How Agencies Monetize "Statistical Lives" Expected to Be Saved By Regulations

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March 24, 2010

Congressional Research Service
7-....
www.crs.gov
R41140

CRS Report for Congress
Prepared for Members and Committees of Congress

Summary

Federal health, safety, and environmental regulations are often designed to reduce the risk of death, illness, or injury from exposure to a particular hazard (e.g., arsenic in drinking water or rollover car crashes). As part of an economic analysis required by Executive Order 12866, the issuing agencies often place a monetary value on these expected health benefits by determining the number of "statistical lives" that the rules are expected to extend or save, and then multiplying that number by an estimated "value of a statistical life" (VSL). For example, if 100,000 people are each willing to pay an average of $50 to reduce a 1 in 100,000 risk of dying from a particular risk, then the VSL for the population relative to that risk is $5 million ($50 times 100,000).

The monetization of regulatory health benefits is often controversial, and the process by which federal agencies do so is not widely understood. This report summarizes current government-wide requirements for benefit-cost analysis and the monetization of health benefits, and describes agency-specific policies in selected health, safety, and environmental agencies. Also, the report provides examples of final rules published by the selected agencies from 2007 through 2009 that monetized expected health benefits and describes how those values were used in the economic analyses for the rules. Finally, the report offers some concluding observations.

OMB Circular A-4, which was issued in September 2003, delineates what is expected in a good regulatory analysis while giving the agencies substantial flexibility. The circular notes that academic studies have identified VSLs from $1 million to $10 million, but it does not recommend that agencies use a particular VSL. Circular A-4 says that VSLs should not vary by age, but recommends that agencies consider providing estimates in terms of both VSLs and the value of statistical life years (VSLY) extended. The circular says that agencies should use larger VSLYs for senior citizens, but does not specify how much larger or what constitutes a "senior citizen." When the benefits and costs of a rule are expected to occur at different times, the circular says agencies should compare them in "present values" using both a 3% and a 7% discount rate.

Some federal agencies have written policies on the monetization of expected health benefits, and those policies differ in some respects. For example, in 2009, the Department of Transportation's (DOT) VSL was $6.0 million while the Environmental Protection Agency's (EPA) VSL was nearly $7.9 million. Other agencies tended to use the DOT or EPA VSLs, or used VSLs that they or other agencies have used in previous rules. DOT's policy established the value of injuries prevented as percentages of the VSL, whereas EPA's policy does not recommend particular values for injuries or illnesses.

In more than 20 final rules that were issued between 2007 and 2009, federal agencies used somewhat different VSLs, and used VSL information in different ways. The agencies often compared monetized health benefits with costs to determine whether to regulate, but in some cases the agencies used VSL estimates in "break-even" analyses (showing at what point the value of the health benefits equals the cost), or to rule out a regulatory option. The agencies sometimes used lower and higher VSLs, and sometimes used multiple discount rates, in sensitivity analyses. Some of the rules illustrated that the size of the VSL used can affect whether a rule is expected to produce positive net benefits. Some of the apparent variations in the agencies' economic analyses may be due to differences in the degree to which the agencies disclosed their procedures.

This report will not be updated.

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Introduction

Many federal health, safety, and environmental regulations are primarily designed to reduce the risk of death, illness, or injury from exposure to a particular hazard (e.g., arsenic in drinking water, rollover car crashes, or terrorist attacks on airplanes). The agencies issuing these regulations often place a monetary value on these expected health benefits by determining the number of "statistical lives" that the rules are expected to save, and then multiplying that number by an estimated "value of a statistical life." The term "statistical life" is used to reflect the degree of risk reduction expected in a given population, and does not refer to any individual's life.

For example, on January 15, 2010, the Federal Railroad Administration (FRA) within the Department of Transportation (DOT) published a final rule in the *Federal Register* defining criteria for "positive train control" systems that were required on certain passenger and freight rail lines by the Rail Safety Improvement Act of 2008 (P.L. 110-432, 122 Stat. 4854, October 16, 2008).[1] Congress enacted the statutory requirement in the wake of several serious rail accidents involving dozens of fatalities and hundreds of injuries. FRA estimated that the rule would reduce deaths and injuries from this type of accident by more than 50%, valued each "statistical life" expected to be saved by the rule at $6 million, and considered each prevented injury a percentage of the value of a statistical life. The agency ultimately valued the estimated reductions in deaths over the next 20 years at between $175 million and $269 million (in 2009 dollars), and valued the reductions in injuries at between $133 million and $204 million (also in 2009 dollars). Together, these monetized health benefits represented more than 70% of the rule's estimated total benefits.

The monetization of reductions in the number of expected fatalities, injuries, and illnesses in the rulemaking process is often controversial, and the process by which federal agencies place monetary values on such benefits is not widely understood. This report summarizes current government-wide requirements for benefit-cost analysis and the monetization of health benefits, and describes agency-specific policies in selected health, safety, and environmental agencies. Also, the report provides examples of final rules published by the selected agencies from 2007 through 2009 that monetized expected health benefits, and describes how those values were used in the economic analyses for the rules. Finally, the report offers some concluding observations.

Government-Wide Standards

Although a variety of statutes and executive orders require some form of economic analysis during the rulemaking process,[2] the most broadly applicable of those requirements is in Executive Order 12866, which was issued by President Clinton in 1993.[3] The executive order requires

[1] U.S. Department of Transportation, Federal Railroad Administration, "Positive Train Control Systems," 75 *Federal Register* 2598, January 15, 2010. "Positive train control systems" refers to technology that can prevent accidents such as train-to-train collisions and train movements through a switch left in the wrong position.

[2] Other analytical requirements are in the Unfunded Mandates Reform Act of 1995, the National Environmental Policy Act of 1969, and the Regulatory Flexibility Act of 1980. For a discussion of these and other rulemaking requirements, see CRS Report RL32240, *The Federal Rulemaking Process: An Overview*, by (name redacted).

[3] The President, Executive Order 12866, "Regulatory Planning and Review," 58 *Federal Register* 51735, October 4, 1993. Earlier executive orders (e.g., Executive Order 12291) had also required economic analyses for certain rules.

covered federal agencies[4] to determine the costs and benefits of all "significant" regulatory actions, and requires more complete benefit-cost analyses for all regulatory actions that are expected to be "economically significant" (e.g., have an annual $100 million impact on the economy).[5] In recent years, an average of about 600 federal rules have been considered "significant" each year, of which about 100 have been considered "economically significant."[6] The executive order also says that agencies are to adopt a regulation only after determining that the benefits of the rule "justify" its costs.[7]

With regard to regulatory benefits, Section 6(a)(3)(C) of Executive Order 12866 requires the issuing agency to provide to the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB) "an assessment, including the underlying analysis, of benefits anticipated from the regulatory action (such as, but not limited to, the promotion of the efficient functioning of the economy and private markets, the enhancement of health and safety, the protection of the natural environment, and the elimination or reduction of discrimination or bias) together with, to the extent feasible, a quantification of those benefits." The executive order requires similar assessments of regulatory costs, and an explanation of why the planned regulatory action is preferable to potential alternatives.

OMB Circular A-4

The regulatory analysis requirements in Executive Order 12866 are more fully delineated in OMB Circular A-4, which was issued in September 2003.[8] The circular states that it is "designed to assist analysts in the regulatory agencies by defining good regulatory analysis ... and standardizing the way benefits and costs of Federal regulatory actions are measured and reported."[9] Although Circular A-4 states that a "complete regulatory analysis includes a

[4] Section 3(b) of Executive Order 12866 defines a covered agency as "any authority of the United States that is an 'agency' under 44 U.S.C. 3502(1), other than those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(10)." Exempt independent regulatory agencies include the Federal Communications Commission, the Nuclear Regulatory Commission, and the Securities and Exchange Commission.

[5] Section 3(f) of Executive Order 12866 defines a "significant" regulatory action as "any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order." Regulatory actions meeting the first of these four criteria are considered "economically significant."

[6] See http://www.reginfo.gov/public/do/eoCountsSearchInit?action=init for information on the number of rules considered "significant" and "economically significant" under Executive Order 12866.

[7] Section 1(b)(6) of Executive Order 12866. Some statutes forbid any consideration of costs in setting a health standard (e.g., the national ambient air quality standards in the Clean Air Act), and such prohibitions have been upheld in court (e.g., *Whitman v. American Trucking Associations*, 531 U.S. 457 (2001)). Other statutes establish other requirements (e.g., requiring agencies to regulate to the extent "feasible" or "achievable") whose effect on the use of cost-benefit analysis in decision making is less clear.

[8] OMB Circular A-4, "Regulatory Analysis," September 17, 2003. The circular is available at http://www.whitehouse.gov/omb/assets/regulatory_matters_pdf/a-4.pdf. Circular A-4 refined a "best practices" document of 1996 that was issued as guidance in 2000. The circular took effect for economically significant proposed rules on January 1, 2004, and for economically significant final rules on January 1, 2005.

[9] Ibid., p. 1.

discussion of non-quantified as well as quantified benefits and costs,"[10] it also says that a "distinctive feature of [benefit-cost analysis] 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."[11] It goes on to say that agencies "should monetize quantitative estimates whenever possible."[12]

Estimates of regulatory health benefits are sometimes derived from risk assessments, which systematically determine whether a particular hazard exists, and if so how much damage or injury can be expected from exposures to that hazard.[13] In addition to its use in benefit-cost analysis, risk assessment can also help agencies identify issues of potential concern (e.g., whether exposure to a given risk agent causes effects such as cancer), and can help them select regulatory options.

As noted previously, the number of "statistical lives" expected to be saved reflects the degree of risk reduction expected in a given population, and does not refer to any particular individual.[14] For example, if a regulation is expected to reduce the annual risk of death from a particular hazard by 1 in 100,000 for a population of 100,000, that effect is characterized as representing one "statistical life" extended or "saved" per year. The number of statistical lives saved is a function of the size of the population involved and the size of the risk. For example, if the annual risk of death from the same hazard is reduced by one in 1 million for each of 1 million people, the regulation is also characterized as saving one statistical life per year. Alternatively, if the risk is reduced by 1 in 100,000 for a population of 500,000, the rule is said to save five statistical lives.

Willingness-to-Pay and the Value of a Statistical Life

Circular A-4 indicates that the concept of "opportunity cost" "is the appropriate concept for valuing both benefits and costs," and describes the principle of "willingness-to-pay" as capturing the notion of opportunity cost "by measuring what individuals are willing to forgo to enjoy a particular benefit."[15] The public's willingness-to-pay is often measured using surveys (sometimes referred to as "stated preference" studies) in which respondents are asked how much they would be willing to pay to avoid particular risks or outcomes. For example, if 100,000 people are each willing to pay an average of $50 to reduce a 1 in 100,000 risk of dying from exposure to a particular risk, then the "value of a statistical life" (VSL) for the population relative to that risk is $5 million ($50 times 100,000).

An alternative to "willingness-to-pay" is to measure individuals' "willingness-to-accept" a risk, which Circular A-4 says "can also provide a valid measure of opportunity cost."[16] These "revealed preference" studies use data from market transactions or observed behavior to estimate the value of certain risks. One example is wage-risk studies, in which researchers compare

[10] Ibid., p. 3.

[11] Ibid., p. 10.

[12] Ibid., p. 27.

[13] For information on current, government-wide risk assessment policies, see "Updated Principles for Risk Analysis," which was issued in September 2007 by OIRA and the Office of Science and Technology Policy (available at http://www.whitehouse.gov/omb/assets/regulatory_matters_pdf/m07-24.pdf). For information on OMB's efforts to issue other risk analysis guidance, see CRS Report RL33500, *OMB and Risk Assessment*, by (name redacted).

[14] Circular A-4, p. 29.

[15] Ibid., p. 18.

[16] Ibid.

workers' earnings in occupations with varying levels of on-the-job risks. Circular A-4 says that revealed preference studies "are sometimes difficult to implement given the complexity of market transactions and the paucity of relevant data."[17]

The circular also says that economists tend to view willingness-to-pay as "the most appropriate measure of opportunity costs,"[18] and that the willingness-to-pay approach is "the best methodology to use if reductions in fatality risks are monetized."[19] In monetizing health benefits, the circular states that a willingness-to-pay 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," and also because it "allows you to directly compare your results to the other benefits and costs in your analysis."[20]

Circular A-4 draws a clear distinction between monetizing anticipated reductions in the risk of death and placing a value on human life.

> 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.[21]

Flexibility and Transparency

OMB has, in the past, used a particular VSL to assign a monetary value to agencies' quantified (but unmonetized) regulatory health benefits.[22] However, Circular A-4 does not recommend that agencies use a particular VSL in all of their economic analyses. Noting the "considerable body of academic literature" available on the valuation of reductions in premature mortality,[23] the circular simply states that a "substantial majority of the resulting estimates of VSL vary from roughly $1 million to $10 million per statistical life."[24] Circular A-4 permits agencies substantial flexibility in determining how expected reductions in mortality and morbidity are valued, but requires agencies to be transparent with regard to those decisions.

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[17] Ibid., p. 20.

[18] Ibid.

[19] Ibid., p. 29.

[20] Ibid., p. 28.

[21] Ibid., p. 29.

[22] For example, in OMB's 2002 report to Congress on the costs and benefits of regulations, to develop estimates of the benefits and costs of 20 major rules, OMB said it assumed a VSL of $5 million in Department of Labor rules where fatality risks were quantified but not monetized. See Office of Management and Budget, *Stimulating Smarter Regulation*, 2002, pp. 109-112, http://www.whitehouse.gov/omb/assets/omb/inforeg/2002_report_to_congress.pdf.

[23] See, for example, W. Kip Viscusi and Joseph E. Aldy, "The Value of a Statistical Life: A Critical Review of Market Estimates throughout the World," *Journal of Risk and Uncertainty* vol. 27 (2003), pp. 239-256.

[24] Circular A-4, p. 30. In some cases, agencies have viewed this statement as an OMB approval of VSLs in this range. For example, DOT's February 2008 guidance states that OMB Circular A-4 "endorses values between $1 million and $10 million." See p. 1 of "Revised Departmental Guidance" portion of the February 2008 DOT memorandum discussed later in this report.

> 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 risk from environmental hazards), you should explain your selection of estimates and any adjustments of the estimates to reflect the nature of the risks 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.[25]

As a consequence of this flexibility, federal agencies reportedly use somewhat different VSLs.[26]

VSLs and Contextual Factors

Circular A-4 also notes 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."[27] Contextual factors that have been considered potentially relevant include whether the death being prevented by the rule is sudden or prolonged, whether the risk is incurred voluntarily or not, and the age of the affected population. Age has been a particularly controversial contextual issue, with some asserting that older beneficiaries of a rule with relatively little additional life expectancy should be valued less than younger beneficiaries with much longer life expectancies.[28]

In May 2003, the Environmental Protection Agency (EPA) used an "age adjustment factor" that valued the "statistical lives" of older people 37% less than those of younger people in calculating the benefits of the George W. Bush Administration's "Clear Skies" initiative ($2.3 million per statistical life for older people versus $3.7 million for younger people).[29] Using the lower VSL for older people in a "sensitivity analysis"[30] had the effect of lowering the annual estimated benefits

[25] Ibid., pp. 30-31.

[26] Memorandum from Tyler D. Duvall, Assistant Secretary for Transportation Policy, and D.J. Gribbin, General Counsel, to DOT secretarial officers and modal administrators, "Treatment of the Economic Value of a Statistical Life in Departmental Analyses," February 5, 2008, available at http://ostpxweb.dot.gov/policy/reports/080205.htm. According to this memorandum, OMB said that the Food and Drug Administration tended to use VSLs of $5 million and $6.5 million, the Environmental Protection Administration (EPA) had used values as high as $7 million, and that the Department of Labor followed the lead of EPA. See also, Lisa A Robinson, "How U.S. Government Agencies Value Mortality Risk Reductions," *Review of Environmental Economics and Policy*, vol. 1 (Summer 2007) pp. 283-299; and Lisa A. Robinson, "Valuing Mortality Risk Reductions in Homeland Security Regulatory Analyses," June 2008, pp. 10-21, available from the author of this report.

[27] Ibid.

[28] See, for example, Cass R. Sunstein, "Lives, Life Years, and Willingness to Pay," *Columbia Law Review*, vol. 104 (January 2004), pp. 205-252, in which the author said that "A program that saves younger people is better, along every dimension, than an otherwise identical program that saves older people." Sunstein was confirmed as administrator of OIRA in September 2009.

[29] Steve Cook, "OMB, EPA Accused of Suggesting Lives of Older People Valued Less Than Others," *BNA Daily Report for Executives*, May 8, 2003. EPA used the "age adjustment factor" as part of an alternative "sensitivity" analysis for this initiative. The OIRA administrator at the time later said that the Clinton Administration first used such a factor in 2000 emissions limits for highway diesel engines.

[30] A sensitivity analysis tests the effect that changes in certain variables (e.g., the VSL) has on the results of an analysis.

of the Clear Skies initiative by more than $13 billion from the base estimate. After criticisms from some interest groups and Members of Congress, the EPA administrator announced that the age adjustment factor (which had been characterized by critics as a "senior death discount") would no longer be used.[31] The OIRA administrator later issued a memorandum to the President's Management Council advising analysts at EPA and other federal agencies to discontinue the use of age adjustment factors in VSL analysis.[32] Subsequently, a general provision in the FY2004 consolidated appropriations bill prohibited funding for any economic analyses that used age-adjustment factors.[33]

Circular A-4 states that "[i]n light of continuing questions over the effect of age on VSL estimates, you should not use an age-adjustment factor in an analysis using VSL estimates."[34] The circular notes that an EPA science advisory board had examined the issue of whether differing valuations should be used for age and other contextual factors and concluded that "the available literature does not support adjustments of VSL for most of these factors."[35]

Value of Statistical Life Years (VSLY)

Circular A-4 does, however, recommend that federal agencies consider providing estimates of both VSL and another measure of reductions in fatality risks—the "value of statistical life years (VSLY) extended."[36] As described in the circular,

> 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.[37]

The circular goes on to say that when agencies 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

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[31] Cindy Skrzycki, "Under Fire, EPA Drops the 'Senior Death Discount,'" *Washington Post*, May 13, 2003, p. E-1.

[32] See http://www.whitehouse.gov/omb/assets/regulatory_matters_pdf/pmc_benefit_cost_memo.pdf for a copy of this memorandum.

[33] Section 419 of the Consolidated Appropriations Act for 2004 (P.L. 108-199, 118 Stat. 416) stated that "none of the funds provided in this Act may be expended to apply, in a numerical estimate of the benefits of an agency action prepared pursuant to Executive Order No. 12866 or section 312 of the Clean Air Act (42 U.S.C. 7612), monetary values for adult premature mortality that differ based on the age of the adult."

[34] Circular A-4, p. 30.

[35] Ibid. The panel did, however, reportedly consider it appropriate to adjust those values for changes in income and any time lag in the occurrence of adverse health effects.

[36] The OIRA administrator at the time, John Graham, had recommended the use of both VSL and VSLY methods when performing benefit-cost analyses in his May 30, 2003, memorandum to the President's Management Council. For a copy of this memorandum, see http://www.whitehouse.gov/omb/assets/regulatory_matters_pdf/pmc_benefit_cost_memo.pdf.

[37] Circular A-4, p. 30. The current OIRA administrator, Cass Sunstein, voiced strong support for using VSLY instead of VSL. See Cass R. Sunstein, "Lives, Life Years, and Willingness to Pay," *Columbia Law Review*, vol. 104 (January 2004), pp. 205-252.

health and safety."[38] Circular A-4 does not indicate how much larger the VSLY should be for senior citizens, or what constitutes a "senior citizen."[39] The circular goes on to say that agencies should not conclude that regulations with greater numbers of life-years extended are necessarily better than regulations with fewer numbers of life-years extended.[40]

Some observers have criticized the use of VSLY as discriminatory against older people, for older people have shorter life expectancies and, therefore, lower cumulative values of life than younger people.[41] They assert that the use of VSLYs can have the same bottom-line effect as using a lower VSL for older people (i.e., causing lower values being placed on mortality risks to the old).[42] This effect can occur even if a much larger VSLY is used for senior citizens. For example, an agency could use a $400,000 VSLY for those 65 years of age or older with an average life expectancy of 15 years, yielding an effective VSL of $6 million. However, using a VSLY of only $200,000 for younger citizens with an average life expectancy of 40 years yields an effective VSL of $8 million.

Others have voiced strong support for the use of VSLY in agencies' regulatory analyses, with some preferring its use over VSLs. For example, current OIRA administrator Cass Sunstein wrote the following in 2004 (five years before he became administrator in 2009):

> My simplest claim in this Essay is that in terms of welfare, it is fully appropriate to focus on life-years, not merely lives, and that both academic and public criticisms of the life years approach are misconceived. The reasons for this conclusion are simple. No program literally "saves" lives; life-extension is always what is at issue. If the goal is to promote people's welfare by lengthening their lives, a regulation that saves five hundred life-years (and, let us say, twenty-five people) is, other things being equal, better than a regulation that saves fifty life-years (also, let us say, twenty-five people). A program that saves younger people is better, in this sense, than an otherwise identical program that saves older people—a statement that seems controversial only if we see life as a snapshot in which people are frozen at their current points in the age distribution.[43]

[38] Ibid. OIRA Administrator Graham also took this position in his May 30, 2003, memorandum to the President's Management Council.

[39] In his May 30, 2003, memorandum to the President's Management Council, OIRA Administrator Graham said that EPA had used $434,000 per life-year saved for persons over age 65 and $172,000 per life-year saved for those under age 65. However, the administrator did not recommend those values, saying that "more research is needed to provide a complete picture of how VSLY varies over the life span."

[40] Circular A-4, p. 30.

[41] See, for example, Laura J. Lowenstein and Richard L. Revesz, "Anti-Regulation Under the Guise of Rational Regulation: The Bush Administration's Approaches to Valuing Lives in Environmental Cost-Benefit Analyses," *Environmental Law Reporter*, vol. 34 (2004), pp. 10954 – 10994. The authors cite three basic problems in the VSLY approach: (1) inconsistency with the willingness-to-pay tenet of economic theory, (2) inconsistency with the standard economic observation that individuals generally assign greater value to goods that are limited in supply, and (3) inconsistency with existing empirical data.

[42] See, for example, Steve Cook, "OMB Calls for Cost-Benefit Analysis Assigning Less Value to Lives of Elderly," *BNA Daily Report for Executives*, June 5, 2003, p. A-23. The article referred to the endorsement of VSLY in the OIRA administrator's May 30, 2003, memorandum. Lisa Heinzerling of the Center for Progressive Regulation was quoted as saying that using VSLYs accomplishes the same thing as the age-adjustment factor, devaluing the lives of seniors.

[43] Cass R. Sunstein, "Lives, Life Years, and Willingness to Pay," *Columbia Law Review*, vol. 104 (January 2004), pp. 205-252, at pp. 208-209.

Sunstein goes on to suggest that, when "willingness to pay" is used as part of a benefit-cost analysis, "primary attention should be paid to VSLY rather than VSL."[44]

Discount Rates

In many instances, the benefits and the costs of a regulation are expected to occur at different times. For example, EPA may require that oil refineries spend money immediately to reduce a certain type of air pollution, but the anticipated reductions in pollution-related deaths and illnesses may not be expected to occur until years or even decades later. In such situations, Circular A-4 states that "a discount factor should be used to adjust the estimated benefits and costs for differences in timing."[45] The circular cites three primary rationales for discounting:

> (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. [46]

Discounted benefits or costs are sometimes referred to as "discounted present values," or simply "present values." Circular A-4 states that costs and benefits can be compared to determine net benefits only when they have been discounted to present values, and says that agencies should provide estimates of net benefits in regulatory analyses using both a 3% and a 7% discount rate.[47] However, noting that the 7% rate is "the average before-tax rate of return to private capital in the U.S. economy," the circular also says that the 7% rate "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."[48]

Some observers assert that while discounting makes sense in financial decision making (e.g., $100 received today is worth more than $100 received 10 years from now), the use of discounting in health, safety, and environmental regulation is inappropriate in that it diminishes the value of lives saved in the future. For example, they argue, using a 3% discount rate, $100 million in monetized "statistical lives" saved 20 years from now has a discounted present value of just $55 million. Using a 5% discount rate, $100 million 20 years from now has a present value of only

[44] Ibid., p. 211.

[45] Circular A-4, p. 32. OMB's basic guidance on discount rates is in OMB Circular A-94. To view a copy of this circular, see http://www.whitehouse.gov/omb/assets/a94/a094.pdf.

[46] Ibid.

[47] Ibid., p. 34. Circular A-94 provides OMB's basic guidance on discount rates, which states that the 7% rate be used as a base case for regulatory analysis.

[48] Ibid., p. 33.

$38 million.[49] Other, more normative concerns have also been raised regarding the ethics of intergenerational discounting.[50]

Cost-Effectiveness Analysis

In addition to benefit-cost analysis, Circular A-4 also recommends that agencies use cost-effectiveness analysis, which attempts to determine how a given regulatory goal can be achieved at the least cost (e.g., dollars per life saved). The circular says that agencies should prepare both benefit-cost analysis and cost-effectiveness analysis "wherever possible."[51] It also says that agencies "should prepare [cost-effectiveness analyses] 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."[52] Benefit-cost analysis should be performed for such rules "to the extent that valid monetary values can be assigned to the primary expected health and safety outcomes."[53]

Circular A-4 also says that final outcomes such as lives saved or life-years saved are better measures of effectiveness than more intermediate measures such as tons of pollution reduced or crashes avoided.[54] It goes on to say that more integrated measures of effectiveness, such as the number of "equivalent lives" saved or "quality-adjusted life years" saved, have the advantage of accounting for a rule's impact on both morbidity (i.e., nonfatal illness, injury, and impairment of the quality of life) as well as premature death, although such measures also have certain disadvantages (e.g., assumptions about individual preferences).[55] Ultimately, Circular A-4 does not require agencies to use any specific measure of effectiveness. Instead, it encourages agencies to report results with multiple measures of effectiveness, and to explain why certain measures were used.[56]

Break-Even Analysis

When non-quantified benefits and costs are likely to be important considerations in a rule, Circular A-4 states that agencies should carry out a "threshold" or "break-even" analysis to evaluate their significance.[57] This type of analysis answers the question "How small could the value of the non-quantified benefits be before the costs exceed the benefits?" In the context of health and safety regulations that are expected to reduce fatalities, a break-even analysis could use different VSLs or VSLYs to determine the point at which net benefits would be provided. For

[49] Lisa Heinzerling and Frank Ackerman, "Pricing the Priceless: Cost-Benefit Analysis of Environmental Protection," Georgetown University, 2002, p. 6.

[50] For a discussion of this issue, see Cass R. Sunstein and Arden Rowell, "On Discounting Regulatory Benefits: Risk, Money, and Intergenerational Equity," *University of Chicago Law Review*, vol. 74 (Winter 2007), pp. 171-209. This article is part of a symposium in that issue of the *Review* on "Intergenerational Equity and Discounting."

[51] Circular A-4., p. 9.

[52] Ibid.

[53] Ibid.

[54] Ibid., p. 12.

[55] "Quality-adjusted life year" measures attempt to assess not only the quantity of life extensions, but also the quality of life during that period. For example, whereas a year of perfect health might be weighted 1.0, a year in which a person is forced to remain in bed might be weighted 0.5.

[56] Ibid., p. 13.

[57] Ibid., p. 2.

example, if a rule is expected to cost $100 million, at a VSL of $5 million, the rule would only have to prevent 20 deaths for the benefits to equal the costs (assuming that prevented premature mortalities are the only benefits). However, if the VSL is $10 million, the rule would only have to prevent 10 deaths for the benefits to equal the costs.

Agency-Specific Policies

In addition to the government-wide policies established in OMB Circular A-4, some federal departments and agencies have established their own policies regarding how expected reductions in deaths, illnesses, and injuries are to be valued in their economic analyses. Other departments and agencies have no written policies regarding how such benefits should be valued, but indicated that they rely on the policies of other departments or agencies, or have a consistent approach even without a written policy.

Department of Transportation

Since the early 1980s, DOT has had written policies regarding how expected reductions in fatalities and non-fatal injuries should be valued by agencies throughout the department. In June 1990, DOT issued departmental guidance recommending that agencies use $1.5 million as the dollar value of a statistical life in economic analyses, but noted that research was underway that could cause that value to be revised.[58] In January 1993, DOT concluded that research and established the value of a statistical life to be used in departmental analyses at $2.5 million.[59] DOT later adjusted that value for inflation to $2.7 million in March 1995, and to $3.0 million in January 2002.

The DOT VSL remained at that level until February 2008, when the department's general counsel and assistant secretary for transportation policy issued a memorandum stating that recent scholarship and a comparison with the practices of other federal agencies had demonstrated that the $3.0 million value was "seriously out of date."[60] The memorandum stated that the best estimate of the economic value of preventing a human fatality at that time was $5.8 million, and said that this value "should be used, effective immediately, for analyses performed by DOT analysts."[61] To develop its $5.8 million VSL, DOT used the average of five studies that ranged from $2.6 million to $8.5 million in 2007 dollars. DOT also required sensitivity analyses at $3.2 million and $8.4 million to "assist decision-makers in recognizing the necessary imprecision of any assumption of the value of a statistical life, as well as the sensitivity of a cost-benefit

[58] Cited in a memorandum from Walter B. McCormick, Jr., General Counsel, and Jeffrey N. Shane, Assistant Secretary for Policy and International Affairs, to assistant secretaries and modal administrators, January 8, 1993, available from the author of this report.

[59] Memorandum from Walter B. McCormick, Jr, General Counsel, and Jeffrey N. Shane, Assistant Secretary for Policy and International Affairs, to assistant secretaries and modal administrators, January 8, 1993, available from the author. DOT said that the 1993 value was based primarily on a 1988 study that yielded a likely VSL of $2.2 million in 1988 dollars. See T.R. Miller, "The Plausible Range for the Value of Life—Red Herrings Among the Mackerel," *Journal of Forensic Economics*, vol. 3 (1990), pp. 17-40.

[60] Memorandum from Tyler D. Duvall, Assistant Secretary for Transportation Policy, and D.J. Gribbin, General Counsel, to DOT secretarial officers and modal administrators, "Treatment of the Economic Value of a Statistical Life in Departmental Analyses," February 5, 2008, available at http://ostpxweb.dot.gov/policy/reports/080205.htm.

[61] Ibid., p. 1.

calculation to changes in that value."[62] Also, analysts were required to disaggregate the major elements of each regulatory action to "enable decision-makers to appreciate the arguments for including or excluding each item."

In March 2009, the deputy assistant secretary for transportation policy and the acting general counsel issued a memorandum increasing the VSL from $5.8 million to $6.0 million.[63] The memorandum said the increase was based on the wages and salaries component of the Employment Cost Index and the Consumer Price Index. It also said that DOT analysts need not modify analyses already prepared if doing so would be time consuming and would not have a significant impact on the comparison of benefits and costs. The memorandum did not mention changing the values for supplementary analyses (which had been set in 2008 at $3.2 million and $8.4 million).

Value of Preventing Injuries

DOT's January 1993 VSL guidance also established the relative value of injuries of varying severity as a percentage of the economic value of a statistical life. DOT said it did so because detailed willingness-to-pay estimates for a range of injuries were unavailable, and using previously conducted research,[64] based the percentages on the Maximum Abbreviated Injury Scale (MAIS), which categorizes non-fatal injuries into five levels ranging from minor to critical. The percentages used in the January 1993 guidance have not been updated, and are reflected in **Table 1** below. The last column of the table shows the monetary value of those percentages using DOT's current $6.0 million VSL.

Table 1. Valuation of Non-fatal Injuries at DOT

MAIS Level	Severity	Fraction of VSL	Dollar Value at VSL of $6.0 million
MAIS 1	Minor	0.0020	$12,000
MAIS 2	Moderate	0.0155	$93,000
MAIS 3	Serious	0.0575	$345,000
MAIS 4	Severe	0.1875	$1,125,000
MAIS 5	Critical	0.7625	$4,575,000

Source: Memorandum from Tyler D. Duvall, Assistant Secretary for Transportation Policy, and D.J. Gribbin, General Counsel, to DOT secretarial officers and modal administrators, February 5, 2008, which was included as an attachment to DOT's March 2009 policy memorandum.

[62] Ibid.

[63] Memorandum from Joel Szabat, Deputy Assistant Secretary for Transportation Policy, and Lindy Knapp, Acting General Counsel, to secretarial officers and modal administrators, "Treatment of the Economic Value of a Statistical Life in Departmental Analyses—2009 Annual Revision," March 18, 2009. For a copy of this memorandum, see http://regs.dot.gov/docs/VSL%20Guidance%202008%20and%202009rev.pdf.

[64] Ted R Miller, C. Philip Brinkman, and Stephen Luchter, "Crash Costs and Safety Investment," Proceedings of the 32nd Annual Conference, Association for the Advancement of Automotive Medicine, Des Plaines, IL, 1988.

Department of Homeland Security

An official from the Department of Homeland Security (DHS) told CRS that the department does not have a written policy regarding the valuation of the expected health or safety benefits of its rules.[65] When DHS was first established in 2003, he said the department tended to rely on DOT's policies regarding how reductions in fatality and injury risks should be valued, particularly in those DHS agencies that were originally housed within DOT (e.g., the U.S. Coast Guard and the Transportation Security Administration (TSA)). As indicated later in this report, although DHS was created in 2003, some DHS agencies have continued to reference DOT's VSL policy in rules that they issued in 2008 and 2009.[66]

A June 2008 report prepared for U.S. Customs and Border Protection (CBP) within DHS stated that wage-risk studies "provide the most appropriate source for VSL estimates for application in the homeland security context."[67] The report recommended the use of a VSL of $6.1 million in 2007 dollars, with a 95% confidence interval of $4.8 million to $7.6 million. After adjustment of the estimates for changes in real income over time, the values rose to $6.3 million, with a range of $4.9 million to $7.9 million in 2008 dollars.[68] Also, because available evidence suggests that the public may be willing to pay more to avoid the risk of terrorism, the report suggested that DHS may wish to conduct a sensitivity analysis with a mean value of $12.6 million (i.e., twice the $6.3 million estimate used in the main analysis).[69]

At least one other agency within DHS has used the CBP report to establish a VSL. In a December 2008 proposed rule, the Coast Guard estimated that the total discounted benefits (injuries and fatalities) resulting from 68 marine casualty cases between 1996 and 2003 were between $24.7 million and $30.6 million, using the $6.3 million VSL recommended in the CBP report at discount rates of 7% and 3%. The Coast Guard also used the $6.3 million VSL in a break-even analysis showing the extent to which the risk of casualty would have to be reduced for benefits to equal costs.[70]

Environmental Protection Agency

The Environmental Protection Agency (EPA) issued its first guidance on the valuation of mortality and morbidity risks in December 1983.[71] The guidance said that if mortality risks are to

[65] Telephone conversation with David Houser, Chief Regulatory Economist, Office of the General Counsel, Department of Homeland Security, January 26, 2009.

[66] See, for example, U.S. Department of Homeland Security, Transportation Security Administration, "Air Cargo Screening," 74 *Federal Register* 47672, September 16, 2009, in which TSA specifically mentioned DOT's VSL policy. See also, U.S. Department of Homeland Security, Transportation Security Administration, "Large Aircraft Security Program, Other Aircraft Security Program, and Airport Operator Security Program," 74 *Federal Register* 64790, October 30, 2008, p. 64822.

[67] Lisa A. Robinson, "Valuing Mortality Risk Reductions in Homeland Security Regulatory Analyses," June 2008, p. v, available from the author.

[68] According to the Bureau of Labor Statistics' inflation calculator, these values were virtually the same in 2009.

[69] "Valuing Mortality Reductions in Homeland Security Regulatory Analyses," p. vi.

[70] U.S. Department of Homeland Security, Coast Guard, "Vessel Requirements for Notices of Arrival and Departure, and Automatic Identification System," 73 *Federal Register* 76295, December 16, 2008, p. 76308.

[71] U.S. Environmental Protection Agency, *Guidelines for Performing Regulatory Impact Analyses*, December 1983. See http://yosemite.epa.gov/ee/epa/eerm.nsf/vwAN/EE-0228A-1.pdf/$file/EE-0228A-1.pdf for a copy of these guidelines.

be assessed directly, then a range of values should be used to determine the sensitivity of the results to those values, and noted workplace studies that suggest VSLs ranging from $0.4 million to $7.0 million (in 1982 dollars).[72] The guidance also said that illnesses should be valued by measuring their direct costs (e.g., medical costs and lost wages), but cautioned that this approach underestimates benefits and should be treated as a lower bound. EPA updated and reprinted the guidance in 1991.

EPA's current policies on the valuation of health risks are contained in the agency's *Guidelines for Preparing Economic Analyses*, which was published in September 2000.[73] The guidelines were reportedly based on 26 studies published between 1974 and 1991, most of which were market studies that examined the additional compensation that workers received for additional risk.[74] With regard to mortality risks, after discussing the academic literature on the valuation of statistical life estimates (with mean values ranging from $0.7 million to $16.3 million in 1997 dollars), the document states that "EPA recommends a central estimate of $4.8 million (1990$), updated to the base year of the analysis. For example, updating this figure for inflation produces an estimate of $6.1 million in 1999 dollars."[75] Although EPA has not changed its guidance since 2000, further updating that central estimate for inflation indicates that it was nearly $7.9 million in 2009.[76]

The EPA guidelines also state that "it is important to consider differences in the nature of the base and policy cases," and that for fatal risks these differences fall into two major categories: (1) differences in the characteristics of the population (e.g., age/longevity and health status); and (2) differences in the characteristics of the risks being valued (e.g., whether the risk is voluntary or involuntary, and whether the risk is delayed or immediate). In summary, the guidelines say the following:

> Due to current limitations in the existing economic literature, these guidelines conclude that an appropriate default approach for valuing these [mortality risk reduction] benefits is provided by the central VSL estimate described earlier. However, analysts should carefully present the limitations of this estimate. Economic analyses should also fully characterize the nature of the risk and populations affected by the policy action and should confirm that these parameters are within the scope of the situations considered in these guidelines. While a qualitative discussion of these issues is generally warranted in EPA economic analyses, analysts should also consider a variety of quantitative sensitivity analyses on a case-by-case basis as data allow.[77]

[72] Ibid., p. M-9.

[73] U.S. Environmental Protection Agency, National Center for Environmental Economics, *Guidelines for Preparing Economic Analyses*, September 2000, available at http://yosemite.epa.gov/ee/epa/eed.nsf/pages/Guidelines.html. The discussion regarding valuation of mortality and morbidity risks is on pp. 87-98.

[74] U.S. Environmental Protection Agency, National Center for Environmental Economics, "Frequently Asked Questions on Mortality Risk Valuation," available at http://yosemite.epa.gov/ee/epa/eed.nsf/webpages/MortalityRiskValuation.html#adjustments.

[75] *Guidelines for Preparing Economic Analyses*, p. 90.

[76] Using the Bureau of Labor Statistics' inflation calculator, $4.8 million in 1990 dollars was worth $7,878,941 in 2009. See http://data.bls.gov/cgi-bin/cpicalc.pl for the Bureau of Labor Statistics' inflation calculator.

[77] *Guidelines for Preparing Economic Analyses*, pp. 93-94.

Valuation of Prevented Illnesses and Injuries

With regard to the valuation of preventing illnesses and injuries, the EPA guidance states that analysts must consider a more diverse set of issues than in mortality valuation. For example, the nature of any illnesses or injuries vary with respect to their severity, discomfort, duration, and the availability of existing value estimates. After discussing available methods for estimating morbidity values (e.g., measuring the actual avoided cost of illness, averting behavior, and stated preference methods), the guidance concludes that all of them have certain shortcomings.[78] It goes on to say that "addressing these shortcomings explicitly, conducting appropriate sensitivity analysis, and clearly stating assumptions can greatly enhance the credibility of the benefits analysis."[79] In contrast to the valuation of mortality, the EPA guidance does not recommend the use of a central monetary estimate, or multiple estimates, for the valuation of non-fatal health effects.

EPA Science Advisory Board Recommendations

In October 2007, in response to a request from EPA's National Center for Environmental Economics, the EPA Science Advisory Board (SAB) sent a memorandum to the EPA administrator regarding "issues in valuing mortality risk reduction."[80] Among other things, the SAB said that before combining VSL estimates from different studies, the agency should identify important characteristics that are associated with differences in those estimates, and should establish criteria for what constitutes a set of acceptable empirical studies. The SAB also recommended that EPA "determine which studies are appropriate for estimating the VSL in a specific policy context, depending on the nature of the risk addressed by a policy and the population affected."[81] Only then, the SAB said, could appropriate statistical techniques be used to combine the VSL estimates.

The SAB also said that both stated preference and revealed preference studies had particular strengths and weaknesses, and recommended that EPA not rely exclusively on either approach in all contexts. In addition, the SAB said it did not believe that the literature on the relationship between age and the VSL was "sufficiently robust to allow the Agency to use a VSL that varies with age," and that the use of a constant VSLY (which assumes that the VSL is strictly proportional to remaining life expectancy) was "unwarranted." (However, like Circular A-4, the SAB did not indicate how much VSLYs should vary, or even in what direction.) Finally, because reductions in the risk of death constitute most of the benefits from air pollution and drinking water regulations, the SAB urged EPA to fund more research on empirical estimates of the VSL.

Use of Lower VSL by EPA's Office of Air and Radiation

In July 2008, the Associated Press reviewed EPA benefit-cost analyses for more than 12 years and concluded that the agency had reduced the VSL it used in the agency's air office regulations.[82] A

[78] For example, the guidance says that the cost-of-illness method captures only certain expenses, and should be considered the lower bounds of willingness-to-pay.

[79] *Guidelines for Preparing Economic Analyses*, p. 98.

[80] See http://www.epa.gov/sab/pdf/sab-08-001.pdf for a copy of this memorandum and report.

[81] Ibid., p. 1.

[82] Seth Borenstein, "An American Life Worth Less Today," *Connecticut Post*, July 10, 2010; and "American Life (continued...)

separate analysis by a noted expert in the field reached a similar conclusion.[83] According to that study, from 1996 until 2004, the EPA Office of Air and Radiation had consistently used a VSL of nearly $8 million (in 2008 dollars), but starting in 2004 the office began using $7 million (in 2008 dollars) for most of its rules. Meanwhile, EPA's Office of Water reportedly used VSLs of $9 million in a 2005 rule and $8.5 million in a 2006 rule (both in 2008 dollars). Although critics of this VSL change suspected that the reduced values for air office rules were used to lower the expected benefits of the rules, EPA said the reductions were based on more current information about what individuals were willing to pay for risk reduction. EPA said that the air office used the results of three "meta-analyses" of the labor market literature on the VSL that were published after the agency's guidelines were issued in 2000.[84] The co-author of one of those studies ultimately questioned the reasoning behind that decision:

> A possibly sound policy evaluation approach would be to select the average VSL estimate based on one of the three studies that EPA considered to have attributes that made it the most reliable estimate of the VSL. Instead, the EPA Air Office selected as its preferred VSL the midpoint of the 25th percentile of the estimates in [one study] and the 75th percentile of [another study]. This unusual mathematical formulation creates the illusion of precision but lacks any scientific basis. [85]

He went on to say that there were "substantial differences in methodology and the resulting estimates" in these studies,[86] and raised broader questions about whether agencies' choice of a VSL should be based on meta-analyses or more focused studies. According to EPA, the agency

> neither changed its official guidance on the use of VSL in rule-makings nor subjected the interim estimate to a scientific peer-review process through the Science Advisory Board (SAB) or other peer-review group. While the Agency is updating its guidance by incorporating the most up-to-date literature and recent recommendations from the SAB-EEAC, it has determined that a single, peer-reviewed estimate applied consistently best reflects the SAB-EEAC advice until updated guidance is available. Therefore, EPA has decided to return to the value established in the 2000 Guidelines for all its actions until a revised estimate can be fully vetted within the Agency and by EPA's Science Advisory Board.[87]

Legislative Reaction to EPA's Lowered VSL

In reaction to the concerns expressed about the lowered VSL at EPA, Senator Barbara Boxer introduced the "Restoring the Value of Every American in Environmental Decisions Act" (S. 3564, 110th Congress). The bill was ordered to be reported by the Senate Committee on

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(...continued)

Worth Less Today, EPA Says," *Pitsburgh Post-Gazette*, July 11, 2008, p. A-7.

[83] W. Kip Viscusi, "The Devaluation of Life," *Regulation & Governance* (June 2009), pp. 103-127.

[84] Ibid., pp. 115-117. Viscusi co-authored one of the three studies that the EPA air office used to reset the VSL. EPA also said that the estimate was based on these three studies in its "Frequently Asked Questions on Mortality Risk Valuation," available at http://yosemite.epa.gov/ee/epa/eed.nsf/webpages/MortalityRiskValuation.html#adjustments.

[85] Ibid., p. 116.

[86] Ibid.

[87] U.S. Environmental Protection Agency, National Center for Environmental Economics, "Frequently Asked Questions on Mortality Risk Valuation," undated, available at http://yosemite.epa.gov/ee/epa/eed.nsf/webpages/MortalityRiskValuation.html#adjustments.

Environment and Public Works in September 2008, but it was not subsequently voted on by the Senate. Among other things, the bill would have required the administrator of EPA to (1) not reduce the agency's VSL below the highest value of statistical life used in a decision making before the enactment of the legislation; and (2) increase that value at least once each year, by adjusting the value to reflect the average annual total compensation of individuals, the average capital that may be liquidated upon the death of an individual, and the value of nonpaid activities. It would have also prohibited the EPA administrator from decreasing the VSL based on age, income, race, illness, disability, date of death, or any other personal attribute or relativistic analysis of the value of life." Finally, the bill would have required the administrator to (1) ensure that the process for establishing a value of statistical life is open to the public; and (2) provide to specified congressional committees, concurrently with public notice, any proposed revision of a VSL.

Department of Health and Human Services

An official in the Executive Secretariat within the Department of Health and Human Services (HHS) told CRS that he was not aware of any department-wide policy governing the valuation of mortality or morbidity risks in rulemaking.[88] He described HHS as similar to a "holding company" of federal agencies, and suggested contacting each agency in the department to determine whether they had any agency-specific VSL policies.

An official in the Food and Drug Administration (FDA) within HHS said that FDA did not have written policies in this regard, and said that the agency tended to follow EPA policies.[89] A 2007 article also indicated that FDA did not have formal internal guidance on this issue, but "applies a similar approach across many of its rules."[90] Examining rules issued between 2003 and 2005, the article indicated that FDA often used a VSL of $5 million for premature mortality, and only occasionally adjusted its VSL estimates for scenario differences or used alternative VSLY estimates for mortality risks. VSLY estimates were reportedly a key component in FDA valuations of non-fatal risk reductions, however, with the agency using values ranging from $100,000 to $500,000 per life-year.[91]

An official in the Centers for Medicare and Medicaid Services (CMS) said that she had researched the issue in conjunction with the development of a 2008 CMS rule on automatic sprinkler systems and was unaware of any CMS-specific policies in this area.[92] As discussed more fully later in this report, CMS said in the 2008 rule that it used VSL and life-year estimates derived from a 2006 FDA rule on patient examinations and surgeons' gloves.[93] In that rule, FDA

[88] Telephone conversation between the author and John Gallivan, Executive Secretariat, Department of Health and Human Services, January 27, 2010.

[89] Telephone conversation between the author and Clark Nardinelli, Food and Drug Administration, January 27, 2010.

[90] Lisa A Robinson, "How U.S. Government Agencies Value Mortality Risk Reductions," *Review of Environmental Economics and Policy*, vol. 1 (Summer 2007) pp. 283-299, p. 293.

[91] Ibid.

[92] Telephone conversation between the author and Danielle Shearer, CMS, January 27, 2010. Ms. Shearer was a listed contact for a CMS rule on "Medicare and Medicaid Programs; Fire Safety Requirements for Long Term Care Facilities, Automatic Sprinkler Systems," 73 *Federal Register* 47075, August 13, 2008.

[93] U.S. Department of Health and Human Services, Food and Drug Administration, "Medical Devices: Patient Examination and Surgeons Gloves; Test Procedures and Acceptance Criteria," 71 *Federal Register* 75865, December 19, 2006.

started with a VSL of $5 million, but then calculated a quality-adjusted life-year value of between $213,000 and $373,000 (at 3% and 7% discount rates, respectively).

Occupational Safety and Health Administration

According to an official in the Occupational Safety and Health Administration (OSHA), the agency does not have a written policy on the valuation of mortality or morbidity risks.[94] He said the clearest explanation of what OSHA does in this area was provided in a February 2006 rule on occupational exposure to hexavalent chromium, a substance that is believed to cause lung cancer in workers.[95] The rule established an eight-hour average exposure limit of 5 micrograms of hexavalent chromium per cubic meter of air, which was estimated to prevent 1,782 to 6,546 lung cancers over the working lifetime of the current worker population.

In that rule, OSHA said it could not use benefit-cost analysis as a basis for determining the permissible exposure limits for a health standard,[96] so the agency said that it estimated the monetary value of the rule's health benefits "for informational purposes only."[97] To estimate those benefits, OSHA said it had reviewed the approaches that other agencies used and decided to adopt EPA's approach of valuing each premature fatality avoided at $6.8 million.[98] OSHA said that it did so because "occupational illnesses are analogous to the types of illnesses targeted by EPA regulations."

For nonfatal cases of lung cancer, OSHA decided to use EPA's "cost of illness" approach as the lower bound value of nonfatal cases of lung cancer, updated to 2003 and with values for lost productivity added ($188,502). For the upper-bound value of nonfatal lung cancer, OSHA used an EPA "willingness to pay" value of 58.3% of the value of a fatal cancer (0.583 times $6.8 million, or nearly $4 million). OSHA also assigned monetary values to other health effects of occupational exposure to hexavalent chromium (e.g., dermatitis) using a "cost of illness" approach plus lost productivity, but did not attempt to place a value on reductions in other health effects (e.g., nasal perforations and ulcerations) due to insufficient data.

Summary of Agencies' VSL Policies

Table 2 below summarizes the selected agencies' VSL policies. Only DOT and EPA reported having a written policy, and their base VSLs varied by nearly $2 million (in 2009 dollars). The other agencies said they tend to use VSLs used in DOT, EPA, or other agencies and rules.

[94] Telephone conversation between the author and Robert Burt, Director, Office of Regulatory Analysis, OSHA, January 26, 2010.

[95] U.S. Department of Labor, Occupational Safety and Health Administration, "Occupational Exposure to Hexavalent Chromium," 71 *Federal Register* 10100, February 28, 2006.

[96] See *American Textile Manufacturers Institute v. Donovan*, 452 U.S. 491 (1981).

[97] "Occupational Exposure to Hexavalent Chromium," p. 10305.

[98] Ibid.

Table 2. Summary of Department/Agency VSL Policies

Department/Agency	VSL Policy
Department of Transportation	Policy requires base VSL of $6.0 million in 2009, with supplementary analyses at $3.2 million and $8.4 million (last set in 2008).
Department of Homeland Security	No department-wide policy. Some agencies (e.g., TSA) tend to follow DOT's policy. A report to CBP in 2008 recommended base VSL of $6.3 million, with supplementary analyses at $4.9 million and $7.9 million.
Environmental Protection Agency	Policy requires base VSL of $6.1 million (in 1999 dollars, or $7.9 million in 2009 dollars).
Department of Health and Human Services	No department-wide policy. FDA has no policy, but tends to follow EPA's VSL policy. CMS has no policy, but in 2008 used $5 million VSL from a 2006 FDA rule.
Occupational Safety and Health Administration	No agency-wide policy, but OSHA used EPA's VSL of $6.8 million in a 2006 rule that reportedly describes OSHA's general approach.

Source: CRS.

Valuation of Health Benefits in Selected Agency Rules

In addition to describing agencies' written or unwritten policies regarding the valuation of health benefits in rulemaking, it is helpful to examine how those policies are carried out in the context of specific regulations. The rules discussed below were selected by searching the GPO Access database using the terms "statistical life" and "statistical lives,"[99] and by examining a database of rules considered "major" under the Congressional Review Act.[100] In most of the rules, the issuing agency stated in the preamble to the rules what VSL, VSLY, or other monetization method was used to determine the value of anticipated health benefits. In other cases, however, the agencies did not clearly indicate in the preamble what VSL or VSLY was used, but those values could be determined from the information provided, or from the regulatory impact analysis in the rulemaking docket.

In most of the selected rules, the agencies used the monetized health benefits information to show whether the rules would produce positive net benefits (i.e., regulatory benefits that were greater than the costs). In other cases, the agencies used VSL estimates in break-even analyses, or to rule out a regulatory option. The agencies frequently indicated what central VSL or VSLY estimate was used, and sometimes used lower and higher estimates in a sensitivity analysis. In a few of the rules discussed below, although the agencies indicated that the rules would provide health benefits, the agencies did not monetize those benefits using VSLs or VSLYs.

[99] See http://www.gpoaccess.gov/fr/index.html.

[100] See http://www.gao.gov/fedrules/.

Department of Transportation

Regulatory agencies within DOT monetized the expected health benefits of their rules relatively frequently, using VSLs that were relatively consistent with each other and with departmental policies (i.e., $5.8 million in 2008, and $6.0 million in 2009). Nevertheless, there were some differences in how the agencies used VSL information in their economic analyses.

FRA—Highway-Rail Grade Crossing Action Plans

A September 2, 2009, direct final rule issued by the Federal Railroad Administration (FRA) complied with a statutory mandate that DOT issue a rule to require the 10 states with the most highway-rail grade crossing collisions to develop action plans.[101] The rule discussed the contents of the required action plans and time periods for implementation. FRA noted in the preamble to the rule that almost 4,200 grade crossing collisions in the 10 states with the most such accidents from 2006 through 2008 resulted in 546 fatalities and 1,666 injuries. FRA valued each fatality at $6.0 million per statistical life saved, and concluded that the total value of the statistical lives lost was $3.28 billion. Also, FRA "conservatively" assumed that all of the injuries were minor (i.e., did not require professional medical treatment), and valued each injury at $12,000 (i.e., 0.2% of the VSL), resulting in total estimated injury costs of nearly $20 million. In what was essentially a break-even analysis, FRA concluded that the monetized benefits of preventing one average accident (valued at $792,000) more than exceeded the total expected costs of the rule (estimated at between $217,000 and $326,000). The agency also said it was "reasonable to expect that such an incident may be prevented by implementing this rule."[102]

NHTSA—Truck Tractor Air Brake Systems

A July 27, 2009, final rule that was issued by the National Highway Traffic Safety Administration (NHTSA) amended the federal motor vehicle safety standard on air brake systems to improve the stopping distance performance of truck tractors.[103] The rule required most new heavy truck tractors to achieve a 30% reduction in stopping distance compared to currently required levels. NHTSA estimated that the rule would prevent an average of 227 fatalities and 300 serious injuries each year. In the net benefits analysis provided in the final regulatory impact analysis (but not discussed in the preamble to the rule), NHTSA valued injury and fatality benefits at $6.1 million per statistical life, and concluded that the net benefits ranged from $1.27 billion to $1.75 billion (depending on the brake system used and whether benefits are discounted at 3% or 7%).[104] The

[101] U.S. Department of Transportation, Federal Railroad Administration, "State Highway-Rail Grade Crossing Action Plans," 74 *Federal Register* 45336, September 2, 2009. The statutory mandate was in Section 202 of the Rail Safety Improvement Act of 2008 (P.L. 110-432, October 16, 2008).

[102] Ibid., p. 45339. On November 13, 2009, FRA removed this direct final rule and published a notice of proposed rulemaking that contained similar information. The agency said it had received one adverse comment regarding the direct final rule, and under FRA regulations, the agency was required to withdraw it and publish a proposed rule. For the removal, see U.S. Department of Transportation, Federal Railroad Administration, "State Highway-Rail Grade Crossing Action Plans," 74 *Federal Register* 58560, November 13, 2009. For the proposed rule, see U.S. Department of Transportation, Federal Railroad Administration, "State Highway-Rail Grade Crossing Action Plans," 74 *Federal Register* 58589, November 13, 2009.

[103] U.S. Department of Transportation, National Highway Traffic Safety Administration, "Federal Motor Vehicle Safety Standards; Air Brake Systems," 74 *Federal Register* 37122, July 27, 2009.

[104] U.S. Department of Transportation, National Highway Traffic Safety Administration, "FMVSS No. 121: Air Brake Systems Amended Stopping Distance," Final Regulatory Impact Analysis, July 2009. To view a copy of this analysis, (continued...)

preamble to the rule discussed the agency's cost-effectiveness analysis, which estimated that the highest net cost per equivalent life saved would be $108,000 (i.e., much less than the $6.1 million VSL). In most scenarios, NHTSA concluded that the estimated value of just the property damages prevented exceeded the expected costs of the rule.

NHTSA—Roof Crush Resistance

As part of a comprehensive plan to reduce the risk of rollover crashes and the risk of death and serious injury, on May 12, 2009, NHTSA published a final rule that upgraded the agency's safety standard in roof crush resistance in several ways (e.g., doubling the amount of force that the roof structure must withstand).[105] The rule had been mandated by Section 10301 of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU, P.L. 109-59), which required the Secretary to upgrade roof crush protection regulations.

NHTSA estimated that the rule would prevent 135 fatalities and 1,065 nonfatal injuries annually. The agency estimated the value of each prevented fatality at $6.1 million ($5.8 million as specified in DOT's guidance at the time of the analysis plus $300,000 of "economic savings to represent the comprehensive societal benefit from preventing a fatality.") NHTSA also translated the 1,065 nonfatal injuries expected to be prevented into 55 "fatality equivalents" (i.e., with each injury considered an average of about 5.2% of one fatality), yielding a total of 190 equivalent fatalities (156 at a 3% discount rate, and 125 at a 7% discount rate). Using these values, and estimating regulatory costs at $875 million to nearly $1.4 billion, NHTSA estimated the impact of the rule at between $6 million in net benefits and a net loss of $458 million. NHTSA also did an uncertainty analysis, and concluded that if each statistical life was valued at $8.7 million, the impact of the rule could range from $388 million in net benefits to a net loss of $151 million. On the other hand, if each statistical life was valued at $3.5 million, net losses could range from $376 million to $824 million. In a cost-effectiveness analysis, NHTSA concluded that the rule would cost from $6.1 million to $9.8 million per equivalent life saved.

FMCSA—Intermodal Equipment Inspection

On December 17, 2008, the Federal Motor Carrier Safety Administration (FMCSA) issued a final rule that, among other things, required intermodal equipment providers to (1) register and file a report with the agency; (2) establish a systematic inspection, repair, and maintenance program; and (3) maintain documentation of their maintenance program.[106] The rule implemented Section 4118 of SAFETEA-LU, and made intermodal equipment providers subject to Federal Motor Carrier Safety Regulations for the first time.

(...continued)

see http://www.regulations.gov/search/Regs/home.html#documentDetail?R=09000064809fbbb7.

[105] U.S. Department of Transportation, National Highway Traffic Safety Administration, "Federal Motor Vehicle Safety Standards; Roof Crush Resistance; Phase-In Reporting Requirements," 74 *Federal Register* 22348, May 12, 2009.

[106] U.S. Department of Transportation, Federal Motor Carrier Safety Administration, "Requirements for Intermodal Equipment Providers and for Motor Carriers and Drivers Operating Intermodal Equipment," 73 *Federal Register* 76814, December 17, 2008. "Intermodal equipment" is an international freight system that permits transshipping among sea, highway, rail, and air modes of transportation.

Although FMCSA said the rule was expected to save lives and prevent injuries, the preamble to the rule did not specifically discuss monetization of those health benefits. Instead, the agency said it did a "threshold" (breakeven) analysis because of a lack of data that specifically identified crashes associated with hauling intermodal freight. In that analysis, FMCSA said it had computed crash costs using a VSL of $5.8 million ("in accordance with DOT guidance"), and estimated the average cost of a truck crash involving a truck tractor with a single semitrailer at $170,229.[107] FMCSA said the net present value of a single crash avoided per year over 10 years, discounted at 7%, was about $1.25 million The present value of compliance costs over the same period (also discounted at 7%) were estimated at between $52.4 million and $285.4 million. Therefore, FMCSA said the final rule would need to prevent between about 40 and 230 crashes per year to yield positive net benefits ($52.4 million divided by $1.25 million equals 41.9; $285.4 million divided by $1.25 million equals 229.6).

FMCSA—New Entrant Safety Audits

On December 16, 2008, FMCSA issued a final rule that, among other things, raised the standard of compliance for passing the new entrant safety audit, and identified 16 regulations that are required elements of basic safety management controls needed to operate in interstate commerce.[108] FMCSA estimated that the rule would eliminate nearly 40,000 crashes over 10 years, avoiding a total of 487 fatalities. To monetize these expected health benefits, the agency used a baseline VSL of $5.8 million, but also used $3.2 million and $8.4 million as part of a sensitivity analysis. FMCSA concluded that "even the lowest [VSL] still results in strong positive net benefits." For example, using a $3.2 million VSL and a 7% discount rate resulted in five times more benefits than costs. At the other extreme, using an $8.4 million VSL and a 7% discount rate yielded nearly 11 times more benefits than costs.

FMCSA—Hours of Service for Commercial Drivers

On November 19, 2008, FMCSA adopted as final a December 17, 2007, interim final rule concerning hours of service for commercial motor vehicle drivers.[109] Among other things, the rule allowed drivers to continue to drive up to 11 hours within a 14-hour window, following at least 10 consecutive hours off duty. FMCSA conducted a sensitivity analysis in which it (among other things) increased the VSL from $5.5 million to more than $10 million (which the regulatory impact analysis described as "the upper limit of the range recommended by OMB"). Although the change resulted in increased safety benefits related to costs, FMCSA said that "none of these changes in individual assumptions made elimination of the 11th driving hour cost beneficial." However, there was no discussion in the preamble to the rule about the monetized health benefits of the regulatory option selected.

[107] This estimate was derived from a December 2006 study that included medical costs, pain and suffering, quality of life adjustments, and lost productivity. See footnote 15 of the rule at 73 *Federal Register* 76816.

[108] U.S. Department of Transportation, Federal Motor Carrier Safety Administration, "New Entrant Safety Assurance Process," 73 *Federal Register* 76472, December 16, 2008. According to the rule, "new entrants" include motor carrier owners and operators who are granted new operating authority. Congress mandated increased oversight of new entrants because studies indicated these operators had a much higher rate of non-compliance with basic safety management requirements and were subject to less oversight than established operators.

[109] U.S. Department of Transportation, Federal Motor Carrier Safety Administration, "Hours of Service of Drivers," 73 *Federal Register* 69567, November 19, 2008. The earlier rule can be found at 72 *Federal Register* 71247.

Department of Homeland Security

In many of the rules that DHS has issued in recent years, the department did not monetize or quantify its estimates of regulatory benefits.[110] For example, in its April 2007 rule on "Chemical Facility Anti-Terrorism Standards," DHS estimated the cost of the rule to be $3.6 billion during the period from 2006 through 2009, and $8.5 billion from 2006 through 2015.[111] DHS described the benefits of the rule in qualitative terms (e.g., increased ability of site personnel to detect, delay, and respond to unauthorized access to facilities). There was no discussion of a benefit-cost analysis or break-even analysis, and the listing of supporting material in the rulemaking docket contained no references to such studies.

In the rules describe below, DHS agencies used VSLs to monetize possible health benefits as part of a break-even analysis. In response to comments about one such analysis, the agency issuing the rule said the following:

> A break-even analysis is not a traditional benefit-cost ratio. The qualitative description of benefits ... is appropriate as no assertion is made of an exact level. All DHS components are working hard to improve the methods of presenting security benefits in relationship to costs. The very nature of terrorism makes it impossible to assign traditional probabilities to events or to describe a risk as a specific probability. At present, the break-even analysis balances the need to present comparable methodologies among rules while not disclosing any highly sensitive intelligence. [112]

TSA—Air Cargo Screening

A September 16, 2009, Transportation Security Administration (TSA) final rule implemented a statutory requirement in Section 1602 of the 9/11 Commission Act of 2007 (P.L. 110-53) that the agency establish a system to screen 100% of cargo transported on passenger aircraft by August 2010.[113] The rule required affected passenger aircraft operators to ensure that either an aircraft operator or certified cargo screening facility does so in accordance with TSA standards (or TSA itself would screen all cargo). TSA assessed the benefits of the rule through a break-even analysis of the cost of the reduction in risk with the dollar amount of the benefit of the rule in four attack scenarios involving (1) a standard narrow body aircraft and 119 fatalities, (2) an average U.S. commercial passenger aircraft and 133 fatalities, (3) an average U.S. commercial passenger wide-body aircraft and 210 fatalities, and (4) four wide body aircraft and 840 fatalities.

TSA used a $5.8 million VSL in its analysis (citing DOT's policy), and concluded that for the benefits of the rule to equal costs (estimated at $276.9 million per year after discounting at 7%), the rule would have to stop one attack (1) every 2.6 years in the first scenario, (2) every 2.8 years in the second scenario, (3) every 4.5 years in the third scenario, or (4) every 18.2 years in the

[110] For example, in its annual reports to Congress on the costs and benefits of federal rules, OIRA has frequently noted that most homeland security rules do not have quantified or monetized estimates of benefits. See, for example, http://www.whitehouse.gov/omb/assets/legislative_reports/2009_final_BC_Report_01272010.pdf.

[111] U.S. Department of Homeland Security, "Chemical Facility Anti-Terrorism Standards," 72 *Federal Register* 17688, April 9, 2007.

[112] U.S. Department of Homeland Security, Transportation Security Administration, "Secure Flight Program," 73 *Federal Register* 64018, October 28, 2008, p. 64048.

[113] U.S. Department of Homeland Security, Transportation Security Administration, "Air Cargo Screening," 74 *Federal Register* 47672, September 16, 2009.

fourth scenario. Although TSA said the rule would provide "increased security of commercial passenger aviation," the agency did not indicate that the rule would, in fact, prevent any of the four types of attack.

TSA—Secure Flight Program

On October 28, 2008, TSA published a final rule implementing a requirement in Section 4012(a) of the Intelligence Reform and Terrorism Prevention Act of 2004 (P.L. 108-458) that DHS assume the function of conducting pre-flight comparisons of airline passenger information to federal watch lists.[114] In the preamble to the resulting "secure flight" rule, TSA estimated that it would cost air carriers and others an estimated $3.2 billion over 10 years (before discounting), but described the benefits in non-quantitative terms (e.g., more accurate, timely and comprehensive screening, and reducing redundancies between similar programs, in turn resulting in improvements in national security "through more efficient and targeted use of national resources").[115] TSA indicated that it had conducted a break-even analysis for the rule, but the results were not presented in the preamble.

In the break-even analysis provided in the rulemaking docket, TSA used three attack scenarios: (1) the destruction of an airplane and the loss of 132 lives; (2) the use of a large aircraft as a missile in a densely populated urban area, resulting in 3,000 fatalities and more than $21 billion in property damage; and (3) the use of an aircraft to deliver a nuclear or biohazard device to an urban center, resulting in more than $1 trillion in direct consequences from the loss of hundreds of thousands of lives and enormous property damage. Using the DOT VSL at the time of $5.8 million, TSA estimated that prevention of the lowest level attack would be worth nearly $790 million.[116] At that rate, the analysis said that the rule would have to reduce the risk of attack by more than 40% for the rule's benefits and costs to "break even." On the other hand, the analysis said that if the rule prevented the much more catastrophic attack in the third scenario, the rule would only have to reduce the risk of attack by 0.03% for benefits to equal costs. TSA did not indicate in either the preamble to the rule or the sensitivity analysis whether the agency believed the rule would prevent any of the three types of attack.

CBP—Transmission of Manifests on Private Flights

On November 18, 2008, U.S. Customs and Border Protection (CBP) published a final rule that (among other things) required private aircraft pilots or their designees arriving in the U.S. from a foreign port or location, or departing from the U.S. to a foreign port or location, to transmit electronically to CBP passenger manifest information for each individual on board.[117] The agency said that key data were not available to estimate the reduction in the probability of a successful terrorist attack, the consequences of the avoided event, or individuals' willingness to pay for risk reduction. Therefore, the agency conducted a break-even analysis to determine what change in the reduction of risk would be necessary for the benefits to exceed the cost. CBP used two estimates

[114] Ibid. This rule is related to an August 23, 2007, rule issued by CBP that is discussed elsewhere in this report.

[115] Ibid., p. 64052.

[116] Loss of life was valued at $766 million (132 lives times $5.8 million), and loss of the aircraft was valued at $22 million.

[117] U.S. Department of Homeland Security, Customs and Border Protection, "Advance Information on Private Aircraft Arriving and Departing the United States," 73 *Federal Register* 68295, November 18, 2008.

of the VSL ($3 million and $6 million), four attack scenarios, and four levels of casualties within each VSL. The results indicated when the VSL is $3 million and the attack resulted in four deaths, the rule would have to reduce annual risk by 184%. (The agency said it recognized that reductions in risk of more than 100% are not possible.) At the other extreme, when the VSL is $6 million and the attack resulted in 1,000 casualties and catastrophic loss of property, CBP said that the rule would have to reduce risk by less than 1% for the costs to equal the benefits.

CBP—Transmission of Manifests on Commercial Flights

On August 23, 2007, CBP published a final rule amending its regulations concerning electronic manifest transmission requirements relative to travelers (e.g., passengers and crew members) onboard international commercial flights and voyages arriving in and departing from the U.S.[118] Among other things, the rule provided three options for air carriers to transmit manifest data. CBP said that key data were not available to estimate the rule's reduction in the probability of a successful terrorist attack, the consequences of the avoided event, or individuals' willingness to pay for risk reduction. Therefore, the agency conducted a break-even analysis to determine what change in the reduction of risk would be necessary for the benefits to exceed the cost. CBP used two estimates of the value of a statistical life ($3 million and $6 million), three attack scenarios, and five levels of casualties within each VSL. The results indicated that when the VSL was $3 million and the attack resulted in 100 deaths, the rule would have to reduce annual risk by as much as 44% for net costs to equal benefits. At the other extreme, when the VSL was $6 million and the attack resulted in 3,000 deaths and catastrophic loss of property, the rule would have to reduce risk by as little as 0.2% in order for net costs to equal benefits. In an accounting statement included with the rule, CBP estimated 10-year monetized costs of the rule at $126.8 million (in 2005 dollars), and estimated the 10-year monetized benefits at $15 million, plus unquantified "enhanced security" benefits.

Environmental Protection Agency

Nonroad Spark-Ignition Engines

An October 8, 2008, EPA final rule established emission standards for new nonroad spark ignition engines (e.g., marine engines and garden equipment).[119] EPA estimated that by the year 2030, reductions in emissions would annually prevent 230 premature deaths related to particulate matter, between 77 and 350 premature deaths related to ozone, and approximately 1,700 hospitalizations and emergency room visits.[120] Total annual benefits in 2030 were estimated at between $1.6 billion and $4.4 billion, and costs in 2030 were estimated at about $190 million.

[118] U.S. Department of Homeland Security, Customs and Border Protection, "Advance Electronic Transmission of Passenger and Crew Member Manifests for Commercial Aircraft and Vessels," 72 *Federal Register* 48320, August 23, 2007.

[119] U.S. Environmental Protection Agency, "Control of Emissions from Nonroad Spark-Ignition Engines and Equipment," 73 *Federal Register* 59034, October 8, 2008.

[120] EPA also presented other estimates of the rule's health effects, but the values cited here were those cited in the rule summary. For example, a "Six-Cities study" indicated that the rule would prevent 510 particulate matter premature fatalities in the year 2030, and experts reportedly said the number of such deaths could be anywhere between 120 and 1,300.

Although EPA did not specifically indicate in the preamble to the rule what VSL was used to monetize the benefits from reductions in premature mortality or morbidity, the agency provided estimates of the number of those effects and the dollar values associated with each estimate. For example, the 230 premature deaths related to particulate matter that were expected to be prevented in 2030 were valued (in 2005 dollars) at $1.6 billion. Therefore, it appears that the agency effectively used a VSL of nearly $7 million ($1.6 billion divided by 230) to value these averted deaths. EPA appears to have used VSLs of about $7.5 million for averted deaths related to ozone.[121] EPA appears to have valued the prevention of a case of chronic bronchitis in 2030 at $500,000 (220 cases valued at a total of $110 million), and valued the prevention of an acute, non-fatal heart attack that year at about $98,000 (530 cases valued at a total of $52 million).[122]

Locomotive Engine Emissions

On June 30, 2008, EPA issued a rule on "Control of Emissions of Air Pollution from Locomotive Engines and Marine Compression-Ignition Engines Less Than 30 Liters per Cylinder."[123] EPA estimated that by the year 2030, the reductions in particulate matter as a result of the rule would prevent up to 1,100 premature deaths per year, 280 premature ozone-related deaths, and would provide other non-fatal health benefits. The agency valued these annual health benefits in 2030 at between $9.2 billion and $11 billion, assuming a 3% discount rate; and at between $8.4 billion and $10 billion, assuming a 7% discount rate. The projected costs of the rule in 2030 were estimated at $740 million.

EPA did not specifically indicate in the preamble to the rule what VSL was used to monetize the benefits from reductions in premature mortality or morbidity. However, the agency provided estimates of the number of those effects and the dollar values associated with each estimate. For example, the estimated 1,100 premature deaths averted in 2030 because of reduced particulate matter were valued at $8.1 billion (in 2006 dollars, using a 3% discount rate), or about $7.4 million per averted death.[124] EPA valued 2,500 prevented acute, non-fatal heart attacks at $260 million, or just over $100,000 per attack, and valued the prevention of 680 cases of chronic bronchitis at $340 million, or $500,000 per case.

Stationary Spark Ignition Engines

In a January 18, 2008, EPA rule on "Standards of Performance for Stationary Spark Ignition Internal Combustion Engines and National Emission Standards for Hazardous Air Pollutants for Reciprocating Internal Combustion Engines," EPA used a different approach to monetize human health benefits.[125] Rather than placing an explicit or implicit value on statistical lives or illnesses,

[121] For example, EPA valued the low-end estimate 77 premature deaths averted from ozone at $590 million (in 2005 dollars), or about $7.7 million per death. EPA valued the high-end estimate of 350 premature deaths averted from ozone at $2.6 billion, or about $7.4 million per death.

[122] U.S. Environmental Protection Agency, "Control of Emissions from Nonroad Spark-Ignition Engines and Equipment," 73 *Federal Register* 59034, October 8, 2008, pp. 59155-59158.

[123] U.S. Environmental Protection Agency, "Control of Emissions of Air Pollution from Locomotive Engines and Marine Compression-Ignition Engines Less Than 30 Liters per Cylinder," 73 *Federal Register* 37096, June 30, 2008.

[124] Ibid., pp. 37178-31180. Using a 7% discount rate, the 1,100 averted deaths were valued at $7.3 billion, or about $6.6 million per averted death.

[125] U.S. Environmental Protection Agency, "Standards of Performance for Stationary Spark Ignition Internal Combustion Engines and National Emission Standards for Hazardous Air Pollutants for Reciprocating Internal (continued...)

EPA used what it termed a "benefits transfer approach" that it had used in an earlier air pollution rule.[126] In this rule, EPA estimated the expected reductions in ozone emissions (77,362 tons), placed a dollar value on each ton of emissions ($2,800), and calculated the monetized benefits that were expected to result from the rule by 2015 ($220 million in 2005 dollars, using a 3% discount rate). Annualized costs were estimated to be $22 million. Although EPA indicated that the benefits estimate was based on a mortality estimate in an earlier study of particulate matter, and although the agency indicated in the regulatory impact analysis that premature mortality typically accounts for at least 90% of total benefits, EPA did not indicate how many deaths were expected to be avoided or place a monetary value on such deaths.[127]

Lead Exposure in Renovation, Repair, and Painting

On April 22, 2008, EPA issued a final rule addressing "hazards created by renovation, repair, and painting activities that disturb lead-based paint in target housing and child-occupied facilities."[128] Among other things, the rule established requirements for training renovators and others, certifying these firms, renovation work practices, and recordkeeping requirements. Among the benefits discussed in the rule was the avoidance of IQ loss in 1.4 million children under the age of six through reduced lead exposure.[129]

EPA estimated the 50-year annualized cost of the rule at $400 million when using either a 3% or 7% discount rate. EPA estimated the 50-year annualized benefits of the rule to children at $700 million to $1.7 billion per year when using a 3% discount rate, and $700 million to $1.8 billion using a 7% discount rate. Although EPA did not indicate in the preamble to the rule the annual benefits of not losing IQ points, it appears to be about $500 to $1,300 per child ($700 million to $1.8 billion divided by 1.4 million children). In the regulatory impact analysis in the rulemaking docket, EPA said that it estimated the economic value of avoiding lost IQ points "by using an estimate of the foregone lifetime income due to IQ point loss. The estimated value per IQ point lost is $8,346 (1995 dollars)."[130] In a sensitivity analysis, EPA also valued each IQ point at $6,847.

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Combustion Engines," 73 *Federal Register* 3568, January 18, 2008.

[126] Ibid., p. 3587. EPA cited the technical supporting document accompanying the agency's 2007 benefits analysis of the proposed changes to the National Ambient Air Quality Standards for Ozone.

[127] EPA used a similar approach in another 2008 rule. See U.S. Environmental Protection Agency, "Standards of Performance for Petroleum Refineries," 73 *Federal Register* 35838, June 24, 2008, at pp. 35861-35862. The agency estimated the number of tons of emissions expected to be reduced as a result of the rule, placed a monetary value on each ton for each pollutant, and calculated a total benefit.

[128] U.S. Environmental Protection Agency, "Lead; Renovation, Repair, and Painting Program," 73 *Federal Register* 21692, April 22, 2008.

[129] EPA said that data were insufficient to develop dose-response functions for other health effects in children or for pregnant women, and the benefits of avoided exposure to 5.4 million adults were not quantified due to uncertainties about their exposure.

[130] U.S. Environmental Protection Agency, "Economic Analysis of Toxic Substances Control Act Section 403: Lead-Based Paint Hazard Standards," December 21, 2000.

Department of Health and Human Services

FDA—Manufacturing Practices for Dietary Supplements

On June 25, 2007, FDA issued a final rule establishing minimum current good manufacturing practices necessary for activities related to manufacturing, packaging, labeling, or holding dietary supplements to ensure their quality.[131] Using data on the number of recalls per year, FDA estimated that the rule would have reduced 1,180 acute illnesses per year during the 1990 through 1999 period, and estimated the average value of preventing each such illness at $33,800.[132] FDA assumed that the benefits for the average year for this period represented the annual average benefits that could be expected in the future. Therefore, the monetized benefits from fewer acute illnesses totaled nearly $40 million (1,180 illnesses times an average of $33,800 per illness)—more than 90% of the rule's central estimate of $44 million in benefits. FDA estimated the baseline annual costs of the rule at about $164 million.

In a discussion of "uncertainties in the analysis," FDA said it assumed $5 million as the VSL and $300,000 as the value of a quality-adjusted life year in calculating its $40 million baseline estimate of the rule's health benefits.[133] In a sensitivity analysis, FDA also used values of $3 million for a statistical life and $100,000 for a quality-adjusted life year to generate a "low" estimate of health benefits, and values of $7 million and $500,000 to generate a "high" estimate. The agency also used alternative assumptions of regulatory costs. In each scenario, the costs of the rule far exceeded the quantified benefits.[134] FDA said that many benefits could not be quantified, however, and stated that the total benefits of the rule justified the costs.

FDA—Identification of Hepatitis C Donors

On August 24, 2007, FDA published a final rule that (among other things) required establishments collecting whole blood or blood components to establish, maintain, and follow an "appropriate system" for identifying donations from someone who tests reactive for hepatitis C infection in a subsequent donation.[135] The rule also revised the HIV "lookback" requirements for consistency with the hepatitis C virus requirements, and extended the record retention requirements for 10 years. FDA said it was taking this action to help ensure the safety of the blood supply, and to help ensure that recipients of infected blood were aware of these issues.

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[131] U.S. Department of Health and Human Services, Food and Drug Administration, "Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements," 72 *Federal Register* 34752, June 25, 2007.

[132] To monetize these illnesses, FDA used a base estimate of $300,000 for a quality-adjusted life year, which was converted to $822 per quality-adjusted life day ($300,000 divided by 365). In some cases, the cost of an acute illness was roughly equivalent to the VSL. For example, FDA valued a case of spina bifida at $5 million ($4.5 million in lost quality-adjusted life years plus $500,000 in direct medical costs).

[133] "Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements," p. 34936.

[134] For example, at the low estimate, annual quantified benefits were $36 million and annual costs were $109 million. At the high estimate, annual quantified benefits were $54 million, and annual costs were $260 million.

[135] U.S. Department of Health and Human Services, Food and Drug Administration, "Current Good Manufacturing Practice for Blood and Blood Components; Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting Hepatitis C Virus Infection," 72 *Federal Register* 48766, August 24, 2007.

By allowing recipients of the infected blood to be treated, the agency estimated that the rule would provide one-time benefits of 2,640 quality-adjusted life years with an estimated discounted value of between $264 million (at $100,000 per quality-adjusted life year) to $1,228 million (at $465,000 per quality-adjusted life year). FDA said it used the $100,000 figure as a lower bound, and derived the $465,000 value by starting with a $10 million VSL and annualizing it over 35 years at a 3% discount rate. A more central $300,000 value for a quality-adjusted life year (derived by annualizing a $6.5 million VSL over 35 years at 3%) yielded one-time benefits of $792 million, with annualized net benefits of $82.5 million. FDA also did a cost effectiveness analysis, showing that the present value of all costs ($87.6 million) divided by the anticipated number of quality-adjusted life years gained (2,640) results in a cost per quality-adjusted life year of $33,200.

FDA—Warning and Labels for Certain Over-the-Counter Drugs

On April 29, 2009, FDA published a final rule requiring new warnings and labels for certain over-the-counter drugs (e.g., acetaminophen and NSAIDs), informing consumers about the risks of liver injury and stomach bleeding.[136] The agency estimated that there were about 100 deaths per year related to unintentional acetaminophen overdose, estimated that the rule would prevent one to three of those deaths per year, and monetized those expected benefits by using a VSL of $5 million (in 2001 dollars). FDA said it used the $5 million VSL because it had done so in a rule issued in January 2001.[137] The agency also monetized expected reductions in illnesses related to unintentional overdosing at between $0.6 million to $1.8 million per year. Therefore, the total monetized value of prevented illnesses and death were estimated at $5.6 million to $16.8 million per year. The one-time cost of the rule to industry was estimated at $32 million (in 2001 dollars). FDA concluded that, over a 10-year period, the benefits of the rule would exceed the costs even with the most conservative estimates of health effects and the highest discount rate. For example, using the lowest estimates of mortality and morbidity effects (i.e., preventing one death per year and $0.6 million in illness benefits), the 10-year benefits would be $41.2 million (in 2001 dollars), more than the $32 million in estimated costs.[138]

Because of the uncertainty in its estimates of the health effects of the rule, FDA also did a break-even analysis and determined that the rule would have to prevent less than one death each year over 10 years (0.9 deaths at a 7% discount rate and 0.7 deaths at a 3% discount rate) for the benefits to equal costs. Alternatively, if no deaths are prevented, FDA said that the rule would need to prevent 407 to 476 hospitalizations per year (using a 3% or a 7% discount rate, respectively) to reach the "break even" point.[139]

[136] U.S. Department of Health and Human Services, Food and Drug Administration, "Organ-Specific Warnings; Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Final Monograph," 74 *Federal Register* 19385, April 29, 2009.

[137] The rule that was referenced was U.S. Department of Health and Human Services, Food and Drug Administration, "Hazard Analysis and Critical Control Point (HAACP); Procedures for the Safe and Sanitary Processing and Importing of Juice," 66 *Federal Register* 6137, January 19, 2001.

[138] "Organ-Specific Warnings; Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Final Monograph," p. 19405.

[139] Ibid., p. 19406.

On June 30, 2009, FDA published a corrected benefits-cost comparison that reached somewhat different conclusions.[140] The agency increased the estimated 10-year costs of the rule from $32 million to nearly $80 million (in 2007 dollars), and used both a $5 million and a $7 million VSL. Using the most conservative assumptions of regulatory benefits (e.g., the $5 million VSL), FDA concluded that the annualized costs of the rule exceeded the annualized benefits. However, at the mid- and upper-end of the benefits range (e.g., using the $7 million VSL), the agency said that the benefits exceeded the costs.[141] FDA also corrected the break-even analysis, saying that for benefits to equal costs, the rule would need to prevent about two deaths each year over 10 years (up from less than one death per year in the original rule), or 928 to 1,058 hospitalizations each year (up from 407 to 476 in the original rule).

FDA—Prevention of Salmonella Enteritidis in Shell Eggs

On July 9, 2009, FDA published a final rule requiring shell egg producers to implement procedures to prevent Salmonella Enteritidis (SE) from contaminating eggs on the farm or growing during storage and transportation, and to maintain certain records and register with the agency.[142] FDA said it was taking this action because SE was one of the leading causes of foodborne illnesses in the U.S., and shell eggs are a primary source of human SE infections. To monetize the expected reduction in SE health consequences, the agency used two VSLs ($5 million and $6.5 million) to value expected reductions in death, three VSLYs ($100,000, $300,000, and $500,000) to value expected reductions illnesses and arthritis cases at different levels of severity and duration, and two discount rates (3% and 7%). The expected value of a typical case of SE ranged from $7,600 to $49,500 (depending on which VSL, VSLY, and discount rate was used), so FDA used $17,900 as a central estimate (based on a VSL of $5 million, VSLY of $300,000, and a discount rate of 7%). Ultimately, FDA estimated that the rule would prevent 79,170 SE cases per year, and the rule would cost about $1,000 per case—much less than the expected $17,900 value of an SE related illness. Also, the agency estimated that the rule would cost between $9,300 and $16,100 per life-year saved—much less than the most conservative estimate used ($100,000). Using the central estimate assumptions, FDA estimated that the rule would provide annual net benefits of more than $1.4 billion.

CMS—Automatic Sprinkler Systems in Long Term Care Facilities

In an August 13, 2008, final rule, the Centers for Medicare and Medicaid Services (CMS) required that all long term care facilities be equipped with automatic sprinkler systems within five years of the date the rule was published, and required such facilities to maintain those systems after they are installed.[143] CMS estimated that installing sprinklers in facilities without them would save five lives each year, and using data on the life expectancy of an average resident in

[140] U.S. Department of Health and Human Services, Food and Drug Administration, "Organ-Specific Warnings; Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Final Monograph; Corrections," 74 *Federal Register* 31177, June 30, 2009.

[141] Ibid., p. 31179. For example, at a 3% discount rate, annualized costs over 10 years were estimated at $9.4 million, and benefits were estimated at a low of $6.3 million, and a high of $23.7 million.

[142] U.S. Department of Health and Human Services, Food and Drug Administration, "Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation," 74 *Federal Register* 33030, July 9, 2009.

[143] U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, "Medicare and Medicaid Programs; Fire Safety Requirements for Long Term Care Facilities, Automatic Sprinkler Systems," 73 *Federal Register* 47075, August 13, 2008.

such facilities (6.6 years), calculated that the rule would save 33 life years annually (five lives saved times 6.6 years per life). Noting that a 2006 FDA rule had used a VSL of $5 million,[144] CMS concluded that the annual life-saving benefits of the rule once all facilities are compliant would be approximately $25 million (five lives saved each year times $5 million per life). Over a 20-year period, CMS said that the undiscounted mortality benefits would be as much as $500 million (five lives times $5 million times 20 years). Also, noting that the 2006 FDA rule had valued each quality-adjusted life year at between $213,000 and $373,000, CMS assumed that the number of severe non-fatal injuries were equal to the number of life years, and estimated that the benefits from morbidity reduction ranged from $7 million to $10 million (33 life years times 20 years times either $213,000 or $373,000). CMS ultimately estimated that the rule would provide total 20-year benefits of $722.4 million to $991.4 million, with total costs estimated at between $715.0 and $806.4 million (using discount rates of 7% and 3%, respectively).

Occupational Safety and Health Administration

Payment for Personal Protective Equipment

On November 15, 2007, OSHA published a final rule stating that, when an employer is required to provide employees with personal protective equipment (e.g., hard hats, gloves, goggles, and safety shoes), employers are generally required to do so at no cost to the employee.[145] Using estimates of the number of injuries that were expected to be prevented by the rule for various body parts (e.g., eye, face and ear, hand and finger, foot and toe), OSHA estimated that the rule would prevent more than 6,700 injuries each year with an estimated "willingness to pay" value of more than $337 million (an average of nearly $50,000 per injury). The agency estimated that the rule would prevent 1.7 fatalities each year, which it valued at $7 million per fatality (totaling nearly $12 million). Therefore, the total monetized annual benefits were estimated at $349 million using the "willingness to pay" approach. OSHA also used the "direct cost" approach to value the benefits, and estimated the annual benefits at $228 million. The total annual cost of compliance to employers was estimated to be $85.7 million.

Electrical Standard

On February 14, 2007, OSHA issued a final rule revising the general industry electrical installation standard (Subpart S of 29 CFR Part 1910) for the first time since 1981.[146] The rule centered on safety in the design and installation of electrical equipment in the workplace, and reflected changes in consensus standards that had more recently been updated. Focusing on just one type of electrical accident in seven states, OSHA estimated that the rule would save between one and two lives per year, which the agency valued at $6.1 million each (using EPA's VSL in 1999 dollars). Therefore, the monetized benefit of avoiding these deaths was estimated to be between $6.1 million and $12.2 million (or $7.2 million to $14.4 million in 2005 dollars). OSHA

[144] The rule that was referenced was U.S. Department of Health and Human Services, Food and Drug Administration, "Medical Devices: Patient Examination and Surgeon's Gloves; Test Procedures and Acceptance Criteria," 71 *Federal Register* 75865, December 19, 2006.

[145] U.S. Department of Labor, Occupational Safety and Health Administration, "Employer Payment for Personal Protective Equipment," 72 *Federal Register* 64342, November 15, 2007.

[146] U.S. Department of Labor, Occupational Safety and Health Administration, "Electrical Standard," 72 *Federal Register* 7136, February 14, 2007.

did not provide an estimate for the injuries that could be avoided by the rule. The agency estimated the cost of the rule for all employers at $9.6 million.

Summary of Monetization in Rules

Table 3 below summarizes the information provided above in narrative form. The information suggests that "statistical lives" that are expected to be saved by rules are valued somewhat differently across and within federal departments and agencies. The VSL estimates are also used by the agencies differently—sometimes to demonstrate that the rule provides net benefits at those levels of monetized health improvements, sometimes to demonstrate how effective a rule would have to be to yield net benefits, and sometimes to eliminate a regulatory option.

Table 3. Summary of Monetization of Health Benefits in Selected Rules

Date	Department/ Agency: Rule	VSL	Valuation of Injuries	Other
09/02/09	DOT/FRA: Grade Crossing Plans	Used $6.0 million (M) VSL	Valued each injury "conservatively" at $12,000 (0.2% of VSL)	FRA concluded that the benefits of preventing one average accident would exceed the cost of the rule.
07/27/09	DOT/NHTSA: Air Brake Systems	Valued 227 prevented fatalities at $6.1M ($5.8M VSL + $300K in economic savings)	Translated 300 prevented serious injuries to 80 equivalent fatalities (26.7% of death)	Net benefits were estimated at $1.4B to $1.7B with the most likely braking system.
05/12/09	DOT/NHTSA: Roof Crush Resistance	Valued 135 prevented fatalities at $6.0M; $5.8M VSL + $300K in societal benefits. Also did uncertainty analysis using $3.5M and $8.7M for each prevented fatality.	Translated 1,065 prevented injuries to 55 "fatality equivalents" (each injury averaged 5.2% of death)	In most scenarios, the rule yields negative net benefits. Base net benefits ranged from -$458M to $6M. Cost-effectiveness (CE) analysis indicates rule will cost $6.1M to $9.8M per life saved. Rule was required by statute.
12/17/08	DOT/FMCSA: Intermodal Equipment Inspection	Used VSL of $5.8M in break-even analysis	N/A	Break-even analysis concluded that the rule would have to prevent between 40 and 230 crashes per year to yield positive net benefits.
12/16/08	DOT/FMCSA: New Entrant Safety Audits	Used base VSL of $5.8M; also used VSLs of $3.2M and $8.4M in sensitivity analysis	N/A	Analysis indicated strong positive net benefits even with lowest VSL and highest discount rate.

Date	Department/ Agency: Rule	VSL	Valuation of Injuries	Other
11/19/08	DOT/FMCSA: Hours of Service for Commercial Drivers	Used base VSL of $5.5M; used $10.0M VSL in sensitivity analysis.	N/A	Analysis was used to eliminate the regulatory option of driving 11 hours.
09/16/09	DHS/TSA: Air Cargo Screening	Used VSL of $5.8M (citing DOT's policy) and four attack scenarios in break-even analysis.	N/A	Break-even analysis shows rule would have to avert one attack every 2.6 to 18.2 years for benefits to equal costs (depending on the attack scenario).
10/28/08	DHS/TSA: Secure Flight	Used VSL of $5.8M (citing DOT's policy) and three attack scenarios in break-even analysis.	N/A	Break-even analysis shows rule would have to reduce the risk of attack by 41%, 0.83%, or 0.03% for benefits to equal cost (depending on the attack scenario).
11/18/08	DHS/CBP: Transmission of Manifests on Private Flights	Used VSLs of $3.0M and $6.0M, four attack scenarios, and four levels of casualties within each VSL in break-even analysis.	N/A	Break-even analysis shows rule would have to reduce risk by less than 1% to 184% for benefits to equal costs (depending on the VSL and attack scenario).
08/23/07	DHS/CBP: Transmission of Manifests on Commercial Flights	Used VSLs of $3.0M and $6.0M, three attack scenarios, and five levels of casualties within each VSL.	N/A	Break-even analysis shows rule would have to be 0.2% to 44% effective for benefits to equal costs (depending on the VSL and attack scenario).
06/25/07	HHS/FDA: Dietary Supplements	N/A, but FDA noted it had used $5.0M in other rules. Some illnesses expected to be prevented were valued at that level (e.g., spina bifida).	Used $300,000 as base value of a quality-adjusted life year (QALY), adjusted to quality-adjusted life days ($822/day), with sensitivity analysis at QALYs of $100,000 and $500,000. Did not quantify chronic illnesses.	Estimated costs of rule were more than three times the monetized benefits. CE analysis shows $3,370 in costs per quality-adjusted life day.

Date	Department/ Agency: Rule	VSL	Valuation of Injuries	Other
08/24/07	HHS/FDA: Identification of Donors with Hepatitis	N/A, although FDA said the $300,000 QALY was based on a VSL of $6.5M discounted at 3% over 35 years.	Used three values of QALYs ($100,000, $300,000, and $465,000). At $300,000, annual net benefits estimated at $82.5 million.	Cost-effectiveness analysis showed that present value of all costs was $33,200 per QALY (less than most conservative value of a QALY).
04/29/09 (corrected on 06/30/09)	HHS/FDA: Over-the-Counter Drug Warnings	Used VSLs of $5.0M and $7.0M. Also used two estimates of rule effectiveness (1% and 3%), and two discount rates (3% and 7%).	Different illnesses valued at various levels. In break-even analysis, average hospitalization valued at $8,936 (lowest monetized value of poisoning at 7% discount rate).	At lower end of assumptions (1% effectiveness and $5M VSL), costs exceeded benefits. To break even, rule would have to prevent 2 deaths per year over 10 years, or 1,058 hospitalizations per year.
07/29/09	HHS/FDA: Prevention of Salmonella in Shell Eggs	Used VSLs of $5M and $6.5M.	Used VSLYs of $100,000, $300,000, and $500,000. Typical illness valued at $17,900.	Cost of the rule was estimated at $1,000 per case. CE analysis showed rule would cost $9,300 to $16,100 per life-year saved (less than most conservative VSLY).
08/13/08	HHS/CMS: Automatic Sprinkler Systems	Used VSL of $5.0M.	Used VSLYs of $213,000 to $373,000.	Estimated 20-year benefits of $722.4 million to $991.4 million; costs estimated at between $715.0 and $806.4 million.
11/15/07	DOL/OSHA: Personal Protective Equipment	Used VSL of $7.0M.	Average injury estimated at $50,000.	Annual benefits estimated at $349M. Using "direct costs," benefits estimated at $228M. Costs estimated at $88.5M.
02/14/07	DOL/OSHA: Electrical Standard	Used VSL of $6.1M, based on EPA's estimate in 1999 ($7.2M in 2007 dollars).	No estimate.	Annual mortality benefits estimated at $7.2M to $12.2M. Costs estimated at $9.6M.
10/08/08	EPA: Nonroad Spark-Ignition Engines	Appears to have used VSL of about $7.0M for particulate matter; $7.5M for ozone (in 2005 dollars).	Case of chronic bronchitis appears to be $500,000; acute, non-fatal heart attack appears to be $98,000.	Benefits in 2030 estimated at between $1.6B and $4.4B; costs were estimated at about $190M.

Date	Department/ Agency: Rule	VSL	Valuation of Injuries	Other
06/30/08	EPA: Locomotive Engine Emissions	Appears to have used VSL of about $7.4M for particulate matter.	Case of chronic bronchitis appears to be $500,000; acute, non-fatal heart attack appears to be $100,000.	Benefits in 2030 estimated at between $8.4 billion and $11.0 billion; costs were estimated at $740 million.
01/18/08	EPA: Stationary Spark Ignition Engines	Statistical lives saved not directly valued. Instead, EPA valued each ton of ozone emission reduced at $2,800.	Injuries not directly valued. Instead, EPA valued each ton of ozone emission reduced at $2,800.	Benefits by 2015 estimated at $220 million; costs were estimated at $22 million.
04/22/08	EPA: Lead-Based Paint Exposure	N/A	Avoided IQ loss by 1.4 million children under age 6 valued at up to $1.8 billion per year or about $500 to $1,300 per child. (No estimate for 5.4 million affected adults.)	The 50-year annualized net benefits were estimated at $300 million to $1.3 billion per year.

Source: CRS, based on information provided in agencies' rules and other documents.

Concluding Observations

Broad Government-Wide Policies Give Agencies Discretion

The government-wide policies regarding the monetization of regulatory health benefits in OMB Circular A-4 are often very general, giving federal agencies substantial discretion in how to proceed. For example, OMB Circular A-4 does not require the agencies to use a particular VSL; it simply notes that academic studies have suggested values between $1 million and $10 million. The circular also suggests that agencies "consider" providing estimates of both VSL and VSLY, but does not require that agencies do so. It says that agencies should do a cost-effectiveness analysis "wherever possible," and should do a break-even analysis when the agencies conclude that non-quantified benefits are "likely to be important." More definitive government-wide requirements would help ensure that agencies' policies and practices are more consistent, but doing so could prevent agencies from tailoring those policies and practices to the particular types of risk and population at issue in their rules.

Circular A-4 does require agencies to take some specific actions, but some of those requirements could arguably be updated or clarified. For example, the circular requires agencies to discount future costs or benefits to present values, and says that agencies should use discount rates of both 3% and 7%. The circular says that the 7% rate is the "average before-tax rate of return to private capital in the U.S. economy," and that 7% 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." While the average pre-tax rate of return may have been 7% in September 2003 when Circular A-4 was

issued, rates of return have fallen sharply in recent years. An appendix to Circular A-94 (OMB's basic guidance on discount rates) has reduced discount rates used in other types of analyses in recent years, but specifically indicates that those reduced rates are not to be used in regulatory benefit-cost analyses. The most recent OMB update of the discount rate in December 2009 placed the 30-year real interest rate on Treasury notes and bonds at 2.7%.[147]

Also, although Circular A-4 states that agencies should use a larger VSLY estimate for senior citizens, it does not indicate how much larger the value should be, or at what age individuals should be considered "senior citizens." As a result, variations could occur in which two agencies addressing similar types of risk for similar populations could reach very different conclusions regarding whether a particular regulatory approach is advisable. Also, as noted earlier in this report, even if a larger VSLY estimate is used for senior citizens, it may still result in the "statistical lives" of those citizens being valued less than the lives of younger citizens.

No Policies in Some Departments/Agencies

DOT and EPA have each had written, department-wide policies in place for nearly 30 years regarding the monetization of health benefits in agencies' regulatory analyses. Other departments and agencies, however, do not appear to have such policies, and instead sometimes refer to the policies and values used by other agencies. For example:

- HHS does not appear to have a departmental-wide policy, with FDA indicating that it tends to follow EPA policies, and CMS saying in one rule that it used VSL and life-year estimates that FDA had used in an earlier rule.
- OSHA said that it reviewed the approaches that other agencies used, and decided to use EPA's VSL because "occupational illnesses are analogous to the types of illnesses targeted by EPA regulations."[148]
- DHS does not appear to have a departmental-wide policy, and some DHS agencies have cited DOT's policy in establishing VSLs in break-even analyses. Also, the Coast Guard cited a study conducted for CBP in establishing a VSL.

Agencies have also said that they used a particular VSL because they or another agency had done so previously, sometimes years earlier. For example, in FDA's April 2009 rule on warnings and labels for certain over-the-counter drugs, the agency indicated that it used a $5 million VSL because it had done so in a previous, unrelated rule more than eight years earlier. Adopting earlier VSLs, whether from the same agency or another agency, without increasing the value for inflation can result in VSLs that are lower than they would be if kept whole for changes in inflation.

Agencies' use of other departments' and agencies' VSLs and VSLYs in their economic analyses can provide a degree of consistency across agencies in how economic analyses are conducted. However, application of the VSL used in one policy area to a completely different area may not accurately reflect the public's "willingness to pay" to prevent a specific mortality risk. EPA's Science Advisory Board indicated in its October 2007 memorandum that before combining VSLs from a variety of empirical studies, EPA should determine which studies are appropriate "in a

[147] See http://www.whitehouse.gov/omb/assets/memoranda_2010/m10-07.pdf for a copy of this memorandum.

[148] U.S. Department of Labor, Occupational Safety and Health Administration, "Occupational Exposure to Hexavalent Chromium," 71 *Federal Register* 10100, February 28, 2006.

specific policy context, depending on the nature of the risk addressed by a policy and the population affected." Similar care would appear to be appropriate before using VSLs and VSLYs from other agencies, or from earlier unrelated rules within the same agency.

Similar VSLs, but Some Differences

The VSLs that agencies used in their regulatory impact analyses were generally somewhat similar, with most agencies using central values ranging from about $5.0 million to $8.0 million (in 2009 dollars). Agencies sometimes did sensitivity analyses using VSLs as low as $3 million and as high as $10 million. One study suggested that DHS conduct sensitivity analyses using values as high as $12.6 million.

There appeared to be some differences in how fatalities were valued, and in how injuries were valued. For example:

- In its May 2009 rule on roof crush resistance, NHTSA used the DOT VSL at the time of the analysis of $5.8 million, but added $300,000 in "economic savings to represent the comprehensive societal benefit from preventing a fatality." It is not clear whether the $5.8 million VSL in DOT's policy already included such economic savings. Other DOT rules that used the department's VSL did not appear to include the "economic savings" supplement.
- In the same roof crush resistance rule, NHTSA converted more than 1,000 non-fatal injuries into 55 "fatality equivalents," each of which the agency valued at $6.1 million. Although the use of such integrated measures of effectiveness are specifically permitted in Circular A-4, DOT's policy indicates that non-fatal injuries should be valued on the MAIS scale provided in the department's January 1993 guidance.

The agencies' VSLs also appeared to vary in age and how they were developed. For example, whereas the DOT VSL has been revised several times in recent years, the EPA guidance has not been changed in nearly 10 years. However, the EPA guidance does recommend updating the agency's $6.1 million VSL in 1999 dollars to "the base year of the analysis" (which would have been nearly $7.9 million in 2009, using an inflation calculator provided by the Bureau of Labor Statistics). Also, EPA's September 2000 guidelines were reportedly based on 26 studies published between 1974 and 1991, 21 of which were market studies that examined the additional compensation that workers received for additional risk. Circular A-4 cautions against the use of inappropriate literature-based VSL estimates, and characterizes the use of occupational risk premiums to value reductions in risk from environmental hazards as an example of this practice.[149]

[149] Circular A-4, pp. 30-31. Also, Chapter 7 of the EPA guidance indicates that hedonic wage studies capture different types of risk than those affected by environmental regulation (e.g., hedonic studies focus on accidental deaths among prime-age males who voluntarily accept risk, whereas deaths due to environmental risks are often involuntarily borne by the elderly with an extended latency period).

Agencies Used VSLs in Different Ways

The agencies also appeared to vary in how the VSL information was used. For example, whereas most departments and agencies used VSLs to monetize health benefits in a traditional benefit-cost comparison, DHS agencies did not do so in any of the rules that were examined. Instead, the agencies did break-even analyses in which VSL estimates were used as one variable in determining how effective the rule would have to be in order for benefits to equal costs. The DHS agencies said they did so because key data were not available to estimate the reduction in the probability of a successful terrorist attack, the consequences of an avoided attack, or individuals' willingness to pay for risk reduction. Similarly, although DOT agencies monetized health benefits in most of their rules, FMCSA did not do so in its December 2008 rule on intermodal equipment, reportedly because of a lack of data showing which crashes were associated with hauling intermodal freight. Instead, the agency did a "threshold" (i.e., breakeven) analysis showing the number of crashes that would have to be prevented for the rule to produce net benefits.

In other rules, the agencies implicitly or explicitly used VSL information in cost-effectiveness analyses. For example, in NHTSA's truck tractor air brake systems rule, the agency estimated that the highest net cost per equivalent life saved would be $108,000 (i.e., much less than the department's $6.1 million VSL). In its roof crush resistance rule, however, NHTSA concluded that the new standard would cost from $6.1 million to $9.8 million per equivalent life saved (i.e., potentially more than the department's VSL).

In the FMCSA rule on hours of service for drivers, the agency used VSL information to eliminate a regulatory option (here, ruling out the prohibition on the 11th hour of driving). Another DOT agency also used VSL information in a 2009 advance notice of proposed rulemaking to indicate why a regulatory option did not appear feasible.[150] In that notice, NHTSA presented its initial research efforts on an initiative to amend Federal Motor Vehicle Safety Standards on rearview mirrors to improve drivers' ability to see behind a vehicle and reduce backover accidents. Two of the regulatory options that the agency considered were rear object detection sensors (e.g., ultrasonic or radar-based devices) and rearview video camera systems. However, NHTSA said "none of the systems are cost effective compared to our comprehensive cost estimate for a statistical life of $6.1 million."[151]

VSL and Other Variables Can Affect Regulatory Conclusions

Some of the rules discussed in this report illustrate that the size of the VSL used in the economic analysis and other variables have the potential to affect whether the rule is expected to produce positive net benefits. For example:

- The May 2009 NHSTA rule on roof crush resistance indicated that raising the VSL from $6.1 million to $8.7 million could, with changes to other variables, cause the upper-level estimate of net benefits to go from about $6 million to $388

[150] U.S. Department of Transportation, National Highway Traffic Safety Administration, "Federal Motor Vehicle Safety Standard; Rearview Mirrors," 74 *Federal Register* 9478, March 4, 2009.

[151] Ibid., p. 9479. NHTSA said that the net cost per equivalent life saved for the camera systems ranged from $13.8 million to $72.2 million, and the net cost per life saved for the sensors ranged from $11.3 million to $62.5 million—more than the DOT $6.1 million VSL.

million. On the other hand, lowering the VSL to $3.5 million could cause the upper-level estimate to drop to a net loss of about $376 million.

- In its April 2009 rule on over-the-counter drugs, FDA initially determined that the benefits exceeded the costs even with the most conservative estimate of health benefits and the highest discount rate. However, when FDA issued a correction two months later, the agency concluded that the annualized costs exceeded the benefits using the most conservative assumptions of regulatory benefits (e.g., a $5 million VSL).

In other cases, however, the size of the VSL did not appear to affect whether the rule yielded net benefits. For example:

- The November 2008 FMCSA rule on new entrant safety audits indicated that even the smallest VSL resulted in "strong positive net benefits."
- Although NHTSA did not mention alternative VSLs in its July 2009 air brake rule, the data provided indicated that the use of a VSL one-tenth of that used ($6.1 million) would have still provided net benefits.
- FDA said in its July 2009 rule on salmonella in shell eggs that the estimated monetized benefits of the rule exceeded the estimated costs even when the most conservative VSLY value was used.

Monetization of Injuries and Illnesses

Although Circular A-4 recommends that agencies consider providing estimates of fatality risks using both VSLs and VSLYs, only a few of the rules that were examined appeared to provide both estimates. Instead, the agencies appeared to use life-year measures primarily to determine the value of non-fatal injuries and illnesses. For example in its June 2007 rule on manufacturing practices for dietary supplements, FDA used a base estimate of $300,000 for a quality-adjusted life year, converted that value to "life days" ($822 per life day), and used that information to estimate the average value of preventing a typical illness ($33,800).

The other way that agencies placed a monetary value on injuries is by viewing them as a percentage of a death (e.g., the MAIS scale in DOT's policy), or by assigning a specific average value to an injury. For example:

- In the FRA highway-rail grade crossing rule, the agency "conservatively" assumed that all of the injuries in grade crossing collisions were minor, and valued each injury at $12,000 in determining the benefits of preventing an average accident.
- In the OSHA rule on personal protective equipment, the agency developed estimates of workers' "willingness to pay" to prevent certain types of injuries, and valued the injuries expected to be prevented by the rule at more than $337 million (an average of nearly $50,000 per injury).

In other rules, however, the agencies did not estimate the number or monetary value of injuries that could be avoided by rules (e.g., OSHA's electrical standard rule).

Statutory Mandates Can Alter the Use of Benefits Information

In a standard benefit-cost analysis, estimates of the expected health benefits of a rule are monetized, added to other expected benefits, and that total is compared to the total estimated costs of the rule to help decision makers determine whether or not the rule should be issued. Executive Order 12866 states that agencies should adopt regulations only if the benefits of the rule "justify" its costs.

In some of the rules discussed in this report, even after monetizing the health benefits, the expected costs of the rules were greater than the benefits. In those instances, the agencies issuing the rules often indicated that the rules were statutorily required. For example:

- In the "positive train control systems" rule that was cited at the beginning of this report, FRA estimated that the cost of the rule would be about 20 times greater than the estimated benefits. (The 20-year costs of the rule were estimated at between $9.5 billion and $13.2 billion; benefits were estimated at between $440 million and $674 million.) FRA noted this imbalance in the rule, but said it was "constrained by the requirements of [the Rail Safety Improvement Act of 2008], which do not provide latitude for implementing [positive train controls] differently."[152]
- The August 2007 CBP rule on electronic transmission of manifests on commercial flights had estimated 10-year costs of about $126 million, and 10-year estimated monetized benefits of about $15 million (plus unquantified benefits of "enhanced security"). Sections 4012 and 4071 of the Intelligence Reform and Terrorism Prevention Act of 2004 (P.L. 108-458) require DHS to establish procedures to allow for pre-departure vetting of passengers onboard aircraft, and passengers and crew onboard vessels, bound for and departing from the United States.

In other cases, however, the agencies appeared to issue rules with quantified net losses even when the underlying statutes did not specifically require them to do so. For example, the June 2007 FDA rule on good manufacturing practices for dietary supplements had a 10-year central estimate of net loss of $120 million, but FDA noted that the losses could be as low as $96 million, or as high as $258 million. The underlying statute, DSHEA, says that FDA "may" establish these practices; the agency does not appear to have been required to do so. FDA said that it was unable to quantify certain benefits, and that the benefits of the rule "justified" the costs.

Also, as OSHA noted in its February 2006 rule on hexavalent chromium,[153] certain statutes prohibit the consideration of costs in setting a health standard, and such prohibitions have been upheld in court.[154] Therefore, even if the monetized estimated benefits of a rule are less than the estimated costs, the issuing agency cannot use that information in determining whether to

[152] U.S. Department of Transportation, Federal Railroad Administration, "Positive Train Control Systems," 75 *Federal Register* 2598, January 15, 2010, p. 2685.

[153] U.S. Department of Labor, Occupational Safety and Health Administration, "Occupational Exposure to Hexavalent Chromium," 71 *Federal Register* 10100, February 28, 2006.

[154] See, for example, *Whitman v. American Trucking Associations*, 531 U.S. 457 (2001), a case that involved the national ambient air quality standards issued by EPA.

regulate. Including such information in the preamble to the rule, however, can improve the transparency of the rulemaking process.

Variations May Be Due to Transparency Differences

The agencies appeared to vary substantially in the degree to which they used various techniques in the monetization of health benefits. For example, some agencies discussed cost-effectiveness studies that they conducted in addition to benefit-cost analyses, while other agencies did not mention such studies. Some agencies used VSLs at various levels to show the effect on net benefits, while other agencies did not appear to use other VSLs. Some showed discounting at 3% and 7%, while others did not discuss discounting or only showed discounting at one level.

These differences may reflect real variations in agency practices, or they may simply reflect differences in the degree to which the agencies disclosed their analytic procedures in the preambles to their rules or elsewhere. For example, the preamble to the NHTSA rule on air brake systems did not discuss what VSL was used to monetize the projected reductions in fatalities and serious injuries, but that information was included in the regulatory impact analysis that was located in the agency's rulemaking docket. The agencies that did not mention sensitivity analyses using different VSLs may have done so but just did not discuss that effort. The information provided in this report is drawn primarily from the preambles to the rules and any retrievable final economic analyses that were retrievable from the agency's electronic docket at http://www.regulations.gov.

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