engaged in passenger-carrying operations, cargo operations, or both with airplanes when common carriage is not involved, are regulated under Part 125. 14 C.F.R. 119.23. Air tours are regulated under Part 119 or Part 136, as applicable. 14 C.F.R. 119.1(e). General aviation is regulated under 14 C.F.R. Part 91 and agricultural aircraft operations are regulated under 14 C.F.R. Part 137. All of these types of operations obviously involve "pilots."

ting comments that "Part 135 operations [commuter and air-demand operations] are fundamentally different from part 121 operations, and thus, these operations should not be subject to the same requirements") (JA 8).

Similarly without merit is petitioner's argument (P. Br. at 39) that consideration of costs and benefits is necessarily precluded by Section's 212(a) statement that the Administrator address the problem of pilot fatigue and issue regulations by reference to "the best available scientific information."[11] Petitioner fails to come to grips with the language of Section 212(a)(1), which states that "scientific information" is to be used "to address problems relating to pilot fatigue" and thus scientific information may be used to determine the *scope* of the "problem" and not merely the remedy for the "problem," once determined. Here, the Final Supplemental Regulatory Impact Analysis presents a careful, scientific analysis of the problem of pilot fatigue and applied fatigue science to assess the relative costs and benefits of alternative ways of addressing that problem. FAA-2009-1093-2541 (JA 3314). Nothing in the Section 212 requires the Administrator to ignore "scientific information" concerning costs and benefits in assessing the scope and nature of the problem.

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[11] The FAA indisputably applied fatigue science in developing the Rule at issue here. See, e.g., FAA-2009-1093-0019 at 7 et seq. (Notice of Proposed Rulemaking) (JA 419).

The discretion accorded the Administrator with respect to defining the "problem" is reinforced by subsection (M)'s language permitting the Administrator to consider "any other matters" that the Administrator may find "appropriate" in issuing the Section 212 regulations. As detailed above, "any" should be given its ordinary dictionary meaning, see *Harrison*, 446 U.S. at 588, and the terms "other matters" that may be "appropriate" are likewise extremely broad in their reach. Indeed, if subsection (M) cannot be construed to permit the consideration of costs, it is hard to discern what it might otherwise include, especially given the otherwise comprehensive list of factors set forth in subsections (A)-(L). IPA has not proffered any other meaning for the terms "any other matters" that the Administrator may consider as "appropriate." See *Alpers*, 338 U.S. at 682 (noting the canon cannot be used to "render general words meaningless"); *Christopher*, 132 S.Ct. at 2171 (same).

As set forth below, there is substantial record evidence, supported by a healthy dose of common sense, that the "problem" with respect to all-cargo pilots is far different than the "problem" is for passenger pilots. Not only are all-cargo operations a relatively small part (roughly 6%) of the Part 121 universe,[12] it is beyond reasonable dispute that the most serious of "problems" for the

[12] See note 15 and accompanying text, *infra*.

Administrator's consideration is the potential for the loss of life from accidents caused by pilot fatigue. That problem is obviously far more serious with respect to passenger operations. For example, the FAA found that, historically, all-cargo aircraft involved in accidents had an "average of 3.2 people were on board the aircraft." FAA-2009-1093-2541 at 82 (JA 3398). That stands in stark contrast to passenger operations, which typically involve many more lives. See, e.g., http://www.united.com/web/en-US/content/travel/inflight/aircraft/default.aspx (noting passenger capabilities of various aircraft flown by a major U.S. carrier).

In sum, the FAA's focus on passenger operations under Section 212 commands *Chevron* deference under step one. Petitioner does not even attempt to argue that the FAA's interpretation of Section 212 as permitting consideration of costs is "unreasonable" under step two of *Chevron*. Given the Supreme Court's holding in *Michigan* that costs are *always* a relevant consideration under *State Farm*, any such step two argument would obviously fail. The FAA's decision is thus entitled to full *Chevron* deference.

III. SUBSTANTIAL EVIDENCE SUPPORTS THE ADMINISTRATOR'S DETERMINATION

A. Introduction And Standard of Review

Since the regulations are facially valid, the only remaining question is whether the Administrator's cost-benefit analysis is sufficiently supported by the record to survive APA review. On this question, the scope of review is not merely "deferential[]," as IPA grudgingly admits. (P. Br. at 44). Rather, "cost-benefit analyses *epitomize* the types of decisions that are most appropriately entrusted to the expertise of an agency." *Office of Communication of United Church of Christ v. FCC*, 707 F.2d 1413, 1440 (D.C. Cir. 1983) (emphasis added). See also *Sierra Club v. EPA*, 353 F.3d 976, 992 (D.C. Cir. 2004) (same).[13]

For example, in *Consumer Elec. Ass'n v. FCC*, 347 F.3d 291, 303 (D.C. Cir. 2003), this Court stressed that "[w]e will not ... second-guess the [agency's] weighing of costs and benefits." In so holding, the Court emphasized that under *State Farm*, "'a court is not to substitute its judgment for that of the agency," *(id.*, quoting *State Farm*, 463 U.S. at 43), and that this is "a point we have taken to be 'especially true when the agency is called upon to weigh the costs and benefits of

[13] Cf. S*orenson Communications, Inc. v. FCC*, 765 F.3d 37, 51 (D.C. Cir. 2014) ("As we have noted before with regard to ratemaking, '[t]he relevant question is whether the agency's numbers are within a zone of reasonableness, not whether its numbers are precisely right.'"), quoting *WorldCom, Inc. v. FCC*, 238 F.3d 449, 462 (D.C. Cir. 2001) (quotation marks omitted).

alternative polices.'" *Id.*, quoting *Center for Auto Safety v. Peck*, 751 F.2d 1336, 1342 (D.C. Cir. 1985) (Scalia, J.). Accordingly, "while a 'serious flaw' or otherwise arbitrary and capricious reasoning can crash an agency's cost/benefit analysis, *petitioners' 'burden to show error is high*.'" *American Trucking Associations, Inc. v. FMCSA*, 724 F.3d 243, 254 (D.C. Cir. 2013), quoting *Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1040 (D.C. Cir. 2012) (emphasis added). Petitioner never acknowledges these principles or its burden.

Deference to the agency's assessment of costs and benefits is especially appropriate in this case. On this record, the agency's cost-benefit analysis with respect to all-cargo operations is supported by facts, comments, policy considerations, experience, expert judgment and common sense. Indeed, the disparity between the costs of including all-cargo operations in the Rule ($452 million) as compared to the benefits ($3-10 million) is huge. IPA's various arguments, addressed below, simply cannot begin to overcome the enormity of this difference.[14] For all its assertions, the IPA never even attempts to demonstrate that any

[14] IPA's arguments are focused on the FAA's benefits calculations and thus IPA does not challenge the FAA's calculation that the costs of making compliance with this rule mandatory for all-cargo operation would be $452 million. Accordingly, IPA has essentially conceded the extremely high societal cost that would result from its demand. See *New York Rehabilitation Care Management, LLC v. NLRB*, 506 F.3d 1070, 1076 (D.C. Cir. 2007) (holding that an argument must be raised in appellant's opening brief).

of its arguments would, if accepted, would actually make application of the Rule to all-cargo operations cost-effective. In the absence of such proof, the IPA has not carried its "high" "burden" of showing that the FAA's cost-benefit analysis is materially flawed. *American Trucking Associations, Inc.*, 724 F.3d at 254. This Court need go no further to affirm the FAA's decision at issue here. See *Helicopter Ass'n Intern., Inc. v. FAA*, 722 F.3d 430, 439 (D.C. Cir. 2013) (affirming FAA rule where the admitted error in cost assessment would not have made any difference).

Indeed, IPA fails to grasp that the FAA's decision to distinguish between the all-cargo operations and passenger operations makes sense because the cost-benefit analysis changes dramatically if the new Rule were to be extended to cargo operations. The FAA found, and the IPA does not dispute, that the Rule is cost-effective as applied to passenger operations, with high case benefits estimated at $757 million as opposed to total costs of $452 million, with a net high case benefit of $295 million for passenger operations. FAA-1093-2541 at 138 (JA 3454). Yet, the Rule become cost prohibitive if it were extended to include *both* passenger operations and all-cargo operations because the huge net costs for cargo operations (a *minus* $442 million) vastly exceeds (by $147 million) the positive net benefits ($295 million) associated with the high case estimate for the Rule's coverage of

passenger operations only. (Id.). Limiting the Rule to passenger operations is thus sound and rational decision making by the FAA. See *Cablevision Systems Corp. v. FCC*, 597 F.3d 1306, 1311 (D.C. Cir. 2010) ("we will not substitute our judgment for the agency's, especially when, as here, the decision under review requires expert policy judgment of a technical, complex, and dynamic subject").

B. The FAA's Exclusion Of All-Cargo Operations Was A Rational Policy Choice

FAA excluded the cargo operators based upon an assessment of future accident risk and the projected cost-benefit analysis based on that risk. The Notice of Proposed Rulemaking Regulatory Impact Analysis identified the expected costs and benefits of the rule with respect to all-cargo operations as well as passenger operations and, in doing so, applied fatigue science to maximize the benefits relative to costs. Notice of Proposed Rulemaking Regulatory Impact Analysis, FAA-2009-1093-0019 at 1 (JA 413).

The FAA applied a traditional, well-accepted historical accident review, which is based on NTSB findings, is recognized by industry, and easily reproducible. That approach is consistent with the requirements set forth in OMB Circular A-4, 2003 WL 24011971 at 7-13. See Initial Supplemental Regulatory Impact Analysis, 2009-1093-2523 (JA 2718); see also Final Supplemental Regulatory Impact Analysis FAA-2009-1093-2541 (disclosing costs and projected benefits to

both cargo and passenger-carrying operators) (JA 3314). This overall approach is sound and entitled to deference. See *American Trucking*, 724 F.3d at 754 (rejecting a challenge to agency's cost-benefit analysis where the "arguments establish at most that [the agency] made unwise policy decisions, not that the agency acted irrationally or contrary to law").

The IPA complains (P. Br. at 46) that the FAA elected to examine accident data over a 10 year period instead of the 20 year period favored by IPA. Yet, the FAA's choice is rational and fully explained. In selecting a time period of analysis for review, the FAA considered Office of Management and Budget Circular A-4, Regulatory Analysis, Circular No. A-4, 2003 WL 24011971 at 11, which recommends that "the time frame for your analysis should cover a period long enough to encompass all the important benefits and costs likely to result from the rule." In this case, in the Notice of Proposed Rulemaking Regulatory Impact Analysis, the FAA included a 20-year historical accident period, in which 18 accidents were identified where pilot fatigue could have been a factor in the accident. Notice of Proposed Rulemaking Regulatory Impact Analysis, FAA-2009-0019 at 40, 67 (JA 452, 479); see also Proposed Rule Accident Data (FAA-2009-0367) (JA 749), Proposed Rule Accident Mitigation Analysis

(FAA-2009-1093-0351) (JA 751), and Proposed Rule List of Accidents (FAA-2009-1093-0368) (JA 781).

However, in the final Rule, the FAA relied on comments submitted by the Air Transport Association of America, Inc., and reduced the historical accident period review to 10 years. In its comments on behalf of its membership, which includes Federal Express and United Parcel Service, two large cargo operators, ATA asserted that the FAA's initial historical accident analysis was "analytically flawed," in that it failed to take into account safety initiatives implemented by the carriers and that many of the cited accidents were caused by factors unrelated to pilot fatigue. See FAA-2009-1093-2333 at 15 (JA 812); see also comments from Cargo Airline Association (FAA-2009-1093-2221 at 43) (JA 1105), and United Parcel Service (FAA-2009-1093-1898 at 50) (JA 1952).

To test the ATA's assertion, the FAA compared the fatal accident rate in both cargo-only operations and passenger-carrying operations for both the previous 20 and 10 year periods. The FAA found that the fatal accident rate was reduced by more than 50%, during the latest 10 year period (2001-2010, 0.14 accidents per million departures, compared to 0.32 accidents per million departures from 1991-2000). The FAA presented both the 20-year and 10-year historical accident analysis in the initial Supplemental Regulatory Impact Analysis for review and

comment, but ultimately determined that the more recent 10 year historical accident review presented a more realistic basis for predicting the risk of future cargo accidents due to fatigue. See Final Supplemental Regulatory Impact Analysis, FAA-2009-2541 at 23-25 (JA 3339-41). The FAA's decision to use a 10 year period is rationally based on these facts of record.

The IPA also errs in its use of statistics, compiled by the Bureau of Transportation Statistics ("BTS") (P.Br. at 52-53 n.8), when it asserts that it is "three times more likely that there will be a fatigue-based accident involving an all-cargo operation compared to a passenger operation." (P.Br. at 53). In fact, the BTS statistics actually demonstrate that all-cargo operations comprise roughly only 6% of all flight operations under Part 121.[15] That reality obviously bears heavily on the cost-benefit analysis, as a higher rate of accidents applied to 6% of the total flights still results in far fewer actual accidents when compared to a lower rate as

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[15] For example, the numbers for the period of October 2002 - December 2010 (the time period cited by the IPA in their use of BTS statistics in their brief), the BTS website shows that there were 92.6 million departures for all passenger and cargo flights. Of that total, the number of passenger departures was 86.2 million and the number of cargo departures was 6.4 million, or 6.9 % for that particular time period. See http://www.rita.dot.gov/bts/acts/customized/table?adfy=2002&adfm=10&adty=2010&adtm=12&aos=6&artd&arti&arts=3&asts&astns&astt=3&ascc=2&ascp=1. For the full ten year period of 2001 through 2010, the percentage of cargo departures is 6.4 %. See http://www.rita.dot.gov/bts/acts/customized/table?adfy=2001&adfm=1&adty=201.

applied to a much larger (94%) portion for passenger operations. The regulatory goal is to address accidents in a cost-effective manner; an artificially computed *rate* taken in isolation is not controlling in that inquiry. As noted above, the new Rule is cost-*effective* (by $295 million) when applied to roughly 94% of the Part 121 operations and cost-*prohibitive* (by $147 million) when expanded to include the remaining 6% of flights. The FAA acted rationally in taking that reality into account.

C. The FAA Properly Assessed Effectiveness

IPA objects to the FAA's conclusion that the new Rule would be 15% effective in reducing the accident rate for cargo operations, arguing that the FAAs cost-benefit analysis "presumes that all-cargo operators will *already be using the part 117 rules*." (P. Br. at 49) (emphasis in the original). IPA also contends that if the FAA's assumption is valid there can be no additional costs of compliance because all-cargo operators will already be in compliance with Part 117. See Final Supplemental Regulatory Impact Analysis at 18-21 (analyzing accident based on FedEx comments and additional information regarding crewmembers' actual flight, duty, and rest schedules) (JA 3334-3337).

These contentions are wrong. Contrary to IPA's assertion, the FAA has never stated or assumed that all cargo carriers will already be in compliance with

Part 117. As detailed below, the FAA's analysis simply showed that the schedules of the only all-cargo flightcrew to have a fatigue-related accident in the last 10 years would have in compliance with Part 117, if Part 117 had been in effect at that time. Other all-cargo flightcrews may not have the same schedule, as their companies may use different measures to mitigate fatigue.

In its analysis of the effectiveness of the final rule, the FAA reviewed accidents that could have been prevented or could have been influenced by the requirements contained in this final rule. The effectiveness analysis works by assessing the likelihood that the requirements contained in the final Rule would have prevented those accidents. As part of this analysis. the FAA reviewed the accident reports from the National Transportation Safety Board and foreign investigative authorities on all accidents where the NTSB cited fatigue or fatigue was thought to be either a cause or factor. Each accident was then re-evaluated by conducting a scoring process similar to that conducted by the Commercial Aviation Safety Team, a well documented and well understood procedure. The FAA Office of Accident Investigation used the NTSB recommendations, along with other data to score the accidents. The FAA applied this methodology to each flightcrew member fatigue accident to reach an overall effectiveness rating for the requirements contained in this final Rule.

The FAA based its methodology on historical accidents in order to avoid engaging in speculation. Instead of examining hypothetical scenarios, the FAA's analysis allowed it to analyze a set of circumstances that actually resulted in an aviation accident. In its analysis. the FAA found that, out of all of the millions of all-cargo operations that took place from 2001 to 2010, there was only one all-cargo accident (which occurred in 2002) that could be attributed to pilot fatigue. In doing so, the FAA initially determined that the final rule would have been 75% effective in preventing the accident. See Final SRIA FAA-2009-1093-2541 at 64-66 (JA 3380-82). The FAA then applied that effectiveness rating to its future predictive accident rate to determine the potential benefits of the rule for fatigue-related all-cargo operations. This formed the initial base case estimate of benefits for all-cargo operations.

The FAA revisited this conclusion in conducting its Supplemental Regulatory Impact Analysis. Based on comments to the Initial Supplemental RIA filed by the Cargo Airline Association and Atlas Air Worldwide Holdings, the FAA reevaluated the NTSB report regarding the 2002 all-cargo accident. The FAA also considered information provided by FedEx as part of the Cargo Airline Association comments regarding the actual work schedules of the accident flightcrew. After determining that the accident flightcrew would have been in compliance with a

majority of the provisions set forth in the final Rule, the FAA reduced the effectiveness rating from 75% to 15% in the Final Supplemental Regulatory Impact Analysis. Final SRIA FAA-2009-1093-2541 at 17-21, 66 (JA , 3333-37, 3382). The FAA then applied that 15% effectiveness rate to determine future benefits. Final SRIA FAA-2009-1093-2541 at 78-83, 156-159 (JA 3394-3399, 3374-77). That process is eminently reasonable.

Moreover, in an abundance of caution, the FAA also took additional steps to take into account any uncertainties associated with the benefits of the Rule. Specifically, the historical accident analysis was used to provide the base case estimate of benefits that could result if the rule were applied to all-cargo operations. That base case estimate assumed that an accident very similar to the 2002 accident would be likely to occur in the 10 year period following issuance of the final rule. In the 2002 accident, there were no fatalities and only loss of the aircraft and some cargo. However, to address uncertainty concerns, such as those raised by IPA, the FAA also then developed a high case estimate, assuming that there would be a catastrophic, fatigue-related cargo accident within the next ten years in which there would be fatalities, as well as complete aircraft loss[16] and

[16] The FAA found that "the average age of the cargo fleet is roughly 20 years and just 1.2 percent of the cargo fleet is less than one year in age." FAA-2009-1093-2541 at 15 (JA 3331). The FAA thus rejected the suggestion that the high benefit

complete cargo loss. The FAA then applied the *original 75%* effectiveness rating to the total pool of benefits estimated for a catastrophic cargo accident to determine the high range of benefits that could be attributable to all-cargo operations. See Initial SRIA, FAA-2009-2523 at 40-43 (JA 2760-63). As noted, that high range of benefits based on these assumptions was still only $10 million. See 79 Fed. Reg. 72970-01 at 10 (JA 3313). That amount obviously is far out-stripped by the $452 million in costs associated with imposing the Rule on all-cargo operations. (Id.). The IPA does not address this analysis.

As a further basis of comparison, the FAA also conducted a break-even analysis to show how many accidents would need to occur in the future for the Rule to be cost effective for all-cargo operations. The FAA found that there would have to be *eight* cargo-only, fatigue-related accidents in the future 10-year period to break even, an extremely remote possibility in light of the fact there was only one such accident in the period 2001-2010. See Final Supplemental Regulatory Impact Analysis, FAA-2009-1093-2541 at 25 (JA 3341). Once again, the IPA never addresses this analysis.

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case include the value of a brand new Boeing 777 on grounds that the scenario selection must be linked to "a reasonable probability occurrence." (Id., citing OMB Circular A-4, 2003 WL 24011971 at 14).

IPA also objects to the 15% effectiveness rate as being based on the facts of a single accident that cannot be prevented as it has already happened. Instead, IPA argued, the FAA should focus on preventing accidents in similar circumstances. The FAA, in fact, conducted that analysis. Indeed, the Final Supplemental Regulatory Impact Analysis explains that "[t]he chances of the exact same circumstances happening again and causing the 'same accident' are virtually nil, but the possibility of preventing a similar set of accidents is real." FAA-2009-1093-2541 at 69 (JA 3385). Thus, the Final Supplemental Regulatory Impact Analysis used its analysis of the past accident to develop an average effectiveness for the Rule, but acknowledged that there is uncertainty. Again, to address this uncertainty, the FAA also calculated a high case for benefits, which is $9.77 million (still far below the $452 million in costs). FAA-2009-1093-2541 at 82-83 (JA 3398-99). IPA's point thus makes absolutely no difference.

IPA also argues (P. Br. 52-53) that if the number of fatigue-related accidents is divided by the total number of departures, the risk associated with an all-cargo accident is three times as high as a passenger accident. IPA did not raise this argument in the comments they filed on the Initial Supplemental Regulatory Impact Analysis and this argument has thus been waived. See 49 U.S.C. §46110(d) (providing a reviewing court may consider an objection to an order of

the Administrator "only if the objection was made in the proceeding conducted by the * * * Administrator or if there was a reasonable ground for not making the objection in the proceeding"); *Wilson Air Center*, 372 F.3d at 814.

Because IPA did not raise this contention in its comments, there is no explicit discussion of this point in the Final Supplemental Regulatory Impact Analysis. However, IPA plainly errs in its calculation of risk. Risk is calculated by multiplying the probability of an accident times the number of potential exposures to that accident. Even assuming *arguendo* that all-cargo operations have a higher probability of an accident than passenger operations, the actual exposure is much smaller because all-cargo operations are, as noted, a small portion of the Part 121 aviation industry and have much fewer departures than passenger operations. On a per-departure basis, the cost of applying Part 117 to an all-cargo flight departures would still be significantly higher than applying Part 117 to a passenger-flight departure, as the number of all-cargo departures are relatively fewer while the costs for all-cargo operations are extremely high. The benefits on a per-departure basis would also be lower for all-cargo operations because they generally lack passengers who would be exposed to the risk of an accident. IPA takes none of these considerations into account.

D. The FAA Took Into Account All Relevant Benefits That Would Have Been Associated With An Extension Of The Rule To Cargo Pilots

IPA argues (P. Br. at 53) that FAA ignored the benefits from preventing fatalities and damages to people on the ground. In particular, IPA asserts that the FAA should have considered the 1992 accident that took place in Amsterdam in which an El Al cargo airplane crashed into two apartment complexes. That contention ignores the FAA's actual consideration of this issue.

The pertinent analysis is in the Final Supplemental Regulatory Impact Analysis. FAA-2009-1093-2541 at 31-33 (JA 3347-49). The FAA's base-case benefits analysis was based on historical accidents, and there were no fatigue-related, all-cargo accidents that injured people on the ground within the 10-year period of analysis (during which millions of all-cargo departures took place). Based on comments from IPA and others on the Initial Supplemental Regulatory Impact Analysis, the FAA did use on-the-ground deaths in its high-case benefits analysis by looking at ground deaths caused by U.S.-carrier cargo accidents that were not attributed to pilot fatigue. The FAA noted that ground deaths caused by cargo operations were rare and averaged only 0.4 fatalities per accident, a ratio calculated from five accidents and two ground deaths. FAA-2009-1093-2541 at 82 (JA 3398).

Moreover, the FAA reasonably determined that the 1992 Amsterdam incident, cited by the IPA, was of limited probative value. See, e.g, *Drexel Burnham Lambert Inc. v. Commodity Futures Trading Com'n*, 850 F.2d 742, 749 (D.C. Cir. 1988) (noting "the deference we owe to an agency's factual determinations, including the reasonable inferences drawn therefrom"); *Environmental Defense Fund v. EPA*, 598 F.2d 62, 90 (D.C. Cir. 1978) (noting that an agency "is not required to 'prove' its case in the reviewing court 'in some sense of weight of the evidence'"). The FAA recognized that worldwide ground deaths were higher with a rate of 5.5 external fatalities per cargo accident. FAA-2009-1093-2541 at 32 n.58 (JA 3348). However, the FAA declined to use worldwide ground deaths "because foreign carriers operate in different operating environments and under different regulations than U.S. carriers." (Id.).

This focus on domestic flights is consistent with the Office of Management Budget's instructions to agencies in OMB Circular A-4, which requires agencies to "focus on benefits and costs that accrue to citizens and residents of the United States. Where you choose to evaluate a regulation that is likely to have effects beyond the borders of the United States, these effects should be reported separately." Circular No. A-4, 2003 WL 24011971 at 11. The FAA concluded that this Rule would not have benefits as far as reducing the on-the-ground

accident deaths outside the United States, because "foreign air carriers are not subject to the FAA regulations that this rule changes." FAA-2009-1093-2541 at 33 n.60 (JA 3349). Again, the 1992 Amsterdam incident involved a foreign carrier (El Al Airlines) operating outside the United States and thus not subject to FAA regulation. The IPA makes no attempt to quantify the additional benefits it claims or how such benefits would actually overcome $452 million in costs to make the Rule's application to all-cargo operations cost-effective.

IPA takes issue (P. Br. at 54) with the FAA's statement that "[t]his low rate of ground fatalities may be due to certain characteristics of the U.S. aviation environment, such as airport buffer zones and the relatively lower population density of the US compared to other parts of the world." FAA-2009-1093-2541 at 33 (JA 3349). The IPA asserts that the FAA fails to cite to any specific support for this assertion. However, the only truly relevant fact is that the on-the-ground deaths in the United States are significantly lower than they are outside the United States, a reality that IPA does not dispute. What is material for purposes of calculating the costs and benefits associated with this Rule are the observable results based on a sample size of millions of all-cargo departures. Those results show that the United States has significantly fewer on-the-ground deaths. The FAA did not err in taking that reality into account.

IPA also argues (P. Br. at 53) that FAA made no effort to quantify the health benefits of reducing fatigue and the possibility of reducing ground accidents and improving overall safety. That argument is likewise misplaced. OMB Circular A-4 allows the FAA to consider unquantified benefits when it lacks sufficient information to quantify those benefits. Circular No. A-4, 2003 WL 24011971 at 2 (instructing that agencies "should exercise professional judgment in determining how important the non-quantified benefits or costs may be in the context of the overall analysis"). As IPA's brief notes (P. Br. at 55), the FAA has acknowledged and considered the health benefits of reducing fatigue and the possibility of reducing ground accidents as unquantified benefits consistently throughout the Notice of Proposed Rule Making, the Final Rule Regulatory Impact Analysis, the Initial Supplemental Regulatory Impact Analysis, and the Final Supplemental Regulatory Impact Analysis. See FAA-2009-1093-2541 at 84 (JA 3400). FAA did in fact give them weight in it's decision making. In the FAA's professional judgment, these unquantified benefits are simply insufficient to overcome the huge costs.

Furthermore, FAA cannot be expected to quantify those benefits where it concludes that it is not feasible or reliable. In particular, the FAA did not err in rejecting IPA's recommendation that FAA quantify these health benefits by

reference to Federal Motor Carrier Safety Administration's estimate of long-term benefits of alleviating fatigue for truck drivers. The FAA noted in the Final Supplemental Regulatory Impact Analysis that it was not able to reproduce this estimate, and thus, consistent with OMB A-4 Circular, the FAA expressly included these estimates as non-quantified benefits. FAA-2009-1093-2541 at 33-34 (JA 3349-50). That approach is sound and is entitled to deference.

IPA similarly errs in contending (P. Br. at 55) that the FAA's application of its benefits framework is inconsistent because Part 117 covers mainline passenger operations even though they did not have any accidents in the period of analysis. The Final Supplemental Regulatory Impact Analysis explains that the analysis differentiates between mainline carrier operations and other carriers solely for the purpose of producing more accurate impact assessment. FAA-2009-1093-2541 at 10-11 (JA 3326-27). That analysis demonstrates that segmentation between passenger and cargo operations is justified because passenger operations involve potentially hundreds of passengers carried by modern passenger aircraft, an impact simply absent from all-cargo operations. Further segmentation is not justified as "the logical consequence of continued segmentation would be safety regulations specific to each individual carrier rather than general regulatory standards." FAA-2009-1093-2541 at 11 (JA 3327). That rationale is sound.

IV. REMEDY

The IPA does not seek vacatur of the Rule (P. Br. at 57), but asks only that this Court order the FAA to extend the Rule to all-cargo operations in addition to passenger operations. (P. Br. at 19). The FAA concurs that the Rule should not be vacated as there is no challenge to the Rule's application to passenger operations. However, should the IPA prevail, the only appropriate remedy is a remand for further proceedings. See *INS v. Orlando Ventura*, 537 U.S. 12, 16-17 (2002) (applying the "ordinary remand" rule); *Gonzales v. Thomas*, 547 U.S. 183, 185 (2006) (per curiam) ("The Ninth Circuit's failure to remand is legally erroneous, and that error is 'obvious in light of *Ventura*,' itself a summary reversal."); *Florida Power & Light Co. v. Lorion*, 470 U.S. 729, 743 (1985) ("If the record before the agency does not support the agency action, if the agency has not considered all relevant factors, or if the reviewing court simply cannot evaluate the challenged agency action on the basis of the record before it, the proper course, except in rare circumstances, is to remand to the agency for additional investigation or explanation."); *Safe Extensions, Inc. v. FAA*, 509 F.3d 593, 599 (D.C. Cir. 2007) (same).

Here, Congress entrusted the FAA, an expert agency, with the responsibility to develop rules to address pilot fatigue. Should this Court invalidate FAA's

decision to exclude all-cargo operations, the stark reality would remain that inclusion of all-cargo operations along with passenger operations would deprive the Rule of any semblance of cost-effectiveness, as it would, as noted, impose $147 million in costs over benefits on combined passenger and all-cargo Part 121 operations. If, for example, the Court were to find the record inadequate, as IPA claims, then a remand would permit the agency to further develop the record. At a minimum, these are matters for the FAA to consider in the first instance. See *Negusie v. Holder*, 555 U.S. 511, 517 (2009).

CONCLUSION

For all the foregoing reasons, the petitions for review should be denied.

Respectfully submitted,

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IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

INDEPENDENT PILOTS ASSOCIATION *Petitioner*, v. FEDERAL AVIATION ADMINISTRATION, *Respondent*.	Nos. 11-1483 -15-1027

CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a)(7)(B) of the Federal Rules of Appellate Procedure, the undersigned hereby certifies that the foregoing Reply Brief for Petitioners is in a proportional font with serifs, i.e., Times New Roman, utilizes 14-point type size in both text and footnotes, is double-spaced, except in headings and footnotes, and is 13,850 words long, excluding from that total the table of contents, the table of authorities, and certificates, as determined by the word-count function of version 17 of the WordPerfect word processing software.

*_/s/ Mark W. Pennak*_____
Mark W. Pennak, Counsel for Respondent

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

INDEPENDENT PILOTS ASSOCIATION *Petitioner*, v. FEDERAL AVIATION ADMINISTRATION, *Respondent*.	Nos. 11-1483 15-1027

CERTIFICATE OF SERVICE

I hereby certify that on November 20, 2015, I served the foregoing Final Brief of Respondent upon the following named counsel by electronic service through the ECF process:

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STATUTORY ADDENDUM

CONTENTS

UNITED STATES PUBLIC LAWS
111th Congress - Second Session
Convening January 05, 2010

Additions and Deletions are not identified in this database.
Vetoed provisions within tabular material are not displayed
Vetoes are indicated by ~~Text~~ ;
stricken material by ~~**Text**~~ .

PL 111–216 [HR 5900]
August 1, 2010
AIRLINE SAFETY AND FEDERAL AVIATION ADMINISTRATION EXTENSION ACT OF 2010

An Act To amend the Internal Revenue Code of 1986 to extend the funding and expenditure authority of the Airport and Airway Trust Fund, to amend title 49, United States Code, to extend airport improvement program project grant authority and to improve **airline safety**, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

<< 49 USCA § 40101 NOTE >>

SECTION 1. SHORT TITLE.

This Act may be cited as the "**Airline Safety** and Federal Aviation Administration Extension Act of 2010".

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

***2349** TITLE I--AIRPORT AND AIRWAY EXTENSION

SEC. 101. EXTENSION OF TAXES FUNDING AIRPORT AND AIRWAY TRUST FUND.

<< 26 USCA § 4081 >>

(a) FUEL TAXES.--Subparagraph (B) of section 4081(d)(2) of the Internal Revenue Code of 1986 is amended by striking “August 1, 2010” and inserting “September 30, 2010”.

(b) TICKET TAXES.--

<< 26 USCA § 4261 >>

(1) PERSONS.--Clause (ii) of section 4261(j)(1)(A) of the Internal Revenue Code of 1986 is amended by striking "August 1, 2010" and inserting "September 30, 2010".

<< 26 USCA § 4261 >>

(2) PROPERTY.--Clause (ii) of section 4271(d)(1)(A) of such Code is amended by striking "August 1, 2010" and inserting "September 30, 2010".

<< 26 USCA § 4081 NOTE >>

(c) EFFECTIVE DATE.--The amendments made by this section shall take effect on August 2, 2010.

SEC. 102. EXTENSION OF AIRPORT AND AIRWAY TRUST FUND EXPENDITURE AUTHORITY.

<< 26 USCA § 9502 >>

(a) IN GENERAL.--Paragraph (1) of section 9502(d) of the Internal Revenue Code of 1986 is amended--

(1) by striking "August 2, 2010" and inserting "October 1, 2010"; and

(2) by inserting "or the **Airline Safety** and Federal Aviation Administration Extension Act of 2010" before the semicolon at the end of subparagraph (A).

<< 26 USCA § 9502 >>

(b) CONFORMING AMENDMENT.--Paragraph (2) of section 9502(e) of such Code is amended by striking "August 2, 2010" and inserting "October 1, 2010".

<< 26 USCA § 9502 NOTE >>

(c) EFFECTIVE DATE.--The amendments made by this section shall take effect on August 2, 2010.

<< 49 USCA § 47104 >>

SEC. 103. EXTENSION OF AIRPORT IMPROVEMENT PROGRAM.

Section 47104(c) of title 49, United States Code, is amended by striking "August 1, 2010," and inserting "September 30, 2010,".

SEC. 104. EXTENSION OF EXPIRING AUTHORITIES.

<< 49 USCA § 40117 >>

(a) Section 40117(l)(7) of title 49, United States Code, is amended by striking "August 2, 2010." and inserting "October 1, 2010.".

<< 49 USCA § 44302 >>

(b) Section 44302(f)(1) of such title is amended--

(1) by striking “August 1, 2010,” and inserting “September 30, 2010,”; and

(2) by striking “October 31, 2010,” and inserting “December 31, 2010,”.

<< 49 USCA § 44303 >>

(c) Section 44303(b) of such title is amended by striking “October 31, 2010,” and inserting “December 31, 2010,”.

<< 49 USCA § 47107 >>

(d) Section 47107(s)(3) of such title is amended by striking “August 2, 2010.” and inserting “October 1, 2010.”.

<< 49 USCA § 47115 >>

(e) Section 47115(j) of such title is amended by striking “fiscal years 2004 through 2009, and for the portion of fiscal year 2010 ending before August 2, 2010,” and inserting “fiscal years 2004 through 2010,”.

<< 49 USCA § 47141 >>

(f) Section 47141(f) of such title is amended by striking “August 1, 2010.” and inserting “September 30, 2010.”.

***2350** << 49 USCA § 49108 >>

(g) Section 49108 of such title is amended by striking “August 1, 2010,” and inserting “September 30, 2010,”.

<< 49 USCA § 47109 NOTE >>

(h) Section 161 of the Vision 100--Century of Aviation Reauthorization Act (49 U.S.C. 47109 note) is amended by striking “fiscal year 2009, or in the portion of fiscal year 2010 ending before August 2, 2010,” and inserting “fiscal year 2009 or 2010”.

(i) Section 186(d) of such Act (117 Stat. 2518) is amended by striking “October 1, 2009, and for the portion of fiscal year 2010 ending before August 2, 2010,” and inserting “October 1, 2010,”.

<< 49 USCA § 40117 NOTE >>

(j) The amendments made by this section shall take effect on August 2, 2010.

<< 49 USCA § 106 >>

SEC. 105. FEDERAL AVIATION ADMINISTRATION OPERATIONS.

Section 106(k)(1)(F) of title 49, United States Code, is amended to read as follows:

“(F) $9,350,028,000 for fiscal year 2010.”.

<< 49 USCA § 48101 >>

SEC. 106. AIR NAVIGATION FACILITIES AND EQUIPMENT.

Section 48101(a)(6) of title 49, United States Code, is amended to read as follows:

"(6) $2,936,203,000 for fiscal year 2010.".

<< 49 USCA § 48102 >>

SEC. 107. RESEARCH, ENGINEERING, AND DEVELOPMENT.

Section 48102(a)(14) of title 49, United States Code, is amended to read as follows:

"(14) $190,500,000 for fiscal year 2010.".

TITLE II--**AIRLINE SAFETY** AND PILOT TRAINING IMPROVEMENT

<< 49 USCA § 44701 NOTE >>

SEC. 201. DEFINITIONS.

(a) DEFINITIONS.--In this title, the following definitions apply:

(1) ADVANCED QUALIFICATION PROGRAM.--The term "advanced qualification program" means the program established by the Federal Aviation Administration in Advisory Circular 120–54A, dated June 23, 2006, including any subsequent revisions thereto.

(2) AIR CARRIER.--The term "air carrier" has the meaning given that term in section 40102 of title 49, United States Code.

(3) AVIATION SAFETY ACTION PROGRAM.--The term "aviation safety action program" means the program established by the Federal Aviation Administration in Advisory Circular 120–66B, dated November 15, 2002, including any subsequent revisions thereto.

(4) FLIGHT CREWMEMBER.--The term "flight crewmember" has the meaning given the term "flightcrew member" in part 1 of title 14, Code of Federal Regulations.

(5) FLIGHT OPERATIONAL QUALITY ASSURANCE PROGRAM.--The term "flight operational quality assurance program" means the program established by the Federal Aviation Administration in Advisory Circular 120–82, dated April 12, 2004, including any subsequent revisions thereto.

(6) LINE OPERATIONS SAFETY AUDIT.--The term "line operations safety audit" means the procedure referenced by the ***2351** Federal Aviation Administration in Advisory Circular 120–90, dated April 27, 2006, including any subsequent revisions thereto.

(7) PART 121 AIR CARRIER.--The term "part 121 air carrier" means an air carrier that holds a certificate issued under part 121 of title 14, Code of Federal Regulations.

(8) PART 135 AIR CARRIER.--The term "part 135 air carrier" means an air carrier that holds a certificate issued under part 135 of title 14, Code of Federal Regulations.

<< 49 USCA § 44701 NOTE >>

SEC. 202. SECRETARY OF TRANSPORTATION RESPONSES TO SAFETY RECOMMENDATIONS.

<< 49 USCA § 1135 >>

(a) IN GENERAL.--The first sentence of section 1135(a) is amended by inserting "to the Board" after "shall give".

(b) AIR CARRIER SAFETY RECOMMENDATIONS.--Section 1135 is amended--

<< 49 USCA § 1135 >>

(1) by redesignating subsection (d) as subsection (e); and

<< 49 USCA § 1135 >>

(2) by inserting after subsection (c) the following:

"(d) ANNUAL REPORT ON AIR CARRIER SAFETY RECOMMENDATIONS.--

"(1) IN GENERAL.--The Secretary shall submit to Congress and the Board, on an annual basis, a report on the recommendations made by the Board to the Secretary regarding air carrier operations conducted under part 121 of title 14, Code of Federal Regulations.

"(2) RECOMMENDATIONS TO BE COVERED.--The report shall cover--

"(A) any recommendation for which the Secretary has developed, or intends to develop, procedures to adopt the recommendation or part of the recommendation, but has yet to complete the procedures; and

"(B) any recommendation for which the Secretary, in the preceding year, has issued a response under subsection (a)(2) or (a)(3) refusing to carry out all or part of the procedures to adopt the recommendation.

"(3) CONTENTS.--

"(A) PLANS TO ADOPT RECOMMENDATIONS.--For each recommendation of the Board described in paragraph (2)(A), the report shall contain--

"(i) a description of the recommendation;

"(ii) a description of the procedures planned for adopting the recommendation or part of the recommendation;

"(iii) the proposed date for completing the procedures; and

"(iv) if the Secretary has not met a deadline contained in a proposed timeline developed in connection with the recommendation under subsection (b), an explanation for not meeting the deadline.

"(B) REFUSALS TO ADOPT RECOMMENDATIONS.--For each recommendation of the Board described in paragraph (2)(B), the report shall contain--

"(i) a description of the recommendation; and

"(ii) a description of the reasons for the refusal to carry out all or part of the procedures to adopt the recommendation.".

***2352** << 49 USCA § 44701 NOTE >>

SEC. 203. FAA PILOT RECORDS DATABASE.

<< 49 USCA § 44703 >>

(a) RECORDS OF EMPLOYMENT OF PILOT APPLICANTS.--Section 44703(h) of title 49, United States Code, is amended by adding at the end the following:

"(16) APPLICABILITY.--This subsection shall cease to be effective on the date specified in regulations issued under subsection (i).".

(b) ESTABLISHMENT OF FAA PILOT RECORDS DATABASE.--Section 44703 of such title is amended--

<< 49 USCA § 44703 >>

(1) by redesignating subsections (i) and (j) as subsections (j) and (k), respectively; and

<< 49 USCA § 44703 >>

(2) by inserting after subsection (h) the following:

"(i) FAA PILOT RECORDS DATABASE.--

"(1) IN GENERAL.--Before allowing an individual to begin service as a pilot, an air carrier shall access and evaluate, in accordance with the requirements of this subsection, information pertaining to the individual from the pilot records database established under paragraph (2).

"(2) PILOT RECORDS DATABASE.--The Administrator shall establish an electronic database (in this subsection referred to as the 'database') containing the following records:

"(A) FAA RECORDS.--From the Administrator--

"(i) records that are maintained by the Administrator concerning current airman certificates, including airman medical certificates and associated type ratings and information on any limitations to those certificates and ratings;

"(ii) records that are maintained by the Administrator concerning any failed attempt of an individual to pass a practical test required to obtain a certificate or type rating under part 61 of title 14, Code of Federal Regulations; and

"(iii) summaries of legal enforcement actions resulting in a finding by the Administrator of a violation of this title or a regulation prescribed or order issued under this title that was not subsequently overturned.

"(B) AIR CARRIER AND OTHER RECORDS.--From any air carrier or other person (except a branch

of the Armed Forces, the National Guard, or a reserve component of the Armed Forces) that has employed an individual as a pilot of a civil or public aircraft, or from the trustee in bankruptcy for the air carrier or person--

"(i) records pertaining to the individual that are maintained by the air carrier (other than records relating to flight time, duty time, or rest time) or person, including records under regulations set forth in--

"(I) section 121.683 of title 14, Code of Federal Regulations;

"(II) section 121.111(a) of such title;

"(III) section 121.219(a) of such title;

"(IV) section 125.401 of such title; and

"(V) section 135.63(a)(4) of such title; and

"(ii) other records pertaining to the individual's performance as a pilot that are maintained by the air carrier or person concerning--

***2353** "(I) the training, qualifications, proficiency, or professional competence of the individual, including comments and evaluations made by a check airman designated in accordance with section 121.411, 125.295, or 135.337 of such title;

"(II) any disciplinary action taken with respect to the individual that was not subsequently overturned; and

"(III) any release from employment or resignation, termination, or disqualification with respect to employment.

"(C) NATIONAL DRIVER REGISTER RECORDS.--In accordance with section 30305(b)(8) of this title, from the chief driver licensing official of a State, information concerning the motor vehicle driving record of the individual.

"(3) WRITTEN CONSENT; RELEASE FROM LIABILITY.--An air carrier--

"(A) shall obtain the written consent of an individual before accessing records pertaining to the individual under paragraph (1); and

"(B) may, notwithstanding any other provision of law or agreement to the contrary, require an individual with respect to whom the carrier is accessing records under paragraph (1) to execute a release from liability for any claim arising from accessing the records or the use of such records by the air carrier in accordance with this section (other than a claim arising from furnishing information known to be false and maintained in violation of a criminal statute).

"(4) REPORTING.--

"(A) REPORTING BY ADMINISTRATOR.--The Administrator shall enter data described in paragraph (2)(A) into the database promptly to ensure that an individual's records are current.

"(B) REPORTING BY AIR CARRIERS AND OTHER PERSONS.--

"(i) IN GENERAL.--Air carriers and other persons shall report data described in paragraphs (2)(B) and (2)(C) to the Administrator promptly for entry into the database.

"(ii) DATA TO BE REPORTED.--Air carriers and other persons shall report, at a minimum, under clause (i) the following data described in paragraph (2)(B):

"(I) Records that are generated by the air carrier or other person after the date of enactment of this paragraph.

"(II) Records that the air carrier or other person is maintaining, on such date of enactment, pursuant to subsection (h)(4).

"(5) REQUIREMENT TO MAINTAIN RECORDS.--The Administrator--

"(A) shall maintain all records entered into the database under paragraph (2) pertaining to an individual until the date of receipt of notification that the individual is deceased; and

"(B) may remove the individual's records from the database after that date.

***2354** "(6) RECEIPT OF CONSENT.--The Administrator shall not permit an air carrier to access records pertaining to an individual from the database under paragraph (1) without the air carrier first demonstrating to the satisfaction of the Administrator that the air carrier has obtained the written consent of the individual.

"(7) RIGHT OF PILOT TO REVIEW CERTAIN RECORDS AND CORRECT INACCURACIES.--Notwithstanding any other provision of law or agreement, the Administrator, upon receipt of written request from an individual--

"(A) shall make available, not later than 30 days after the date of the request, to the individual for review all records referred to in paragraph (2) pertaining to the individual; and

"(B) shall provide the individual with a reasonable opportunity to submit written comments to correct any inaccuracies contained in the records.

"(8) REASONABLE CHARGES FOR PROCESSING REQUESTS AND FURNISHING COPIES.--

"(A) IN GENERAL.--The Administrator may establish a reasonable charge for the cost of processing a request under paragraph (1) or (7) and for the cost of furnishing copies of requested records under paragraph (7).

"(B) CREDITING APPROPRIATIONS.--Funds received by the Administrator pursuant to this paragraph shall--

"(i) be credited to the appropriation current when the amount is received;

"(ii) be merged with and available for the purposes of such appropriation; and

"(iii) remain available until expended.

"(9) PRIVACY PROTECTIONS.--

"(A) USE OF RECORDS.--An air carrier that accesses records pertaining to an individual under paragraph (1) may use the records only to assess the qualifications of the individual in deciding whether or not to hire the individual as a pilot. The air carrier shall take such actions as may be necessary to protect the privacy of the individual and the confidentiality of the records accessed, including ensuring that information contained in the records is not divulged to any individual that is not directly involved in the hiring decision.

"(B) DISCLOSURE OF INFORMATION.--

"(i) IN GENERAL.--Except as provided by clause (ii), information collected by the Administrator under paragraph (2) shall be exempt from the disclosure requirements of section 552 of title 5.

"(ii) EXCEPTIONS.--Clause (i) shall not apply to--

"(I) deidentified, summarized information to explain the need for changes in policies and regulations;

"(II) information to correct a condition that compromises safety;

"(III) information to carry out a criminal investigation or prosecution;

"(IV) information to comply with section 44905, regarding information about threats to civil aviation; and

***2355** "(V) such information as the Administrator determines necessary, if withholding the information would not be consistent with the safety responsibilities of the Federal Aviation Administration.

"(10) PERIODIC REVIEW.--Not later than 18 months after the date of enactment of this paragraph, and at least once every 3 years thereafter, the Administrator shall transmit to Congress a statement that contains, taking into account recent developments in the aviation industry--

"(A) recommendations by the Administrator concerning proposed changes to Federal Aviation Administration records, air carrier records, and other records required to be included in the database under paragraph (2); or

"(B) reasons why the Administrator does not recommend any proposed changes to the records referred to in subparagraph (A).

"(11) REGULATIONS FOR PROTECTION AND SECURITY OF RECORDS.--The Administrator shall prescribe such regulations as may be necessary--

"(A) to protect and secure--

"(i) the personal privacy of any individual whose records are accessed under paragraph (1); and

"(ii) the confidentiality of those records; and

"(B) to preclude the further dissemination of records received under paragraph (1) by the person who

accessed the records.

"(12) GOOD FAITH EXCEPTION.--Notwithstanding paragraph (1), an air carrier may allow an individual to begin service as a pilot, without first obtaining information described in paragraph (2)(B) from the database pertaining to the individual, if--

"(A) the air carrier has made a documented good faith attempt to access the information from the database; and

"(B) the air carrier has received written notice from the Administrator that the information is not contained in the database because the individual was employed by an air carrier or other person that no longer exists or by a foreign government or other entity that has not provided the information to the database.

"(13) LIMITATIONS ON ELECTRONIC ACCESS TO RECORDS.--

"(A) ACCESS BY INDIVIDUALS DESIGNATED BY AIR CARRIERS.--For the purpose of increasing timely and efficient access to records described in paragraph (2), the Administrator may allow, under terms established by the Administrator, an individual designated by an air carrier to have electronic access to the database.

"(B) TERMS.--The terms established by the Administrator under subparagraph (A) for allowing a designated individual to have electronic access to the database shall limit such access to instances in which information in the database is required by the designated individual in making a hiring decision concerning a pilot applicant and shall require that the designated individual provide assurances satisfactory to the Administrator that--

***2356** "(i) the designated individual has received the written consent of the pilot applicant to access the information; and

"(ii) information obtained using such access will not be used for any purpose other than making the hiring decision.

"(14) AUTHORIZED EXPENDITURES.--Of amounts appropriated under section 106(k)(1), a total of $6,000,000 for fiscal years 2010 through 2013 may be used to carry out this subsection.

"(15) REGULATIONS.--

"(A) IN GENERAL.--The Administrator shall issue regulations to carry out this subsection.

"(B) EFFECTIVE DATE.--The regulations shall specify the date on which the requirements of this subsection take effect and the date on which the requirements of subsection (h) cease to be effective.

"(C) EXCEPTIONS.--Notwithstanding subparagraph (B)--

"(i) the Administrator shall begin to establish the database under paragraph (2) not later than 90 days after the date of enactment of this paragraph;

"(ii) the Administrator shall maintain records in accordance with paragraph (5) beginning on the date of enactment of this paragraph; and

"(iii) air carriers and other persons shall maintain records to be reported to the database under paragraph (4)(B) in the period beginning on such date of enactment and ending on the date that is 5 years after the requirements of subsection (h) cease to be effective pursuant to subparagraph (B).

"(16) SPECIAL RULE.--During the one-year period beginning on the date on which the requirements of this section become effective pursuant to paragraph (15)(B), paragraph (7)(A) shall be applied by substituting '45 days' for '30 days'.".

(c) CONFORMING AMENDMENTS.--

(1) LIMITATION ON LIABILITY; PREEMPTION OF STATE LAW.--Section 44703(j) (as redesignated by subsection (b)(1) of this section) is amended--

<< 49 USCA § 44703 >>

(A) in the subsection heading by striking "Limitation" and inserting "Limitations";

(B) in paragraph (1)--

<< 49 USCA § 44703 >>

(i) in the matter preceding subparagraph (A) by striking "paragraph (2)" and inserting "subsection (h)(2) or (i)(3)";

<< 49 USCA § 44703 >>

(ii) in subparagraph (A) by inserting "or accessing the records of that individual under subsection (i)(1)" before the semicolon; and

<< 49 USCA § 44703 >>

(iii) in the matter following subparagraph (D) by striking "subsection (h)" and inserting "subsection (h) or (i)";

<< 49 USCA § 44703 >>

(C) in paragraph (2) by striking "subsection (h)" and inserting "subsection (h) or (i)";

<< 49 USCA § 44703 >>

(D) in paragraph (3), in the matter preceding subparagraph (A), by inserting "or who furnished information to the database established under subsection (i)(2)" after "subsection (h)(1)"; and

***2357** << 49 USCA § 44703 >>

(E) by adding at the end the following:

"(4) PROHIBITION ON ACTIONS AND PROCEEDINGS AGAINST AIR CARRIERS.--

"(A) HIRING DECISIONS.--An air carrier may refuse to hire an individual as a pilot if the individual

did not provide written consent for the air carrier to receive records under subsection (h)(2)(A) or (i)(3)(A) or did not execute the release from liability requested under subsection (h)(2)(B) or (i)(3)(B).

"(B) ACTIONS AND PROCEEDINGS.--No action or proceeding may be brought against an air carrier by or on behalf of an individual who has applied for or is seeking a position as a pilot with the air carrier if the air carrier refused to hire the individual after the individual did not provide written consent for the air carrier to receive records under subsection (h)(2)(A) or (i)(3)(A) or did not execute a release from liability requested under subsection (h)(2)(B) or (i)(3)(B).".

<< 49 USCA § 44703 >>

(2) LIMITATION ON STATUTORY CONSTRUCTION.--Section 44703(k) (as redesignated by subsection (b)(1) of this section) is amended by striking "subsection (h)" and inserting "subsection (h) or (i)".

<< 49 USCA § 44701 NOTE >>

SEC. 204. FAA TASK FORCE ON AIR CARRIER SAFETY AND PILOT TRAINING.

(a) ESTABLISHMENT.--The Administrator of the Federal Aviation Administration shall establish a special task force to be known as the FAA Task Force on Air Carrier Safety and Pilot Training (in this section referred to as the "Task Force").

(b) COMPOSITION.--The Task Force shall consist of members appointed by the Administrator and shall include air carrier representatives, labor union representatives, and aviation safety experts with knowledge of foreign and domestic regulatory requirements for flight crewmember education and training.

(c) DUTIES.--The duties of the Task Force shall include, at a minimum, evaluating best practices in the air carrier industry and providing recommendations in the following areas:

(1) Air carrier management responsibilities for flight crewmember education and support.

(2) Flight crewmember professional standards.

(3) Flight crewmember training standards and performance.

(4) Mentoring and information sharing between air carriers.

(d) REPORT.--Not later than one year after the date of enactment of this Act, and before the last day of each one-year period thereafter until termination of the Task Force, the Task Force shall submit to the Committee on Transportation and Infrastructure of the House of Representatives and the Committee on Commerce, Science, and Transportation of the Senate a report detailing--

(1) the progress of the Task Force in identifying best practices in the air carrier industry;

(2) the progress of air carriers and labor unions in implementing the best practices identified by the Task Force;

(3) recommendations of the Task Force, if any, for legislative or regulatory actions;

***2358** (4) the progress of air carriers and labor unions in implementing training-related, nonregulatory actions recommended by the Administrator; and

(5) the progress of air carriers in developing specific programs to share safety data and ensure implementation of the most effective safety practices.

(e) TERMINATION.--The Task Force shall terminate on September 30, 2012.

(f) APPLICABILITY OF FEDERAL ADVISORY COMMITTEE ACT.--The Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the Task Force.

<< 49 USCA § 44701 NOTE >>

SEC. 205. AVIATION SAFETY INSPECTORS AND OPERATIONAL RESEARCH ANALYSTS.

(a) REVIEW BY DOT INSPECTOR GENERAL.--Not later than 9 months after the date of enactment of this Act, the Inspector General of the Department of Transportation shall conduct a review of the aviation safety inspectors and operational research analysts of the Federal Aviation Administration assigned to part 121 air carriers and submit to the Administrator of the Federal Aviation Administration a report on the results of the review.

(b) PURPOSES.--The purpose of the review shall be, at a minimum--

(1) to review the level of the Administration's oversight of each part 121 air carrier;

(2) to make recommendations to ensure that each part 121 air carrier is receiving an equivalent level of oversight;

(3) to assess the number and level of experience of aviation safety inspectors assigned to each part 121 air carrier;

(4) to evaluate how the Administration is making assignments of aviation safety inspectors to each part 121 air carrier;

(5) to review various safety inspector oversight programs, including the geographic inspector program;

(6) to evaluate the adequacy of the number of operational research analysts assigned to each part 121 air carrier;

(7) to evaluate the surveillance responsibilities of aviation safety inspectors, including en route inspections;

(8) to evaluate whether inspectors are able to effectively use data sources, such as the Safety Performance Analysis System and the Air Transportation Oversight System, to assist in targeting oversight of each part 121 air carrier;

(9) to assess the feasibility of establishment by the Administration of a comprehensive repository of information that encompasses multiple Administration data sources and allows access by aviation safety inspectors and operational research analysts to assist in the oversight of each part 121 air carrier; and

(10) to conduct such other analyses as the Inspector General considers relevant to the review.

<< 49 USCA § 44701 NOTE >>

SEC. 206. FLIGHT CREWMEMBER MENTORING, PROFESSIONAL DEVELOPMENT, AND LEADERSHIP.

(a) AVIATION RULEMAKING COMMITTEE.--

(1) IN GENERAL.--The Administrator of the Federal Aviation Administration shall convene an aviation rulemaking committee to develop procedures for each part 121 air carrier to take the following actions:

***2359** (A) Establish flight crewmember mentoring programs under which the air carrier will pair highly experienced flight crewmembers who will serve as mentor pilots and be paired with newly employed flight crewmembers. Mentor pilots should be provided, at a minimum, specific instruction on techniques for instilling and reinforcing the highest standards of technical performance, airmanship, and professionalism in newly employed flight crewmembers.

(B) Establish flight crewmember professional development committees made up of air carrier management and labor union or professional association representatives to develop, administer, and oversee formal mentoring programs of the carrier to assist flight crewmembers to reach their maximum potential as safe, seasoned, and proficient flight crewmembers.

(C) Establish or modify training programs to accommodate substantially different levels and types of flight experience by newly employed flight crewmembers.

(D) Establish or modify training programs for second-in-command flight crewmembers attempting to qualify as pilot-in-command flight crewmembers for the first time in a specific aircraft type and ensure that such programs include leadership and command training.

(E) Ensure that recurrent training for pilots in command includes leadership and command training.

(F) Such other actions as the aviation rulemaking committee determines appropriate to enhance flight crewmember professional development.

(2) COMPLIANCE WITH STERILE COCKPIT RULE.--Leadership and command training described in paragraphs (1)(D) and (1)(E) shall include instruction on compliance with flight crewmember duties under part 121.542 of title 14, Code of Federal Regulations.

(3) STREAMLINED PROGRAM REVIEW.--

(A) IN GENERAL.--As part of the rulemaking required by subsection (b), the Administrator shall establish a streamlined review process for part 121 air carriers that have in effect, as of the date of enactment of this Act, the programs described in paragraph (1).

(B) EXPEDITED APPROVALS.--Under the streamlined review process, the Administrator shall--

(i) review the programs of such part 121 air carriers to determine whether the programs meet the requirements set forth in the final rule referred to in subsection (b)(2); and

(ii) expedite the approval of the programs that the Administrator determines meet such require-

ments.

(b) RULEMAKING.--The Administrator shall issue--

(1) not later than one year after the date of enactment of this Act, a notice of proposed rulemaking based on the recommendations of the aviation rulemaking committee convened under subsection (a); and

(2) not later than 36 months after such date of enactment, a final rule based on such recommendations.

***2360** << 49 USCA § 44701 NOTE >>

SEC. 207. FLIGHT CREWMEMBER PAIRING AND CREW RESOURCE MANAGEMENT TECHNIQUES.

(a) STUDY.--The Administrator of the Federal Aviation Administration shall conduct a study on aviation industry best practices with regard to flight crewmember pairing, crew resource management techniques, and pilot commuting.

(b) REPORT.--Not later than one year after the date of enactment of this Act, the Administrator shall submit to the Committee on Transportation and Infrastructure of the House of Representatives and the Committee on Commerce, Science, and Transportation of the Senate a report on the results of the study.

<< 49 USCA § 44701 NOTE >>

SEC. 208. IMPLEMENTATION OF NTSB FLIGHT CREWMEMBER TRAINING RECOMMENDATIONS.

(a) RULEMAKING PROCEEDINGS.--

(1) STALL AND UPSET RECOGNITION AND RECOVERY TRAINING.--The Administrator of the Federal Aviation Administration shall conduct a rulemaking proceeding to require part 121 air carriers to provide flight crewmembers with ground training and flight training or flight simulator training--

(A) to recognize and avoid a stall of an aircraft or, if not avoided, to recover from the stall; and

(B) to recognize and avoid an upset of an aircraft or, if not avoided, to execute such techniques as available data indicate are appropriate to recover from the upset in a given make, model, and series of aircraft.

(2) REMEDIAL TRAINING PROGRAMS.--The Administrator shall conduct a rulemaking proceeding to require part 121 air carriers to establish remedial training programs for flight crewmembers who have demonstrated performance deficiencies or experienced failures in the training environment.

(3) DEADLINES.--The Administrator shall--

(A) not later than one year after the date of enactment of this Act, issue a notice of proposed rulemaking under each of paragraphs (1) and (2); and

(B) not later than 36 months after the date of enactment of this Act, issue a final rule for the rulemaking under each of paragraphs (1) and (2).

(b) STICK PUSHER TRAINING AND WEATHER EVENT TRAINING.--

(1) MULTIDISCIPLINARY PANEL.--Not later than 120 days after the date of enactment of this Act, the Administrator shall convene a multidisciplinary panel of specialists in aircraft operations, flight crewmember training, human factors, and aviation safety to study and submit to the Administrator a report on methods to increase the familiarity of flight crewmembers with, and improve the response of flight crewmembers to, stick pusher systems, icing conditions, and microburst and windshear weather events.

(2) REPORT TO CONGRESS AND NTSB.--Not later than one year after the date on which the Administrator convenes the panel, the Administrator shall--

(A) submit to the Committee on Transportation and Infrastructure of the House of Representatives, the Committee on Commerce, Science, and Transportation of the Senate, and the National Transportation Safety Board a report based on the findings of the panel; and

***2361** (B) with respect to stick pusher systems, initiate appropriate actions to implement the recommendations of the panel.

(c) DEFINITIONS.--In this section, the following definitions apply:

(1) FLIGHT TRAINING AND FLIGHT SIMULATOR.--The terms “flight training” and “flight simulator” have the meanings given those terms in part 61.1 of title 14, Code of Federal Regulations (or any successor regulation).

(2) STALL.--The term “stall” means an aerodynamic loss of lift caused by exceeding the critical angle of attack.

(3) STICK PUSHER.--The term “stick pusher” means a device that, at or near a stall, applies a nose down pitch force to an aircraft's control columns to attempt to decrease the aircraft's angle of attack.

(4) UPSET.--The term “upset” means an unusual aircraft attitude.

<< 49 USCA § 44701 NOTE >>

SEC. 209. FAA RULEMAKING ON TRAINING PROGRAMS.

(a) COMPLETION OF RULEMAKING ON TRAINING PROGRAMS.--Not later than 14 months after the date of enactment of this Act, the Administrator of the Federal Aviation Administration shall issue a final rule with respect to the notice of proposed rulemaking published in the Federal Register on January 12, 2009 (74 Fed. Reg. 1280; relating to training programs for flight crewmembers and aircraft dispatchers).

(b) EXPERT PANEL TO REVIEW PART 121 AND PART 135 TRAINING HOURS.--

(1) ESTABLISHMENT.--Not later than 60 days after the date of enactment of this Act, the Administrator shall convene a multidisciplinary expert panel comprised of, at a minimum, air carrier representatives, training facility representatives, instructional design experts, aircraft manufacturers, safety organization representatives, and labor union representatives.

(2) ASSESSMENT AND RECOMMENDATIONS.--The panel shall assess and make recommendations concerning--

(A) the best methods and optimal time needed for flight crewmembers of part 121 air carriers and flight crewmembers of part 135 air carriers to master aircraft systems, maneuvers, procedures, takeoffs and landings, and crew coordination;

(B) initial and recurrent testing requirements for pilots, including the rigor and consistency of testing programs such as check rides;

(C) the optimal length of time between training events for such flight crewmembers, including recurrent training events;

(D) the best methods reliably to evaluate mastery by such flight crewmembers of aircraft systems, maneuvers, procedures, takeoffs and landings, and crew coordination;

(E) classroom instruction requirements governing curriculum content and hours of instruction;

(F) the best methods to allow specific academic training courses to be credited toward the total flight hours required to receive an airline transport pilot certificate; and

(G) crew leadership training.

***2362** (3) BEST PRACTICES.--In making recommendations under subsection (b)(2), the panel shall consider, if appropriate, best practices in the aviation industry with respect to training protocols, methods, and procedures.

(4) REPORT.--Not later than one year after the date of enactment of this Act, the Administrator shall submit to the Committee on Transportation and Infrastructure of the House of Representatives, the Committee on Commerce, Science, and Transportation of the Senate, and the National Transportation Safety Board a report based on the findings of the panel.

<< 49 USCA § 44701 NOTE >>

<< 49 USCA § 41712 >>

SEC. 210. DISCLOSURE OF AIR CARRIERS OPERATING FLIGHTS FOR TICKETS SOLD FOR AIR TRANSPORTATION.

Section 41712 of title 49, United States Code, is amended by adding at the end the following:

“(c) DISCLOSURE REQUIREMENT FOR SELLERS OF TICKETS FOR FLIGHTS.--

“(1) IN GENERAL.--It shall be an unfair or deceptive practice under subsection (a) for any ticket agent, air carrier, foreign air carrier, or other person offering to sell tickets for air transportation on a flight of an air carrier to fail to disclose, whether verbally in oral communication or in writing in written or electronic communication, prior to the purchase of a ticket--

“(A) the name of the air carrier providing the air transportation; and

“(B) if the flight has more than one flight segment, the name of each air carrier providing the air transportation for each such flight segment.

"(2) INTERNET OFFERS.--In the case of an offer to sell tickets described in paragraph (1) on an Internet Web site, disclosure of the information required by paragraph (1) shall be provided on the first display of the Web site following a search of a requested itinerary in a format that is easily visible to a viewer.".

<< 49 USCA § 44701 NOTE >>

SEC. 211. SAFETY INSPECTIONS OF REGIONAL AIR CARRIERS.

The Administrator of the Federal Aviation Administration shall perform, not less frequently than once each year, random, onsite inspections of air carriers that provide air transportation pursuant to a contract with a part 121 air carrier to ensure that such air carriers are complying with all applicable safety standards of the Administration.

<< 49 USCA § 44701 NOTE >>

SEC. 212. PILOT FATIGUE.

(a) FLIGHT AND DUTY TIME REGULATIONS.--

(1) IN GENERAL.--In accordance with paragraph (3), the Administrator of the Federal Aviation Administration shall issue regulations, based on the best available scientific information, to specify limitations on the hours of flight and duty time allowed for pilots to address problems relating to pilot fatigue.

(2) MATTERS TO BE ADDRESSED.--In conducting the rulemaking proceeding under this subsection, the Administrator shall consider and review the following:

(A) Time of day of flights in a duty period.

(B) Number of takeoff and landings in a duty period.

(C) Number of time zones crossed in a duty period.

***2363** (D) The impact of functioning in multiple time zones or on different daily schedules.

(E) Research conducted on fatigue, sleep, and circadian rhythms.

(F) Sleep and rest requirements recommended by the National Transportation Safety Board and the National Aeronautics and Space Administration.

(G) International standards regarding flight schedules and duty periods.

(H) Alternative procedures to facilitate alertness in the cockpit.

(I) Scheduling and attendance policies and practices, including sick leave.

(J) The effects of commuting, the means of commuting, and the length of the commute.

(K) Medical screening and treatment.

(L) Rest environments.

(M) Any other matters the Administrator considers appropriate.

(3) RULEMAKING.--The Administrator shall issue--

(A) not later than 180 days after the date of enactment of this Act, a notice of proposed rulemaking under paragraph (1); and

(B) not later than one year after the date of enactment of this Act, a final rule under paragraph (1).

(b) FATIGUE RISK MANAGEMENT PLAN.--

(1) SUBMISSION OF FATIGUE RISK MANAGEMENT PLAN BY PART 121 AIR CARRIERS.--Not later than 90 days after the date of enactment of this Act, each part 121 air carrier shall submit to the Administrator for review and acceptance a fatigue risk management plan for the carrier's pilots.

(2) CONTENTS OF PLAN.--A fatigue risk management plan submitted by a part 121 air carrier under paragraph (1) shall include the following:

(A) Current flight time and duty period limitations.

(B) A rest scheme consistent with such limitations that enables the management of pilot fatigue, including annual training to increase awareness of--

(i) fatigue;

(ii) the effects of fatigue on pilots; and

(iii) fatigue countermeasures.

(C) Development and use of a methodology that continually assesses the effectiveness of the program, including the ability of the program--

(i) to improve alertness; and

(ii) to mitigate performance errors.

(3) REVIEW.--Not later than 12 months after the date of enactment of this Act, the Administrator shall review and accept or reject the fatigue risk management plans submitted under this subsection. If the Administrator rejects a plan, the Administrator shall provide suggested modifications for resubmission of the plan.

(4) PLAN UPDATES.--

(A) IN GENERAL.--A part 121 air carrier shall update its fatigue risk management plan under paragraph (1) every 2 years and submit the update to the Administrator for review and acceptance.

***2364** (B) REVIEW.--Not later than 12 months after the date of submission of a plan update under subparagraph (A), the Administrator shall review and accept or reject the update. If the Administrator rejects an update, the Administrator shall provide suggested modifications for resubmission of the update.

(5) COMPLIANCE.--A part 121 air carrier shall comply with the fatigue risk management plan of the air

carrier that is accepted by the Administrator under this subsection.

(6) CIVIL PENALTIES.--A violation of this subsection by a part 121 air carrier shall be treated as a violation of chapter 447 of title 49, United States Code, for purposes of the application of civil penalties under chapter 463 of that title.

(c) EFFECT OF COMMUTING ON FATIGUE.--

(1) IN GENERAL.--Not later than 60 days after the date of enactment of this Act, the Administrator shall enter into appropriate arrangements with the National Academy of Sciences to conduct a study of the effects of commuting on pilot fatigue and report its findings to the Administrator.

(2) STUDY.--In conducting the study, the National Academy of Sciences shall consider--

(A) the prevalence of pilot commuting in the commercial air carrier industry, including the number and percentage of pilots who commute;

(B) information relating to commuting by pilots, including distances traveled, time zones crossed, time spent, and methods used;

(C) research on the impact of commuting on pilot fatigue, sleep, and circadian rhythms;

(D) commuting policies of commercial air carriers (including passenger and all-cargo air carriers), including pilot check-in requirements and sick leave and fatigue policies;

(E) postconference materials from the Federal Aviation Administration's June 2008 symposium titled “Aviation Fatigue Management Symposium: Partnerships for Solutions”;

(F) Federal Aviation Administration and international policies and guidance regarding commuting; and

(G) any other matters as the Administrator considers appropriate.

(3) PRELIMINARY FINDINGS.--Not later than 120 days after the date of entering into arrangements under paragraph (1), the National Academy of Sciences shall submit to the Administrator its preliminary findings under the study.

(4) REPORT.--Not later than 9 months after the date of entering into arrangements under paragraph (1), the National Academy of Sciences shall submit a report to the Administrator containing its findings under the study and any recommendations for regulatory or administrative actions by the Federal Aviation Administration concerning commuting by pilots.

(5) RULEMAKING.--Following receipt of the report of the National Academy of Sciences under paragraph (4), the Administrator shall--

(A) consider the findings and recommendations in the report; and

***2365** (B) update, as appropriate based on scientific data, regulations required by subsection (a) on flight and duty time.

<< 49 USCA § 44701 NOTE >>

SEC. 213. VOLUNTARY SAFETY PROGRAMS.

(a) REPORT.--Not later than 180 days after the date of enactment of this Act, the Administrator of the Federal Aviation Administration shall submit to the Committee on Transportation and Infrastructure of the House of Representatives and the Committee on Commerce, Science, and Transportation of the Senate a report on the aviation safety action program, the flight operational quality assurance program, the line operations safety audit, and the advanced qualification program.

(b) CONTENTS.--The report shall include--

(1) a list of--

(A) which air carriers are using one or more of the voluntary safety programs referred to in subsection (a); and

(B) the voluntary safety programs each air carrier is using;

(2) if an air carrier is not using one or more of the voluntary safety programs--

(A) a list of such programs the carrier is not using; and

(B) the reasons the carrier is not using each such program;

(3) if an air carrier is using one or more of the voluntary safety programs, an explanation of the benefits and challenges of using each such program;

(4) a detailed analysis of how the Administration is using data derived from each of the voluntary safety programs as safety analysis and accident or incident prevention tools and a detailed plan on how the Administration intends to expand data analysis of such programs;

(5) an explanation of--

(A) where the data derived from the voluntary safety programs is stored;

(B) how the data derived from such programs is protected and secured; and

(C) what data analysis processes air carriers are implementing to ensure the effective use of the data derived from such programs;

(6) a description of the extent to which aviation safety inspectors are able to review data derived from the voluntary safety programs to enhance their oversight responsibilities;

(7) a description of how the Administration plans to incorporate operational trends identified under the voluntary safety programs into the air transport oversight system and other surveillance databases so that such system and databases are more effectively utilized;

(8) other plans to strengthen the voluntary safety programs, taking into account reviews of such programs by

the Inspector General of the Department of Transportation; and

(9) such other matters as the Administrator determines are appropriate.

***2366** << 49 USCA § 44701 NOTE >>

SEC. 214. ASAP AND FOQA IMPLEMENTATION PLAN.

(a) DEVELOPMENT AND IMPLEMENTATION PLAN.--The Administrator of the Federal Aviation Administration shall develop and implement a plan to facilitate the establishment of an aviation safety action program and a flight operational quality assurance program by all part 121 air carriers.

(b) MATTERS TO BE CONSIDERED.--In developing the plan under subsection (a), the Administrator shall consider--

(1) how the Administration can assist part 121 air carriers with smaller fleet sizes to derive a benefit from establishing a flight operational quality assurance program;

(2) how part 121 air carriers with established aviation safety action and flight operational quality assurance programs can quickly begin to report data into the aviation safety information analysis sharing database; and

(3) how part 121 air carriers and aviation safety inspectors can better utilize data from such database as accident and incident prevention tools.

(c) REPORT.--Not later than 180 days after the date of enactment of this Act, the Administrator shall submit to the Committee on Transportation and Infrastructure of the House of Representatives and the Committee on Commerce, Science, and Transportation of the Senate a copy of the plan developed under subsection (a) and an explanation of how the Administration will implement the plan.

(d) DEADLINE FOR BEGINNING IMPLEMENTATION OF PLAN.--Not later than one year after the date of enactment of this Act, the Administrator shall begin implementation of the plan developed under subsection (a).

<< 49 USCA § 44701 NOTE >>

SEC. 215. SAFETY MANAGEMENT SYSTEMS.

(a) RULEMAKING.--The Administrator of the Federal Aviation Administration shall conduct a rulemaking proceeding to require all part 121 air carriers to implement a safety management system.

(b) MATTERS TO CONSIDER.--In conducting the rulemaking under subsection (a), the Administrator shall consider, at a minimum, including each of the following as a part of the safety management system:

(1) An aviation safety action program.

(2) A flight operational quality assurance program.

(3) A line operations safety audit.

(4) An advanced qualification program.

(c) DEADLINES.--The Administrator shall issue--

(1) not later than 90 days after the date of enactment of this Act, a notice of proposed rulemaking under subsection (a); and

(2) not later than 24 months after the date of enactment of this Act, a final rule under subsection (a).

(d) SAFETY MANAGEMENT SYSTEM DEFINED.--In this section, the term "safety management system" means the program established by the Federal Aviation Administration in Advisory Circular 120–92, dated June 22, 2006, including any subsequent revisions thereto.

<< 49 USCA § 44701 NOTE >>

SEC. 216. FLIGHT CREWMEMBER SCREENING AND QUALIFICATIONS.

(a) REQUIREMENTS.--

***2367** (1) RULEMAKING PROCEEDING.--The Administrator of the Federal Aviation Administration shall conduct a rulemaking proceeding to require part 121 air carriers to develop and implement means and methods for ensuring that flight crewmembers have proper qualifications and experience.

(2) MINIMUM REQUIREMENTS.--

(A) PROSPECTIVE FLIGHT CREWMEMBERS.--Rules issued under paragraph (1) shall ensure that prospective flight crewmembers undergo comprehensive preemployment screening, including an assessment of the skills, aptitudes, airmanship, and suitability of each applicant for a position as a flight crewmember in terms of functioning effectively in the air carrier's operational environment.

(B) ALL FLIGHT CREWMEMBERS.--Rules issued under paragraph (1) shall ensure that, after the date that is 3 years after the date of enactment of this Act, all flight crewmembers--

(i) have obtained an airline transport pilot certificate under part 61 of title 14, Code of Federal Regulations; and

(ii) have appropriate multi-engine aircraft flight experience, as determined by the Administrator.

(b) DEADLINES.--The Administrator shall issue--

(1) not later than 180 days after the date of enactment of this Act, a notice of proposed rulemaking under subsection (a); and

(2) not later than 24 months after such date of enactment, a final rule under subsection (a).

(c) DEFAULT.--The requirement that each flight crewmember for a part 121 air carrier hold an airline transport pilot certificate under part 61 of title 14, Code of Federal Regulations, shall begin to apply on the date that is 3 years after the date of enactment of this Act even if the Administrator fails to meet a deadline established under this section.

<< 49 USCA § 44701 NOTE >>

SEC. 217. AIRLINE TRANSPORT PILOT CERTIFICATION.

(a) RULEMAKING PROCEEDING.--The Administrator of the Federal Aviation Administration shall conduct a rulemaking proceeding to amend part 61 of title 14, Code of Federal Regulations, to modify requirements for the issuance of an airline transport pilot certificate.

(b) MINIMUM REQUIREMENTS.--To be qualified to receive an airline transport pilot certificate pursuant to subsection (a), an individual shall--

(1) have sufficient flight hours, as determined by the Administrator, to enable a pilot to function effectively in an air carrier operational environment; and

(2) have received flight training, academic training, or operational experience that will prepare a pilot, at a minimum, to--

(A) function effectively in a multipilot environment;

(B) function effectively in adverse weather conditions, including icing conditions;

(C) function effectively during high altitude operations;

(D) adhere to the highest professional standards; and

(E) function effectively in an air carrier operational environment.

***2368** (c) FLIGHT HOURS.--

(1) NUMBERS OF FLIGHT HOURS.--The total flight hours required by the Administrator under subsection (b)(1) shall be at least 1,500 flight hours.

(2) FLIGHT HOURS IN DIFFICULT OPERATIONAL CONDITIONS.--The total flight hours required by the Administrator under subsection (b)(1) shall include sufficient flight hours, as determined by the Administrator, in difficult operational conditions that may be encountered by an air carrier to enable a pilot to operate safely in such conditions.

(d) CREDIT TOWARD FLIGHT HOURS.--The Administrator may allow specific academic training courses, beyond those required under subsection (b)(2), to be credited toward the total flight hours required under subsection (c). The Administrator may allow such credit based on a determination by the Administrator that allowing a pilot to take specific academic training courses will enhance safety more than requiring the pilot to fully comply with the flight hours requirement.

(e) RECOMMENDATIONS OF EXPERT PANEL.--In conducting the rulemaking proceeding under this section, the Administrator shall review and consider the assessment and recommendations of the expert panel to review part 121 and part 135 training hours established by section 209(b) of this Act.

(f) DEADLINE.--Not later than 36 months after the date of enactment of this Act, the Administrator shall issue a final rule under subsection (a).

Approved August 1, 2010.

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Circular No. A-4, 2003 WL 24011971 (O.M.B.)

Executive Office of the President
Office of Management and Budget (O.M.B.)

REGULATORY ANALYSIS

September 17, 2003

TO THE HEADS OF EXECUTIVE AGENCIES AND ESTABLISHMENTS

This Circular provides the Office of Management and Budget's (OMB's) guidance to Federal agencies on the development of regulatory analysis as required under Section 6(a)(3)(c) of Executive Order12866, "Regulatory Planning and Review," the Regulatory Right-to-Know Act, and a variety of related authorities. The Circular also provides guidance to agencies on the regulatory accounting statements that are required under the Regulatory Right-to-Know Act.

This Circular refines OMB's "best practices" document of 1996 (http://www.whitehouse.gov/omb/inforeg/riaguide.html), which was issued as a guidance in 2000 (http://www.whitehouse.gov/omb/memoranda/m00-08.pdf), and reaffirmed in 2001 (http://www.whitehouse.gov/omb/memoranda/m01-23.html). It replaces both the 1996 "best practices" and the 2000 guidance.

In developing this Circular, OMB first developed a draft that was subject to public comment, interagency review, and peer review. Peer reviewers included Cass Sunstein, University of Chicago; Lester Lave, Carnegie Mellon University; Milton C. Weinstein and James K. Hammitt of the Harvard School of Public Health; Kerry Smith, North Carolina State University; Jonathan Weiner, Duke University Law School; Douglas K. Owens, Stanford University; and W. Kip Viscusi, Harvard Law School. Although these individuals submitted comments, OMB is solely responsible for the final content of this Circular.

A. Introduction

This Circular is designed to assist analysts in the regulatory agencies by defining good regulatory analysis - called either "regulatory analysis" or "analysis" for brevity - and standardizing the way benefits and costs of Federal regulatory actions are measured and reported. Executive Order 12866 requires agencies to conduct a regulatory analysis for economically significant regulatory actions as defined by Section 3(f)(1). This requirement applies to rulemakings that rescind or modify existing rules as well as to rulemakings that establish new requirements.

The Need for Analysis of Proposed Regulatory Actions[FN1]

Regulatory analysis is a tool regulatory agencies use to anticipate and evaluate the likely consequences of rules. It provides a formal way of organizing the evidence on the key effects - good and bad - of the various alternatives that should be considered in developing regulations. The motivation is to (1) learn if the benefits of an action are likely to justify the costs or (2) discover which of various possible alternatives would be the most cost-effective.

A good regulatory analysis is designed to inform the public and other parts of the Government (as well as the agency conducting the analysis) of the effects of alternative actions. Regulatory analysis sometimes will show that a proposed action is misguided, but it can also demonstrate that well-conceived actions are reasonable and justified.

Benefit-cost analysis is a primary tool used for regulatory analysis. [FN2] Where all benefits and costs can be quantified and expressed in monetary units, benefit-cost analysis provides decision makers with a clear indication of the most efficient alternative, that is, the alternative that generates the largest net benefits to society (ignoring distributional effects). This is useful information for decision makers and the public to receive, even when economic efficiency is not the only or the overriding public policy objective.

It will not always be possible to express in monetary units all of the important benefits and costs. When it is not, the most efficient alternative will not necessarily be the one with the largest quantified and monetized net-benefit estimate. In such cases, you should exercise professional judgment in determining how important the non-quantified benefits or costs may be in the context of the overall analysis. If the non-quantified benefits and costs are likely to be important, you should carry out a "threshold" analysis to evaluate their significance. Threshold or "break-even" analysis answers the question, "How small could the value of the non-quantified benefits be (or how large would the value of the non-quantified costs need to be) before the rule would yield zero net benefits?" In addition to threshold analysis you should indicate, where possible, which non-quantified effects are most important and why.

Key Elements of a Regulatory Analysis

A good regulatory analysis should include the following three basic elements: (1) a statement of the need for the proposed action, (2) an examination of alternative approaches, and (3) an evaluation of the benefits and costs--quantitative and qualitative--of the proposed action and the main alternatives identified by the analysis.

To evaluate properly the benefits and costs of regulations and their alternatives, you will need to do the following:

- Explain how the actions required by the rule are linked to the expected benefits. For example, indicate how additional safety equipment will reduce safety risks. A similar analysis should be done for each of the alternatives.
- Identify a baseline. Benefits and costs are defined in comparison with a clearly stated alternative. This normally will be a "no action" baseline: what the world will be like if the proposed rule is not adopted. Comparisons to a "next best" alternative are also especially useful.
- Identify the expected undesirable side-effects and ancillary benefits of the proposed regulatory action and the alternatives. These should be added to the direct benefits and costs as appropriate.

With this information, you should be able to assess quantitatively the benefits and costs of the proposed rule and its alternatives. A complete regulatory analysis includes a discussion of non-quantified as well as quantified benefits and costs. A non-quantified outcome is a benefit or cost that has not been quantified or monetized in the analysis. When there are important non-monetary values at stake, you should also identify them in your analysis so policymakers can compare them with the monetary benefits and costs. When your analysis is complete, you should present a summary of the benefit and cost estimates for each alternative, including the qualitative and non-monetized factors affected by the rule, so that readers can evaluate them.

As you design, execute, and write your regulatory analysis, you should seek out the opinions of those who will be affected by the regulation as well as the views of those individuals and organizations who may not be affected but have special knowledge or insight into the regulatory issues. Consultation can be useful in ensuring that your analysis addresses all of the relevant issues and that you have access to all pertinent data. Early consultation can be especially helpful. You should not limit consultation to the final stages of your analytical efforts.

You will find that you cannot conduct a good regulatory analysis according to a formula. Conducting high-quality analysis requires competent professional judgment. Different regulations may call for different emphases in the analysis, depending on the nature and complexity of the regulatory issues and the sensitivity of the benefit and cost estimates to the

key assumptions.

A good analysis is transparent. It should be possible for a qualified third party reading the report to see clearly how you arrived at your estimates and conclusions. For transparency's sake, you should state in your report what assumptions were used, such as the time horizon for the analysis and the discount rates applied to future benefits and costs. It is usually necessary to provide a sensitivity analysis to reveal whether, and to what extent, the results of the analysis are sensitive to plausible changes in the main assumptions and numeric inputs.

A good analysis provides specific references to all sources of data, appendices with documentation of models (where necessary), and the results of formal sensitivity and other uncertainty analyses. Your analysis should also have an executive summary, including a standardized accounting statement.

B. The Need for Federal Regulatory Action

Before recommending Federal regulatory action, an agency must demonstrate that the proposed action is necessary. If the regulatory intervention results from a statutory or judicial directive, you should describe the specific authority for your action, the extent of discretion available to you, and the regulatory instruments you might use. Executive Order 12866 states that “Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well being of the American people ... .”

Executive Order 12866 also states that “Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.” Thus, you should try to explain whether the action is intended to address a significant market failure or to meet some other compelling public need such as improving governmental processes or promoting intangible values such as distributional fairness or privacy. If the regulation is designed to correct a significant market failure, you should describe the failure both qualitatively and (where feasible) quantitatively. You should show that a government intervention is likely to do more good than harm. For other interventions, you should also provide a demonstration of compelling social purpose and the likelihood of effective action. Although intangible rationales do not need to be quantified, the analysis should present and evaluate the strengths and limitations of the relevant arguments for these intangible values.

Market Failure or Other Social Purpose

The major types of market failure include: externality, market power, and inadequate or asymmetric information. Correcting market failures is a reason for regulation, but it is not the only reason. Other possible justifications include improving the functioning of government, removing distributional unfairness, or promoting privacy and personal freedom.

1. Externality, common property resource and public good

An externality occurs when one party's actions impose uncompensated benefits or costs on another party. Environmental problems are a classic case of externality. For example, the smoke from a factory may adversely affect the health of local residents while soiling the property in nearby neighborhoods. If bargaining were costless and all property rights were well defined, people would eliminate externalities through bargaining without the need for government regulation. [FN3] From this perspective, externalities arise from high transactions costs and/or poorly defined property rights that prevent people from reaching efficient outcomes through market transactions.

Resources that may become congested or overused, such as fisheries or the broadcast spectrum, represent common property resources. “Public goods,” such as defense or basic scientific research, are goods where provision of the good to some individuals cannot occur without providing the same level of benefits free of charge to other individuals.

2. Market Power

Firms exercise market power when they reduce output below what would be offered in a competitive industry in order to obtain higher prices. They may exercise market power collectively or unilaterally. Government action can be a source of market power, such as when regulatory actions exclude low-cost imports. Generally, regulations that increase market power for selected entities should be avoided. However, there are some circumstances in which government may choose to validate a monopoly. If a market can be served at lowest cost only when production is limited to a single producer - local gas and electricity distribution services, for example - a natural monopoly is said to exist. In such cases, the government may choose to approve the monopoly and to regulate its prices and/or production decisions. Nevertheless, you should keep in mind that technological advances often affect economies of scale. This can, in turn, transform what was once considered a natural monopoly into a market where competition can flourish.

3. Inadequate or Asymmetric Information

Market failures may also result from inadequate or asymmetric information. Because information, like other goods, is costly to produce and disseminate, your evaluation will need to do more than demonstrate the possible existence of incomplete or asymmetric information. Even though the market may supply less than the full amount of information, the amount it does supply may be reasonably adequate and therefore not require government regulation. Sellers have an incentive to provide information through advertising that can increase sales by highlighting distinctive characteristics of their products. Buyers may also obtain reasonably adequate information about product characteristics through other channels, such as a seller offering a warranty or a third party providing information.

Even when adequate information is available, people can make mistakes by processing it poorly. Poor information-processing often occurs in cases of low probability, high-consequence events, but it is not limited to such situations. For instance, people sometimes rely on mental rules-of-thumb that produce errors. If they have a clear mental image of an incident which makes it cognitively “available,” they might overstate the probability that it will occur. Individuals sometimes process information in a biased manner, by being too optimistic or pessimistic, without taking sufficient account of the fact that the outcome is exceedingly unlikely to occur. When mistakes in information processing occur, markets may overreact. When it is time-consuming or costly for consumers to evaluate complex information about products or services (e.g., medical therapies), they may expect government to ensure that minimum quality standards are met. However, the mere possibility of poor information processing is not enough to justify regulation. If you think there is a problem of information processing that needs to be addressed, it should be carefully documented.

4. Other Social Purposes

There are justifications for regulations in addition to correcting market failures. A regulation may be appropriate when you have a clearly identified measure that can make government operate more efficiently. In addition, Congress establishes some regulatory programs to redistribute resources to select groups. Such regulations should be examined to ensure that they are both effective and cost-effective. Congress also authorizes some regulations to prohibit discrimination that conflicts with generally accepted norms within our society. Rulemaking may also be appropriate to protect privacy, permit more personal freedom or promote other democratic aspirations.

Showing That Regulation at the Federal Level Is the Best Way to Solve the Problem

Even where a market failure clearly exists, you should consider other means of dealing with the failure before turning to Federal regulation. Alternatives to Federal regulation include antitrust enforcement, consumer-initiated litigation in the product liability system, or administrative compensation systems.

In assessing whether Federal regulation is the best solution, you should also consider the possibility of regulation at the State or local level. In some cases, the nature of the market failure may itself suggest the most appropriate governmental

level of regulation. For example, problems that spill across State lines (such as acid rain whose precursors are transported widely in the atmosphere) are probably best addressed by Federal regulation. More localized problems, including those that are common to many areas, may be more efficiently addressed locally.

The advantages of leaving regulatory issues to State and local authorities can be substantial. If public values and preferences differ by region, those differences can be reflected in varying State and local regulatory policies. Moreover, States and localities can serve as a testing ground for experimentation with alternative regulatory policies. One State can learn from another's experience while local jurisdictions may compete with each other to establish the best regulatory policies. You should examine the proper extent of State and local discretion in your rulemaking context.

A diversity of rules may generate gains for the public as governmental units compete with each other to serve the public, but duplicative regulations can also be costly. Where Federal regulation is clearly appropriate to address interstate commerce issues, you should try to examine whether it would be more efficient to retain or reduce State and local regulation. The local benefits of State regulation may not justify the national costs of a fragmented regulatory system. For example, the increased compliance costs for firms to meet different State and local regulations may exceed any advantages associated with the diversity of State and local regulation. Your analysis should consider the possibility of reducing as well as expanding State and local rulemaking.

The role of Federal regulation in facilitating U.S. participation in global markets should also be considered. Harmonization of U.S. and international rules may require a strong Federal regulatory role. Concerns that new U.S. rules could act as non-tariff barriers to imported goods should be evaluated carefully.

The Presumption Against Economic Regulation

Government actions can be unintentionally harmful, and even useful regulations can impede market efficiency. For this reason, there is a presumption against certain types of regulatory action. In light of both economic theory and actual experience, a particularly demanding burden of proof is required to demonstrate the need for any of the following types of regulations:

- price controls in competitive markets;
- production or sales quotas in competitive markets;
- mandatory uniform quality standards for goods or services if the potential problem can be adequately dealt with through voluntary standards or by disclosing information of the hazard to buyers or users; or
- controls on entry into employment or production, except (a) where indispensable to protect health and safety (e.g., FAA tests for commercial pilots) or (b) to manage the use of common property resources (e.g., fisheries, airwaves, Federal lands, and offshore areas).

C. Alternative Regulatory Approaches

Once you have determined that Federal regulatory action is appropriate, you will need to consider alternative regulatory approaches. Ordinarily, you will be able to eliminate some alternatives through a preliminary analysis, leaving a manageable number of alternatives to be evaluated according to the formal principles of the Executive Order. The number and choice of alternatives selected for detailed analysis is a matter of judgment. There must be some balance between thoroughness and the practical limits on your analytical capacity. With this qualification in mind, you should nevertheless explore modifications of some or all of a regulation's attributes or provisions to identify appropriate alternatives. The following is a list of alternative regulatory actions that you should consider.

Different Choices Defined by Statute

When a statute establishes a specific regulatory requirement and the agency is considering a more stringent standard, you

should examine the benefits and costs of reasonable alternatives that reflect the range of the agency's statutory discretion, including the specific statutory requirement.

Different Compliance Dates

The timing of a regulation may also have an important effect on its net benefits. Benefits may vary significantly with different compliance dates where a delay in implementation may result in a substantial loss in future benefits (e.g., a delay in implementation could result in a significant reduction in spawning stock and jeopardize a fishery). Similarly, the cost of a regulation may vary substantially with different compliance dates for an industry that requires a year or more to plan its production runs. In this instance, a regulation that provides sufficient lead time is likely to achieve its goals at a much lower overall cost than a regulation that is effective immediately.

Different Enforcement Methods

Compliance alternatives for Federal, State, or local enforcement include on-site inspections, periodic reporting, and non-compliance penalties structured to provide the most appropriate incentives. When alternative monitoring and reporting methods vary in their benefits and costs, you should identify the most appropriate enforcement framework. For example, in some circumstances random monitoring or parametric monitoring will be less expensive and nearly as effective as continuous monitoring.

Different Degrees of Stringency

In general, both the benefits and costs associated with a regulation will increase with the level of stringency (although marginal costs generally increase with stringency, whereas marginal benefits may decrease). You should study alternative levels of stringency to understand more fully the relationship between stringency and the size and distribution of benefits and costs among different groups.

Different Requirements for Different Sized Firms

You should consider setting different requirements for large and small firms, basing the requirements on estimated differences in the expected costs of compliance or in the expected benefits. The balance of benefits and costs can shift depending on the size of the firms being regulated. Small firms may find it more costly to comply with regulation, especially if there are large fixed costs required for regulatory compliance. On the other hand, it is not efficient to place a heavier burden on one segment of a regulated industry solely because it can better afford the higher cost. This has the potential to load costs on the most productive firms, costs that are disproportionate to the damages they create. You should also remember that a rule with a significant impact on a substantial number of small entities will trigger the requirements set forth in the Regulatory Flexibility Act. (5 U.S.C. 603(c), 604).

Different Requirements for Different Geographic Regions

Rarely do all regions of the country benefit uniformly from government regulation. It is also unlikely that costs will be uniformly distributed across the country. Where there are significant regional variations in benefits and/or costs, you should consider the possibility of setting different requirements for the different regions.

Performance Standards Rather than Design Standards

Performance standards express requirements in terms of outcomes rather than specifying the means to those ends. They are generally superior to engineering or design standards because performance standards give the regulated parties the flexibility to achieve regulatory objectives in the most cost-effective way. In general, you should take into account both the cost savings to the regulated parties of the greater flexibility and the costs of assuring compliance through monitoring or some other means.

Market-Oriented Approaches Rather than Direct Controls

Market-oriented approaches that use economic incentives should be explored. These alternatives include fees, penalties, subsidies, marketable permits or offsets, changes in liability or property rights (including policies that alter the incentives of insurers and insured parties), and required bonds, insurance or warranties. One example of a market-oriented approach is a program that allows for averaging, banking, and/or trading (ABT) of credits for achieving additional emission reductions beyond the required air emission standards. ABT programs can be extremely valuable in reducing costs or achieving earlier or greater benefits, particularly when the costs of achieving compliance vary across production lines, facilities, or firms. ABT can be allowed on a plant-wide, firm-wide, or region-wide basis rather than vent by vent, provided this does not produce unacceptable local air quality outcomes (such as “hot spots” from local pollution concentration).

Informational Measures Rather than Regulation

If intervention is contemplated to address a market failure that arises from inadequate or asymmetric information, informational remedies will often be preferred. Measures to improve the availability of information include government establishment of a standardized testing and rating system (the use of which could be mandatory or voluntary), mandatory disclosure requirements (e.g., by advertising, labeling, or enclosures), and government provision of information (e.g., by government publications, telephone hotlines, or public interest broadcast announcements). A regulatory measure to improve the availability of information, particularly about the concealed characteristics of products, provides consumers a greater choice than a mandatory product standard or ban.

Specific informational measures should be evaluated in terms of their benefits and costs. Some effects of informational measures are easily overlooked. The costs of a mandatory disclosure requirement for a consumer product will include not only the cost of gathering and communicating the required information, but also the loss of net benefits of any information displaced by the mandated information. The other costs also may include the effect of providing information that is ignored or misinterpreted, and inefficiencies arising from the incentive that mandatory disclosure may give to overinvest in a particular characteristic of a product or service.

Where information on the benefits and costs of alternative informational measures is insufficient to provide a clear choice between them, you should consider the least intrusive informational alternative sufficient to accomplish the regulatory objective. To correct an informational market failure it may be sufficient for government to establish a standardized testing and rating system without mandating its use, because competing firms that score well according to the system should thereby have an incentive to publicize the fact.

D. Analytical Approaches

Both benefit-cost analysis (BCA) and cost-effectiveness analysis (CEA) provide a systematic framework for identifying and evaluating the likely outcomes of alternative regulatory choices. A major rulemaking should be supported by both types of analysis wherever possible. Specifically, you should prepare a CEA for all major rulemakings for which the primary benefits are improved public health and safety to the extent that a valid effectiveness measure can be developed to represent expected health and safety outcomes. You should also perform a BCA for major health and safety rulemakings to the extent that valid monetary values can be assigned to the primary expected health and safety outcomes. In undertaking these analyses, it is important to keep in mind the larger objective of analytical consistency in estimating benefits and costs across regulations and agencies, subject to statutory limitations. Failure to maintain such consistency may prevent achievement of the most risk reduction for a given level of resource expenditure. For all other major rulemakings, you should carry out a BCA. If some of the primary benefit categories cannot be expressed in monetary units, you should also conduct a CEA. In unusual cases where no quantified information on benefits, costs and effectiveness can be produced, the regulatory analysis should present a qualitative discussion of the issues and evidence.

Benefit-Cost Analysis

A distinctive feature of BCA is that both benefits and costs are expressed in monetary units, which allows you to evaluate different regulatory options with a variety of attributes using a common measure. [FN4] By measuring incremental benefits and costs of successively more stringent regulatory alternatives, you can identify the alternative that maximizes net benefits.

The size of net benefits, the absolute difference between the projected benefits and costs, indicates whether one policy is more efficient than another. The ratio of benefits to costs is not a meaningful indicator of net benefits and should not be used for that purpose. It is well known that considering such ratios alone can yield misleading results.

Even when a benefit or cost cannot be expressed in monetary units, you should still try to measure it in terms of its physical units. If it is not possible to measure the physical units, you should still describe the benefit or cost qualitatively. For more information on describing qualitative information, see the section "*Developing Benefit and Cost Estimates*."

When important benefits and costs cannot be expressed in monetary units, BCA is less useful, and it can even be misleading, because the calculation of net benefits in such cases does not provide a full evaluation of all relevant benefits and costs.

You should exercise professional judgment in identifying the importance of non-quantified factors and assess as best you can how they might change the ranking of alternatives based on estimated net benefits. If the non-quantified benefits and costs are likely to be important, you should recommend which of the non-quantified factors are of sufficient importance to justify consideration in the regulatory decision. This discussion should also include a clear explanation that support designating these non-quantified factors as important. In this case, you should also consider conducting a threshold analysis to help decision makers and other users of the analysis to understand the potential significance of these factors to the overall analysis.

Cost-Effectiveness Analysis[FN5]

Cost-effectiveness analysis can provide a rigorous way to identify options that achieve the most effective use of the resources available without requiring monetization of all of relevant benefits or costs. Generally, cost-effectiveness analysis is designed to compare a set of regulatory actions with the same primary outcome (e.g., an increase in the acres of wetlands protected) or multiple outcomes that can be integrated into a single numerical index (e.g., units of health improvement).

Cost-effectiveness results based on averages need to be treated with great care. They suffer from the same drawbacks as benefit-cost ratios. The alternative that exhibits the smallest cost-effectiveness ratio may not be the best option, just as the alternative with the highest benefit-cost ratio is not always the one that maximizes net benefits. Incremental cost-effectiveness analysis (discussed below) can help to avoid mistakes that can occur when policy choices are based on average cost-effectiveness.

CEA can also be misleading when the "effectiveness" measure does not appropriately weight the consequences of the alternatives. For example, when effectiveness is measured in tons of reduced pollutant emissions, cost-effectiveness estimates will be misleading unless the reduced emissions of diverse pollutants result in the same health and environmental benefits.

When you have identified a range of alternatives (e.g., different levels of stringency), you should determine the cost-effectiveness of each option compared with the baseline as well as its incremental cost-effectiveness compared with successively more stringent requirements. Ideally, your CEA would present an array of cost-effectiveness estimates that would allow comparison across different alternatives. However, analyzing all possible combinations is not practical

when there are many options (including possible interaction effects). In these cases, you should use your judgment to choose reasonable alternatives for careful consideration.

When constructing and comparing incremental cost-effectiveness ratios, you should be careful to determine whether the various alternatives are mutually exclusive or whether they can be combined. If they can be combined, you should consider which might be favored under different regulatory budget constraints (implicit or explicit). You should also make sure that inferior alternatives identified by the principles of strong and weak dominance are eliminated from consideration. [FN6]

The value of CEA is enhanced when there is consistency in the analysis across a diverse set of possible regulatory actions. To achieve consistency, you need to carefully construct the two key components of any CEA: the cost and the "effectiveness" or performance measures for the alternative policy options.

With regard to measuring costs, you should be sure to include all the relevant costs to society - whether public or private. Rulemakings may also yield cost savings (e.g., energy savings associated with new technologies). The numerator in the cost-effectiveness ratio should reflect net costs, defined as the gross cost incurred to comply with the requirements (sometimes called "total" costs) minus any cost savings. You should be careful to avoid double-counting effects in both the numerator and the denominator of the cost-effectiveness ratios. For example, it would be incorrect to reduce gross costs by an estimated monetary value on life extension if life-years are already used as the effectiveness measure in the denominator.

In constructing measures of "effectiveness", final outcomes, such as lives saved or life-years saved, are preferred to measures of intermediate outputs, such as tons of pollution reduced, crashes avoided, or cases of disease avoided. Where the quality of the measured unit varies (e.g., acres of wetlands vary substantially in terms of their ecological benefits), it is important that the measure capture the variability in the value of the selected "outcome" measure. You should provide an explanation of your choice of effectiveness measure.

Where regulation may yield several different beneficial outcomes, a cost-effectiveness comparison becomes more difficult to interpret because there is more than one measure of effectiveness to incorporate in the analysis. To arrive at a single measure you will need to weight the value of disparate benefit categories, but this computation raises some of the same difficulties you will encounter in BCA. If you can assign a reasonable monetary value to all of the regulation's different benefits, then you should do so. But in this case, you will be doing BCA, not CEA.

When you can estimate the monetary value of some but not all of the ancillary benefits of a regulation, but cannot assign a monetary value to the primary measure of effectiveness, you should subtract the monetary estimate of the ancillary benefits from the gross cost estimate to yield an estimated net cost. (This net cost estimate for the rule may turn out to be negative - that is, the monetized benefits exceed the cost of the rule.) If you are unable to estimate the value of some of the ancillary benefits, the cost-effectiveness ratio will be overstated, and this should be acknowledged in your analysis. CEA does not yield an unambiguous choice when there are benefits or costs that have not been incorporated in the net-cost estimates. You also may use CEA to compare regulatory alternatives in cases where the statute specifies the level of benefits to be achieved.

The Effectiveness Metric for Public Health and Safety Rulemakings

When CEA is applied to public health and safety rulemakings, one or more measures of effectiveness must be selected that permits comparison of regulatory alternatives. Agencies currently use a variety of effectiveness measures.

There are relatively simple measures such as the number of lives saved, cases of cancer reduced, and cases of paraplegia

prevented. Sometimes these measures account only for mortality information, such as the number of lives saved and the number of years of life saved. There are also more comprehensive, integrated measures of effectiveness such as the number of “equivalent lives” (ELs) saved and the number of “quality-adjusted life years” (QALYs) saved.

The main advantage of the integrated measures of effectiveness is that they account for a rule's impact on morbidity (nonfatal illness, injury, impairment and quality of life) as well as premature death. The inclusion of morbidity effects is important because (a) some illnesses (e.g., asthma) cause more instances of pain and suffering than they do premature death, (b) some population groups are known to experience elevated rates of morbidity (e.g, the elderly and the poor) and thus have a strong interest in morbidity measurement [FN7] , and (c) some regulatory alternatives may be more effective at preventing morbidity than premature death (e.g., some advanced airbag designs may diminish the nonfatal injuries caused by airbag inflation without changing the frequency of fatal injury prevented by airbags).

However, the main drawback of these integrated measures is that they must meet some restrictive assumptions to represent a valid measure of individual preferences. [FN8] For example, a QALY measure implicitly assumes that the fraction of remaining lifespan an individual would give up for an improvement in health-related quality of life does not depend on the remaining lifespan. Thus, if an individual is willing to give up 10 years of life among 50 remaining years for a given health improvement, he or she would also be willing to give up 1 year of life among 5 remaining years. To the extent that individual preferences deviate from these assumptions, analytic results from CEA using QALYs could differ from analytic results based on willingness-to-pay-measures. [FN9] Though willingness to pay is generally the preferred economic method for evaluating preferences, the CEA method, as applied in medicine and health, does not evaluate health changes using individual willingness to pay. When performing CEA, you should consider using at least one integrated measure of effectiveness when a rule creates a significant impact on both mortality and morbidity.

When CEA is performed in specific rulemaking contexts, you should be prepared to make appropriate adjustments to ensure fair treatment of all segments of the population. Fairness is important in the choice and execution of effectiveness measures. For example, if QALYs are used to evaluate a lifesaving rule aimed at a population that happens to experience a high rate of disability (i.e., where the rule is not designed to affect the disability), the number of life years saved should not necessarily be diminished simply because the rule saves the lives of people with life-shortening disabilities. Both analytic simplicity and fairness suggest that the estimated number of life years saved for the disabled population should be based on average life expectancy information for the relevant age cohorts. More generally, when numeric adjustments are made for life expectancy or quality of life, analysts should prefer use of population averages rather than information derived from subgroups dominated by a particular demographic or income group.

OMB does not require agencies to use any specific measure of effectiveness. In fact, OMB encourages agencies to report results with multiple measures of effectiveness that offer different insights and perspectives. The regulatory analysis should explain which measures were selected and why, and how they were implemented.

The analytic discretion provided in choice of effectiveness measure will create some inconsistency in how agencies evaluate the same injuries and diseases, and it will be difficult for OMB and the public to draw meaningful comparisons between rulemakings that employ different effectiveness measures. As a result, agencies should use their web site to provide OMB and the public with the underlying data, including mortality and morbidity data, the age distribution of the affected populations, and the severity and duration of disease conditions and trauma, so that OMB and the public can construct apples-to-apples comparisons between rulemakings that employ different measures.

There are sensitive technical and ethical issues associated with choosing one or more of these integrated measures for use throughout the Federal government. The Institute of Medicine (IOM) may assemble a panel of specialists in cost-

effectiveness analysis and bioethics to evaluate the advantages and disadvantages of these different measures and other measures that have been suggested in the academic literature. OMB believes that the IOM guidance will provide Federal agencies and OMB useful insight into how to improve the measurement of effectiveness of public health and safety regulations.

Distributional Effects

Those who bear the costs of a regulation and those who enjoy its benefits often are not the same people. The term "distributional effect" refers to the impact of a regulatory action across the population and economy, divided up in various ways (e.g., income groups, race, sex, industrial sector, geography). Benefits and costs of a regulation may also be distributed unevenly over time, perhaps spanning several generations. Distributional effects may arise through "transfer payments" that stem from a regulatory action as well. For example, the revenue collected through a fee, surcharge in excess of the cost of services provided, or tax is a transfer payment.

Your regulatory analysis should provide a separate description of distributional effects (i.e., how both benefits and costs are distributed among sub-populations of particular concern) so that decision makers can properly consider them along with the effects on economic efficiency. Executive Order 12866 authorizes this approach. Where distributive effects are thought to be important, the effects of various regulatory alternatives should be described quantitatively to the extent possible, including the magnitude, likelihood, and severity of impacts on particular groups. You should be alert for situations in which regulatory alternatives result in significant changes in treatment or outcomes for different groups. Effects on the distribution of income that are transmitted through changes in market prices can be important, albeit sometimes difficult to assess. Your analysis should also present information on the streams of benefits and costs over time in order to provide a basis for assessing intertemporal distributional consequences, particularly where intergenerational effects are concerned.

E. Identifying and Measuring Benefits and Costs

This Section provides guidelines for your preparation of the benefit and cost estimates required by Executive Order 12866 and the "Regulatory Right-to-Know Act." The discussions in previous sections will help you identify a workable number of alternatives for consideration in your analysis and an appropriate analytical approach to use.

General Issues

1. Scope of Analysis

Your analysis should focus on benefits and costs that accrue to citizens and residents of the United States. Where you choose to evaluate a regulation that is likely to have effects beyond the borders of the United States, these effects should be reported separately. The time frame for your analysis should cover a period long enough to encompass all the important benefits and costs likely to result from the rule.

2. Developing a Baseline

You need to measure the benefits and costs of a rule against a baseline. This baseline should be the best assessment of the way the world would look absent the proposed action. The choice of an appropriate baseline may require consideration of a wide range of potential factors, including:

- evolution of the market,
- changes in external factors affecting expected benefits and costs,
- changes in regulations promulgated by the agency or other government entities, and
- the degree of compliance by regulated entities with other regulations.

It may be reasonable to forecast that the world absent the regulation will resemble the present. If this is the case,

however, your baseline should reflect the future effect of current government programs and policies. For review of an existing regulation, a baseline assuming “no change” in the regulatory program generally provides an appropriate basis for evaluating regulatory alternatives. When more than one baseline is reasonable and the choice of baseline will significantly affect estimated benefits and costs, you should consider measuring benefits and costs against alternative baselines. In doing so you can analyze the effects on benefits and costs of making different assumptions about other agencies' regulations, or the degree of compliance with your own existing rules. In all cases, you must evaluate benefits and costs against the same baseline. You should also discuss the reasonableness of the baselines used in the sensitivity analyses. For each baseline you use, you should identify the key uncertainties in your forecast.

EPA's 1998 final PCB disposal rule provides a good example of using different baselines. EPA used several alternative baselines, each reflecting a different interpretation of existing regulatory requirements. In particular, one baseline reflected a literal interpretation of EPA's 1979 rule and another the actual implementation of that rule in the year immediately preceding the 1998 revision. The use of multiple baselines illustrated the substantial effect changes in EPA's implementation policy could have on the cost of a regulatory program. In the years after EPA adopted the 1979 PCB disposal rule, changes in EPA policy -- especially allowing the disposal of automobile “shredder fluff” in municipal landfills -- reduced the cost of the program by more than $500 million per year.

In some cases, substantial portions of a rule may simply restate statutory requirements that would be self-implementing, even in the absence of the regulatory action. In these cases, you should use a pre-statute baseline. If you are able to separate out those areas where the agency has discretion, you may also use a post-statute baseline to evaluate the discretionary elements of the action.

3. Evaluation of Alternatives

You should describe the alternatives available to you and the reasons for choosing one alternative over another. As noted previously, alternatives that rely on incentives and offer increased flexibility are often more cost-effective than more prescriptive approaches. For instance, user fees and information dissemination may be good alternatives to direct command-and-control regulation. Within a command-and-control regulatory program, performance-based standards generally offer advantages over standards specifying design, behavior, or manner of compliance.

You should carefully consider all appropriate alternatives for the key attributes or provisions of the rule. The previous discussion outlines examples of appropriate alternatives. Where there is a “continuum” of alternatives for a standard (such as the level of stringency), you generally should analyze at least three options: the preferred option; a more stringent option that achieves additional benefits (and presumably costs more) beyond those realized by the preferred option; and a less stringent option that costs less (and presumably generates fewer benefits) than the preferred option.

You should choose reasonable alternatives deserving careful consideration. In some cases, a regulatory program will focus on an option that is near or at the limit of technical feasibility. In this case, the analysis would not need to examine a more stringent option. For each of the options analyzed, you should compare the anticipated benefits to the corresponding costs.

It is not adequate simply to report a comparison of the agency's preferred option to the chosen baseline. Whenever you report the benefits and costs of alternative options, you should present both total and incremental benefits and costs. You should present incremental benefits and costs as differences from the corresponding estimates associated with the next less-stringent alternative. [FN10] It is important to emphasize that incremental effects are simply differences between successively more stringent alternatives. Results involving a comparison to a “next best” alternative may be especially useful.

In some cases, you may decide to analyze a wide array of options. In 1998, DOE analyzed a large number of options in setting new energy efficiency standards for refrigerators and freezers and produced a rich amount of information on their relative effects. This analysis -- examining more than 20 alternative performance standards for one class of refrigerators with top-mounted freezers -- enabled DOE to select an option that produced $200 more in estimated net benefits per refrigerator than the least attractive option.

You should analyze the benefits and costs of different regulatory provisions separately when a rule includes a number of distinct provisions. If the existence of one provision affects the benefits or costs arising from another provision, the analysis becomes more complicated, but the need to examine provisions separately remains. In this case, you should evaluate each specific provision by determining the net benefits of the proposed regulation with and without it.

Analyzing all possible combinations of provisions is impractical if the number is large and interaction effects are widespread. You need to use judgment to select the most significant or relevant provisions for such analysis. You are expected to document all of the alternatives that were considered in a list or table and which were selected for emphasis in the main analysis.

You should also discuss the statutory requirements that affect the selection of regulatory approaches. If legal constraints prevent the selection of a regulatory action that best satisfies the philosophy and principles of Executive Order 12866, you should identify these constraints and estimate their opportunity cost. Such information may be useful to Congress under the Regulatory Right-to-Know Act.

4. Transparency and Reproducibility of Results

Because of its influential nature and its special role in the rulemaking process, it is appropriate to set minimum quality standards for regulatory analysis. You should provide documentation that the analysis is based on the best reasonably obtainable scientific, technical, and economic information available. To achieve this, you should rely on peer-reviewed literature, where available, and provide the source for all original information.

A good analysis should be transparent and your results must be reproducible. You should clearly set out the basic assumptions, methods, and data underlying the analysis and discuss the uncertainties associated with the estimates. A qualified third party reading the analysis should be able to understand the basic elements of your analysis and the way in which you developed your estimates.

To provide greater access to your analysis, you should generally post it, with all the supporting documents, on the internet so the public can review the findings. You should also disclose the use of outside consultants, their qualifications, and history of contracts and employment with the agency (e.g., in a preface to the RIA). Where other compelling interests (such as privacy, intellectual property, trade secrets, etc.) prevent the public release of data or key elements of the analysis, you should apply especially rigorous robustness checks to analytic results and document the analytical checks used.

Finally, you should assure compliance with the Information Quality Guidelines for your agency and OMB's “Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies” (“data quality guidelines”) http:// www.whitehouse.gov/omb/fedreg/reproducible.html.

Developing Benefit and Cost Estimates

1. Some General Considerations

The analysis document should discuss the expected benefits and costs of the selected regulatory option and any reason-

able alternatives. How is the proposed action expected to provide the anticipated benefits and costs? What are the monetized values of the potential real incremental benefits and costs to society? To present your results, you should:

- include separate schedules of the monetized benefits and costs that show the type and timing of benefits and costs, and express the estimates in this table in constant, undiscounted dollars (for more on discounting see "Discount Rates" below);
- list the benefits and costs you can quantify, but cannot monetize, including their timing;
- describe benefits and costs you cannot quantify; and
- identify or cross-reference the data or studies on which you base the benefit and cost estimates.

When benefit and cost estimates are uncertain (for more on this see "*Treatment of Uncertainty*" below), you should report benefit and cost estimates (including benefits of risk reductions) that reflect the full probability distribution of potential consequences. Where possible, present probability distributions of benefits and costs and include the upper and lower bound estimates as complements to central tendency and other estimates.

If fundamental scientific disagreement or lack of knowledge prevents construction of a scientifically defensible probability distribution, you should describe benefits or costs under plausible scenarios and characterize the evidence and assumptions underlying each alternative scenario.

2. The Key Concepts Needed to Estimate Benefits and Costs

"Opportunity cost" is the appropriate concept for valuing both benefits and costs. The principle of "willingness-to-pay" (WTP) captures the notion of opportunity cost by measuring what individuals are willing to forgo to enjoy a particular benefit. In general, economists tend to view WTP as the most appropriate measure of opportunity cost, but an individual's "willingness-to-accept" (WTA) compensation for not receiving the improvement can also provide a valid measure of opportunity cost.

WTP and WTA are comparable measures under special circumstances. WTP and WTA measures may be comparable in the following situations: if a regulation affects a price change rather than a quantity change; the change being evaluated is small; there are reasonably close substitutes available; and the income effect is small. [FN11] However, empirical evidence from experimental economics and psychology shows that even when income/wealth effects are "small", the measured differences between WTP and WTA can be large. [FN12] WTP is generally considered to be more readily measurable. Adoption of WTP as the measure of value implies that individual preferences of the affected population should be a guiding factor in the regulatory analysis.

Market prices provide rich data for estimating benefits and costs based on willingness-to-pay if the goods and services affected by the regulation are traded in well-functioning competitive markets. The opportunity cost of an alternative includes the value of the benefits forgone as a result of choosing that alternative. The opportunity cost of banning a product -- a drug, food additive, or hazardous chemical -- is the forgone net benefit (i.e., lost consumer and producer surplus [FN13]) of that product, taking into account the mitigating effects of potential substitutes.

The use of any resource has an opportunity cost regardless of whether the resource is already owned or has to be purchased. That opportunity cost is equal to the net benefit the resource would have provided in the absence of the requirement. For example, if regulation of an industrial plant affects the use of additional land or buildings within the existing plant boundary, the cost analysis should include the opportunity cost of using the additional land or facilities.

To the extent possible, you should monetize any such forgone benefits and add them to the other costs of that alternative. You should also try to monetize any cost savings as a result of an alternative and either add it to the benefits or subtract it from the costs of that alternative. However, you should not assume that the "avoided" costs of not doing another regulat-

ory alternative represent the benefits of a regulatory action where there is no direct, necessary relationship between the two. You should also be careful when the costs avoided are attributable to an existing regulation. Even when there is a direct relationship between the two regulatory actions, the use of avoided costs is problematic because the existing regulation may not maximize net benefits and thus may itself be questionable policy. (See the section, “Direct Use of Market Data,” for more detail.)

Estimating benefits and costs when market prices are hard to measure or markets do not exist is more difficult. In these cases, you need to develop appropriate proxies that simulate market exchange. Estimates of willingness-to-pay based on revealed preference methods can be quite useful. As one example, analysts sometimes use “hedonic price equations” based on multiple regression analysis of market behavior to simulate market prices for the commodity of interest. The hedonic technique allows analysts to develop an estimate of the price for specific attributes associated with a product. For instance, a house is a product characterized by a variety of attributes including the number of rooms, total floor area, and type of heating and cooling. If there are enough data on transactions in the housing market, it is possible to develop an estimate of the implicit price for specific attributes, such as the implicit price of an additional bathroom or for central air conditioning. This technique can be extended, as well, to develop an estimate for the implicit price of public goods that are not directly traded in markets. An analyst can develop implicit price estimates for public goods like air quality and access to public parks by assessing the effects of these goods on the housing market. Going through the analytical process of deriving benefit estimates by simulating markets may also suggest alternative regulatory strategies that create such markets.

You need to guard against double-counting, since some attributes are embedded in other broader measures. To illustrate, when a regulation improves the quality of the environment in a community, the value of real estate in the community generally rises to reflect the greater attractiveness of living in a better environment. Simply adding the increase in property values to the estimated value of improved public health would be double counting if the increase in property values reflects the improvement in public health. To avoid this problem you should separate the embedded effects on the value of property arising from improved public health. At the same time, an analysis that fails to incorporate the consequence of land use changes when accounting for costs will not capture the full effects of regulation.

3. Revealed Preference Methods

Revealed preference methods develop estimates of the value of goods and services -- or attributes of those goods and services -- based on actual market decisions by consumers, workers and other market participants. If the market participant is well informed and confronted with a real choice, it may be feasible to determine accurately and precisely the monetary value needed for a rulemaking. There is a large and well-developed literature on revealed preference in the peer-reviewed, applied economics literature.

Although these methods are well grounded in economic theory, they are sometimes difficult to implement given the complexity of market transactions and the paucity of relevant data. When designing or evaluating a revealed preference study, the following principles should be considered:

- the market should be competitive. If the market isn't competitive (e.g., monopoly, oligopoly), then you should consider making adjustments such that the price reflects the true value to society (often called the “shadow price”);
- the market should not exhibit a significant information gap or asymmetric information problem. If the market suffers from information problems, then you should discuss the divergence of the price from the underlying shadow price and consider possible adjustments to reflect the underlying shadow price;
- the market should not exhibit an externality. In this case, you should discuss the divergence of the price from the underlying shadow price and consider possible adjustments to reflect the underlying shadow price;
- the specific market participants being studied should be representative of the target populations to be affected by

the rulemaking under consideration;

- a valid research design and framework for analysis should be adopted. Examples include using data and/or model specifications that include the markets for substitute and complementary goods and services and using reasonably unrestricted functional forms. When specifying substitute and complementary goods, the analysis should preferably be based on data about the range of alternatives perceived by market participants. If such data are not available, you should adopt plausible assumptions and describe the limitations of the analysis.
- the statistical and econometric models employed should be appropriate for the application and the resulting estimates should be robust in response to plausible changes in model specification and estimation technique; and
- the results should be consistent with economic theory.

You should also determine whether there are multiple revealed-preference studies of the same good or service and whether anything can be learned by comparing the methods, data and findings from different studies. Professional judgment is required to determine whether a particular study is of sufficient quality to justify use in regulatory analysis. When studies are used in regulatory analysis despite their technical weaknesses (e.g., due to the absence of other evidence), the regulatory analysis should discuss any biases or uncertainties that are likely to arise due to those weaknesses. If a study has major weaknesses, the study should not be used in regulatory analysis.

a. Direct Uses of Market Data

Economists ordinarily consider market prices as the most accurate measure of the marginal value of goods and services to society. In some instances, however, market prices may not reflect the true value of goods and services due to market imperfections or government intervention. If a regulation involves changes to goods or services where the market price is not a good measure of the value to society, you should use an estimate that reflects the shadow price. Suppose a particular air pollutant damages crops. One of the benefits of controlling that pollutant is the value of the crop yield increase as a result of the controls. That value is typically measured by the price of the crop. However, if the price is held above the market price by a government program that affects supply, a value estimate based on this price may not reflect the true benefits of controlling the pollutant. In this case, you should calculate the value to society of the increase in crop yields by estimating the shadow price, which reflects the value to society of the marginal use of the crop. If the marginal use is for exports, you should use the world price. If the marginal use is to add to very large surplus stockpiles, you should use the value of the last units released from storage minus storage cost. If stockpiles are large and growing, the shadow price may be low or even negative.

Other goods whose market prices may not reflect their true value include those whose production or consumption results in substantial (1) positive or negative external effects or (2) transfer payments. For example, the observed market price of gasoline may not reflect marginal social value due to the inclusion of taxes, other government interventions, and negative externalities (e.g., pollution). This shadow price may also be needed for goods whose market price is substantially affected by existing regulations that do not maximize net benefits.

b. Indirect Uses of Market Data

Many goods or attributes of goods that are affected by regulation--such as preserving environmental or cultural amenities--are not traded directly in markets. The value for these goods or attributes arise both from use and non-use. Estimation of these values is difficult because of the absence of an organized market. However, overlooking or ignoring these values in your regulatory analysis may significantly understate the benefits and/or costs of regulatory action.

“Use values” arise where an individual derives satisfaction from using the resource, either now or in the future. Use values are associated with activities such as swimming, hunting, and hiking where the individual makes use of the natural environment.

"Non-use values" arise where an individual places value on a resource, good or service even though the individual will not use the resource, now or in the future. Non-use value includes bequest and existence values.

General altruism for the health and welfare of others is a closely related concept but may not be strictly considered a "non-use" value. [FN14] A general concern for the welfare of others should supplement benefits and costs equally; hence, it is not necessary to measure the size of general altruism in regulatory analysis. If there is evidence of selective altruism, it needs to be considered specifically in both benefits and costs.

Some goods and services are indirectly traded in markets, which means that their value is reflected in the prices of related goods and services that are directly traded in markets. Their use values are typically estimated through revealed preference methods. Examples include estimates of the values of environmental amenities derived from travel-cost studies, and hedonic price models that measure differences or changes in the value of real estate. It is important that you utilize revealed preference models that adhere to economic criteria that are consistent with utility maximizing behavior. Also, you should take particular care in designing protocols for reliably estimating the values of these attributes.

4. Stated Preference Methods

Stated Preference Methods (SPM) have been developed and used in the peer-reviewed literature to estimate both "use" and "non-use" values of goods and services. They have also been widely used in regulatory analyses by Federal agencies, in part, because these methods can be creatively employed to address a wide variety of goods and services that are not easy to study through revealed preference methods.

The distinguishing feature of these methods is that hypothetical questions about use or non-use values are posed to survey respondents in order to obtain willingness-to-pay estimates relevant to benefit or cost estimation. Some examples of SPM include contingent valuation, conjoint analysis and risk-tradeoff analysis. The surveys used to obtain the health-utility values used in CEA are similar to stated-preference surveys but do not entail monetary measurement of value. Nevertheless, the principles governing quality stated-preference research, with some obvious exceptions involving monetization, are also relevant in designing quality health-utility research.

When you are designing or evaluating a stated-preference study, the following principles should be considered:

- the good or service being evaluated should be explained to the respondent in a clear, complete and objective fashion, and the survey instrument should be pre-tested;
- willingness-to-pay questions should be designed to focus the respondent on the reality of budgetary limitations and alerted to the availability of substitute goods and alternative expenditure options;
- the survey instrument should be designed to probe beyond general attitudes (e.g., a "warm glow" effect for a particular use or non-use value) and focus on the magnitude of the respondent's economic valuation;
- the analytic results should be consistent with economic theory using both "internal" (within respondent) and "external" (between respondent) scope tests such as the willingness to pay is larger (smaller) when more (less) of a good is provided;
- the subjects being interviewed should be selected/sampled in a statistically appropriate manner. The sample frame should adequately cover the target population. The sample should be drawn using probability methods in order to generalize the results to the target population;
- response rates should be as high as reasonably possible. Best survey practices should be followed to achieve high response rates. Low response rates increase the potential for bias and raise concerns about the generalizability of the results. If response rates are not adequate, you should conduct an analysis of non-response bias or further study. Caution should be used in assessing the representativeness of the sample based solely on demographic profiles. Statistical adjustments to reduce non-response bias should be undertaken whenever feasible and appropriate;

- the mode of administration of surveys (in-person, phone, mail, computer, internet or multiple modes) should be appropriate in light of the nature of the questions being posed to respondents and the length and complexity of the instrument;
- documentation should be provided about the target population, the sampling frame used and its coverage of the target population, the design of the sample including any stratification or clustering, the cumulative response rate (including response rate at each stage of selection if applicable); the item non-response rate for critical questions; the exact wording and sequence of questions and other information provided to respondents; and the training of interviewers and techniques they employed (as appropriate);
- the statistical and econometric methods used to analyze the collected data should be transparent, well suited for the analysis, and applied with rigor and care.

Professional judgment is necessary to apply these criteria to one or more studies, and thus there is no mechanical formula that can be used to determine whether a particular study is of sufficient quality to justify use in regulatory analysis. When studies are used despite having weaknesses on one or more of these criteria, those weaknesses should be acknowledged in the regulatory analysis, including any resulting biases or uncertainties that are likely to result. If a study has too many weaknesses with unknown consequences for the quality of the data, the study should not be used.

The challenge in designing quality stated-preference studies is arguably greater for non-use values and unfamiliar use values than for familiar goods or services that are traded (directly or indirectly) in market transactions. The good being valued may have little meaning to respondents, and respondents may be forming their valuations for the first time in response to the questions posed. Since these values are effectively constructed by the respondent during the elicitation, the instrument and mode of administration should be rigorously pre-tested to make sure that responses are not simply an artifact of specific features of instrument design and/or mode of administration.

Since SPM generate data from respondents in a hypothetical setting, often on complex and unfamiliar goods, special care is demanded in the design and execution of surveys, analysis of the results, and characterization of the uncertainties. A stated-preference study may be the only way to obtain quantitative information about non-use values, though a number based on a poor quality study is not necessarily superior to no number at all. Non-use values that are not quantified should be presented as an “intangible” benefit or cost.

If both revealed-preference and stated-preference studies that are directly applicable to regulatory analysis are available, you should consider both kinds of evidence and compare the findings. If the results diverge significantly, you should compare the overall size and quality of the two bodies of evidence. Other things equal, you should prefer revealed preference data over stated preference data because revealed preference data are based on actual decisions, where market participants enjoy or suffer the consequences of their decisions. This is not generally the case for respondents in stated preference surveys, where respondents may not have sufficient incentives to offer thoughtful responses that are more consistent with their preferences or may be inclined to bias their responses for one reason or another.

5. Benefit-Transfer Methods

It is often preferable to collect original data on revealed preference or stated preference to support regulatory analysis. Yet conducting an original study may not be feasible due to the time and expense involved. One alternative to conducting an original study is the use of “benefit transfer” methods. (The transfer may involve cost determination as well). The practice of “benefit transfer” began with transferring existing estimates obtained from indirect market and stated preference studies to new contexts (i.e., the context posed by the rulemaking). The principles that guide transferring estimates from indirect market and stated preference studies should apply to direct market studies as well.

Although benefit-transfer can provide a quick, low-cost approach for obtaining desired monetary values, the methods are often associated with uncertainties and potential biases of unknown magnitude. It should therefore be treated as a last-resort option and not used without explicit justification.

In conducting benefit transfer, the first step is to specify the value to be estimated for the rulemaking. You should identify the relevant measure of the policy change at this initial stage. For instance, you can derive the relevant willingness-to-pay measure by specifying an indirect utility function. This identification allows you to "zero in" on key aspects of the benefit transfer.

The next step is to identify appropriate studies to conduct benefit transfer. In selecting transfer studies for either point transfers or function transfers, you should base your choices on the following criteria:

- The selected studies should be based on adequate data, sound and defensible empirical methods and techniques.
- The selected studies should document parameter estimates of the valuation function.
- The study context and policy context should have similar populations (e.g., demographic characteristics). The market size (e.g., target population) between the study site and the policy site should be similar. For example, a study valuing water quality improvement in Rhode Island should not be used to value policy that will affect water quality throughout the United States.
- The good, and the magnitude of change in that good, should be similar in the study and policy contexts.
- The relevant characteristics of the study and the policy contexts should be similar. For example, the effects examined in the original study should be "reversible" or "irreversible" to a degree that is similar to the regulatory actions under consideration.
- The distribution of property rights should be similar so that the analysis uses the same welfare measure. If the property rights in the study context support the use of WTA measures while the rights in the rulemaking context support the use of WTP measures, benefit transfer is not appropriate.
- The availability of substitutes across study and policy contexts should be similar.

If you can choose between transferring a function or a point estimate, you should transfer the entire demand function (referred to as benefit function transfer) rather than adopting a single point estimate (referred to as benefit point transfer). [FN15]

Finally, you should not use benefit transfer in estimating benefits if:

- resources are unique or have unique attributes. For example, if a policy change affects snowmobile use in Yellowstone National Park, then a study valuing snowmobile use in the state of Michigan should not be used to value changes in snowmobile use in the Yellowstone National Park.
- If the study examines a resource that is unique or has unique attributes, you should not transfer benefit estimates or benefit functions to value a different resource and vice versa. For example, if a study values visibility improvements at the Grand Canyon, these results should not be used to value visibility improvements in urban areas.
- There are significant problems with applying an "*ex ante*" valuation estimate to an "ex post" policy context. If a policy yields a significant change in the attributes of the good, you should not use the study estimates to value the change using a benefit transfer approach.
- You also should not use a value developed from a study involving, small marginal changes in a policy context involving large changes in the quantity of the good.

Clearly, all of these criteria are difficult to meet. However, you should attempt to satisfy as many as possible when choosing studies from the existing economic literature. Professional judgment is required in determining whether a particular transfer is too speculative to use in regulatory analysis.

6. Ancillary Benefits and Countervailing Risks

Your analysis should look beyond the direct benefits and direct costs of your rulemaking and consider any important ancillary benefits and countervailing risks. An ancillary benefit is a favorable impact of the rule that is typically unrelated or secondary to the statutory purpose of the rulemaking (e.g., reduced refinery emissions due to more stringent fuel economy standards for light trucks) while a countervailing risk is an adverse economic, health, safety, or environmental consequence that occurs due to a rule and is not already accounted for in the direct cost of the rule (e.g., adverse safety impacts from more stringent fuel-economy standards for light trucks).

You should begin by considering and perhaps listing the possible ancillary benefits and countervailing risks. However, highly speculative or minor consequences may not be worth further formal analysis. Analytic priority should be given to those ancillary benefits and countervailing risks that are important enough to potentially change the rank ordering of the main alternatives in the analysis. In some cases the mere consideration of these secondary effects may help in the generation of a superior regulatory alternative with strong ancillary benefits and fewer countervailing risks. For instance, a recent study suggested that weight-based, fuel-economy standards could achieve energy savings with fewer safety risks and employment losses than would occur under the current regulatory structure.

Like other benefits and costs, an effort should be made to quantify and monetize ancillary benefits and countervailing risks. If monetization is not feasible, quantification should be attempted through use of informative physical units. If both monetization and quantification are not feasible, then these issues should be presented as non-quantified benefits and costs. The same standards of information and analysis quality that apply to direct benefits and costs should be applied to ancillary benefits and countervailing risks.

One way to combine ancillary benefits and countervailing risks is to evaluate these effects separately and then put both of these effects on the benefits side, not on the cost side. Although it is theoretically appropriate to include disbenefits on the cost side, legal and programmatic considerations generally support subtracting the disbenefits from direct benefits.

7. Methods for Treating Non-Monetized Benefits and Costs

Sound quantitative estimates of benefits and costs, where feasible, are preferable to qualitative descriptions of benefits and costs because they help decision makers understand the magnitudes of the effects of alternative actions. However, some important benefits and costs (e.g., privacy protection) may be inherently too difficult to quantify or monetize given current data and methods. You should carry out a careful evaluation of non-quantified benefits and costs. Some authorities [FN16] refer to these non-monetized and non-quantified effects as “intangible”.

a. Benefits and Costs that are Difficult to Monetize

You should monetize quantitative estimates whenever possible. Use sound and defensible values or procedures to monetize benefits and costs, and ensure that key analytical assumptions are defensible. If monetization is impossible, explain why and present all available quantitative information. For example, if you can quantify but cannot monetize increases in water quality and fish populations resulting from water quality regulation, you can describe benefits in terms of stream miles of improved water quality for boaters and increases in game fish populations for anglers. You should describe the timing and likelihood of such effects and avoid double-counting of benefits when estimates of monetized and physical effects are mixed in the same analysis.

b. Benefits and Costs that are Difficult to Quantify

If you are not able to quantify the effects, you should present any relevant quantitative information along with a description of the unquantified effects, such as ecological gains, improvements in quality of life, and aesthetic beauty. You should provide a discussion of the strengths and limitations of the qualitative information. This should include informa-

tion on the key reason(s) why they cannot be quantified. In one instance, you may know with certainty the magnitude of a risk to which a substantial, but unknown, number of individuals are exposed. In another instance, the existence of a risk may be based on highly speculative assumptions, and the magnitude of the risk may be unknown.

For cases in which the unquantified benefits or costs affect a policy choice, you should provide a clear explanation of the rationale behind the choice. Such an explanation could include detailed information on the nature, timing, likelihood, location, and distribution of the unquantified benefits and costs. Also, please include a summary table that lists all the unquantified benefits and costs, and use your professional judgment to highlight (e.g., with categories or rank ordering) those that you believe are most important (e.g., by considering factors such as the degree of certainty, expected magnitude, and reversibility of effects).

While the focus is often placed on difficult to quantify benefits of regulatory action, some costs are difficult to quantify as well. Certain permitting requirements (e.g., EPA's New Source Review program) restrict the decisions of production facilities to shift to new products and adopt innovative methods of production. While these programs may impose substantial costs on the economy, it is very difficult to quantify and monetize these effects. Similarly, regulations that establish emission standards for recreational vehicles, like motor bikes, may adversely affect the performance of the vehicles in terms of driveability and 0 to 60 miles per hour acceleration. Again, the cost associated with the loss of these attributes may be difficult to quantify and monetize. They need to be analyzed qualitatively.

8. Monetizing Health and Safety Benefits and Costs

We expect you to provide a benefit-cost analysis of major health and safety rulemakings in addition to a CEA. The BCA provides additional insight because (a) it provides some indication of what the public is willing to pay for improvements in health and safety and (b) it offers additional information on preferences for health using a different research design than is used in CEA. Since the health-preference methods used to support CEA and BCA have some different strengths and drawbacks, it is important that you provide decision makers with both perspectives.

In monetizing health benefits, a WTP measure is the conceptually appropriate measure as compared to other alternatives (e.g., cost of illness or lifetime earnings), in part because it attempts to capture pain and suffering and other quality-of-life effects. Using the WTP measure for health and safety allows you to directly compare your results to the other benefits and costs in your analysis, which will typically be based on WTP.

If well-conducted revealed-preference studies of relevant health and safety risks are available, you should consider using them in developing your monetary estimates. If appropriate revealed-preference data are not available, you should use valid and relevant data from stated-preference studies. You will need to use your professional judgment when you are faced with limited information on revealed preference studies and substantial information based on stated preference studies.

A key advantage of stated-preference and health-utility methods compared to revealed preference methods is that they can be tailored to address the ranges of probabilities, types of health risks and specific populations affected by your rule. In many rulemakings there will be no relevant information from revealed-preference studies. In this situation you should consider commissioning a stated-preference study or using values from published stated-preference studies. For the reasons discussed previously, you should be cautious about using values from stated-preference studies and describe in the analysis the drawbacks of this approach.

a. Nonfatal Health and Safety Risks

With regard to nonfatal health and safety risks, there is enormous diversity in the nature and severity of impaired health states. A traumatic injury that can be treated effectively in the emergency room without hospitalization or long-term care

is different from a traumatic injury resulting in paraplegia. Severity differences are also important in evaluation of chronic diseases. A severe bout of bronchitis, though perhaps less frequent, is far more painful and debilitating than the more frequent bouts of mild bronchitis. The duration of an impaired health state, which can range from a day or two to several years or even a lifetime (e.g., birth defects inducing mental retardation), need to be considered carefully. Information on both the severity and duration of an impaired health state is necessary before the task of monetization can be performed.

When monetizing nonfatal health effects, it is important to consider two components: (1) the private demand for prevention of the nonfatal health effect, to be represented by the preferences of the target population at risk, and (2) the net financial externalities associated with poor health such as net changes in public medical costs and any net changes in economic production that are not experienced by the target population. Revealed-preference or stated-preference studies are necessary to estimate the private demand; health economics data from published sources can typically be used to estimate the financial externalities caused by changes in health status. If you use literature values to monetize nonfatal health and safety risks, it is important to make sure that the values you have selected are appropriate for the severity and duration of health effects to be addressed by your rule.

If data are not available to support monetization, you might consider an alternative approach that makes use of health-utility studies. Although the economics literature on the monetary valuation of impaired health states is growing, there is a much larger clinical literature on how patients, providers and community residents value diverse health states. This literature typically measures health utilities based on the standard gamble, the time tradeoff or the rating scale methods. This health utility information may be combined with known monetary values for well-defined health states to estimate monetary values for a wide range of health states of different severity and duration. If you use this approach, you should be careful to acknowledge your assumptions and the limitations of your estimates.

b. Fatality Risks

Since agencies often design health and safety regulation to reduce risks to life, evaluation of these benefits can be the key part of the analysis. A good analysis must present these benefits clearly and show their importance. Agencies may choose to monetize these benefits. The willingness-to-pay approach is the best methodology to use if reductions in fatality risk are monetized.

Some describe the monetized value of small changes in fatality risk as the “value of statistical life” (VSL) or, less precisely, the “value of a life.” The latter phrase can be misleading because it suggests erroneously that the monetization exercise tries to place a “value” on individual lives. You should make clear that these terms refer to the measurement of willingness to pay for reductions in only small risks of premature death. They have no application to an identifiable individual or to very large reductions in individual risks. They do not suggest that any individual's life can be expressed in monetary terms. Their sole purpose is to help describe better the likely benefits of a regulatory action.

Confusion about the term “statistical life” is also widespread. This term refers to the sum of risk reductions expected in a population. For example, if the annual risk of death is reduced by one in a million for each of two million people, that is said to represent two “statistical lives” extended per year (2 million people x 1/1,000,000 = 2). If the annual risk of death is reduced by one in 10 million for each of 20 million people, that also represents two statistical lives extended.

The adoption of a value for the projected reduction in the risk of premature mortality is the subject of continuing discussion within the economic and public policy analysis community. A considerable body of academic literature is available on this subject. This literature involves either explicit or implicit valuation of fatality risks, and generally involves the use of estimates of VSL from studies on wage compensation for occupational hazards (which generally are in the range of 10^{-4} annually), on consumer product purchase and use decisions, or from an emerging literature using stated prefer-

ence approaches. A substantial majority of the resulting estimates of VSL vary from roughly $1 million to $10 million per statistical life. [FN17]

There is a continuing debate within the economic and public policy analysis community on the merits of using a single VSL for all situations versus adjusting the VSL estimates to reflect the specific rule context. A variety of factors have been identified, including whether the mortality risk involves sudden death, the fear of cancer, and the extent to which the risk is voluntarily incurred. [FN18] The consensus of EPA's recent Science Advisory Board (SAB) review of this issue was that the available literature does not support adjustments of VSL for most of these factors. The panel did conclude that it was appropriate to adjust VSL to reflect changes in income and any time lag in the occurrence of adverse health effects.

The age of the affected population has also been identified as an important factor in the theoretical literature. However, the empirical evidence on age and VSL is mixed. In light of the continuing questions over the effect of age on VSL estimates, you should not use an age-adjustment factor in an analysis using VSL estimates. [FN19]

Another way that has been used to express reductions in fatality risks is to use the life expectancy method, the “value of statistical life-years (VSLY) extended.” If a regulation protects individuals whose average remaining life expectancy is 40 years, a risk reduction of one fatality is expressed as “40 life-years extended.” Those who favor this alternative approach emphasize that the value of a statistical life is not a single number relevant for all situations. In particular, when there are significant differences between the effect on life expectancy for the population affected by a particular health risk and the populations studied in the labor market studies, they prefer to adopt a VSLY approach to reflect those differences. You should consider providing estimates of both VSL and VSLY, while recognizing the developing state of knowledge in this area.

Longevity may be only one of a number of relevant considerations pertaining to the rule. You should keep in mind that regulations with greater numbers of life-years extended are not necessarily better than regulations with fewer numbers of life-years extended. In any event, when you present estimates based on the VSLY method, you should adopt a larger VSLY estimate for senior citizens because senior citizens face larger overall health risks from all causes and they may have accumulated savings to spend on their health and safety. [FN20]

The valuation of fatality risk reduction is an evolving area in both results and methodology. Hence, you should utilize valuation methods that you consider appropriate for the regulatory circumstances. Since the literature-based VSL estimates may not be entirely appropriate for the risk being evaluated (e.g., the use of occupational risk premia to value reductions in risks from environmental hazards), you should explain your selection of estimates and any adjustments of the estimates to reflect the nature of the risk being evaluated. You should present estimates based on alternative approaches, and if you monetize mortality risk reduction, you should do so on a consistent basis to the extent feasible. You should clearly indicate the methodology used and document your choice of a particular methodology. You should explain any significant deviations from the prevailing state of knowledge. If you use different methodologies in different rules, you should clearly disclose the fact and explain your choices.

c. Valuation of Reductions in Health and Safety Risks to Children

The valuation of health outcomes for children and infants poses special challenges. It is rarely feasible to measure a child's willingness to pay for health improvement and an adult's concern for his or her own health is not necessarily relevant to valuation of child health. For example, the wage premiums demanded by workers to accept hazardous jobs are not readily transferred to rules that accomplish health gains for children.

There are a few studies that examine parental willingness to pay to invest in health and safety for their children. Some of

these studies suggest that parents may value children's health more strongly than their own health. Although this parental perspective is a promising research strategy, it may need to be expanded to include a societal interest in child health and safety.

Where the primary objective of a rule is to reduce the risk of injury, disease or mortality among children, you should conduct a cost-effectiveness analysis of the rule. You may also develop a benefit-cost analysis to the extent that valid monetary values can be assigned to the primary expected health outcomes. For rules where health gains are expected among both children and adults and you decide to perform a benefit-cost analysis, the monetary values for children should be at least as large as the values for adults (for the same probabilities and outcomes) unless there is specific and compelling evidence to suggest otherwise. [FN21]

Discount Rates

Benefits and costs do not always take place in the same time period. When they do not, it is incorrect simply to add all of the expected net benefits or costs without taking account of when the actually occur. If benefits or costs are delayed or otherwise separated in time from each other, the difference in timing should be reflected in your analysis.

As a first step, you should present the annual time stream of benefits and costs expected to result from the rule, clearly identifying when the benefits and costs are expected to occur. The beginning point for your stream of estimates should be the year in which the final rule will begin to have effects, even if that is expected to be some time in the future. The ending point should be far enough in the future to encompass all the significant benefits and costs likely to result from the rule.

In presenting the stream of benefits and costs, it is important to measure them in constant dollars to avoid the misleading effects of inflation in your estimates. If the benefits and costs are initially measured in prices reflecting expected future inflation, you can convert them to constant dollars by dividing through by an appropriate inflation index, one that corresponds to the inflation rate underlying the initial estimates of benefits or costs.

1. The Rationale for Discounting

Once these preliminaries are out of the way, you can begin to adjust your estimates for differences in timing. (This is a separate calculation from the adjustment needed to remove the effects of future inflation.) Benefits or costs that occur sooner are generally more valuable. The main rationales for the discounting of future impacts are:

(a) Resources that are invested will normally earn a positive return, so current consumption is more expensive than future consumption, since you are giving up that expected return on investment when you consume today.

(b) Postponed benefits also have a cost because people generally prefer present to future consumption. They are said to have positive time preference.

(c) Also, if consumption continues to increase over time, as it has for most of U.S. history, an increment of consumption will be less valuable in the future than it would be today, because the principle of diminishing marginal utility implies that as total consumption increases, the value of a marginal unit of consumption tends to decline.

There is wide agreement with point (a). Capital investment is productive, but that point is not sufficient by itself to explain positive interest rates and observed saving behavior. To understand these phenomena, points (b) and (c) are also necessary. If people are really indifferent between consumption now and later, then they should be willing to forgo current consumption in order to consume an equal or slightly greater amount in the future. That would cause saving rates and investment to rise until interest rates were driven to zero and capital was no longer productive. As long as we observe positive interest rates and saving rates below 100 percent, people must be placing a higher value on current consumption than on future consumption.

To reflect this preference, a discount factor should be used to adjust the estimated benefits and costs for differences in timing. The further in the future the benefits and costs are expected to occur, the more they should be discounted. The discount factor can be calculated given a discount rate. The formula is 1/ (1+ the discount rate)^{t} where "t" measures the number of years in the future that the benefits or costs are expected to occur. Benefits or costs that have been adjusted in this way are called "discounted present values" or simply "present values". When, and only when, the estimated benefits and costs have been discounted, they can be added to determine the overall value of net benefits.

2. Real Discount Rates of 3 Percent and 7 Percent

OMB's basic guidance on the discount rate is provided in OMB Circular A-94 (http://www.whitehouse.gov/omb/circulars/index.html). This Circular points out that the analytically preferred method of handling temporal differences between benefits and costs is to adjust all the benefits and costs to reflect their value in equivalent units of consumption and to discount them at the rate consumers and savers would normally use in discounting future consumption benefits. This is sometimes called the "shadow price" approach to discounting because doing such calculations requires you to value benefits and costs using shadow prices, especially for capital goods, to correct for market distortions. These shadow prices are not well established for the United States. Furthermore, the distribution of impacts from regulations on capital and consumption are not always well known. Consequently, any agency that wishes to tackle this challenging analytical task should check with OMB before proceeding.

As a default position, OMB Circular A-94 states that a real discount rate of 7 percent should be used as a base-case for regulatory analysis. The 7 percent rate is an estimate of the average before-tax rate of return to private capital in the U.S. economy. It is a broad measure that reflects the returns to real estate and small business capital as well as corporate capital. It approximates the opportunity cost of capital, and it is the appropriate discount rate whenever the main effect of a regulation is to displace or alter the use of capital in the private sector. OMB revised Circular A-94 in 1992 after extensive internal review and public comment. In a recent analysis, OMB found that the average rate of return to capital remains near the 7 percent rate estimated in 1992. Circular A-94 also recommends using other discount rates to show the sensitivity of the estimates to the discount rate assumption.

Economic distortions, including taxes on capital, create a divergence between the rate of return that savers earn and the private rate of return to capital. This divergence persists despite the tendency for capital to flow to where it can earn the highest rate of return. Although market forces will push after-tax rates of return in different sectors of the economy toward equality, that process will not equate pre-tax rates of return when there are differences in the tax treatment of investment. Corporate capital, in particular, pays an additional layer of taxation, the corporate income tax, which requires it to earn a higher pre-tax rate of return in order to provide investors with similar after-tax rates of return compared with non-corporate investments. The pre-tax rates of return better measure society's gains from investment. Since the rates of return on capital are higher in some sectors of the economy than others, the government needs to be sensitive to possible impacts of regulatory policy on capital allocation.

The effects of regulation do not always fall exclusively or primarily on the allocation of capital. When regulation primarily and directly affects private consumption (e.g., through higher consumer prices for goods and services), a lower discount rate is appropriate. The alternative most often used is sometimes called the "social rate of time preference." This simply means the rate at which "society" discounts future consumption flows to their present value. If we take the rate that the average saver uses to discount future consumption as our measure of the social rate of time preference, then the real rate of return on long-term government debt may provide a fair approximation. Over the last thirty years, this rate has averaged around 3 percent in real terms on a pre-tax basis. For example, the yield on 10-year Treasury notes has averaged 8.1 percent since 1973 while the average annual rate of change in the CPI over this period has been 5.0 percent, implying a real 10-year rate of 3.1 percent.

For regulatory analysis, you should provide estimates of net benefits using both 3 percent and 7 percent. An example of this approach is EPA's analysis of its 1998 rule setting both effluent limits for wastewater discharges and air toxic emission limits for pulp and paper mills. In this analysis, EPA developed its present-value estimates using real discount rates of 3 and 7 percent applied to benefit and cost streams that extended forward for 30 years. You should present a similar analysis in your own work.

In some instances, if there is reason to expect that the regulation will cause resources to be reallocated away from private investment in the corporate sector, then the opportunity cost may lie outside the range of 3 to 7 percent. For example, the average real rate of return on corporate capital in the United States was approximately 10 percent in the 1990s, returning to the same level observed in the 1950s and 1960s. If you are uncertain about the nature of the opportunity cost, then you should present benefit and cost estimates using a higher discount rate as a further sensitivity analysis as well as using the 3 and 7 percent rates.

3. Time Preference for Health-Related Benefits and Costs

When future benefits or costs are health-related, some have questioned whether discounting is appropriate, since the rationale for discounting money may not appear to apply to health. It is true that lives saved today cannot be invested in a bank to save more lives in the future. But the resources that would have been used to save those lives can be invested to earn a higher payoff in future lives saved. People have been observed to prefer health gains that occur immediately to identical health gains that occur in the future. Also, if future health gains are not discounted while future costs are, then the following perverse result occurs: an attractive investment today in future health improvement can always be made more attractive by delaying the investment. For such reasons, there is a professional consensus that future health effects, including both benefits and costs, should be discounted at the same rate. This consensus applies to both BCA and CEA.

A common challenge in health-related analysis is to quantify the time lag between when a rule takes effect and when the resulting physical improvements in health status will be observed in the target population. In such situations, you must carefully consider the timing of health benefits before performing present-value calculations. It is not reasonable to assume that all of the benefits of reducing chronic diseases such as cancer and cardiovascular disease will occur immediately when the rule takes effect. For rules addressing traumatic injury, this lag period may be short. For chronic diseases it may take years or even decades for a rule to induce its full beneficial effects in the target population.

When a delay period between exposure to a toxin and increased probability of disease is likely (a so-called latency period), a lag between exposure reduction and reduced probability of disease is also likely. This latter period has sometimes been referred to as a “cessation lag,” and it may or may not be of the same duration as the latency period. As a general matter, cessation lags will only apply to populations with at least some high-level exposure (e.g., before the rule takes effect). For populations with no such prior exposure, such as those born after the rule takes effect, only the latency period will be relevant.

Ideally, your exposure-risk model would allow calculation of reduced risk for each year following exposure cessation, accounting for total cumulative exposure and age at the time of exposure reduction. The present-value benefits estimate could then reflect an appropriate discount factor for each year's risk reduction. Recent analyses of the cancer benefits stemming from reduction in public exposure to radon in drinking water have adopted this approach. They were supported by formal risk-assessment models that allowed estimates of the timing of lung cancer incidence and mortality to vary in response to different radon exposure levels. [FN22]

In many cases, you will not have the benefit of such detailed risk assessment modeling. You will need to use your professional judgment as to the average cessation lag for the chronic diseases affected by your rule. In situations where inform-

ation exists on latency but not on cessation lags, it may be reasonable to use latency as a proxy for the cessation lag, unless there is reason to believe that the two are different. When the average lag time between exposures and disease is unknown, a range of plausible alternative values for the time lag should be used in your analysis.

4. Intergenerational Discounting

Special ethical considerations arise when comparing benefits and costs across generations. Although most people demonstrate time preference in their own consumption behavior, it may not be appropriate for society to demonstrate a similar preference when deciding between the well-being of current and future generations. Future citizens who are affected by such choices cannot take part in making them, and today's society must act with some consideration of their interest.

One way to do this would be to follow the same discounting techniques described above and supplement the analysis with an explicit discussion of the intergenerational concerns (how future generations will be affected by the regulatory decision). Policymakers would be provided with this additional information without changing the general approach to discounting.

Using the same discount rate across generations has the advantage of preventing time-inconsistency problems. For example, if one uses a lower discount rate for future generations, then the evaluation of a rule that has short-term costs and long-term benefits would become more favorable merely by waiting a year to do the analysis. Further, using the same discount rate across generations is attractive from an ethical standpoint. If one expects future generations to be better off, then giving them the advantage of a lower discount rate would in effect transfer resources from poorer people today to richer people tomorrow.

Some believe, however, that it is ethically impermissible to discount the utility of future generations. That is, government should treat all generations equally. Even under this approach, it would still be correct to discount future costs and consumption benefits generally (perhaps at a lower rate than for intragenerational analysis), due to the expectation that future generations will be wealthier and thus will value a marginal dollar of benefits or costs by less than those alive today. Therefore, it is appropriate to discount future benefits and costs relative to current benefits and costs, even if the welfare of future generations is not being discounted. Estimates of the appropriate discount rate appropriate in this case, from the 1990s, ranged from 1 to 3 percent per annum. [FN23]

A second reason for discounting the benefits and costs accruing to future generations at a lower rate is increased uncertainty about the appropriate value of the discount rate, the longer the horizon for the analysis. Private market rates provide a reliable reference for determining how society values time within a generation, but for extremely long time periods no comparable private rates exist. As explained by Martin Weitzman [FN24], in the limit for the deep future, the properly averaged certainty-equivalent discount factor (i.e., $1/[1+r]^t$) corresponds to the minimum discount rate having any substantial positive probability. From today's perspective, the only relevant limiting scenario is the one with the lowest discount rate - all of the other states at the far-distant time are relatively much less important because their expected present value is so severely reduced by the power of compounding at a higher rate.

If your rule will have important intergenerational benefits or costs you might consider a further sensitivity analysis using a lower but positive discount rate in addition to calculating net benefits using discount rates of 3 and 7 percent.

5. Time Preference for Non-Monetized Benefits and Costs

Differences in timing should be considered even for benefits and costs that are not expressed in monetary units, including health benefits. The timing differences can be handled through discounting. EPA estimated cost-effectiveness in its 1998 rule, “Control of Emissions from Nonroad Diesel Engines,” by discounting both the monetary costs and the non-monetized emission reduction benefits over the expected useful life of the engines at the 7 percent real rate recommended

in OMB Circular A-94.

Alternatively, it may be possible in some cases to avoid discounting non-monetized benefits. If the expected flow of benefits begins as soon as the cost is incurred and is expected to be constant over time, then annualizing the cost stream is sufficient, and further discounting of benefits is unnecessary. Such an analysis might produce an estimate of the annualized cost per ton of reduced emissions of a pollutant.

6. The Internal Rate of Return
The internal rate of return is the discount rate that sets the net present value of the discounted benefits and costs equal to zero. The internal rate of return does not generally provide an acceptable decision criterion, and regulations with the highest internal rate of return are not necessarily the most beneficial. Nevertheless, it does provide useful information and for many it will offer a meaningful indication of regulation's impact. You should consider including the internal rate of return implied by your regulatory analysis along with other information about discounted net present values.

Other Key Considerations

1. Other Benefit and Cost Considerations
You should include these effects in your analysis and provide estimates of their monetary values when they are significant:

- Private-sector compliance costs and savings;
- Government administrative costs and savings;
- Gains or losses in consumers' or producers' surpluses;
- Discomfort or inconvenience costs and benefits; and
- Gains or losses of time in work, leisure and/or commuting/travel settings.

Estimates of benefits and costs should be based on credible changes in technology over time. For example, retrospective studies may provide evidence that “learning” will likely reduce the cost of regulation in future years. The weight you give to a study of past rates of cost savings resulting from innovation (including “learning curve” effects) should depend on both its timeliness and direct relevance to the processes affected by the regulatory alternative under consideration. In addition, you should take into account cost-saving innovations that result from a shift to regulatory performance standards and incentive-based policies. On the other hand, significant costs may result from a slowing in the rate of innovation or of adoption of new technology due to delays in the regulatory approval process or the setting of more stringent standards for new facilities than existing ones. In some cases agencies are limited under statute to consider only technologies that have been demonstrated to be feasible. In these situations, it may be useful to estimate costs and cost savings assuming a wider range of technical possibilities.

When characterizing technology changes over time, you should assess the likely technology changes that would have occurred in the absence of the regulatory action (technology baseline). Technologies change over time in both reasonably functioning markets and imperfect markets. If you assume that technology will remain unchanged in the absence of regulation when technology changes are likely, then your analysis will over-state both the benefits and costs attributable to the regulation.

Occasionally, cost savings or other forms of benefits accrue to parties affected by a rule who also bear its costs. For example, a requirement that engine manufacturers reduce emissions from engines may lead to technologies that improve fuel economy. These fuel savings will normally accrue to the engine purchasers, who also bear the costs of the technologies. There is no apparent market failure with regard to the market value of fuel saved because one would expect that consumers would be willing to pay for increased fuel economy that exceeded the cost of providing it. When these cost

savings are substantial, and particularly when you estimate them to be greater than the cost associated with achieving them, you should examine and discuss why market forces would not accomplish these gains in the absence of regulation. As a general matter, any direct costs that are averted as a result of a regulatory action should be monetized wherever possible and either added to the benefits or subtracted from the costs of that alternative.

2. The Difference between Costs (or Benefits) and Transfer Payments

Distinguishing between real costs and transfer payments is an important, but sometimes difficult, problem in cost estimation. Benefit and cost estimates should reflect real resource use. Transfer payments are monetary payments from one group to another that do not affect total resources available to society. A regulation that restricts the supply of a good, causing its price to rise, produces a transfer from buyers to sellers. The net reduction in the total surplus (consumer plus producer) is a real cost to society, but the transfer from buyers to sellers resulting from a higher price is not a real cost since the net reduction automatically accounts for the transfer from buyers to sellers. However, transfers from the United States to other nations *should* be included as costs, and transfers from other nations to the United States as benefits, as long as the analysis is conducted from the United States perspective.

You should not include transfers in the estimates of the benefits and costs of a regulation. Instead, address them in a separate discussion of the regulation's distributional effects. Examples of transfer payments include the following:

- Scarcity rents and monopoly profits
- Insurance payments
- Indirect taxes and subsidies

Treatment of Uncertainty

The precise consequences (benefits and costs) of regulatory options are not always known for certain, but the probability of their occurrence can often be developed. The important uncertainties connected with your regulatory decisions need to be analyzed and presented as part of the overall regulatory analysis. You should begin your analysis of uncertainty at the earliest possible stage in developing your analysis. You should consider both the statistical variability of key elements underlying the estimates of benefits and costs (for example, the expected change in the distribution of automobile accidents that might result from a change in automobile safety standards) and the incomplete knowledge about the relevant relationships (for example, the uncertain knowledge of how some economic activities might affect future climate change).[FN25] By assessing the sources of uncertainty and the way in which benefit and cost estimates may be affected under plausible assumptions, you can shape your analysis to inform decision makers and the public about the effects and the uncertainties of alternative regulatory actions.

The treatment of uncertainty must be guided by the same principles of full disclosure and transparency that apply to other elements of your regulatory analysis. Your analysis should be credible, objective, realistic, and scientifically balanced. [FN26] Any data and models that you use to analyze uncertainty should be fully identified. You should also discuss the quality of the available data used. Inferences and assumptions used in your analysis should be identified, and your analytical choices should be explicitly evaluated and adequately justified. In your presentation, you should delineate the strengths of your analysis along with any uncertainties about its conclusions. Your presentation should also explain how your analytical choices have affected your results.

In some cases, the level of scientific uncertainty may be so large that you can only present discrete alternative scenarios without assessing the relative likelihood of each scenario quantitatively. For instance, in assessing the potential outcomes of an environmental effect, there may be a limited number of scientific studies with strongly divergent results. In such cases, you might present results from a range of plausible scenarios, together with any available information that might help in qualitatively determining which scenario is most likely to occur.

When uncertainty has significant effects on the final conclusion about net benefits, your agency should consider additional research prior to rulemaking. The costs of being wrong may outweigh the benefits of a faster decision. This is true especially for cases with irreversible or large upfront investments. If your agency decides to proceed with rulemaking, you should explain why the costs of developing additional information--including any harm from delay in public protection--exceed the value of that information.

For example, when the uncertainty is due to a lack of data, you might consider deferring the decision, as an explicit regulatory alternative, pending further study to obtain sufficient data. [FN27] Delaying a decision will also have costs, as will further efforts at data gathering and analysis. You will need to weigh the benefits of delay against these costs in making your decision. Formal tools for assessing the value of additional information are now well developed in the applied decision sciences and can be used to help resolve this type of complex regulatory question.

“Real options” methods have also formalized the valuation of the added flexibility inherent in delaying a decision. As long as taking time will lower uncertainty, either passively or actively through an investment in information gathering, and some costs are irreversible, such as the potential costs of a sunk investment, a benefit can be assigned to the option to delay a decision. That benefit should be considered a cost of taking immediate action versus the alternative of delaying that action pending more information. However, the burdens of delay--including any harm to public health, safety, and the environment--need to be analyzed carefully.

1. Quantitative Analysis of Uncertainty

Examples of quantitative analysis, broadly defined, would include formal estimates of the probabilities of environmental damage to soil or water, the possible loss of habitat, or risks to endangered species as well as probabilities of harm to human health and safety. There are also uncertainties associated with estimates of economic benefits and costs, such as the cost savings associated with increased energy efficiency. Thus, your analysis should include two fundamental components: a quantitative analysis characterizing the probabilities of the relevant outcomes and an assignment of economic value to the projected outcomes. It is essential that both parts be conceptually consistent. In particular, the quantitative analysis should be conducted in a way that permits it to be applied within a more general analytical framework, such as benefit-cost analysis. Similarly, the general framework needs to be flexible enough to incorporate the quantitative analysis without oversimplifying the results. For example, you should address explicitly the implications for benefits and costs of any probability distributions developed in your analysis.

As with other elements of regulatory analysis, you will need to balance thoroughness with the practical limits on your analytical capabilities. Your analysis does not have to be exhaustive, nor is it necessary to evaluate each alternative at every step. Attention should be devoted to first resolving or studying the uncertainties that have the largest potential effect on decision making. Many times these will be the largest sources of uncertainties. In the absence of adequate data, you will need to make assumptions. These should be clearly identified and consistent with the relevant science. Your analysis should provide sufficient information for decision makers to grasp the degree of scientific uncertainty and the robustness of estimated probabilities, benefits, and costs to changes in key assumptions.

For major rules involving annual economic effects of $1 billion or more, you should present a formal quantitative analysis of the relevant uncertainties about benefits and costs. In other words, you should try to provide some estimate of the probability distribution of regulatory benefits and costs. In summarizing the probability distributions, you should provide some estimates of the central tendency (e.g., mean and median) along with any other information you think will be useful such as ranges, variances, specified low-end and high-end percentile estimates, and other characteristics of the distribution.

Your estimates cannot be more precise than their most uncertain component. Thus, your analysis should report estimates in a way that reflects the degree of uncertainty and not create a false sense of precision. Worst-case or conservative analyses are not usually adequate because they do not convey the complete probability distribution of outcomes, and they do not permit calculation of an expected value of net benefits. In many health and safety rules, economists conducting benefit-cost analyses must rely on formal risk assessments that address a variety of risk management questions such as the baseline risk for the affected population, the safe level of exposure or, the amount of risk to be reduced by various interventions. Because the answers to some of these questions are directly used in benefits analyses, the risk assessment methodology must allow for the determination of expected benefits in order to be comparable to expected costs. This means that conservative assumptions and defaults (whether motivated by science policy or by precautionary instincts), will be incompatible with benefit analyses as they will result in benefit estimates that exceed the expected value. Whenever it is possible to characterize quantitatively the probability distributions, some estimates of expected value (e.g., mean and median) must be provided in addition to ranges, variances, specified low-end and high-end percentile estimates, and other characteristics of the distribution.

Whenever possible, you should use appropriate statistical techniques to determine a probability distribution of the relevant outcomes. For rules that exceed the $1 billion annual threshold, a formal quantitative analysis of uncertainty is required. For rules with annual benefits and/or costs in the range from 100 million to $1 billion, you should seek to use more rigorous approaches with higher consequence rules. This is especially the case where net benefits are close to zero. More rigorous uncertainty analysis may not be necessary for rules in this category if simpler techniques are sufficient to show robustness. You may consider the following analytical approaches that entail increasing levels of complexity:

- Disclose qualitatively the main uncertainties in each important input to the calculation of benefits and costs. These disclosures should address the uncertainties in the data as well as in the analytical results. However, major rules above the $1 billion annual threshold require a formal treatment.
- Use a numerical sensitivity analysis to examine how the results of your analysis vary with plausible changes in assumptions, choices of input data, and alternative analytical approaches. Sensitivity analysis is especially valuable when the information is lacking to carry out a formal probabilistic simulation. Sensitivity analysis can be used to find “switch points” -- critical parameter values at which estimated net benefits change sign or the low cost alternative switches. Sensitivity analysis usually proceeds by changing one variable or assumption at a time, but it can also be done by varying a combination of variables simultaneously to learn more about the robustness of your results to widespread changes. Again, however, major rules above the $1 billion annual threshold require a formal treatment.
- Apply a formal probabilistic analysis of the relevant uncertainties - possibly using simulation models and/or expert judgment as revealed, for example, through Delphi methods. [FN28] Such a formal analytical approach is appropriate for complex rules where there are large, multiple uncertainties whose analysis raises technical challenges, or where the effects cascade; it is required for rules that exceed the $1 billion annual threshold. For example, in the analysis of regulations addressing air pollution, there is uncertainty about the effects of the rule on future emissions, uncertainty about how the change in emissions will affect air quality, uncertainty about how changes in air quality will affect health, and finally uncertainty about the economic and social value of the change in health outcomes. In formal probabilistic assessments, expert solicitation is a useful way to fill key gaps in your ability to assess uncertainty. [FN29] In general, experts can be used to quantify the probability distributions of key parameters and relationships. These solicitations, combined with other sources of data, can be combined in Monte Carlo simulations to derive a probability distribution of benefits and costs. You should pay attention to correlated inputs. Often times, the standard defaults in Monte Carlo and other similar simulation packages assume independence across distributions. Failing to correctly account for correlated distributions of inputs can cause the resultant output uncertainty intervals to be too large, although in many cases the overall effect is ambiguous. You should make a special effort to portray the probabilistic results--in graphs and/or tables--clearly and meaningfully.

New methods may become available in the future. This document is not intended to discourage or inhibit their use, but rather to encourage and stimulate their development.

2. Economic Values of Uncertain Outcomes
In developing benefit and cost estimates, you may find that there are probability distributions of values as well for each of the outcomes. Where this is the case, you will need to combine these probability distributions to provide estimated benefits and costs.

Where there is a distribution of outcomes, you will often find it useful to emphasize summary statistics or figures that can be readily understood and compared to achieve the broadest public understanding of your findings. It is a common practice to compare the "best estimates" of both benefits and costs with those of competing alternatives. These "best estimates" are usually the average or the expected value of benefits and costs. Emphasis on these expected values is appropriate as long as society is "risk neutral" with respect to the regulatory alternatives. While this may not always be the case, you should in general assume "risk neutrality" in your analysis. If you adopt a different assumption on risk preference, you should explain your reasons for doing so.

3. Alternative Assumptions
If benefit or cost estimates depend heavily on certain assumptions, you should make those assumptions explicit and carry out sensitivity analyses using plausible alternative assumptions. If the value of net benefits changes from positive to negative (or vice versa) or if the relative ranking of regulatory options changes with alternative plausible assumptions, you should conduct further analysis to determine which of the alternative assumptions is more appropriate. Because different estimation methods may have hidden assumptions, you should analyze estimation methods carefully to make any hidden assumptions explicit.

F. Specialized Analytical Requirements
In preparing analytical support for your rulemaking, you should be aware that there are a number of analytic requirements imposed by law and Executive Order. In addition to the regulatory analysis requirements of Executive Order 12866, you should also consider whether your rule will need specialized analysis of any of the following issues.

Impact on Small Businesses and Other Small Entities
Under the Regulatory Flexibility Act (5 U.S.C. chapter 6), agencies must prepare a proposed and final "regulatory flexibility analysis" (RFA) if the rulemaking could "have a significant impact on a substantial number of small entities." You should consider posting your RFA on the internet so the public can review your findings.

Your agency should have guidelines on how to prepare an RFA and you are encouraged to consult with the Chief Counsel for Advocacy of the Small Business Administration on expectations concerning what is an adequate RFA. Executive Order 13272 (67 FR 53461, August 16, 2002) requires you to notify the Chief Counsel for Advocacy of any draft rules that might have a significant economic impact on a substantial number of small entities. Executive Order 13272 also directs agencies to give every appropriate consideration to any comments provided by the Advocacy Office. Under SBREFA, EPA and OSHA are required to consult with small business prior to developing a proposed rule that would have a significant effect on small businesses. OMB encourages other agencies to do so as well.

Analysis of Unfunded Mandates
Under the Unfunded Mandates Act (2 U.S.C. 1532), you must prepare a written statement about benefits and costs prior to issuing a proposed or final rule (for which your agency published a proposed rule) that may result in aggregate expenditure by State, local, and tribal governments, or by the private sector, of $100,000,000 or more in any one year (adjusted annually for inflation). Your analytical requirements under Executive Order 12866 are similar to the analytical

requirements under this Act, and thus the same analysis may permit you to comply with both analytical requirements.

Information Collection, Paperwork, and Recordkeeping Burdens

Under the Paperwork Reduction Act (44 U.S.C. chapter 35), you will need to consider whether your rulemaking (or other actions) will create any additional information collection, paperwork or recordkeeping burdens. These burdens are permissible only if you can justify the practical utility of the information for the implementation of your rule. OMB approval will be required of any new requirements for a collection of information imposed on 10 or more persons and a valid OMB control number must be obtained for any covered paperwork. Your agency's CIO should be able to assist you in complying with the Paperwork Reduction Act.

Information Quality Guidelines

Under the Information Quality Law, agency guidelines, in conformance with the OMB government-wide guidelines (67 FR 8452, February 22, 2002), have established basic quality performance goals for all information disseminated by agencies, including information disseminated in support of proposed and final rules. The data and analysis that you use to support your rule must meet these agency and OMB quality standards. Your agency's CIO should be able to assist you in assessing information quality. The Statistical and Science Policy Branch of OMB's Office of Information and Regulatory Affairs can provide you assistance. This circular defines OMB's minimum quality standards for regulatory analysis.

Environmental Impact Statements

The National Environmental Policy Act (42 U.S.C. 4321-4347) and related statutes and executive orders require agencies to consider the environmental impacts of agency decisions, including rulemakings. An environmental impact statement must be prepared for "major Federal actions significantly affecting the quality of the human environment." You must complete NEPA documentation before issuing a final rule. The White House Council on Environmental Quality has issued regulations (40 C.F.R. 1500-1508) and associated guidance for implementation of NEPA, available through CEQ's website (http:// www.whitehouse.gov/ceq/index.html).

Impacts on Children

Under Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks," each agency must, with respect to its rules, "to the extent permitted by law and appropriate, and consistent with the agency's mission," "address disproportionate risks to children that result from environmental health risks or safety risks." For any substantive rulemaking action that "is likely to result in" an economically significant rule that concerns "an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children," the agency must provide OMB/OIRA "an evaluation of the environmental health or safety effects of the planned regulation on children," as well as "an explanation of why the planned regulation is preferable to other potentially and reasonably feasible alternatives considered by the agency."

Energy Impacts

Under Executive Order 13211 (66 FR 28355, May 22, 2001), agencies are required to prepare and submit to OMB a Statement of Energy Effects for significant energy actions, to the extent permitted by law. This Statement is to include a detailed statement of "any adverse effects on energy supply, distribution, or use (including a shortfall in supply, price increases, and increased use of foreign supplies)" for the action and reasonable alternatives and their effects. You need to publish the Statement or a summary in the related NPRM and final rule. For further guidance, see OMB Memorandum 01-27 ("Guidance on Implementing Executive Order 13211", July 13, 2001), available on OMB's website.

G. Accounting Statement

You need to provide an accounting statement with tables reporting benefit and cost estimates for each major final rule for

your agency. You should use the guidance outlined above to report these estimates. We have included a suggested format for your consideration.

Categories of Benefits and Costs

To the extent feasible, you should quantify all potential incremental benefits and costs. You should report benefit and cost estimates within the following three categories: monetized quantified, but not monetized; and qualitative, but not quantified or monetized.

These categories are mutually exclusive and exhaustive. Throughout the process of listing preliminary estimates of benefits and costs, agencies should avoid double-counting. This problem may arise if more than one way exists to express the same change in social welfare.

Quantifying and Monetizing Benefits and Costs

You should develop quantitative estimates and convert them to dollar amounts if possible. In many cases, quantified estimates are readily convertible, with a little effort, into dollar equivalents.

Qualitative Benefits and Costs

You should categorize or rank the qualitative effects in terms of their importance (e.g., certainty, likely magnitude, and reversibility). You should distinguish the effects that are likely to be significant enough to warrant serious consideration by decision makers from those that are likely to be minor.

Treatment of Benefits and Costs over Time

You should present undiscounted streams of benefit and cost estimates (monetized and net) for each year of the analytic time horizon. You should present annualized benefits and costs using real discount rates of 3 and 7 percent. The stream of annualized estimates should begin in the year in which the final rule will begin to have effects, even if the rule does not take effect immediately. Please report all monetized effects in 2001 dollars. You should convert dollars expressed in different years to 2001 dollars using the GDP deflator.

Treatment of Risk and Uncertainty

You should provide expected-value estimates as well as distributions about the estimates, where such information exists. When you provide only upper and lower bounds (in addition to best estimates), you should, if possible, use the 95 and 5 percent confidence bounds. Although we encourage you to develop estimates that capture the *5* of plausible outcomes for a particular alternative, detailed reporting of such distributions is not required, but should be available upon request.

The principles of full disclosure and transparency apply to the treatment of uncertainty. Where there is significant uncertainty and the resulting inferences and/or assumptions have a critical effect on the benefit and cost estimates, you should describe the benefits and costs under plausible alternative assumptions. You may add footnotes to the table as needed to provide documentation and references, or to express important warnings.

In a previous section, we identified some of the issues associated with developing estimates of the value of reductions in premature mortality risk. Based on this discussion, you should present alternative primary estimates where you use different estimates for valuing reductions in premature mortality risk.

Precision of Estimates

Reported estimates should reflect, to the extent feasible, the precision in the analysis. For example, an estimate of $220 million implies rounding to the nearest $10 million and thus a precision of +/-$5 million; similarly, an estimate of $222 million implies rounding to the nearest $1 million and thus, a precision of +/-$0.5 million.

Separate Reporting of Transfers

You should report transfers separately and avoid the misclassification of transfer payments as benefits or costs. Transfers occur when wealth or income is redistributed without any direct change in aggregate social welfare. To the extent that regulatory outputs reflect transfers rather than net welfare gains to society, you should identify them as transfers rather than benefits or costs. You should also distinguish transfers caused by Federal budget actions -- such as those stemming from a rule affecting Social Security payments -- from those that involve transfers between non-governmental parties -- such as monopoly rents a rule may confer on a private party. You should use as many categories as necessary to describe the major redistributive effects of a regulatory action. If transfers have significant efficiency effects in addition to distributional effects, you should report them.

Effects on State, Local, and Tribal Governments, Small Business, Wages and Economic Growth

You need to identity the portions of benefits, costs, and transfers received by State, local, and tribal governments. To the extent feasible, you also should identify the effects of the rule or program on small businesses, wages, and economic growth. [FN30] Note that rules with annual costs that are less than one billion dollars are likely to have a minimal effect on economic growth.

OMB #: **Agency/Program Office:**

Rule Title:

RIN#: **Date:**

Category	*Primary Estimate*	*Minimum Estimate*	*Maximum Estimate*	*Source Citation (RIA, preamble, etc.)*
BENEFITS				
monetized benefits				
Annualized quantified, but unmonetized, benefits				
(unquantified) benefits				
COSTS				
Annualized monetized costs				
Annualized quantified, but unmonetized, costs				
Qualitative (unquantified) costs				
TRANSFERS				
Annualized monetized transfers: “on budget”				
from whom to whom?				
Annualized monetized				

transfers: "off-budget"		
From whom to whom?		
Category	*Effects*	*Source Citation (RIA, preamble, etc.)*
Effects on State, local, and/or tribal governments		
Effects on small businesses		
Effects on wages		
Effects on growth		

H. Effective Date

The effective date of this Circular is January 1, 2004 for regulatory analyses received by OMB in support of proposed rules, and January 1, 2005 for regulatory analyses received by OMB in support of final rules. In other words, this Circular applies to the regulatory analyses for draft proposed rules that are formally submitted to OIRA after December 31, 2003, and for draft final rules that are formally submitted to OIRA after December 31, 2004. (However, if the draft proposed rule is subject to the Circular, then the draft final rule will also be subject to the Circular, even if it is submitted prior to January 1, 2005.) To the extent practicable, agencies should comply earlier than these effective dates. Agencies may, on a case-by-case basis, seek a waiver from OMB if these effective dates are impractical.

FN1. We use the term "proposed" to refer to any regulatory actions under consideration regardless of the stage of the regulatory process.

FN2. See Mishan EJ (1994), *Cost-Benefit Analysis*, fourth edition, Routledge, New York.

FN3. See Coase RH (1960), *Journal of Law and Economics*, 3, 1-44.

FN4. Mishan EJ (1994), *Cost-Benefit Analysis*, fourth edition, Routledge, New York.

FN5. For a full discussion of CEA, see Gold, ML, Siegel, JE, Russell, LB, and Weinstein, MC (1996), *Cost Effectiveness in Health and Medicine: The Report of the Panel on Cost-Effectiveness in Health and Medicine*, Oxford University Press, New York.

FN6. Gold ML, Siegel JE, Russell LB, and Weinstein MC (1996), *Cost Effectiveness in Health and Medicine: The Report of the Panel on Cost-Effectiveness in Health and Medicine*, Oxford University Press, New York, pp. 284-285.

FN7. Russell LB and Sisk JE (2000), "Modeling Age Differences in Cost Effectiveness Analysis", *International Journal of Technology Assessment in Health Care*, 16(4), 1158-1167.

FN8. Plisk in JS, Shepard DS, and Weinstein MC (1980), "Utility Functions for Life Years and Health Status," *Operations Research*, 28(1), 206-224.

FN9. Hammitt JK (2002), "QALYs Versus WTP," *Risk Analysis*, 22(5), pp. 985-1002.

FN10. For the least stringent alternative, you should estimate the incremental benefits and costs relative to the baseline. Thus, for this alternative, the incremental effects would be the same as the corresponding totals. For each alternative that is more stringent than the least stringent alternative, you should estimate the incremental benefits and costs relative to the closest less-stringent alternative.

FN11. See Hanemann WM (1991), *American Economic Review*, 81(3), 635-647.

FN12. See Kahneman D, Knetsch JL, and Thaler RH (1991), "Anomalies: The Endowment Effect, Loss Aversion, and Status Quo Bias," *Journal of Economic Perspectives* 3(1), 192-206.

FN13. Consumer surplus is the difference between what a consumer pays for a unit of a good and the maximum amount the consumer would be willing to pay for that unit. It is measured by the area between the price and the demand curve for that unit. Producer surplus is the difference between the amount a producer is paid for a unit of a good and the minimum amount the producer would accept to supply that unit. It is measured by the area between the price and the supply curve for that unit.

FN14. See McConnell KE (1997), *Journal of Environmental Economics and Management*, 32, 22-37.

FN15. See Loomis JB (1992), *Water Resources Research*, 28(3), 701-705 and Kirchoff, S, Colby, BG, and LaFrance, JT (1997), *Journal of Environmental Economics and Management*, 33, 75-93.

FN16. Mishan EJ (1994), *Cost-Benefit Analysis*, fourth edition, Routledge, New York.

FN17. See Viscusi WK and Aldy JE, *Journal of Risk and Uncertainty* (forthcoming) and Mrozek JR and Taylor LO (2002), *Journal of Policy Analysis and Management*, 21(2), 253-270.

FN18. Distinctions between "voluntary" and "involuntary" should be treated with care. Risks are best considered to fall within a continuum from "voluntary" to "involuntary" with very few risks at either end of this range. These terms are also related to differences in the cost of avoiding risks.

FN19. Graham JD (2003), Memorandum to the President's Management Council, Benefit-Cost Methods and Lifesaving Rules. This memorandum can be found at http://www.whitehouse.gov/omb/inforeg/pmc_benefit_cost_memo.pdf

FN20. Office of Information and Regulatory Affairs, OMB, Memorandum to the President's Management Council, ibid.

FN21. For more information, see Dockins C., Jenkins RR, Owens N, Simon NB, and Wiggins LB (2002), *Risk Analysis*, 22(2), 335-346.

FN22. Committee on Risk Assessment of Exposure to Radon in Drinking Water, Board on Radiation Effects Research, Commission on Life Sciences (1996), *Risk Assessment of Radon in Drinking Water*, National Research Council, National Academy Press, Washington, DC.

FN23. Portney PR and Weyant JP, eds. (1999), *Discounting and Intergenerational Equity*, Resources for the Future, Washington, DC.

FN24. Weitzman ML In Portney PR and Weyant JP, eds. (1999), *Discounting and Intergenerational Equity*, Resources for the Future, Washington, DC.

FN25. In some contexts, the word "variability" is used as a synonym for statistical variation that can be described by a

theoretically valid distribution function, whereas “uncertainty” refers to a more fundamental lack of knowledge. Throughout this discussion, we use the term “uncertainty” to refer to both concepts.

FN26. When disseminating information, agencies should follow their own information quality guidelines, issued in conformance with the OMB government-wide guidelines (67 FR 8452, February 22, 2002).

FN27. Clemen RT (1996), *Making Hard Decisions: An Introduction to Decision Analysis*, second edition, Duxbury Press, Pacific Grove.

FN28. The purpose of Delphi methods is to generate suitable information for decision making by eliciting expect judgment. The elicitation is conducted through a survey process which eliminates the interactions between experts. See Morgan MG and Henrion M (1990), *Uncertainty: A Guide to Dealing with Uncertainty in Quantitative Riskand Policy Analysis*, Cambridge University Press.

FN29. Cooke RM (1991), *Experts in Uncertainty: Opinion and Subjective Probability in Science*, Oxford University Press.

FN30. The Regulatory Flexibility Act (5 U.S.C. 603(c), 604).

Circular No. A-4, 2003 WL 24011971 (O.M.B.)

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