Putting a Pricetag on Life: The Value of Life and the FDA

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ALISON PROUT
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ABSTRACT

Regulatory agencies like the Food and Drug Administration are in the business of protecting American lives. These agencies are constantly making judgment calls as to whether prospective products are sufficiently safe, whether proposed regulations will do more harm than good, and whether costs of compliance will justify the benefits. And yet, what cost is too high to save a human life? Although we would like to live in a world that needed not spare any expense to save a life, we know that ours is a world of scarcity. This fact requires that we, as a society, make difficult decisions about how much to spend to save lives – in other words, how to value human life.

This paper first looks at different theoretical approaches for deriving a value of life, and asks which is the most appropriate for use in the regulatory context. The paper next considers the legal framework that plays a role in guiding agencies in the use of value of life figures. Finally, the paper examines the practices of regulatory agencies, the FDA in particular, regarding setting a value of life, and applying it in their decision-making. A web of legal authority, political pressures, and shear administrative difficulties come into play. Together, these competing influences create significant challenges to the usefulness of value of life analysis.

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INTRODUCTION

Society makes decisions about how to value life all of the time. We decide how we value our own lives when we take risky actions or make spending decisions concerning our health and safety. Courts value lives when they force defendants to compensate wrongful death victims. Governments value lives in countless contexts, including income redistribution decisions and imposing a national draft. Sometimes decision-makers are explicit about placing a value on life, but this is more the exception than the rule. Unfortunately, when decisions are made on an ad hoc basis, they often fail to optimize life-saving potential. For example, imagine a town that commits half of its fire department to rescuing a child trapped in a well, but also chooses to permit landfills that accept toxic waste. As the example illustrates, choices about saving lives are inextricably linked to money. Spending to protect one group requires forgoing protection of another. Unless these decisions are made with full consciousness of the cost-life tradeoffs, chances are, they may be leaving some attractive life-saving opportunities on the table.

Questions about how to value life have been explored extensively since the 1970s by economists focusing on methodologies, legal scholars focusing on the morality and legal authority to do so, and administrators focusing on how to apply such a value. Because the economic literature has become so well-developed, current scholarship has tended to revolve around intricacies and minute details about various methods. While this level of detail is needed to advance our understanding of the value of life, it can be difficult to obtain a high-level understanding of what is actually involved in valuing life. One goal of this paper is to provide a survey of the current wisdom surrounding the value of life, and to evaluate its suitability for use in the regulatory context. Parts I through III deal with that endeavor. The legal literature has actively explored value of life issues, in particular, their impact on several regulatory agencies. The Environmental Protection Agency ("EPA") and the Occupational Safety and Health

Administration ("OSHA") have received extensive scholarly attention. Curiously, the Food and Drug Administration ("FDA") has escaped all but the most general mentions in this context. The second goal of this paper is to fill in that gap. Parts IV and V provide some legal context for value of life issues. Because value of life questions are inherently tied to financial choices, much of the legal doctrine bearing on them comes under the more general issue of cost-benefit analysis ("CBA"). Finally, Part VI addresses FDA's practices in detail.

FDA is a critical federal agency in advancing the health and safety of America. It oversees the safety of 80% of America's food supply, which amounts to $255 billion of commerce.[1] Between food, drugs, medical devices and cosmetics, every single American encounters many FDA-regulated products every day of her life. And yet, despite its crucial role, its budget is naturally limited – amounting to only 0.08% of our national expenditures.[2] How does FDA decide whether a new regulation ought to be promulgated? Does FDA think about the value of life, and if so, how does its thinking affect its decision process?

I. WHY VALUE LIFE

The process of valuing human life raises a number of significant hurdles. Moral and political challenges almost pale next to the conceptual and empirical difficulties. That so many scholars and government agencies have nonetheless undertaken the task suggests the importance of the endeavor. But why exactly is understanding the value of life important? Society places a value on life in many different contexts. Courts use it to determine compensation for wrongful

[1] U.S. Food and Drug Administration, Keeping the Nation's Food Supply Safe: FDA's Big Job Done Well, *available at* http://www.fda.gov/opacom/factsheets/justthefacts/2cfsan.html (last visited Feb. 16, 2004).

[2] The FDA's proposed budget for the 2003 fiscal year is $1.727 billion. U.S. Food and Drug Administration, FDA Talk Paper, FDA's Budget Proposal for FY 2003 (Feb. 2002), *available at* http://www.fda.gov/bbs/topics/ANSWERS/2002/ANS01135.html. The 2003 federal budget was $2,128 billion. Budget of the United States Government, Fiscal Year 2003, Summary Tables, *available at* http://www.gpoaccess.gov/usbudget/fy03/browse.html (last visited Feb. 25, 2004).

death, or to create deterrence from future harm. Individuals constantly make choices that trade off our safety for other desires, like a tasty food or a sports car. Moreover, and the focus of this paper, regulators make choices about whether safety-enhancing regulations merit their cost. "The ultimate purpose of the value-of-life literature is to provide some basis for sensitive social decisions."[3] The literature has focused largely on two different aspects of the problem: what the appropriate value of human life is, and how to use it in cost-benefit analysis ("CBA"). Answering the first question is necessary to determine whether the benefits of a particular project or regulation outweigh its costs. The second question has broader implications for setting regulatory policy and prioritizing competing initiatives.

Regulations naturally have costs – the cost to the government of promulgating and enforcing them, and the cost to society (individuals or industry) of complying with them. Understanding the full effect of these two types of cost reveals the importance of valuing life.

From the government's perspective, knowing the value of human life can help agencies make regulatory decisions in two ways. At the most basic level, they can make better "go or no-go" decisions by assessing whether the benefits of a proposed regulation, often measured in lives saved, outweigh the costs. Moreover, scholars have thoroughly demonstrated the link between income and health and safety, the so-called "wealth equals health" effect.[4] Wealthier people simply receive better healthcare and avoid more physical risks than poorer individuals.[5] By comparing death rates and income levels, it has been shown that as a community's income

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[3] W. KIP VISCUSI, FATAL TRADEOFFS 19 (1992) [hereinafter, VISCUSI, FATAL TRADEOFFS]

> [Monetary estimates of the value of life have] been relied on to argue that the costs of many environmental regulations exceed their benefits, that many regulations are cost-ineffective or that there are cheaper ways of saving human lives, that expensive regulations endanger human lives by their very expense, and that government does not set priorities in a rational manner, indeed, that risk regulation is a 'crazy quilt' (internal citations omitted).

Id. at 19.

[4] Robert W. Hahn, Randall W. Lutter and W. Kip Viscusi, Do Federal Regulations Reduce Mortality? 6 (AEI-Brookings 2000) (chronicling the literature on this topic).

[5] *See* VISCUSI, FATAL TRADEOFFS, *supra* note 3, at 29.

increases by about $10 million, it will experience one fewer death.[6] Therefore, the cost of compliance to society actually imposes risks on people's lives.[7] Agencies ought not promulgate regulations that raise society's compliance costs unless they generate a sufficiently offsetting benefit. Agencies must understand the value of life to make those determinations. Using too high a value of life in a cost-benefit analysis could result in an agency undertaking costly and unworthy regulations, while using too low a value could cause agencies to forego valuable life-saving regulations.[8]

With a more sophisticated process, government agencies can use the value of life to compare and prioritize all of their initiatives – ranking those with the lowest cost per life saved highest. In our world of scarce resources, agencies constantly forego certain projects in order to pursue others deemed more important. For example, while FDA has devoted enormous attention to certain dietary supplements in recent years, it has all but ignored monitoring of the cosmetics industry. It undoubtedly follows this course because its commissioners have believed that it could better protect the public by monitoring Ephedra, for example, than cosmetics. An analysis comparing the two using a constant value of human life could confirm or disprove this. The importance of this prioritization cannot be overstated. Tengs and Graham estimated that the government commits the "statistical murder" of 60,000 people per year by misallocating its regulatory resources.[9]

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[6] *See* Randall Lutter and John F. Morrall, *Health-Health Analysis: A New Way to Evaluate Health and Safety Regulation*, 8 J. RISK UNCERTAINTY 43 (1994). This represents a refinement of original estimates which placed the expenditures levels results in a statistical death at $50 million. *See* W. Kip Viscusi, *The Value of Life in Legal Contexts: Survey and Critique*, 2 AMERICAN LAW AND ECONOMICS REVIEW 217, n21 (2000) [hereinafter Viscusi, *Legal Contexts*].

[7] *See generally* Viscusi, *Legal Contexts*, *supra* note 6, at 195, 200 (explaining the development of risk-risk analysis).

[8] This assumes that regulatory *monetary* costs are being compared to a benefit which includes lives saved. This is the case in the vast majority of federal agencies' regulatory impact analyses I have examined. If a regulation's costs include the non-monetary increased risk of death, the impact of inaccurate estimates of the value of life could be the reverse.

[9] Tammy O. Tengs & John D. Graham, *The Opportunity Cost of Haphazard Social Investments* in ROBERT W. HAHN, LIFE-SAVING, IN RISKS, COSTS, AND LIVES SAVED, 172, 176 (1996) ("Retaining our present pattern of investments … we could more than double the life-saving potential of our current investments").

Project prioritization can be taken to the next level by using such analysis to allocate resources *across* agencies. Agencies jockeying for funds and clout naturally have incentive to manipulate their estimates of the value of life to demand bigger budgets. The use of a consistent value of life would reduce (though certainly not eliminate) the ability of government agencies to use cost-benefit analysis as a political tool. Further, such comparisons could help eliminate any insipid discrimination in the government. For example, it would help expose whether agencies that predominantly served particular segments of the population were over- or under-funded. It could compare the efficiency of programs focusing on urban poor, like those created by the Department of Housing and Urban Development, with, for instance, farm subsidy programs. A consistent value of human life could help the legislature appropriate resources across agencies to protect the greatest number of lives, promoting equity and fairness.

In addition to the efficiency benefits of valuing human life, the practice also promotes predictability. In a heavily regulated industry like the drug industry, daily business decisions require predictions about what FDA will do. If FDA used a constant and published value of life, companies under its purview could incorporate this into their decision calculus. While certainly such a number would not substitute for agency discretion, the more transparent and consistent the agency's decision-process, the better the industry will be able to tailor its behavior to comply with FDA.

In spite of the important potential uses of a value of human life, vocal critics argue against it. Criticisms fall into two camps: positive and normative. Positive critiques include charges of political manipulation, empirical difficulties of measuring the value of life, and methodological questions, like the choice of a discount rate. These will be discussed below in the section exploring the difficulties of valuing life.[10] This part will explore the main normative critique:

[10] *See infra* Part III.

that placing a monetary value on human life is immoral. Proponents of this view believe that we as Americans view life as sacred and priceless.[11] To monetize life, they argue, ignores life's intrinsic value and treats people as commodities. This is insensitive and worse, an inappropriate undertaking for the government. While the moral critics seem correct to observe that placing a value on human life is indeed crass and unpleasant, they neglect certain realities. The first reality is that decisions trading off life and health for money occur all the time. The government makes such tradeoffs when funding certain social programs over others. We, as individuals, also make such tradeoffs. For example, many of us choose means of transportation based on the cost and speed rather than the risk. Similarly, we may forgo preventive medical treatment due to high cost. To pretend such tradeoffs do not exist merely causes them to be made implicitly, and hence more arbitrarily. The second reality is that choosing not to value life has moral consequences potentially as severe as choosing to do it. As explained above, allocating resources inefficiently can amount to statistical murder. Advocates of valuing life argue that it raises no unique ethical issues not already dealt with by regulators.[12] In short, while the moral critique is not meritless, it seems to be outweighed by other practical and moral reasons *to* value life.

II. METHODS OF VALUING LIFE

As observed above, valuing human life can serve numerous purposes. The appropriate method of valuation depends on the context for which the value is to be used. The methodology and context will impact the actual dollar value arrived at. Although this might seem unsettling, it

[11] *See, e.g.*, Steve P. Calandrillo, *Responsible Regulation: A Sensible Cost-Benefit, Risk Versus Risk Approach to Federal Health and Safety Regulation*, 81 B.U. L. REV. 957, 968 (2001).
[12] *See*, *e.g.*, VISCUSI, FATAL TRADEOFFS, *supra* note 3 at 32.

should not be. It merely reminds us that there is no one true or natural value of human life, but rather that it varies by the person, the circumstances, and the question at hand.[13]

The arrays of methods can be broken down into two general categories: ex post and ex ante valuations. Ex post valuations are generally used to value of the life of a known individual or group that has died. Because the specific victims and outcomes are known, these valuations can be used to compensate individual losses, as in the case of wrongful death damages or the September 11th Fund.[14] Ex ante valuations estimate the value of a "statistical life," or the life of an unknown member of a known population. These estimates are more useful for making normative policy and specific regulatory decisions. In this paper, unless specifying an ex post value, I will use "value of life" to mean the value of a statistical life.

Ex Post Valuation

The most prevalent ex post valuation method is the human capital approach. It developed from Adam Smith's idea in the 18th century that the monetary value of a person could be measured by his or her output.[15]

The basic approach involves calculating the present value of an individual's lost earnings. Today's methodology has become more complex to capture many different aspects of lost human capital. In particular, seven variables are considered to measure a person's human capital:[16]

1) *Base year income* – Earnings at the time of death can be computed using observable salary information, or tables of weekly median earnings published by the Census Bureau.[17] This is quite straightforward.

[13] *See* Viscusi, *Legal Contexts*, *supra* note 6, at 195.
[14] *See id*. at 197 (arguing that the human capital approach is appropriate for compensating individuals, not prevention).
[15] Ted R. Miller, *Willingness to Pay Comes of Age: Will the System Survive?*, 83 NW. U.L. REV. 876, 876 (1989).
[16] See Elizabeth M. King and James P. Smith, *Computing Economic Loss in Cases of Wrongful Death, Rand: The Institute for Civil Justice* (1988), for a discussion of the seven variables.
[17] U.S. Census Bureau, Statistical Abstract of the United States: 2002, Labor Force, Employment and Earnings, Table No. 613.

2) *Salary growth* – This depends on three components. First, productivity growth in the overall economy is considered. Second, knowledge of the economic life cycle of earnings is used. Certain patterns of salary growth are commonly observed across workers. Salaries tend to rise early in one's working life, peak around the 40s or 50s, then gradually decline. Third, the individual's specific productivity and trajectory is considered. This tends to be one of the most subjective inputs in the human capital model.

3) *Work life expectancy* – This calculation estimates how much longer the individual would have continued to work before the event in question. It considers current working status, life expectancy, probability of unemployment, education level and gender.[18] The table commonly used is controversial for several reasons. First, being over fifteen years old, it is thought to underestimate women's working years and overestimate men's. Second, it uses education level as a proxy for probability of unemployment although some dispute the correlation.

4) *Nonmarket loss* – This input improves on Adam Smith's model by taking productive activity *outside* the workplace into account. It primarily captures time spent on housework, relying on studies of individual time budgets.[19] The debate over this input concerns whether to value time spent on housework at its replacement cost (the cost of hiring an outside housekeeper) or at the higher opportunity cost (the income the homemaker could have otherwise earned).

5) *Personal consumption offset* – This capture the notion that two can live more cheaply together than one. The idea is straightforward.

[18] U.S. Department of Labor, *Work Life Estimates*, 1986.
[19] F. Thomas Juster and Frank P. Stafford, *Times, Goods, and Well-Being* (Ann Arbor: University of Michigan, 1985) Tables 5.1, 5.2 and 7.3.

6) *Taxes* – Consideration of tax captures the reduction of income the individual would have faced from paying income tax, but also the tax that survivors will owe on any investment return on the damage award.

7) *Discount rate* – This takes into account the time-value of money, or the idea that a dollar today is worth more to us than a dollar next year. While the theory is uncontroversial, there is no consensus on the appropriate discount rate, and different choices can wildly affect the final value of life. In the human capital context, the impact is minimal because a number between two and four percent is commonly used.[20] However, as is discussed below, the choice of a discount rate is one of the biggest challenged facing ex ante valuations.[21]

The human capital approach has several important benefits. The largest is its capacity to tailor valuations to specific individuals. This makes it particularly appropriate for individual wrongful death computations. In addition, its simple process of pulling several numbers off of a table makes the valuation highly transparent and unambiguous. Once the tables are agreed upon, there is limited room for manipulation. Its simplicity also makes multiple calculations easy to administer. This could be one of the reasons the human capital approach was used by the administrator of the September 11th Fund.[22]

In spite of its benefits, the human capital approach does have some large disadvantages. The first is its unsuitability for use in policy decisions. Because its values are calculated according to extremely specific personal data, it does not make sense to use it to estimate the impact of a potential harm on a large, heterogeneous population. However, even when used in

[20] Professor Joni Hersch, Empirical Methods for Legal Analysis, Course Pack , Harvard Law School (Fall 2003).
[21] *See infra* Part III, *Discount Rate*.
[22] However, not everyone agrees with how the human capital approach was used to compensation September 11th victims. *See, e.g.*, William Glaberson, *Lawyers' Math in Sept. 11 Deaths Shows Varying Values for Life*, N.Y. TIMES, Nov. 11, 2001, B1; Jon E. Hilsenrath, *Economist Criticize Sept. 11 Fund Over Its Formula for Compensation*, WALL STREET JOURNAL, Jan. 7, 2002, A22.

appropriate contexts, the method gives rise to three main difficulties. First, there are debates about whether the seven inputs capture the complete picture. For example, some argue that person's net consumption should be subtracted.[23] Others complain that it neglects to value noneconomic activities, like the value of leisure time.[24] Taking those shortcomings together yields the disturbing and clearly erroneous result that the death of children or the elderly could be a net positive for society. Second, there is a theoretical debate about whose value the human capital approach really captures-- perhaps it describes the value of a man to his family, but not to society.[25] Third, some believe that the methodology is inherently discriminatory. Because some of the tables give different values by race, and many differ by gender, women and minorities consistently receive lower values of life.[26]

While this method is still used by courts in wrongful death cases, it has long fallen out of favor for use in policy settings.[27] No government agency relies on this methodology for determining the value of life, with the exception of the Department of Transportation, which uses a variant of this method that involves estimating future earnings.[28]

Ex Ante Valuation

Ex ante valuations estimate the value of life before an actual death occurs. Because these techniques are used to calculate the value of life before it is known who will die, they rely on society-wide data rather than individual-specific information. For this reason, these methods are said to yield the value of a "statistical life."[29] While some find the terminology objectionable, it

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[23] *See*, *e.g.*, Miller, *supra* note 15, at 877.
[24] *See id*.
[25] *See id*.
[26] *See id*. at 878.
[27] In 1989, Gillette and Hopkins provided an early comprehensive look at value of life literature and its implications for regulatory policy. *See* Clayton Gillette & Thomas Hopkins, *Federal Agency Valuations of Human Life, A Report to the Administrative Conference of the United States* 386-87, 398 (1989) (arguing that this method could still be useful to develop policy to stimulate economic growth); *see also* Viscusi, *Legal Contexts*, *supra* note 6, at 214.
[28] *See infra* note 163.
[29] *See* Lisa Heinzerling, *Regulatory Costs of Mythic Proportions*, 107 YALE L.J. 1981, 2000 (1998) [hereinafter Heinzerling]. This terminology has also been adopted by several federal agencies employing value-of-life analysis, e.g.,

seems appropriate when the purpose is forward-looking deterrence rather than individual compensation.

Willingness-to-Pay

Since the 1970s, the most accepted methodology by both economists and policy analysts for performing ex ante valuation is the willingness-to-pay method.[30] The basic approach is to analyze how much people will pay to avoid different physical risks including the risk of death.[31] It was first conceived of in 1968 by Thomas Schelling, although the concept was suggested much earlier by Adam Smith's theory of compensating differentials.[32] Smith realized that workers would demand higher compensation for jobs that imposed higher risk.

Two techniques, relying on different types of empirical data, are used in these value-of-life computations. The more common, known as the hedonic pricing method, infers a value of life using observable market behavior.[33] As some of the most readily available data is from the labor market, economists have particularly studied the extra wages that are paid for risky jobs.[34] Analysis confirms that laborers do require higher wages for riskier jobs. For example, mining and construction tend to have the highest hourly wage among blue collar jobs, and they also have the highest fatality rates. Economists use regression analysis to control for other factors that could explain the difference in wages, such as education level or years of experience. Consumer behavior, such as the purchase of smoke detectors or the demand for products that enhance health

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the U.S. Coast Guard, 61 Fed. Reg. 13284 (Mar. 26, 1996), the FAA, 56 Fed. Reg. 48370 (Sept. 24, 1991), the EPA, 66 Fed. Reg. 6976 (Jan. 22, 2001), the USDA, 68 Fed. Reg. 34208 (Jun. 6, 2003), and the FDA, 68 Fed. Reg. 6062 (Feb. 6, 2003), 68 Fed. Reg. 12500 (Mar. 14, 2003), 68 Fed. Reg. 6062 (Jun. 6, 2003), and 68 Fed. Reg. 41434 (Jul. 11, 2003).

[30] *See* VISCUSI, FATAL TRADEOFFS, *supra* note 3, at 73; Miller, *supra* note 15, at 879, 883; Robert H. Frank & Cass R. Sunstein, *Cost-Benefit Analysis and Relative Position*, 68 U. CHI. L. REV. 323, 325 (2001) [hereinafter Frank & Sunstein].

[31] The most basic equation is expressed: value of a statistical life = change in income/change in risk. To control for other personal factors that might explain individuals' different preferences, a regression analysis can be performed. *See* Hersch, *supra* note 20, at 191.

[32] *See* Gillette & Hopkins, *supra* note 27, at 390.

[33] *See* Frank & Sunstein, *supra* note 30, at 325; Robert W. Hahn & John A. Hird, *The Costs and Benefits of Regulation: Review and Synthesis*, 8 YALE J. ON REG. 233, 242 (1991).

[34] *See, e.g.*, Viscusi, *Legal Contexts*, *supra* note 6, at 206, Table 1 (listing a number of value of life studies based on labor market data).

and safety, along with behavioral data, like the use of seat belts has also been used in these calculations.[35]

The second technique is called the contingent valuation approach. This technique requires surveys of individuals asking how much they would be willing to pay to avoid a variety of risks. While generally considered less desirable since it calls upon people to make difficult estimates that might differ from their actual behavior in the circumstance, it is useful for capturing risks not available in the consumer or labor market data.[36] In both techniques, large amounts of data are aggregated across individuals to obtain the value of an average, or anonymous, or statistical life.

Two important features of the willingness-to-pay methodology should be observed. First, it does not measure what people would actually be *able* to pay to avoid death. This would cause clear problems as a statistical life in a wealthy population would be valued more highly than one in a poor population. Second, it is expected that individuals' willingness to pay for different risky behavior will vary. This is an important reminder that there is no one natural or true value of a human life. It also indicates the importance of the selected population in arriving at a value. Anytime a value of a statistical life is used, it should be based upon a wide sample of the *relevant* population.[37]

The willingness-to-pay method enjoys three key benefits which make it so widely accepted by economists, and so commonly used by policy-makers. Perhaps the most important is its intuitive appeal of being based on people's actual preferences.[38] Unlike the human capital approach that imposes analysts' interpretations of the source of human value, the willingness-to-pay method requires no such assumptions. Along those lines, it captures a more complete picture

[35] *See* VISCUSI, FATAL TRADEOFFS, *supra* note 3, at 8, 70; Miller, *supra* note 15, at 880, Frank & Sunstein, *supra* note 30, at 325 for some of the observable behavior used in willingness-to-pay calculations.
[36] *See* VISCUSI, FATAL TRADEOFFS, *supra* note 3, at 70.
[37] *See* Viscusi, *Legal Contexts*, *supra* note 6, at 203. This will be discussed further *infra* in Part III.
[38] *See* Gillette & Hopkins, *supra* note 27, at 390.

of the value of human life, because it does not neglect the soft variables that are included in people's personal behavioral choices.[39] Finally, the methodology has the capacity to measure more aspects of the value of life than merely the complete value of life compared to death. By looking at people's behavior in avoiding risk of accidents as well as death, willingness-to-pay can be used to estimate the value of injuries and disabilities.[40] This could be extremely useful in policy analysis when a regulation in question does not impose fatal risks, but does impose other lesser risks, for example, the risk of birth defects.

In spite of its wide use, the willingness-to-pay method is far from perfect. Criticisms fall into three principle categories: problems with the conceptual approach, high level problems with the methodologies used, and problems with the technical application of the methodology. Several additional troubling aspects that apply to all value of life methodologies are discussed in detail below.[41]

The primary conceptual problem with willingness-to-pay is that it is not appropriate for use in ex post compensation.[42] As discussed above, the methodology requires compiling a broad range of population data to arrive at an *average* value. Individuals within a population could call for widely different values of life. However, even when used in the appropriate ex ante context, the method has limits. Some have a philosophical problem with valuing anonymous lives.[43] Others fault the methodology for focusing only on lives saved and ignoring quality of life or the total years of life at stake.[44] Economists today have made some refinements in response to that criticism. The Office of Management and Budget of the president ("OMB") currently

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[39] *See id*. at 390.
[40] Frank & Sunstein, *supra* note 30, at 325.
[41] *See infra* Part III.
[42] *See* Viscusi, *Legal Contexts*, *supra* note 6, at 214.
[43] *See* Gillette & Hopkins, *supra* note 27. (mentioning this as one critique of the method).
[44] Heinzerling criticizes Morrall, the author of the seminal study estimating the value of human life using the willingness-to-pay methodology, for this narrow focus. *See* Heinzerling, *supra* note 29, at 1985 & 2042.

recommends that federal agencies make use of some modern methodologies designed to tailor the value of life to those differences.[45]

Four high level critiques of the technique primarily attack assumptions implicit in the methodology. Each of these suggests that the methodology systematically undervalues human life. The first deals with the method's focus on how an individual values her own life. This neglects the losses suffered by others, such as her family. By ignoring these externalities, the method underestimates the value of life.[46] Second, focusing on the labor market could distort and undervalue life. The riskier jobs are blue collar work. White collar jobs tend not to be incorporated into the analysis. The result is that calculations tend to be based on blue collar behavior, while wealthier people probably have a higher willingness to pay. Third, the method assumes that people only care about their absolute living standard, and it only captures this value. Frank and Sunstein challenge this assumption, asserting that humans care very much about their relative economic position.[47] Finally, the methodology assumes that people have free mobility and can choose their jobs with no constraints. This neglects obvious realities of the labor market.[48]

Even if everyone agreed that both the theory behind willingness-to-pay and its methodology were sound, arriving at actual dollar values poses its own set of practical challenges. First, to solve the willingness-to-pay equation for the value of life, the actual risk of the jobs or behavior in question must be known.[49] However, as Lisa Heinzerling demonstrates, there is not uniform acceptance of these various risk levels, and variations can significantly

[45] Office of Management & Budget, Circular A-4, Regulatory Analysis, at 30 (Sept. 17, 2003), *available at* http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf [hereinafter OMB Circular].
[46] *See* Gillette & Hopkins, *supra* note 27, at 393.
[47] Frank & Sunstein, *supra* note 30, at 326 and generally.
[48] *See* Gillette & Hopkins, *supra* note 27, at 392.
[49] See the basic value of life equation, *supra*, note 31.

impact the final number.[50] Because the behavior or jobs in question typically have very low fatality rates, problems arise when analysts attempt to extrapolate, for example, from animal studies or high does to low dose.[51]

Beyond understanding the magnitude of the actual risks, the analysis relies on individuals' estimates of the risks they face. If people misjudge the riskiness of a certain behavior, or behave irrationally, their choices reflect a willingness to pay for something other than what they are getting. Unfortunately, a significant body of literature has documented individuals' tendency to make mistakes in estimating physical risks.[52] For example, people tend of overestimate the chance of low-probability events that have often been called to attention and the chance of particularly catastrophic events.[53] At the same time, people often undervalue the likelihood of small ubiquitous risks.[54]

Once proper estimates of the risks have been made, economists perform a regression analysis to control for other factors that might explain the variation in wages or behavior. While it is essential to take these factors into account, doing so also complicates the analysis. Specifically, multicollinearity may result.[55] Multicollinearity occurs when several variables in an econometric model are correlated with each other. If any variables are correlated with the variable in question (here, how well risk explains wages), the importance of that variable can be masked. On the flip side, ignoring important explanatory factors leads to an econometric problem known as omitted variable bias ("OVB"). The result of OVB is that the importance of the variable in question will be overstated. These problems do not invalidate the willingness-to-

[50] *See* Heinzerling, *supra* note 29, at 2025-39.
[51] *See id*. at 2057.
[52] *See*, *e.g.*, Miller, *supra* note 15, at 883; Hahn & Hird, *supra* note 33, at 242; Gillette & Hopkins, *supra* note 27, at 392.
[53] *See* VISCUSI, FATAL TRADEOFFS, *supra* note 3, at 70; Gillette & Hopkins, *supra* note 27, at 394-95.
[54] Gillette & Hopkins, *supra* note 27, at 394-95.
[55] Hahn & Hird, *supra* note 33, at 242 (discussing possible problems of multicollinearity and omitted variable bias).

pay methodology. They merely call for a careful examination of how each individual analysis is performed.

In sum, although the willingness-to-pay methodology is generally accepted for use in policy analysis, the devil lies in the details. As evidence of the difficulty in performing the computation, see Table 1, below, comparing a variety of academics' willingness-to-pay studies.

Table 1[56]
Estimates of Value of Anonymous Life,
By Type of Study
(in 2003 after-tax dollars, millions)

Average of 29 Studies	$ 3.3
Range of Extra Wages for Risky Jobs	1.7-5.2
Demand and Price	
Safer Cars	3.2
Smoke Detectors	1.7-3.0
Houses in Polluted Areas	3.9
Life Insurance	1.8
Behavior	
Pedestrian Tunnel Use	3.0
Safety Belt Use	2.2-5.2
Speed Choice	2.2-2.7
Driver's Travel Time	1.7-2.0
Surveys	
Cancer	4.0
Safer Bus	4.4
Safer Job	3.4
Auto Safety	3.7

The author who compiled the table evaluated each study to verify its quality, and converted each value into consistent terms. Nonetheless, values range from $1.7 million to $5.2 million. Miller's table found academic estimates to vary by a factor of 3, but he notes that another study uncovered values that vary by a factor of 5, and still another found enormous variations of over 120 times. A more recent study, in Table 2, with values more in line with the current wisdom

[56] Reproduced from Miller, *supra* note 15, at 881, Table 1. I have converted his table from 1985 dollars to 2003 dollars using the consumer price index ("CPI"). *See* U.S. Dept of Labor, Bureau of Labor Statistics, Consumer Price Index, *available at* ftp://ftp.bls.gov/pub/special.requests/cpi/cpiai.txt (last visited Feb. 2, 2004). I use the CPI throughout the paper, where noted, to convert values into 2003 dollars.

illustrates not only the variation in overall willingness-to-pay estimates, but also how individuals' willingness to pay to avert death can vary according to the cause of death:

Table 2[57]
Mortality Values by Cause of Death

Category	**Value Estimates** (in 2003 dollars, millions)		
	Low	*Medium*	*High*
Unforeseen instant death	1.2	2.5	6.2
Asthma/bronchitis	1.6	3.1	6.8
Heart disease	1.5	3.4	7.4
Emphysema	1.7	4.3	11.1
Lung cancer	1.8	4.9	11.7

The broad range of values used leaves some in the field skeptical and reminds us that willingness-to-pay is a very indirect method of estimating the value of life.[58] Nonetheless, it is clearly more appropriate than the human capital approach for FDA's purposes of making ex ante policy decisions. Perhaps the difficulty of arriving at a precise value suggests that its proper use is on an advisory level rather than in a nondiscretionary manner. This possibility will be raised in the paper's conclusion.

Retrospective Analysis

An alternative method is available which does not fall neatly into the ex post or ex ante categories. This method is useful only to consider the value of life in the context of regulation. The process involves simply dividing the total cost of a regulation by the actual or expected number of lives saved to arrive at a cost per life saved. I call this "retrospective analysis."[59]

[57] Richard H. Pildes & Cass R. Sunstein, *Reinventing the Regulatory State*, 62 U. Chi. L. Rev. 1, 81, Table 6 (1995) (taken from George Tolley, et. al., *Valuing Health for Policy: An Economic Approach*, 342) [hereinafter Pildes & Sunstein]..
[58] *See* Hahn & Hird, *supra* note 33, at 242.
[59] Retrospective values have also been cited as part of a "regulatory scorecard." *See* Richard W. Parker, *Grading the Government*, 70 U. CHI. L. REV. 1345 (2003).

While the concept itself is straightforward, applying the method is far from it. The method suffers many of the same trappings as the willingness-to-pay method. It involves discounting decisions, quantifying the overall cost of a regulation, and difficulties distinguishing between lives extended versus totally saved, or improvements in quality of life.[60] John Morrall, an economist in the Office of Management and Budget ("OMB") performed the seminal analysis using this method in 1986.[61] Several other scholars have done similar analyses since then. While all of their studies have been used to condemn federal agencies for promulgating widely cost-inefficient regulations, the studies themselves have also been the subject of much critique.[62] One cynic concluded that "the studies … are so fundamentally flawed that they prove nothing at all about the rationality of regulation."[63]

In spite of the critiques, the method provides the unique advantage of being available to evaluate and compare agencies' decisions even when they are not explicit about the use of a value of life estimate. Therefore, retrospective analysis will be used below to compare "official" valuations of human life with the de facto, or retrospective values that different agencies place on life. Specific flaws in the method will be discussed at that point.

III. SPECIAL DIFFICULTIES IN VALUING LIFE

Three difficulties, present in every methodology currently available, arise when setting a value on human life: discounting, political manipulation, and special populations. These issues are so large that they threaten the legitimacy of any final value to both the public and the

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[60] *See id*. (critiquing the use of retrospective values as a means for evaluating government performance).
[61] John F. Morrall, III, *A Review of the Record*, 10 REGULATION 25, 30, Table 4 (1986); *see* Heinzerling, *supra* note 29, at 1983 and n2 for a list of scholars who have relied on Morrall's tables).
[62] The most comprehensive critique of all of the major retrospective studies is Lisa Heinzerling & Frank Ackerman, *Getting Beyond Cynicism: New Theories of the Regulatory State Comment: The Humbugs of the Anti-Regulatory Movement*, 87 CORNELL L. REV. 648 (2002) [hereinafter Heinzerling & Ackerman].
[63] Parker, *supra* note 59, at 1355. Heinzerling also provides an in-depth critique of Morrall's methodology. *See* Heinzerling, *supra* note 29.

academic community. It is therefore essential that, at a minimum, they be dealt with transparently.

Discounting

Discounting is the concept that something is worth more today than it will be in the future. It is uniformly accepted and applied in the financial sphere. For example, when valuing a bond, the future coupons are discounted according to when they will be received – the further off in the future, the less they are worth. Discounting in the context of valuing human life raises three distinct questions: 1) whether to discount life; 2) if so, what lives to discount; and 3) how to choose a discount rate.

Whether to Discount Life

To understand the significance of the discounting decision, we must examine how exactly discounting affects the value of life. The short answer is, it values lives saved today more than lives saved in the future. Therefore, when "lives saved" are being plugged into a cost-benefit analysis as a benefit, the total benefit will be lower if discounting is applied. In an extreme example, "[a]t a discount rate of five per cent, one death next year counts for more than a billion deaths in 500 years."[64] While few policy decisions contemplate impact out to 500 years, environmental regulations can often have impacts that span significant time horizons, like emissions regulations to control global warming, or anti-dumping rules to protect water sources. Food and drug regulations can also have long term impacts, for example, if they affect reproductive health or latent cancer risk. Lisa Heinzerling demonstrated how dramatically discounting can impact a cost-benefit analysis. She found that many regulations promulgated

[64] DEREK PARFIT, REASONS AND PERSONS 357 (1984); *see also* Michael B. Gerrard, *Demons and Angels in Hazardous Waste Regulation: Are Justice, Efficiency, and Democracy Reconcilable?*, 92 NW. L. REV. 706, 742-43 (1998) ("If a human life is considered to be worth $8 million and a ten percent discount rate is chosen, then the present value of saving a life one hundred years from now is only $ 581.")

over the past 30 years, including health and safety regulations, have benefits exceeding their costs if human lives are not discounted, but do not pass cost-benefit analysis when life is discounted.[65]

The decision whether to discount life has moral implications. It means that we choose to value our own lives more than the lives of future generations. I believe that this is not obviously right or wrong. But it should be understood that such a choice is inherent in any value of life methodology. Proponents of discounting argue that since the costs in a CBA are typically discounted, all benefits should be as well to be consistent.[66] This seems reasonable if we choose to view lives as commensurate with dollars. The mere exercise of setting a value on human life suggests some truth to that view. Heinzerling argues that it is philosophically equivalent to the discounting of monetary compensation for the loss of life in the tort context.[67] However, those who oppose discounting argue that lives and dollars are fundamentally different and that future lives are no less valuable than present lives.[68] Heinzerling, declining to take a stance, asserts that "the decision to discount lives saved in the future involves a choice about values, as to which reasonable people may disagree."[69]

What Lives to Discount

If one does choose to adopt discounting, the difficulty does not end there. Richard Revesz has argued that the discounting debate has conflated two distinct issues:

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[65] Heinzerling, *supra* note 29, at 1984-85.
[66] Richard L. Revesz, *Environmental Regulation, Cost-Benefit Analysis, and the Discounting of Human Lives*, 99 COLUM. L. REV. 941, 944 (1999) [hereinafter Revesz].
[67] Heinzerling, *supra* note 29, at 2043.
[68] *See* Thomas O. McGarity & Sidney A, Shapiro, *OSHA's Critics and Regulatory Reform*, 31 WAKE FOREST L. REV. 587, 629 (1996) ("The practice of discounting future benefits to present value ... biases cost-benefit analysis against future generations. A high discount rate clearly biases the analysis against future benefits, even though 'it is not clear why the later-born should have to pay interest to induce their predecessors not to exhaust [depletable resources.]'"); Michael B. Gerrard, *Demons and Angels in Hazardous Waste Regulation: Are Justice, Efficiency, and Democracy Reconcilable?*, 92 NW. L. REV. 706, 743 (1998) ("[The] protection of future generations is not merely a matter for accountants. The Constitution was adopted in part to 'secure the Blessings of Liberty to ourselves and our Posterity.'"); A. Dan Tarlock, *Now, Think Again About Adaptation*, 9 ARIZ. J. INT'L & COMP. L. 169, 173 (1992) ("Speculation about discount rates becomes a disguised debate about our ethical duties toward future generations.").
[69] Heinzerling, *supra* note 29, at 2044.

The first involves harm that will occur to an existing person later in life; the second involves harm to future generations.[70] To understand the first, consider two forty-year-old men; one faces instant death and the other faces potential future harm from exposure to a carcinogenic drug. Clearly, the man facing instant death will lose more life-years, and lose them sooner in life. Revesz maintains that discounting is appropriate for distinguishing between these two scenarios.[71]

The second issue is the one discussed in the preceding section, and more commonly debated in the discounting literature. Revesz believes that discounting the lives of future generations is ethically unjustified. He believes that there is no defensible basis for privileging the interests of the current generation, and that discounting of this nature will lead to unacceptably lax regulations on future harms like global warming.[72]

What Discount Rate to Use

As explained above, discounting decisions can significantly impact the results of a cost-benefit analysis. The choice of how much to discount is as critical as the decisions of whether and how to discount. In finance, a rational basis exists for choosing a discount rate – it should be the opportunity cost of a dollar. The reason that a dollar today is worth more than a dollar in the future is because I can invest the dollar today to turn it into a greater sum in the future. Thus, the appropriate discount rate is typically the risk-free interest rate plus a risk premium. The analogy for human life is unclear. Is there an opportunity cost to saving a life next year rather than a life today? Is there any risk-free return equivalent in life? Viscusi believes that just as discounting

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[70] *See* Revesz, *supra* note 66, generally. As an example of the first issue, Revesz uses an individual exposed to a carcinogen who faces an increased probability of dying in the future, perhaps twenty or thirty years later. For the second, he refers to climate change caused by gases in the atmosphere that will harm future generations. Id. at 945.

[71] *See id*. at 1016.

> The use of discounting [in this context], however, will lead to misleadingly low valuations of life unless it is coupled with significant upward adjustments to account for the dread and involuntary nature of [drug] carcinogens, as well as for higher income levels of the victims. Unfortunately, the regulatory regime has failed to recognize the need for such adjustments.

Id.

[72] *See* Revesz, *supra* note 66, at 948, 1016.

human life should be treated the same as discounting the other components of the cost-benefit analysis, so should the discount rate be the same.[73] For support, he calls upon studies of worker valuations of death risks, and expectations about productivity growth.[74] Morrall, in his seminal retrospective analysis of the value of human life for the OMB, used a 10% discount rate.[75] The difference between his estimates and those of the agencies he analyzed has been attributed to differences in discounting.[76] In contrast, discount rates in the human capital approach are typically between 2% and 4%.[77] While the methods are admittedly different, it is unclear why Morrall's retrospective method, and willingness-to-pay methodology should use a discount rate up to 5 times higher than the human capital approach. I have not identified literature dealing with this discrepancy.

Choosing a discount rate is far from an abstract problem. Federal agencies use widely different discount rates ranging from 0% to 10% in conducting cost-benefit analyses, and to discount the value of life.[78] There is even variation in the rate used *within* a given agency. In this respect, FDA is equally guilty as other federal agencies.[79] The importance of these variations cannot be overstated. Even if all agencies valuing life and performing CBAs were in complete agreement as to the theoretical methodologies, their numbers would be absolutely incomparable without consistent discounting.

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[73] VISCUSI, FATAL TRADEOFFS, *supra* note 3, at 55 ("[T]here is no evidence to indicate that we should use a different rate of discount when weighting the long-term health benefits of polices that affect life extension as compared with other benefit and cost components that these policies many have.").
[74] VISCUSI, FATAL TRADEOFFS, *supra* note 3, at 145; *see also* Revesz, *supra* note 66, at 947 ("Because there are essentially no empirical studies of the value of lives threatened by latent harms, regulatory analyses must adapt valuations derived from threats of instantaneous death in workplace settings.").
[75] Morrall, *supra* note 61, at 28. Today, the OMB has changed its recommended discount rate to 7%. *See* OMB, Benefit-Cost Analysis of Federal Programs, 57 Fed. Reg. at 53520 (1992). For a critique of the OMB's choice of discount rate, see Revesz, *supra* note 66, at 948, 983 (arguing that the use of an inflated discount rate by the OMB artificially undervalues life).
[76] *See* Heinzerling, *supra* note 29, at 2018.
[77] Hersch, *supra* note 20.
[78] See the table in Matthew D. Adler & Eric A. Posner, *Implementing Cost-Benefit Analysis When Preferences Are Distorted*, *29* J. LEGAL STUD. 1105, 1146 (2000) [hereinafter Adler & Posner]. *See also* Edward R. Morrison, *Judicial Review of Discount Rates Used in Regulatory Cost-Benefit Analysis*, 65 U. CHI. L. REV. 1333, 1364-69 (1998) (finding that discount rates used by federal agencies in cost-benefit analyses have ranged from 2-10%).
[79] *See infra* Part VI.

Political Manipulation

An obvious benefit of assigning a quantifiable value to human life for use in cost-benefit analysis is that it gives policy-makers an objective standard for making decisions. However, it would be naïve to imagine that a political appointee could be immune from political or pressure, or could perform a completely nonpartisan cost-benefit analysis.[80] For example, a commissioner of a large federal agency could greatly increase the amount of federal regulation by tweaking upward the value of human life. This could be done quite subtly by lowering the discount rate, or a number of other means. Presidents and White House executives have deliberately distanced themselves from the numbers to avoid the political firestorm.[81]

There are three reasons why potential for political manipulation should not condemn the entire exercise of valuing life. First, although it may be realistically impossible to eliminate all partisanship from value of life estimates, some political input is not necessarily bad. Federal agencies are led by appointed officials. Political heat is most likely to come from elected officials, like congressmen or the president. It is appropriate for elected officials to engage in oversight of appointees. Political influence is, in a sense, the democratic process at work. Second, who would be in a better position to handle the valuation of life than the government?[82] If it is left to the private sector, industry groups will manipulate the numbers downward to limit the regulation imposed on them.[83] As discussed above, if valuation is not done explicitly, it will

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[80] *See* Samuel J. Rascoff & Richard L. Revesz, *The Biases of Risk Tradeoff Analysis: Towards Parity in Environmental and Health-and-Safety Regulation*, 69 U. CHI. L. REV. 1763, 1794 (2002) (arguing that governmental cost-benefit analysis tends to systematically underestimate costs due to its conservative genesis) [hereinafter Rascoff & Revesz]; *see also* Steven Croley, *White House Review of Agency Rulemaking: An Empirical Investigation*, 70 U. CHI. L. REV. 821, 821-22 (2003) (arguing that requiring cost-benefit analysis was originally a tool for conservative administrations to push deregulation, but now has bipartisan acceptance).

[81] Gillette & Hopkins, *supra* note 27, at 375.

[82] ROBERT H. BLANK, LIFE, DEATH AND PUBLIC POLICY 135 (1988) (arguing that valuation of human life should be the province of the government).

[83] Industry already does this in providing the government with cost estimates to assist in agencies' cost-benefit analyses:

> Knowing that the agencies are less likely to impose regulatory options with high price tags (or to support them during the review process), the regulatees have every incentive to err on the high side.

occur implicitly and in an ad hoc manner through the prioritization of regulations. Finally, it is possible to create checks on the valuation process to ensure fairness. Perhaps the strongest check is transparency. Transparency ensures that the numerous scholars who have long studied this field observe the process, and bring flaws to light. It also makes it harder for a new administration to come in and subtly alter the value to further a political agenda. Hence, while political manipulation is a reality, this is merely a reminder of the need for oversight over the regulatory cost-benefit analysis process.

Special Populations

As discussed above, there is not one universal value of life. In the human capital approach, individuals' expected future earnings will vary widely. Similarly, using the willingness-to-pay method, results will depend upon *whose* willingness to pay is being measured. In the human capital approach, when being used for tort compensation, this poses no problem. Indeed, the method's flexibility is in part what recommends it most for that use. However, the impact on ex ante decisions of variations resulting from the willingness-to-pay method is more troubling. A hypothetical example will illustrate the potential problem. The Department of Transportation is deciding whether to allocate its funds toward a new airline safety regulation or improving interstate highways. It requests that the Federal Aviation Administration ("FAA") and the National Highway Traffic Safety Administration ("NHTSA") perform a cost-benefit analysis for each project to determine where the benefits most outweigh the costs. If each agency has

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> Beneficiary groups can complain about the magnitude of cost projections, but they rarely have the wherewithal to second-guess regulatee-generated estimates. The only entities with both the economic incentive to exert a leavening influence and the information and expertise necessary to back it up are the occasional independent vendors of the safety and environmental cleanup technologies. These entities are themselves frequently only subsidiaries of the larger regulated entities or in any event cannot risk alienating their potential customers by demonstrating the excessiveness of the cost projections in a public forum, hence the unremarkable conclusion that the regulatory process routinely yields ex ante cost projections that are likely to be biased upward . …

Thomas O. McGarity & Ruth Ruttenberg, *What We Know and Do Not Know About the Impact of Civil Justice on the American Economy and Policy: Counting the Cost of Health, Safety and Environmental Regulation*, 80 TEX. L. REV. 1997, 1998-99 (2002).

done its own willingness-to-pay study, the FAA would certainly have a higher value of life than the NHSA since airline passengers are more affluent on average than drivers.[84] As a result, airlines would be more heavily regulated than highways. The source of this disparity – the affluence of the respective populations – is strange and extremely controversial.[85] Similar disparities would emerge among regulations that cater to populations of different ages, such as the young or the elderly.[86]

One proposed solution to handling special populations was put forth by Frank and Sunstein, who argue that willingness-to-pay numbers should be modified based on the elasticity of position.[87] This involves understanding how different socio-economic populations' willingness to pay would vary as their incomes changed. Needless to say, this significantly complicates the valuation process. A second solution, also advocated by Sunstein, deals specifically with the problem of age. Economists have developed a methodology under which the willingness-to-pay methodology is used to compute the value of a statistical life, as discussed above. This value, then, is broken down further into the value of a statistical life-year ("VSLY"). This way, the benefits of regulations can be differentiated between those that extended life a little versus those that extend life significantly. Similarly, regulations that affect the elderly would generally be valued lower than those that affect children.[88] Federal agencies, including FDA, have embraced this refinement.[89]

IV. LEGAL HISTORY OF THE VALUE OF LIFE

[84] *See* VISCUSI, FATAL TRADEOFFS, *supra* note 3, at 28.
[85] *See* Viscusi, *Legal Contexts*, *supra* note 6, at 213.
[86] *See* VISCUSI, FATAL TRADEOFFS, *supra* note 3, at 30 (noting that since the young have more to lose than the old, they would have a higher willingness-to-pay value of life).
[87] *See* Frank & Sunstein, *supra* note 30, at 355.
[88] Cass Sunstein explains why this practice does not amount to age discrimination, and results in maximizing benefits for society. *See* Cass R. Sunstein, *Lives, Life-Years, and Willingness to Pay*, 104 COLUM. L. REV. 205 (2004).
[89] *See* OMB Circular, *supra* note 45, and *infra* Part VI.

No statute or executive order explicitly mentions the value of life. And yet, its use has been a contentious legal issue for over 30 years. Debates over the use of value of life methodologies have essentially been subsumed in the extensive legal history concerning the use of cost-benefit analysis. Because the value of life is an essential component of many regulatory CBAs, and possibly all done by FDA, its use and acceptance has risen and fallen (but mostly risen) with attitudes toward CBA. Legal doctrine in its entirety has handled cost-benefit analysis almost schizophrenically, in places requiring it, and in others forbidding it altogether. This, in part, can be explained by the fact that each of the three branches of government has during the course of multiple administrations, attempted to exert its control, or "legislate" in this area. It might also be the result of a deeper tension concerning the appropriate level of agency discretion competing with executive, legislative and judicial oversight.

The Executive Branch

In some respects, the executive branch has led the charge in promoting agencies' use of cost-benefit analysis. Although the initial push might have been an effort to limit federal regulation, today, CBA has received bipartisan executive support as an important technique for managing the efficiency of regulation. Executive control has issued in two forms: formally, through executive orders, and less formally, through actions and recommendations of the Office of Management and Budge ("OMB"). The OMB is the executive office of the president, charged with assisting the president in the development and implementation of budget and regulatory policies.[90]

The earliest push to have agencies monitor the costs and benefits of their actions began in the early 1970s, and was targeted at the Environmental Protection Agency ("EPA"). In 1971,

[90] See OMB, *OMB's Mission*, *available at* http://www.whitehouse.gov/omb/organization/role.html (last visited Feb. 8, 2004)

George Shultz directed agencies to submit significant regulatory proposals to OMB for review.[91] In 1974, President Ford signed the first relevant executive order, which required agencies to prepare an Inflation Impact Statement ("IIS") for every new regulation likely to have a substantial economic effect.[92] The order required agencies to perform a full analysis of costs and benefits, but did not require them to base their decisions on it.[93] Ford changed the name of the IIS to Economic Impact Statement ("EIS") to more accurately reflect its focus – financial cost.[94] The goal of requiring the EIS was to shift regulatory debate to questions of efficiency.[95] The analysis was once again renamed in 1978 by President Carter to a Regulatory Analysis ("RA").[96] Although Carter's executive order did not explicitly mention "cost-benefit analysis," it essentially required the same analysis as the others. It even went one step further in *requiring* the use of some analysis in regulatory decision-making.[97]

In 1981 President Reagan helped catapult the importance of cost-benefit analysis in agency decision making by issuing Executive Order 12291.[98] For the first time, CBA became a key determinant of agency decisions, as agencies were required to demonstrate that the benefits of their regulations exceeded the costs.[99] Executive Order 12291 also renamed the required Regulatory Analysis to its present name, Regulatory Impact Analysis ("RIA"), and gave the OMB pre-clearance responsibility for all "major" rules.[100] The Executive Order had the

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[91] Gillette & Hopkins, *supra* note 27, at 372 (Gillette and Hopkins recount the history of Executive Orders impacting the use of the value of life from 1974 through 1987. Their work has been relied on for much of this section).
[92] Exec. Order No. 11821, 3 C.F.R. 926 (1974).
[93] Exec. Order No. 11821, Gillette & Hopkins, *supra* note 27, at 372.
[94] Exec. Order No. 11949.
[95] Gillette & Hopkins, *supra* note 27, at 372.
[96] Exec. Order No. 12044.
[97] Gillette & Hopkins, *supra* note 27, at 373.
[98] Exec. Order No. 12291, 46 Fed. Reg. 13193 (Feb. 19, 1981).
[99] This is true, provided that such a comparison was not explicitly prohibited by statute. *See* Calandrillo, *supra* note 11, at 965-66.
[100] The Order defined "major" as

> any rule likely to: (1) have an annual effect on the economy of $ 100 million or more; (2) impose a major increase in costs or prices for consumers, industries, government agencies, or geographic regions; or (3) have a significant adverse effect on competition, employment, investment, productivity,

politically conservative anti-regulatory premise that regulation should only be used when it was more effective than market forces.[101] However, it also was premised on a less partisan ideal that CBA could be a means of structuring regulations to maximize the net benefit to society.[102]

Executive Order 12291 led to the proliferation of value of life estimates. John Morrall, who analyzed the cost per life saved of numerous agency regulations before and after the Executive Order, concluded that Reagan's mandate affected regulatory reform in reducing the statistical variance of the value of life by one-third.[103]

In addition to elevating the role of CBA in federal agencies, Reagan also increased the importance of the OMB. In 1985, 12291 was followed by Executive Order 12498, which further spelled out the role of the OMB in overseeing agency analysis.[104] From that point on, the OMB has played a significant role in determining the methodology for calculating the value of life, and for addressing its proper use. For example, in 1987, the OMB endorsed the willingness-to-pay methodology for use by federal agencies.[105] While several agencies had made use of the methodology prior to 1987 to comply with the previous executive orders,[106] it became much more common in agency analysis following the OMB's endorsement.

> innovation, on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Exec. Order. No. 12291.

[101] *See* Gillette & Hopkins, *supra* note 27, at 374 Some greater critics believe that its purpose was just to generally stymie regulation. *See*, *e.g.*, PHILIP J. HILTS, PROTECTING AMERICA'S HEALTH: THE FDA, BUSINESS, AND ONE HUNDRED YEARS OF REGULATION, 215 (2003) (arguing that Reagan's intention with Executive Order 12291 was to "tie up the bureaucrats with paperwork"). In addition, "consumer and citizens' groups denounced the new policies and the arithmetic. They said that the calculations did not include the measure of lives, injuries, and illnesses that might be caused by reducing standards in factories, mills and mines." Id. 216. Others criticized the disguised deregulatory intent, arguing that under the methodology, costs of regulation would be easy to quantify, hence exaggerated compared to benefits, which tend to be more nebulous. *See* Croley, *supra* note 80, at 826. This is a general partisan critique of the use of CBA by government.

[102] *See* Gillette & Hopkins, *supra* note 27, at 374.

[103] *See* Heinzerling, *supra* note 29, at 1993 (citing Morrall, *supra* note 61).

[104] Exec. Order No. 12498 (1985). '[T]he orders [12291 and 12498] have often been characterized as one of the most significant developments in administrative law of the 1980s." Croley, *supra* note 80, at 826.

[105] Gillette & Hopkins, *supra* note 27, at 375 (citing OMB's Regulatory Program (Spring 1987)); *see also* Viscusi, *Legal Contexts*, *supra* note 6, at 208.

[106] Several mentions by federal agencies included disclaimers that they did not officially endorse the values used. *See* 48 Fed. Reg. 45872 (Oct. 7, 1983) (OSHA), and 47 Fed. Reg. 36186 (Aug, 19, 1982) (CPSC).

In line with expectations, President Clinton promptly revoked Executive Orders 12291 and 12498. However, he replaced them with his own Executive Order which was surprisingly similarly to the prior ones.[107] Clinton's order continued the requirement that agencies assess the costs and benefits of major regulations, and maintained the central role of the OMB as the repository and overseer of analysis.[108] However, Clinton's rule was a bit more lax in that it limited the requirement that agencies provide the extensive cost-benefit analysis to regulations meeting the $100 million threshold required by Executive Order 12291, and provided for abbreviated analysis for other rules that had been considered "major" by Reagan's order.

Clinton's order went a long way toward building bipartisan acceptance of cost-benefit analysis and valuations of life. First, by maintaining the emphasis on cost-benefit analysis as a key decision tool, Clinton demonstrated that this traditional economic analysis was not exclusively a political tool for deregulation.[109] Second, Executive Order 12866 explicitly addressed the benefits side of CBA, emphasizing that enhancing public health and safety and protecting the environment were to be included in agencies' assessment of benefits.[110] This was significant to liberal critics of CBA who argued that it systematically underestimated the benefits of regulation. While benefits still tend to be more difficult to pin down, the Clinton order makes clear that large social benefits should not be discounted merely because they are hard to quantify.

In response to the Executive Order, in 1996 the OMB promulgated detailed guidelines for agencies to apply in conducting cost-benefit analyses.[111] These guidelines directly address many

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[107] Exec. Order No. 12866 (1993). *See generally* Pildes & Sunstein, *supra* note 57 (evaluating Executive Order 12866 as part of Clinton's plan for "reinventing government").

[108] The order specified that the Office of Information and Regulatory Affairs ("OIRA") within the OMB would be the "repository of expertise concerning regulatory issues." Exec. Order No. 12866. "Clinton's order embraced both the general principles of cost-benefit analysis, instructing agencies to select regulatory approaches that 'maximize net benefits,' just as Executive Order 12291 did, and the centrality of the White House itself to the rule-planning and rulemaking process, just as Executive Order 12498 did." Croley, *supra* note 80, at 828.

[109] *See* Pildes & Sunstein, *supra* note 57, at 6.

[110] *See* Croley, *supra* note 80, at 828.

[111] Office of Management and Budget, Economic Analysis of Federal Regulations Under Executive Order 12866 (Jan. 11, 1996), *available at* http://www.whitehouse.gov/omb/inforeg/riaguide.html.

value of life questions. They continue to endorse the willingness-to-pay methodology, and make numerous recommendations for handling questions of discounting, and valuing life-years extended, and other improvements to the quality of life. Above all, they emphasize the importance of consistency across regulations and agencies, and call for an explanation for any "significant deviations from the prevailing state of knowledge."[112] The OMB's understanding of cost-benefit analysis has become increasingly sophisticated, as it has embraced the concept of risk tradeoff analysis, a form of CBA that takes into account the ancillary risks created by regulation as well as its more obvious costs and benefits.[113] President George W. Bush has carried forward the influence of the cost-benefit approach to regulations by appointing John D. Graham to head the Office of Information and Regulation Affairs ("OIRA") in 2001.[114] Graham has been closely associated with the development of the concept of risk tradeoff analysis.[115]

Recently, the OMB has refined its recommendations concerning the value of life. Recognizing the current economic current differentiating the value of life according to life-years saved ("VSLY"), it now recommends that agencies perform cost-benefit analyses using both VSL and VSLY.[116]

While there is great value in the OMB's detailed spelling out of value of life methodology, any specificity naturally opens the door for critics. For example, Richard Revesz has critiqued the OMB's recommendations for taking valuations from the workplace setting and

[112] Office of Management and Budget, Economic Analysis of Federal Regulations Under Executive Order 12866 (Jan. 11, 1996), *available at* http://www.whitehouse.gov/omb/inforeg/riaguide.html at B.5.b.
[113] *See generally* Rascoff & Revesz, *supra* note 80 (explaining and critiquing the use of risk tradeoff analysis).
[114] *See* Rascoff and Revesz, *supra* note 80, at 1765.
[115] *See id*. at 1765.
[116] *See* OMB Circular, *supra* note 45, at 30 ("You should consider providing estimates of both VSL and VSLY, while recognizing the developing state of knowledge in this area."); Office of Management & Budget, Memorandum to the President's Management Council, Benefit-Cost Methods and Lifesaving Rules (May 30, 2003), *available at* http://www.whitehouse.gov/omb/inforeg/pmc_benefit_cost_memo.pdf.

reducing them by an inflated discount rate.[117] He believes that the OMB's methodology systematically underestimates the value of life.[118]

In sum, the current Executive Order governing agency analysis is number 12866, together with the corresponding OMB guidelines. Under Executive Order 12866, agencies must assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits, including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity. As will become clear below, this Executive Order is the most controlling authority governing agency-wide risk assessment practices.

The Legislature

As is to be expected due to the nature of the political process, Congress has had much greater difficulty than the president in enacting legislation dealing with the valuation of life, and even simple cost-benefit analysis. Although agency-specific legislation does impose a variety of analysis requirements on federal agencies, ranging from those which require decisions to be justified by cost-benefit analysis to those which outright forbid any such analysis, generic administrative laws are silent on life valuation matters.[119] No comprehensive legislation with specific analytical requirements has been enacted since the Administrative Procedure Act ("APA") in 1946.[120]

Failed Attempts

The lack of comprehensive legislation is not for want of trying. Serious attempts by Congress to legislate in the area of risk assessment began with the 103rd Congress in 1993, by the

[117] *See* Revesz, *supra* note 66, at 946.
[118] *See id*. at 983.
[119] Gillette & Hopkins, *supra* note 27, at 370.
[120] *See* Fred Anderson, et. al., *Regulatory Improvement Legislation: Risk Assessment, Cost-Benefit Analysis, and Judicial Review*, 11 DUKE ENV. L. & POL'Y F. 89, 90 (2000).

Democratic majority.[121] These efforts focused largely on regulating the EPA.[122] The next major bill to be introduced was the Contract with America, by Newt Gingrich and Dick Armey. This bill, which ultimately failed, included extensive and stringent cost-benefit analysis requirements for all health and safety legislation.[123] Between 1993 and 2000, a number of further bills have been introduced, and failed, either when turned over to the second legislative house, or on the president's desk.[124] While none were successful, they did open up a dialogue and increased interest in Congress of acting in this area.

If risk assessment is a difficult political route to navigate, the value of life is like a slalom course. Of the numerous attempts to legislate concerning cost-benefit analysis, no bill has included any guidance as to the valuation of life, or even as to the quantification of benefits from regulation.[125]

Governing Legislation

In the wake of the unsuccessful bills, very little governs federal agencies' risk assessment in the statutory arena. The most important law is the Unfunded Mandates Reform Act from 1995. This act imposes two relevant requirements. First, any significant regulatory actions must be accompanied by a statement that includes "a qualitative and quantitative assessment of the anticipated costs and benefits of the Federal mandate … as well as the effect of the Federal mandate on health, safety, and the natural environment "[126] Second, agencies must "identify and consider a reasonable number of regulatory alternatives and from those alternatives select the

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[121] *See* Anderson, et. al., *supra* note 120, at 96.
[122] *See id*. at 96-98 (detailing the legislative efforts of the 103rd Congress regarding risk assessment regulation).
[123] "Among other things, this cluster of bills would have required that health and safety regulations pass cost-benefit analysis, that agencies implement the most cost-effective means of regulating risk, and that quantitative risk assessment - peer-reviewed and subject to judicial review - be the basis for health and safety regulations." Heinzerling, *supra* note 29, at 1994.
[124] These attempts by Congress have been extensively documented. *See*, *e.g.*, *See* Anderson, et. al., *supra* note 120, at 96-112; Rascoff & Revesz, *supra* note 80, at 1784-85; Cass R. Sunstein, *Congress, Constitutional Moments, and the Cost-Benefit State*, 48 STAN. L. REV. 247 (1996); *See* Revesz, *supra* note 66, at 943; Calandrillo, *supra* note 11, at 1013-15.
[125] *See* Frank & Sunstein, *supra* note 30, at 331.
[126] 2 U.S.C. § 1532(a)(2) (2004).

least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule."[127] While this act does officially call for the use of cost-benefit analysis, in reality, it is of little consequence for two reasons. First, most of its requirements are already encompassed in Executive Order 12866.[128] Second, "in keeping with the pattern that we have seen thus far, they are silent on how agencies are supposed to value the goods at stake."[129]

Two other acts have only an ancillary impact on agency cost-benefit analysis. First, under the Regulatory Flexibility Act, if a rule has a significant economic impact on a substantial number of small entities, an agency must consider alternatives that would minimize the economic impact of the rule on small entities.[130] Second, the Small Business Regulatory Enforcement Fairness Act helps define when a regulation is "major" for the purpose of congressional review.[131]

In sum, despite numerous ambitious attempts to systematize cost-benefit analysis throughout the federal government, omnibus legislation has failed. The result is that the controlling rules on agencies are Executive Order 12866, agency-specific legislation (discussed in Parts V and VI), and limits on agency discretion imposed through judicial review. This last aspect of the law is discussed next.

The Courts

In the absence of clear statutory guidance, courts have filled in some of the gaps by providing a series of default rules governing agencies in the use of cost-benefit analysis. In

[127] *Id*. § 1535(a) (2004).
[128] See a recent FDA Regulatory Impact Analysis which acknowledges this. 68 Fed. Reg. 12158 at 12247 (Mar. 13, 2003).
[129] Frank & Sunstein, *supra* note 30, at 332.
[130] 5 U.S.C. §§ 601-612 (2004).
[131] *Id*. § 801 et. seq. (2004).

general, courts have been extremely receptive to agency cost-benefit analysis.[132] Recent decisions that speak directly to risk assessment issues all apply in light of the principle case on administrative law, *Chevron v. Natural Resources Defense Council*.[133] *Chevron* lays out a two-step inquiry for judicial review of agency decision-making.[134] Courts must first determine whether Congress has directly addressed the relevant question. If not, the agency is entitled to deference in its construction of the statute. Therefore, it is clear that if a statute unambiguously prohibits the consideration of costs or benefits (such as the Delaney Clause), an agency may not use cost-benefit analysis in its decision process. On the other hand, if no statute prohibits such deliberation, an agency is probably free to do so. [135]

The second prong in *Chevron* goes a step further. It requires the court to consider whether the agency's interpretation is reasonable, and not "arbitrary, capricious, or an abuse of discretion." Some courts, namely the D.C. Circuit which is the most important circuit court in interpreting agency law, have interpreted this prong to require some proportionality between cost and benefits.[136] However, there is little indication of precisely what cost-benefit ratio will cause an agency decision to be subject to reversal.[137]

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[132] *See* Grand Canyon Air Tour Coalition v. FAA, 154 F.3d 455, 475 (D.C. Cir. 1998) (approving FAA analysis of costs to air tour industry in considering an over flight restriction rule for Grand Canyon National Park); Natural Resources Defense Council v. EPA, 937 F.2d 641, 645-46 (D.C. Cir. 1991) (approving EPA cost-benefit analysis in applying Clean Air Act to surface coal mines).

[133] 467 U.S. 837 (1994).

[134] *See* Cass R. Sunstein, Cost-Benefit Default Principles, 99 MICH. L. REV. 1651, 1667 (2001) (laying out the *Chevron* standard of review) [hereinafter Sunstein, 2001].

[135] The D.C. Circuit case laying out this ruling is discussed further in the next several paragraphs. *See* Michigan v. EPA, 213 F.3d 663, 678 (D.C. Cir. 2000) ("It is only where there is 'clear congressional intent to preclude consideration of cost' that we find agencies barred from considering costs"); *see also* Sunstein, 2001, *supra* note 134, at 1667-68 (interpreting *Chevron*, combined with several additional circuit court cases to derive a set of default principles).

[136] *See* Am. Trucking Ass'n v. EPA, 175 F.3d 1027, 1052 (D.C. Cir. 1999) ("It seems bizarre that a statute intended to improve human health would ... lock the agency into looking at only one half of a substance's health effects in determining the maximum level for that substance"); AFL-CIO v. OSHA, 965 F.2d 962, 986 (11th Cir. 1992) (invalidating OSHA's air contaminants standard for failing to determine the "material risk" posed by the contaminants); Indus. Union Dept., AFL-CIO v. Am. Petroleum Inst., 448 U.S. 607 (1980) (similar); *see also* Frank & Sunstein, note 30, at 323, 330 (citing Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 1223 (5th Cir. 1991) (rejecting regulation whose costs are ten times the benefits, where the cost of saving one statistical life was $71.1 MM));

[137] *See* Frank & Sunstein, *supra* note 30, at 331.

Perhaps the strongest court mandate suggesting that agencies could be *required* to weigh costs and benefits in the absence of a statutory prohibition came from the D.C. Circuit in 2000 in *Michigan v. EPA*.[138] There, the court was reviewing the EPA's decision to approve a state plan regulating ozone. The relevant statute provided that all state plans must prohibit "any source or other type of emissions activity within the state from emitting any air pollutants in amounts which will ... *contribute significantly* to nonattainment in, or interfere with maintenance by, any other State with respect to any such national primary or secondary ambient air quality standard (emphasis added)."[139] The court rejected a straightforward interpretation of "contribute significantly" that would have prohibited any consideration of cost. It instead determined that significance should not "be measured in only one dimension," that of "health alone." Indeed, it stated that the question of significance could at times "begs a consideration of costs."[140]

The most recent and significant Supreme Court case addressing risk assessment is *Whitman v. American Trucking Ass'ns*, from 2001.[141] There, the Court sent a mixed message about the viability of cost-benefit analysis in the face of statutes that apparently preclude consideration of cost.[142] Declining to take the latitude of the D.C. Circuit in *Michigan v. EPA*, the court stated that in regard to national ambient air quality standards, consideration of "public health" required cost-blind analysis. However, Justice Stevens wrote an important concurrence in which he explicitly embraced modern risk assessment methodologies, namely risk tradeoff analysis.[143] In light of the somewhat conflicting treatment of regulatory risk assessment by the

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[138] 213 F.3d 663; *see* Sunstein, 2001, *supra* note 134, at 1678 (analyzing the significance of *Michigan v. EPA*).
[139] 42 U.S.C. § 7410(a)(2)(D)(i)(I) (2004).
[140] *Michigan*, 213 F.3d at 677; The D.C. Circuit expressed similar sympathy for cost-benefit analysis in *Am. Petroleum Inst.*, 448 U.S. 607 (court determined that "reasoned decision-making" by EPA called for a cost-benefit analysis).
[141] 531 U.S. 457 (2001).
[142] *See* Sunstein, *supra* note 134, at 1683 (arguing that American Trucking is not hostile to the court's pre-existing cost-benefit default principles).
[143] Breyer stated that courts "should read silences or ambiguities in the language of regulatory statutes" to permit consideration of "all of a proposed regulation's adverse effects, at least where those effects would clearly be serious and disproportionate." *Whitman,* 531 U.S. at 490 (J. Breyer concur.).

court, it seems likely that "arguments grounded in direct risk tradeoffs may play a prominent role in the judicial review of administrative action."[144]

V. HOW CERTAIN FEDERAL AGENCIES VALUE LIFE

Because even the strongest explicit legal mandate calling for regulatory cost-benefit analysis (Executive Order 12866) is extremely vague in its expectations and does not even mention the value of life, it is not surprising that federal agencies practice widely different methods of both determining a value of life, and using that value. [145]

Explicit and Retrospective Values of Life Used by Agencies

Whether or not agencies explicitly compute a value of life to use in regulatory decision-making, their choices and allocation of resources result in implicit valuations. This part compares the explicit and implicit values of life used by a variety of agencies. Explicit numbers (defined below) were tracked historically by Miller and Adler and Posner. I have updated their tables with more recent values. The implicit values have been computed retrospectively by several sources by dividing the total cost of a regulation by the lives saved.[146] Comparing agencies' explicit value of life with values imputed to them through retrospective analysis can offer some insight into whether agency action corresponds with agency analysis.

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[144] Rascoff & Revesz, *supra* note 80, at 1775; *see also* Sunstein, 2001, *supra* note 134, at 1654 ("[T]he cost-benefit default principles remain mostly the creation of the U.S. Court of Appeals for the District of Columbia. Currently, it is not clear whether the Supreme Court will ultimately adopt them.").

[145] In addition, it should be noted that the Executive Order applies only major regulations, not to simple product approval decisions. In the case of FDA, individual statutes address the appropriate standards to be applied for different categories of products. See infra Part V for a discussion of FDA's statutory framework.

[146] *See supra* Part II, Retrospective Analysis.

Explicit Values

This section compares the explicit values of life used by several federal agencies from the 1980s to the present. By explicit, I mean values clearly labeled as a "value of life" or "value of statistical life" in an agency's regulatory impact analysis. Calling these values "explicit" is perhaps euphemistic, as agencies rarely post documents discussing their use of value of life numbers within a standardized cost-benefit methodology.[147] This section hopes to provide two useful comparisons. First, I examine how value of life estimates have evolved over their past 25 years of use within various agencies. Second, I compare values across agencies to determine the level of consistency of this critical input in their CBAs. The difficulty in doing the latter is that clear acknowledgements of a use of a value of a statistical life do not appear regularly in either regulatory impact analyses or public agency documents. Therefore, without conducting a thorough investigation into each of the examined agencies, this research is only illustrative. An interesting further study would be to compare all uses of value of life estimates by federal agencies to detect any more subtle patterns.

My results are summarized in Table 3, below. For a more visual comparison, please see Appendices A through E below. You will see that the variation in values occurs across as well as within agencies, and that the accepted values have not clearly risen or fallen over time.

[147] For an exception, see a publication by the EPA's OAQPS (Office of Air Quality Planning and Standards) Economic Analysis Resource Document, 7-17 (Apr. 1999) *available at* http://www.epa.gov/ttn/ecas/econdata/6807-305.pdf (the document falls short of recommending the use of one value of life across programs with the agency, "it does suggest that the central tendency of $5 million … may provide the best starting point.") [hereinafter OAQPS Analysis].

Table 3
Values of Anonymous Life Used by Government Agencies

Agency	Value in 2003 dollars, millions (year established)		
	Pre-1993[148]	**1993-1998**	**Post-1998**
CPSC	$ 2.9-3.9 (1981)	$5.8 (1996)[149]	$5.3 (2000)[150]
OSHA	$ 3.6-5.5 (1983)	OSHA apparently espoused no explicit values during this period[151]	
EPA	$ 2.9-14.6 (1983) $4.6 (1988)[152]	$5.5 (1997)[153] $6.5 (1998)	$5.5 (1999)[154] $6.4 (1999)[155]
DOT	$ 1.7-2.5 (1986)	$2.1 (1990)[156] $3.1-3.5 (1996)	$2.8 (2002)[157]
USDA	$1.9 (1985)	$1.8, $3.7 (1994)[158] $1.9 (1996)	$5.3 (2001)[159] $4.8 (2003)[160]
FDA[161]	No apparent explicit use before 1993	$1.9-3.8 (1993) $6.3 (1993) $3.0 (1996) $5.6 (1998)	$5.3 (2000) $5.0 (2003) $2.2 (2003) $5-6.5 (2003)

This table, though illustrative only, suggests the following findings about agencies' use of value of life estimates:

- Although variation exists both across and within agency practice, values seem to hover between $1.7 million and $6.5 million.

[148] Numbers, unless otherwise noted, taken from Miller, *supra* note 15, at 888, Table 2. I use a 1993 cutoff since that is the year that Executive Order 12866 was promulgated.
[149] 61 Fed. Reg. 19818 (May 3, 1996).
[150] 65 Fed. Reg. 58968 (Oct. 3, 2000).
[151] 57 Fed. Reg. 26002 (June 12, 1992) (Reviewing estimates from $1.8-38 million, but espousing none).
[152] Adler & Posner, *supra* note 78.
[153] All values in this box are from Adler & Posner, *supra* note 78.
[154] OAQPS Analysis, *supra* note 147.
[155] Adler & Posner, *supra* note 78.
[156] All values in this box are from Adler & Posner, *supra* note 78.
[157] 67 Fed. Reg. 17556 (Apr. 10, 2002).
[158] All values in this box are from Adler & Posner, *supra* note 78.
[159] 66 Fed. Reg. 4970 (Jan. 18, 2001).
[160] 68 Fed. Reg. 34208 (June 6, 2003).
[161] *See* Table 5, *infra*, for more detail and sources. This represents just a sample of FDA uses of a value of life.

- Agencies rarely adjust their values for inflation. Therefore, the consistency of their results might fluctuate more than they realize.[162]
- While values varied within agencies, some ordinal comparison of the agencies is possible. The DOT systematically uses the lowest estimates.[163] The EPA frequently uses the highest. The USDA, and CPSC fall in between, but closer to the EPA. It is more difficult to generalize about the FDA.

In sum, this high level swath primarily illustrates the degree of variation both between and within agencies' explicit use of value of life numbers. In assessing whether this amount of variation is acceptable, we must ask, is a range of $1.7 million to $6.5 million big or small? While in the scheme of all possible values, it does not seem enormous, these numbers vary by a factor of 3.8. That is to say, an FDA or EPA regulation using a value of $6.5 million per statistical life could pass a CBA with expenses almost 4 times higher than a DOT regulation analyzed with a $1.7 million value of life. In those terms, this degree of variation seems to undermine any potential consistency to be gained from performed CBAs across the board. Finally, the degree of variation has not apparently narrowed in more recent years, as uses of the value of life have become more common.

Retrospective Values

Retrospective values, discuss above in Part II, are computed by dividing the total cost of a regulation by the number of lives saved. While difficulties exist with the methodology similar to those of the willingness-to-pay method, the advantage of the method is that it does not require an agency to be explicit about its use of a value of life estimate. Rather, the value of life can be imputed to agencies based on their regulatory choices. Three leading scholars, Morrall, Tengs

[162] For example, the FDA used a value of $5 million in 2000, 2001, 2002, 2003 and 2004.
[163] This is certainly because the DOT uses the human capital approach rather than willingness-to pay. *See* VISCUSI, FATAL TRADEOFFS, *supra* note 3, at 28.

and Graham, and Hahn, have each performed their own retrospective analysis of agency regulations. Morrall has updated his own numbers several times since 1986. In addition, Heinzerling has compared Morrall's estimates to actual agency estimates. Since a good deal of controversy exists as to which is the best analysis, I will provide each of their estimates below in Table 4, except Tengs and Grahams. Their analysis was done in such a way that makes it difficult to identify the regulations that correspond to the life-saving measures they analyzed.[164] These sources, the only available data, have two limitations. First, they do not analyze regulations after 1997, and only eight regulations after 1993. This is particularly unfortunate since Executive Order 12866 was issued in 1993. It would be very interesting to learn whether agency practices have become more reasonable since then, although the limited data points suggest that they have not. Second, the data considers very few (four) FDA regulations. Although computing my own retrospective values falls beyond the scope of this paper, it would be a valuable direction to take further research.

[164] See Tammy O. Tengs, et. al., *Five-Hundred Life-Saving Interventions and Their Cost-Effectiveness*, 15 J. RISK ANALYSIS 369 (1993).

Table 4
Retrospective Values
in 2003 dollars, millions[165]

Agency	Regulation	Year	Agency Estimates[166]	Hahn's Estimates[167]	Morrall's Initial Estimates[168]	Morrall's Updated Estimates[169]
CPSC	Children's Sleepwear Flammability	1973			2.3	1.1
	Unvented Space Heater Ban	1980			0.2	0.1
	Childproof Lighters	1993		0.6		
EPA	Uranium Mill Tailings/Inactive	1983	2.9		49.2	43.7
	Uranium Mill Tailings/Active	1983	4.6		94.6	62.0
	Arsenic/Glass Plant	1986	7.9		34.2	18.6
	Arsenic/Low Arsenic Copper	1986	6.9		1,364.7	31.7
	Land Disposal	1986	3.9	480.3	6,251.8	
	Solvent/Dioxin Disposal	1986		240.1		
	Underground Storage Tanks	1988		(420.2)		
	Asbestos	1989		22.8	182.4	152.5
	Hazardous Waste Toxicity	1990		(9,965.4)		
	Wood Preservatives	1990		60.0		7,851,345.3
	Land Disposal	1990		228.1		
	Water Contamination	1991		30.0		
	Solid Waste Disposal	1991		43,223.5		26,318.5
	Drinking Water	1992		11,526.3		126,819.5
	Sewage Sludge	1993		228.1		
	Land Disposal	1994		1,092.6		
FAA	Aircraft Seat Cushion Flammability	1984			1.1	0.6
	Aircraft Floor Emergency Lighting	1984			1.2	0.8
	Aircraft Cabin Fire Protection	1985			0.4	0.1
	Low-Altitude Windshear Equip	1988				1.8
	Traffic Alert/Collision Avoidance	1988				2.1
FDA	DES Cattlefeed Ban	1979			231.0	171.9
	Food Labeling	1993		0.4		
	Tobacco Sales	1996		(0.6)		
HHS	Quality Mammography	1997		0.4		
	Organ Transplant Data	1998		0.3		
HUD	Wind Standards	1994		(44.4)		
OSHA	Asbestos	1972	0.8		13.2	11.4
	Coke Ovens	1976	14.9		110.3	87.5
	Acrylonitrile	1978	10.3		67.1	70.9
	Arsenic	1978	29.4		165.2	147.2

[165] All numbers have been converted to 2003 dollars using the CPI.
[166] Heinzerling & Ackerman, *supra* note 62, at 658, Table 3.
[167] Hahn, Lutter & Viscusi, *supra* note 4, at 16-17, Table 3-1. Negative values indicate regulations with negative net costs, that is, where the costs are exceeded by cost savings.
[168] Morrall, *supra* note 61, at 30, Table 4.
[169] Office of Management and Budget, Regulatory Program of the United States Government (1991-1992) 12, Table 2.

Ethylene Oxide	1984	3.6-6.9		45.6	28.2
Benzene	1985	3.1		30.5	
Formaldehyde	1985	37.3	468.3	128,613.8	118,736.9
Asbestos	1986	4.6		159.2	101.9
Occ. Exp. To Benzene	1987		8.5		122.6
Hazardous Chemical Process	1992		(4.0)		
Occ. Exp. To Methylenedianiline	1992		21.6		
Asbestos	1994		32.4		
Occ. Exp. to Methylene Chloride	1997		10.2		

In spite of the shortcomings, the data offer several important insights into agency practice. First, it demonstrates that DOT (through the FAA) and CPSC behave consistently with their explicit values used, as well as value of life literature, with DOT in particular having a very low cost per life saved that corresponds with using the human capital approach to valuation. FDA appears, with the limited data available, to be quite reasonable in its cost per life saved, with the exception of a 1979 regulation regarding a ban of DES cattlefeed. However, Morrall's analysis of this regulation was specifically called into question by Heinzerling, who noted that she was "unable to locate any source documenting the risks avoided and costs imposed by this rule (other than Morrall's own article)."[170] On the other hand, OSHA and EPA clearly pay no heed to their value of life estimates when promulgating regulations. Their costs per live saved regularly exceed the bounds of what any economist would consider reasonable.

Second and more importantly, it suggests a truth about agency behavior. While Gillette and Hopkins observed in 1988 that agencies' values of statistical life tended to converge around $1-2 million,[171] that clearly does not indicate a convergence in regulatory behavior. Whether it corresponds to an increase in the complexity of cost-benefit analysis literature, or merely to a general loosening of agency discretion, retrospective values of life fluctuate tremendously. Perhaps this is a general lesson that agency behavior and agency analysis are two separate

[170] Heinzerling, *supra* note 29, at n392.
[171] *See* Gillette & Hopkins, *supra* note 27, at 368.

matters. Therefore, tightening up analysis requirements will only impact behavior if the two are mandatorily linked.[172]

Specific Agency Practices

While dozens of federal agencies use a value of life, implicitly or explicitly, in their decision-making, their individual statutory frameworks provide more specific guidance as to their analytical behavior. This section zooms in on the EPA and OSHA, agencies with a similar mandate to FDA: to protect the public health. I look in some detail at what they are permitted, or required to analyze by law, and how this impacts their use of the value of life. It should be noted that my research into these agencies only skims the surface regarding their legal mandates and specific uses of the value of life. It is intended only to provide a rough comparison to FDA practices.

EPA

The EPA interprets its primary mission as to "protect human health and to safeguard the natural environmental … upon which life depends."[173] Ironically, while the EPA has tended to argue that cost-benefit analysis requirements contravene its mandate of protecting the public health,[174] it has also been among the most active agencies in developing its own methodologies and computations regarding the value of life.[175] The inconsistency can be explained, at least in part, by the varying and often contradictory requirements imposed statutorily on the agency.[176]

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[172] *See* Robert W. Hahn et al., Assessing Regulatory Impact Analyses: The Failure of Agencies to Comply With Executive Order 12866, *23 Harv. J.L. & Pub. Policy 859 (2000)* (noting that "regulations aimed at protecting health, safety, and the environment alone cost over two hundred billion dollars annually - about two-thirds as much as outlays for federal, non-defense discretionary programs. Yet the economic impacts of federal regulation receive much less scrutiny than the budget").

[173] U.S. Environmental Protection Agency, Agency Mission Statement, *available at* http://www.epa.gov/history/org/origins/mission.htm (last visited Feb. 16, 2004).

[174] *See*, *e.g.*, Whitman v. Am. Trucking Ass'ns, 531 U.S. 437 (2001) (EPA successfully defended against the imposition of a cost-benefit requirement).

[175] *See* EPA, Valuing Reductions in Risks: A Review of the Empirical Estimates – Summary (1983).

[176] A more cynical explanation would reason that if EPA *is* to be forced to performs CBAs, it would prefer to have dominion over its inputs. By raising the value of life high enough, almost any regulation can appear analytically justified.

For example, certain statutes clearly mandate cost-benefit analysis. In considering national drinking water regulations, the Safe Drinking Water Act requires that the agency perform a "health risk reduction and cost analysis," going as far as to specify the components to be analyzed.[177] Similarly, the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") instructs the EPA, prior to the registration of a pesticide, to consider its "risk to man or the environment, taking into account the economic, social, and environmental costs and benefits" of its use.[178] At the same time, the primary provision of the Clean Air Act dealing with the national ambient air quality has been repeatedly interpreted to require the agency to consider "public health" alone, precluding any weighing of the associated costs.[179]

In line with the unclear direction given to the agency, its use of value of life numbers has been erratic and confusing. In the early days of value of life analysis, the agency used numbers that varied from $400,000 to $7 million.[180] More recently, the value has settled at approximately $6.6 million, when the agency explicitly includes the valuation of life in its analysis.[181] However, when examined with retrospective analysis, the EPA frequently issues regulations with enormous costs per life saved. For example, a 1990 regulation concerning land disposal had a cost per life saved of $228 million, and a 1994 land disposal regulation had a cost per life saved of over $1 billion.[182] A more in depth study of the EPA would be necessary to understand the rationale for some of these outlandishly costly regulations.

However, in the EPA's defense, three important critiques of retrospective analysis made by Heinzerling and Ackerman should be kept in mind. First, examining regulation through such

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[177] 42 U.S.C. § 300g-1(b)(3)(C) (2004).
[178] 7 U.S.C. § 136 (bb) (2004).
[179] *Whitman*, 531 U.S. at 466.
[180] Gillette & Hopkins, *supra* note 27, at 368 (citing Interview with Chief of Economic Studies Branch of EPA, Ralph A. Luken).
[181] In 2003 dollars. *See, e.g.*, 68 Fed. Reg. 49548 at 49630 (Aug. 18, 2003) ($4.8 million in 1990 dollars); 66 Fed. Reg. 6976 at 7012 (Jan. 22, 2001) (using a value of $6.1 million in 1999 dollars). Both amount to $6.6 million in 2003 dollars, when adjusting with the CPI.
[182] *See*, *supra*, Table 4.

a lens can lead one to forget that regulations may in fact have other valuable purposes than saving human lives.[183] The EPA is an agency designed to protect humans *and* to protect the environment. A policy designed to protect endangered wildlife might have no direct beneficial impact on human lives, and yet it might still be a worthy endeavor. Second, EPA regulations could also suffer under a second difficulty of retrospective analysis, one that also plagues willingness-to-pay analysis – discounting.[184] EPA regulations often involve regulating toxins. The most common reason to regulate toxins is to reduce the risk of cancer. But because cancer has a long latency period, the lives saved in EPA regulations have often been discounted heavily, a decision that might not be justified.[185] Third, Heinzerling and Ackerman point out that many of the EPA regulations analyzed above were never actually implemented.[186] In some instances, the EPA withdrew the regulation precisely because its high cost did not justify the limited benefits. In sum, the mere fact that explicit and retrospective values of life do not correspond is not enough in itself to condemn agency practices. The discrepancies should be used, rather, to highlight regulations that merit further investigation, and to consider whether the agency is striking the appropriate balance between protecting the environment and people.

OSHA

OSHA views its job as "to save lives, prevent injuries and protect the health of America's workers."[187] OSHA's practices regarding the value of life largely resemble EPA's, both in statutory mandate and actual use. Statutes appear conflicted as to whether the agency must, may or may not weigh costs and benefits in promulgating regulations. For example, the agency is charged with assuring "so far as possible [that] every working man and woman in the Nation

[183] *See* Heinzerling & Ackerman, *supra* note 62, 655-56.
[184] *See id*. at 656-62.
[185] *See infra* Section III, Discounting.
[186] *See* Heinzerling & Ackerman, *supra* note 62, at 653-55.
[187] U.S. Department of Labor, Occupational Safety & Health Administration, OSHA's Mission, *available at* http://www.osha.gov/oshinfo/mission.html (last visited Feb. 16, 2004).

[have] safe and healthful working conditions."[188] It is unclear whether this mandate permits cost-benefit analysis, but does not require it, or whether it flatly prohibits it.[189] On the other hand, another statute calls for OSHA to regulate toxic substances "to the extent feasible."[190] The agency interprets this language as a requirement to weigh the economic practicality of the regulation.[191]

Yet similar to the EPA, while OSHA occasionally endorsed formal value of life analysis, it promulgates certain regulations that cannot be justified when a reasonable value of life is considered. Early in the life of valuations of life, OSHA engaged in a battle with the OMB as to the appropriate value of life. Compromising between OSHA's claim of $3 million, and OMB's figure of $1 million, the two settled on a value of $2 million in 1985.[192] Today, OSHA seems to decline to espouse any explicit value of life. However, actual practice confirms lack of any commitment to value of life analysis. A 1985 proposed regulation concerning exposure to formaldehyde would have yielded a cost per life saved of over $100 billion, according to Morrall.[193] Similarly egregious, the agency insisted on tightening hospital regulations limiting exposure to ethylene oxide, even though the increased stringency produced no reduction in the risk of cancer at all.[194]

OSHA's mission does not suggest the same easy explanation for its expensive regulations as EPA. Further, while some of OSHA's most expensive regulations were ultimately rejected,

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[188] 29 U.S.C. § 651(b) (2004).
[189] The Supreme Court has expressly held that OSHA is not required to use cost-benefit balancing as a decision criterion in promulgating occupational health standards, but the door has not been entirely closed. *See* Am. Textile Mfrs. Inst. v. Donovan, 452 U.S. 490, 509 (1981)*;.but see* Indus. Union Dept., AFL-CIO v. Am. Petroleum Inst., 448 U.S. 607, 642-52 (1980) (holding that OSHA must show that the hazards regulated pose a "significant" risk to human health and are "reasonably necessary or appropriate to provide safe or healthful employment").
[190] 29 U.S.C. § 655(b)(5) (2004).
[191] *See* Sunstein, 2001, *supra* note 134, at 1654.
[192] *See* Miller, *supra* note 15, at 887 (This is equivalent to $3.4 million in 2003 dollars).
[193] *See supra* Table 4.
[194] *See* Calandrillo, *supra* note 11, at 979.

regulations with costs per life saved of over $100 million were actually implemented.[195] Nonetheless, there could be other legitimate explanations. Inappropriate or excessive discounting might explain some of the exceptionally high costs per life saved. Further, not all of the regulations are attempts to prolong or save lives. Non-living saving benefits are not reflected in the single cost-per-life-saved metric. In short, the same limitations of value of life analysis discussed above should be kept in mind here. However, that should not stop a regulation with a cost per life saved of over $100 million from raising eyebrows and meriting further examination.

VI. FDA VALUING LIFE

FDA regulations are notorious for systematically depriving Americans of lifesaving drug therapies in the name of safety.[196] FDA frequently comes under fire for being too slow to approve new drugs and devices and for being too risk averse to the detriment of America's ill. This section seeks to answer the following questions: 1) Does FDA's legislative mandate require that it act with risk averseness? 2) How do FDA's practices surrounding the value of life impact its behavior, and how do they compare to other federal agencies?

Is Anything Special About FDA Regarding the Value of Life?

As the previous section demonstrated, federal agencies are no strangers to value of life analyses. However, as has also been discussed, patterns in one agency cannot be inferred from any other because of the lack of overarching risk analysis guidelines, and the divergent set of mandates governing each agency. This section explores the complex mandate of FDA and asks

[195] Morrall, *supra* note 61, at 30, Table 4 (Arsenic, Asbestos and Coke Ovens for example).
[196] Frank B. Cross, *The Public Role in Risk Control*, 24 ENVTL. L. 888, 947 (1994) (citing RICHARD L. STROUP & JOHN C. GOODMAN, MAKING THE WORLD LESS SAFE: THE UNHEALTHY TREND IN HEALTH, SAFETY AND ENVIRONMENTAL REGULATION 27 (1989)); *see also* Richard J. Zeckhauser and W. Kip Viscusi, *The Risk Management Dilemma*, 545 ANNALS 144, 150 (1996) ("The consensus of outside analysts is that the agency has erred on the side of excessive caution, suggesting that society's net risk has been increased by delays in approving beneficial new drugs").

the question: is there anything special about FDA that would impact its performance of the valuation of human life?

The answer to the preceding question is, 'yes and no.' The Agency's self-described mission statement is the following:

> The FDA is responsible for *protecting the public health* by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for *advancing the public health* by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health (emphasis added).[197]

It is tempting to view the agency as the lone white knight protecting all Americans. Under this conception, one might argue that FDA, because of its special watchdog role, should avoid weighing the benefits of the products it oversees, and only conduct analyses of risk, or cost. Therefore, it should steer clear of the business of valuing human life, since this only plays a role in tallying up the benefits of a new product. However, FDA does not have a unique claim to keeping the American public safe. In this sense, FDA is no different than many other federal agencies whose mandates are to protect the American public. For example, EPA and OSHA, discussed above, seek to protect human health and save lives. And CPSC sees itself as responsible for protecting the public from unreasonable risks of serious injury or death from consumer products.[198] To argue that all agencies protecting the American public should seek only to minimize risk without regard to benefit would result in an oppressively risk-averse world.

On the other hand, as discussed above, to understand precisely what sort of cost-benefit analysis is required, or permitted, or prohibited, we must look to the agency's statutory authority.

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[197] Food and Drug Administration, FDA's Mission Statement, *available at* http://www.fda.gov/opacom/morechoices/mission.html (last visited Feb. 16, 2004). Notice that the mission statement itself includes both responsibility for avoiding danger ("protecting the public health"), as well as promoting improvement ("advancing the public health"). This suggests that it actually views cost-benefit analysis as inherent in its mission.

[198] U.S. Consumer Product Safety Commission, CPSC Overview, *available at* http://www.cpsc.gov/about/about.html (last visited Feb. 16, 2004).

Just as EPA and OSHA receive conflicting statutory directives concerning appropriate risk assessment, FDA's statutory framework in this area is confusing and bordering contradictory.

One other important feature of FDA should be noted. Because of the nature of the products regulated by FDA, approval decisions are frequently made based on extremely limited scientific data.[199] Primarily ethical considerations, but also time and cost limitations restrict the amount of human testing considered sufficient for making approval determinations.[200] Frequently, animal tests combined with small clinical trials will provide the basis for important decisions about drug safety and effectiveness.[201] Rarely will the type of statistically significant epidemiological findings that scientists prefer to rely on be available. This high degree of uncertainty introduces its own major challenges into FDA's cost-benefit calculus. The quality of a value of life estimate may be entirely overshadowed by FDA's larger hurdles concerning predictability and safety and effectiveness measurements.

FDA's Legislative Mandate

FDA's statutory framework is the result of 100 years of fine-tuning, combined with historical happenstance. As such, Congress has given the agency individualized standards for the approval of food, drugs and medical devices and cosmetics.[202] In certain instances, the standards

[199] *See* William O. Fisher, *Key Disclosure Issues for Life Science Companies: FDA Product Approval, Clinical Test Results, and Government Inspections*, 8 MICH. TELCOMM. TECH. L. REV. 115 (2001) (discussing the difficulty of interpreting clinical test results and the possibility of reaching conflicting conclusions about a drug's safety).

[200] *See generally* Michael D. Greenberg, *Information, Paternalism, and Rational Decision-Making: The Balance of FDA New Drug Approval*, 13 ALB. L.J. SCI. & TECH. 663 (2003) (analyzing the balancing of interests at play in FDA drug approvals); Michael Baram, *Making Clinical Trials Safer for Human Subjects*, 27 AM. J.L. & MED. 253 (2001) (discussing FDA's oversight of clinical trials and ethical problems in human testing).

[201] Animal testing is used to measure how much of a drug is absorbed into the blood, how it is broken down chemically in the body, the toxicity of the drug and its breakdown products (metabolites), and how quickly the drug and its metabolites are excreted from the body. See FDA, Animal Testing, at http://www.fda.gov/cder/handbook/animal.htm (last visited Mar. 17, 2004).

[202] Because cosmetics receive such little attention of the FDA relative to food, drugs and medical devices, this section will skip a discussion of the standard for evaluating cosmetics.

even seem internally inconsistent. At any rate, the Agency's legislative mandate can only be understood product by product.

Food

To a large extent, FDA evaluates food exclusively for safety, without regard to offsetting benefits. For example, for food containing no additives, the agency must determine "[i]f it bears or contains any poisonous or deleterious substance which may render it injurious to health."[203] Food containers are subject to the same standard.[204] Similarly, food additives and color additives are to be evaluated based on whether they are "safe" for their intended uses.[205] None of these standards *requires* that the agency perform a cost-benefit analysis. In fact, by focusing exclusively on safety, it could be argued that the agency is actively *precluded* from any CBA. However, the recent receptiveness of the courts to CBA suggests that such an interpretation is likely to be an uphill battle.[206]

One infamous clause of the Federal Food Drug and Cosmetic Act, the Delaney Clause, does explicitly prohibit a weighing of costs and benefits. Regarding the evaluation of the safety of food additives, the Delaney Clause states "no additive shall be deemed to be safe if it is found to induce cancer."[207] This clause's unique zero-risk tolerance standard has been the subject of much consternation and debate.[208] However, as an indication of the growing acceptance of the principles of cost-benefit analysis, after 38 years, the Food Quality Protection Act recently cut

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[203] 21 U.S.C. § 342(a)(1) (2004).
[204] *Id*. § 342(a)(1)(6).
[205] *Id*. § 342(a)(2)(C)(i), 21 U.S.C. § 348(a) (2004) and 21 U.S.C. § 342(c) (2004).
[206] *See supra* Part IV, The Courts; *see also* Michgan v. EPA, 213 F.3d 663, 678 (D.C. Cir. 2000) ("Only where there is clear congressional intent to preclude consideration of cost are agencies barred from considering costs."); Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 494 (2001), Breyer concurrence ("And what counts as "requisite" to protecting the public health will similarly vary with background circumstances, such as the public's ordinary tolerance of the particular health risk in the particular context at issue.").
[207] 21 U.S.C. § 348(c)(3)(A) (2004).
[208] *See*, *e.g.*, Merrill, *FDA's Implementation of the Delaney Clause: Repudiation of Congressional Choice or Reasoned Adaptation to Scientific Progress?*, 5 YALE J. REG. 1 (1988) (on the difficulty of implementing this standard); Erin E. Moran, *Comment: The Food Quality Protection Act of 1996: Does the Delaney Clause Effectively Protect Against Cancer or Is It Outdated Legislation?*, 30 J. MARSHALL L. REV. 1127 (1997) (arguing in favor of the zero-risk tolerance standard).

back on the sweeping ban. The Act amends the FFDCA Delaney Clause standard of zero-risk tolerance regarding carcinogenic pesticides to a standard of "reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue."[209]

A second herald of the acceptance of CBA is the amended standards pertaining to dietary supplements from the Dietary Supplement Health and Education Act of 1994. With this amendment, dietary supplements were given their own standard for evaluation which seems to call for a weighing of the costs and benefits: A dietary supplement is to be evaluated on the basis of whether it "presents a significant or unreasonable risk of illness or injury."[210] This new balancing standard, by focusing on the reasonableness of the risk, calls for FDA to consider whether dietary supplements have preventive health benefits.[211]

In sum, although most of the standards for evaluating food do not explicitly require a weighing of its costs and benefits, the vague statutory language coupled with the tide of recent court decisions and congressional amendments suggests a generally hospitable environment to such analysis.

Drugs and Medical Devices

The statutory mandates for evaluating drugs and medical devices are generally more friendly to a balanced risk assessment review than the food provisions. After the Thalidomide scare in 1962, Congress amended the FFDCA to require drug manufactures to demonstrate both a drug's safety *and* efficacy.[212] Since then, the notion that a drug's risks and benefits should be balanced has appeared many times. For example, approval of new drugs requires "a fair evaluation of all material facts," including consideration of "whether such drug is safe" and

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[209] 21 U.S.C. § 346a(b)(2) (2004).
[210] *Id*. § 342(f)(1)(A).
[211] *See* Meghan Colloton, *Comment: Dietary Supplements: A Challenge Facing the FDA in Mad Cow Disease Prevention*, 51 AM. U.L. REV. 495, 524-26 (2002) (evaluating the pros and cons of the DSHEA).
[212] *See* Kefauver-Harris Amendments, current version in part at 21 U.S.C. § 321(p)(1) (2004) (defining the term "new drug").

"evidence that the drug will have the effect it purports."[213] Medical devices call for a similar analysis, requiring "reasonable assurance of safe and effective performance."[214]

Hence, one would expect FDA to regularly weigh both the costs and benefits of new drugs and medical devices, along with regulations impacting them. As discussed above, value of human life is critical to such analysis. Therefore, it would be natural for FDA to have given consideration to the issue. Precisely what FDA has and has not done in that regard is the subject of the following section.

FDA Practice

I have examined FDA practice primarily from the perspective of its explicit use of valuations of life only. Unfortunately, we have limited information as to an important piece of the puzzle – that is, whether FDA's explicit values of life correspond to its actual cost per life saved in its regulations. As discussed above in Part V, the few data points available do tend to suggest that the FDA acts with regulatory discipline. Even without more examples of retrospective analysis, the agency frequently provides detailed explanations for its choices and specific uses of the values, making it possible to draw several conclusions from a close examination of the agency's explicit practices. Table 5, below, summarizes the explicit values used by FDA over the past ten years.[215] I could not located any uses prior to 1993. Much of the detail behind each instance could not be neatly summarized in a table, but appears in written form in the bullet points below.

[213] 21 U.S.C. § 355(d)(4), (5) & (7) (2004); *see also id.* § 393(b) (codifying the FDA's function and mission, including its duties to review clinical research and marketing of regulated products, as well as to monitor safety and efficacy of drugs); 351(a)(2)(B) (requiring drugs meet requirements both for "safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess").
[214] *Id.* § 360d(a).
[215] Please see Appendix E, *infra*, for a graphic depiction of these values.

Table 5
Explicit Values of Life Used by FDA

Citation (year)	**Category Impacted**	**Nominal Value of Life** (million, except life-days or life-years)	**Value of Life** (million 2003 dollars)
58 Fed. Reg. 2927 (1993)	Food	$1.5-3.0	$1.9-3.8
58 Fed. Reg. 53305 (1993)	Food	$5.0-11.0 – infant	$6.3-13.9 – infant
61 Fed. Reg. 52602 (1996)	Medical device	$5.0	$5.8
61 Fed. Reg. 44396 (1996)	Medical device	$2.5	$2.9
62 Fed. Reg. 2218 (1997)	Dietary supplement and drug	$5.0 – adult $11.0 – infant	$5.7 – adult $12.6 – infant
62 Fed. Reg. 55852 (1997)	Medical device	$5.0	$5.7
63 Fed. Reg. 24254 (1998)	Food	$5.0	$5.6
64 Fed. Reg. 36516 (1999)	Food	$0.6-8.4	$0.7-9.2
65 Fed. Reg. 69378 (2000)	Drug	$5.0	$5.3
66 Fed. Reg. 6502 (2001)	Food	$630 per life day (translates to $5.0/VSL)	$5.2
67 Fed. Reg. 38878 (2002)	Medical device	$5.0	$5.1
67 Fed. Reg. 76056 (2002)	Medical device	$5.0	$5.1
68 Fed. Reg. 5428 (2003)	Food	$274 per life day (translates to $2.2/VSL)	$2.2
68 Fed. Reg. 6062 (2003)	Drug	$5.0	$5.0
68 Fed. Reg. 12500 (2003)	Drug	$2.0	$2.0
68 Fed. Reg. 15404 (2003)	Medical device	$373k per life year (translates to $5.0/VSL)	$5.0
68 Fed. Reg. 25188 (2003)	Food	$5.0	$5.0
68 Fed. Reg. 41434 (2003)	Food	$5.0-6.5	$5.0-6.5
69 Fed. Reg. 6788 (2004)	Dietary supplement	$5.0-6.5	$5.0-6.5

The following summarizes my findings after a review of all regulations promulgated by FDA over the past ten years:

- The first apparent use of a value of life estimate occurred in 1993, in an analysis of the impact (on the benefits side) of a food labeling regulation. There, the agency engaged in an explication justifying the use of a value of life measure.[216]
- The agency has overwhelmingly relied upon the willingness-to-pay methodology for computing the value of life, using values computed in the economic literature, rather than performing its own calculations.[217]
- The agency has by-and-large used a value of human life of $5 million. (No explanation is given for the deviation in four cases.) This is true even though the value has been used for a period of ten years. In other words, no inflation adjustment appears to have ever been made. The impact of this is that the value of life has fallen, in real terms by about a quarter.[218]
- In spite of the failure to adjust for inflation, the agency appears to have been among the more consistent of federal agencies in using an explicit value of life.
- When made explicit, FDA has generally used a 7% discount rate to discount human life. At times, this is explicitly to discount for a latency of benefit period; elsewhere, the rationale is not stated and appears to be to discount both for latency of benefit, and for future generations.[219]

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[216] 58 Fed. Reg. 2927 (Jan. 6, 1993).
[217] 60 Fed. Reg. 41314 (Aug. 11, 1995); 64 Fed. Reg. 36516 (Jul. 6, 1999); 68 Fed. Reg. 12500 (Mar. 14, 2003); 68 Fed. Reg. 15404 (Mar. 31, 2003); 68 Fed. Reg. 41434 (Jul. 11, 2003); 69 Fed. Reg. 6788 (Feb. 11, 2004); *see also* 58 Fed. Reg. 33860 (June 21, 1993) (comparing human capital approach to willingness-to-pay method).
[218] $5 million used in 1993 is equivalent to $6.3 million in 2003 dollars.
[219] 60 Fed. Reg. 41314 (Aug. 11, 1995); 62 Fed. Reg. 2218 (Jan. 15, 1997); 63 Fed. Reg. 24254 (May 1, 1998); 64 Fed. Reg. 62746 (Nov. 17, 1999); 65 Fed. Reg. 52376 (Aug. 29, 2000); 67 Fed. Reg. 38878 (June 6, 2002); 68 Fed. Reg. 15404 (Mar. 31, 2003); 68 Fed. Reg. 41434 (Jul. 11, 2003) (comparing effects when using both a 3% and 7% discount rate); *but see* 65 Fed. Reg. 69378 (Nov. 16, 2000) (3% discount rate used).

- A number of critical inconsistencies appear in the manner in which the agency has applied the value.
    - Sometimes a range is used, sometimes just one value.
    - Generally a 7% discount rate is used but sometimes a range, or 3% was used.
    - When appropriate, the agency has broken down the value into statistical life-years, often demonstrating a high level of sophistication.[220] However, sometimes this is done using an average number of statistical life-years or days, and other times, the number is individualized for a special population (e.g., children), or for a particular disease in question
    - Different academic sources are cited as the source of the value used, even when regulations rely on the same value. These sources vary in currency – the oldest being fifteen years old from the date used.
- Despite the different standards for each of the products regulated by FDA, it is interesting to observe that the agency's use of the value of life in estimating benefits of proposed regulations has occurred across *all* types of products and regulations for the past ten years.

Conclusions about FDA Practice

That the agency has inserted value of life estimates in a rather spotty and inconsistent manner supports two conclusions: First, that the statutory and executive mandates have succeeded in neither prohibiting a weighing of benefits and cost, nor systematizing such analysis. Second, a close look at the specific manner in which FDA has used value of life estimates confirms many of the theoretical warnings discussed above. As discussed above, even where a consistent value of life *was* used, it was applied at times in an inconsistent manner. The most serious variations appear in the context of calculations using statistical life-years or life-days.

[220] *See*, *e.g.*, 68 Fed. Reg. 41434 (Jul. 11, 2003).

Even when these values are derived from a consistent $5 million value of life, assumptions underlying the age of the population or the impact of a regulation on longevity can entirely drive the output. This highlights an important caveat about using the value of life: applying a precise dollar value may tend to give the appearance of more precision and consistency than the actual analysis achieves. It also casts doubt on the comparability of the various regulatory impact analyses within the agency, let alone across agencies, where even if value of life assumptions are synchronized, assumptions surrounding how to apply it might not have been.

CONCLUSION

This paper highlights both the importance of using valuations of life, and the concomitant risks. Without understanding the fundamental economic mechanics of the valuation, it will be too easy for numbers to be manipulated for one-time political agendas. And without appreciating legal mandates, judicial standards of review, and other pressures bearing down on agency commissioners, it is unlikely that any changes in actual practice will be successfully implemented. To effectively make use of value of life analysis in regulatory decision-making, it is critical to understand both the technical economic basis for the valuation, as well as the regulatory and political arena in which such analysis will be performed.

Several specific lessons can be drawn from this research. On the technical side, the difficulty of arriving at a precise value of life, and challenges around applying it consistently suggest that value of life numbers be used only in an advisory way. Perhaps, they can be used in sensitivity analyses or to understand the orders of magnitude of a regulation's potential benefits. However, comparisons should be made with great caution. Full disclosure of all assumptions behind any values use is necessary to make such comparisons possible. Furthermore, any future attempts by Congress to enact omnibus nondiscretionary cost-benefit legislation should be done

with an appreciation of the potential for manipulation of value of life numbers, and hence, overall outcomes.

On the regulatory side, evidence from several federal agencies suggests that their behavior will not correspond to mandated cost-benefit analysis unless it is explicitly required to do so. However, such a requirement could have the negative consequence of either removing too much agency discretion or encouraging aggressive manipulation of data (rendering it worse than useless). Perhaps one way around this quandary is to establish oversight of the cost-benefit analysis process removed from the political process (and hence, outside the OMB). For example, neutral academic review boards could oversee and endorse or disapprove of agency analyses. These could be modeled directly off of FDA's current Advisory Committees used to review product safety.

Despite the difficulties of effectively using values of life, agencies should not be deterred. A world of ad hoc decision-making, and exclusively implied valuations of life is not preferable. Only with explicit use and transparent disclosure of assumptions can the dialogue continue, and can technical and administrative procedures be improved upon.

APPENDIX