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## ARTICLE

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### SAVING LIVES THROUGH ADMINISTRATIVE LAW AND ECONOMICS

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*This Article examines the recent history and the future of federal lifesaving regulation. The Article argues that, considering both philosophical and practical perspectives, lifesaving regulation informed by benefit-cost analysis (BCA) has compelling advantages compared to regulation informed by the main alternatives to BCA. Contrary to the popular belief that BCA exerts only an antiregulation influence, I show, based on firsthand experience in the White House from 2001 to 2006, that BCA is also an influential tool in protecting or advancing valuable lifesaving rules, especially in a pro-business Republican administration. Various criticisms of BCA that are common in the legal literature are shown to be unconvincing: the tool's alleged immorality when applied to lifesaving situations, its supposed indeterminacy due to conceptual and empirical shortcomings, and the alleged biases in the way benefits and costs are computed. But the Article also pinpoints problems in the benefit-cost state, and opportunities for improvement in the process of lifesaving regulation. Innovations in analytic practice, coupled with improvements in the design of regulatory systems, are proposed to strengthen the efficiency and fairness of federal lifesaving regulation. The Article's suggestions provide a menu of promising reforms for consideration by the new administration and the new Congress as they take office in January 2009.*

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## INTRODUCTION

Public health, safety, and environmental regulation, launched with optimism during the Progressive Era, the New Deal, and the Great Society,<sup>1</sup> survived the deregulatory impulses of the early Reagan years and the Gingrich era.<sup>2</sup> Sometimes called “lifesaving” regulation for short,<sup>3</sup> these rules differ from curative medicine because they do

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<sup>1</sup> See Cass R. Sunstein, *Congress, Constitutional Moments, and the Cost-Benefit State*, 48 STAN. L. REV. 247, 255 (1996) (explaining how the New Deal and the “rights revolution of the 1960s and 1970s” spawned vast new regulatory responsibilities, but that “no mechanism was created to evaluate regulatory performance”).

<sup>2</sup> See MATTHEW D. ADLER & ERIC A. POSNER, *NEW FOUNDATIONS OF COST-BENEFIT ANALYSIS 2* (2006) (arguing that the Left/Right debate on regulatory policy has shifted from regulation versus deregulation to different visions of better regulation).

<sup>3</sup> The term “lifesaving” is understood to encompass rules that curtail risk of nonfatal injury and illness (morbidity) as well as the risk of premature death (mortality). This use of the terminology “lifesaving” as a field of regulatory study was advanced by Richard Zeckhauser, *Procedures for Valuing Lives*, 23 PUB. POL’Y 419 (1975), and Richard Zeckhauser & Donald Shepard, *Where Now for Saving Lives?*, LAW & CONTEMP. PROBS., Autumn 1976, at 5. It is quite rare for a regulation to save lives without reducing morbidity or to curtail morbidity without saving any lives. Typically, while the counts of morbidity from a hazard are larger than the counts of premature deaths, the estimated benefit from mortality reduction often dominates the overall estimates of health benefit because preventing a premature death is assigned greater monetary value than preventing a case of nonfatal injury or illness. See, e.g., CASS R. SUNSTEIN, *THE COST-BENEFIT STATE: THE FUTURE OF REGULATORY PROTECTION* app. A at 141-48 (2002) (noting that for Environmental Protection Agency (EPA) rules aimed at reducing ozone and particulate matter in the air, the reductions in the number of nonfatal adverse events exceed the reductions in the number of fatal ones by at least a factor of

not seek to improve the health of identifiable individuals.<sup>4</sup> Unlike an effort to save a trapped coal miner or a patient dying from kidney disease, administrative law saves lives by reducing small probabilities of premature death, injury, or illness among large numbers of anonymous workers, consumers, travelers, and residents. The names of those whose lives will be saved are unknown when the rule is adopted and may never be known.<sup>5</sup> They are sometimes called “statistical lives.”<sup>6</sup>

Thanks to advances in probability research and statistics, we now know that federal lifesaving regulations do save lives, and there is no basis for believing that these lives are any less real than the lives saved by physicians and nurses in emergency rooms. Although the evaluation literature is not as comprehensive and robust as one would prefer, there is a variety of studies showing that specific federal rules (or combinations of rules) have saved lives,<sup>7</sup> and, in fact, such rules now account for a majority of the major rules issued each year by the U.S. federal government.<sup>8</sup>

1000 and that the relative size of the mortality and morbidity benefits from the EPA’s air-quality standards for ozone and particulate matter vary significantly).

<sup>4</sup> The distinction between identifiable and statistical lives originates with T.C. Schelling, *The Life You Save May Be Your Own*, in PROBLEMS IN PUBLIC EXPENDITURE ANALYSIS 127, 129-33 (Samuel B. Chase, Jr., ed., 1968). Both economic and legal scholars have expressed concern that societies tend to spend lavishly to save identified lives (e.g., the trapped coal miner) while devoting insufficient resources to saving statistical lives. See, e.g., Joanne Linnerooth, *Murdering Statistical Lives . . . ?*, in THE VALUE OF LIFE AND SAFETY 229, 229 (M.W. Jones-Lee ed., 1982) (observing that, to the public, “[t]he identifiable life . . . seem [sic] deserving of special priority over the statistical life”).

<sup>5</sup> See, e.g., PER-OLOV JOHANSSON, EVALUATING HEALTH RISKS: AN ECONOMIC APPROACH 61 (1995).

<sup>6</sup> See generally, e.g., James K. Hammitt & Nicolas Treich, *Statistical vs. Identified Lives in Benefit-Cost Analysis*, 35 J. RISK & UNCERTAINTY 45 (2007).

<sup>7</sup> See, e.g., W. KIP VISCUSI, FATAL TRADEOFFS: PUBLIC AND PRIVATE RESPONSIBILITIES FOR RISK 166-73, 219-20, 276 (1992) (demonstrating safety benefits both of Occupational Safety and Health Administration regulations—despite early studies that questioned their effectiveness—and of the National Highway Safety Administration’s (NHTSA) rear-window-brake-light requirement); John D. Graham & Steven Garber, *Evaluating the Effects of Automobile Safety Regulation*, 3 J. POL’Y ANALYSIS & MGMT. 206, 207 (1984) (noting studies showing significant safety gains resulting from the original federal auto-safety standards); H. Scott Matthews, *Analysis of the Benefits and Costs of Clean Air*, in IMPROVING REGULATION: CASES IN ENVIRONMENT, HEALTH, AND SAFETY 405, 410-15 (Paul S. Fischbeck & R. Scott Farrow eds., 2001) (valuing the lifesaving benefits of environmental regulations); K.M. Thompson et al., *Validating Analytical Judgments: The Case of the Airbag’s Lifesaving Effectiveness*, 66 RELIABILITY ENGINEERING & SYS. SAFETY 57, 60-61 (1999) (reviewing studies evaluating the effectiveness of airbag regulations).

<sup>8</sup> Of the forty-five major rules for which the Office of Management and Budget (OMB) completed review from October 1, 2003, to September 30, 2004, twenty-six

Lifesaving is the focus of this Article because the pursuit of wise societal investments in lifesaving is a major social objective and a central challenge of law, economics, and public policy. There are many more opportunities to save lives with smart regulatory policies guided by public health science.<sup>9</sup>

Who are the lifesaving regulators? Measured by recent rulemaking activity, they include the Department of Agriculture (USDA), the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), and the Department of Transportation (DOT). Independent agencies such as the Nuclear Regulatory Commission (NRC) and the Consumer Product Safety Commission (CPSC) play an important role outside the purview of White House oversight. Since September 11, 2001, the Department of Homeland Security (DHS) also has been charged with lifesaving responsibilities.<sup>10</sup>

Over the last generation, a loose coalition of scholars—sometimes called “regulatory reformers”—made the case that federal lifesaving regulation could be improved through rigorous use of benefit-cost analysis (BCA)<sup>11</sup> and related tools.<sup>12</sup> Unlike some of the libertarians and free-market enthusiasts of the early Reagan years, who often sought deregulation,<sup>13</sup> the reformers of lifesaving regulation urged

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were defined as “social regulations,” which are predominantly public health, safety, and environmental regulations of the private sector. OFFICE OF INFO. & REGULATORY AFFAIRS, OFFICE OF MGMT. & BUDGET, VALIDATING REGULATORY ANALYSIS: 2005 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF FEDERAL REGULATIONS AND UNFUNDED MANDATES ON STATE, LOCAL, AND TRIBAL ENTITIES 11 (2005) [hereinafter 2005 OIRA REGULATORY REPORT].

<sup>9</sup> See, e.g., U.S. DEP’T OF HEALTH & HUMAN SERVS., HEALTHY PEOPLE 2010: MIDCOURSE REVIEW 1-30 (2006), available at <http://www.healthypeople.gov/Data/midcourse/html/default.htm> (identifying and assessing progress toward a set of federal health objectives).

<sup>10</sup> On the growth of homeland-security regulation, see OFFICE OF INFO. & REGULATORY AFFAIRS, OFFICE OF MGMT. & BUDGET, INFORMING REGULATORY DECISIONS: 2003 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF FEDERAL REGULATIONS AND UNFUNDED MANDATES ON STATE, LOCAL, AND TRIBAL ENTITIES 64-86 (2003).

<sup>11</sup> I prefer the acronym BCA to CBA because placing benefits before costs is a reminder that the purpose of BCA is as much to enhance benefits as it is to reduce costs. In any event, “B” has the alphabetical advantage.

<sup>12</sup> See, e.g., SUSAN ROSE-ACKERMAN, RETHINKING THE PROGRESSIVE AGENDA: THE REFORM OF THE AMERICAN REGULATORY STATE 16-19, 157-58, 190-93 (1992) (advocating rule-by-rule BCA, supplemented by considerations of distributive justice, as a response to the abusive deregulatory policies of the Reagan years).

<sup>13</sup> See generally REGULATION AND THE REAGAN ERA: POLITICS, BUREAUCRACY AND THE PUBLIC INTEREST (Roger E. Meiners & Bruce Yandle eds., 1989).

smarter regulatory policies<sup>14</sup> that could achieve more protection against risk at less overall cost to the private and public sectors.<sup>15</sup> It has been alleged that some reformers may have advocated reform as a cover for deregulation,<sup>16</sup> but the substance of the reform agenda was aimed at smarter lifesaving regulation, not less regulation.<sup>17</sup>

Instead of treating lifesaving regulation as a matter of protecting “rights,”<sup>18</sup> reformers urged regulators to analyze lifesaving opportunities in a welfarist framework that draws heavily on the physical and life sciences, engineering, probability and statistics, psychology, and economics.<sup>19</sup> Reformers argued that a science-based approach to lifesaving would establish regulatory priorities based on relative risk,<sup>20</sup> promote wise investments in lifesaving,<sup>21</sup> minimize the unintended risks<sup>22</sup>

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<sup>14</sup> See, e.g., Sunstein, *supra* note 1, at 251 (identifying in the 104th Congress “technocratic forces seeking to discipline agency decisions with better policy analysis”).

<sup>15</sup> During my decade as Director of the Harvard Center for Risk Analysis (1990–2001), I wrote widely on this topic. See, e.g., John D. Graham, *Legislative Approaches to Achieving More Protection Against Risk at Less Cost*, 1997 U. CHI. LEGAL F. 13, 41–53 [hereinafter Graham, *Legislative Approaches*] (offering a “menu of legislative reforms” to improve risk regulations). More generally, see John D. Graham, *Making Sense of Risk: An Agenda for Congress*, in *RISKS, COSTS, AND LIVES SAVED: GETTING BETTER RESULTS FROM REGULATION 183* (Robert W. Hahn ed., 1996) [hereinafter Graham, *Agenda for Congress*], which suggests legislative reforms through which Congress can improve regulation by requiring increased use of risk analysis.

<sup>16</sup> See THOMAS O. MCGARITY, *REINVENTING RATIONALITY: THE ROLE OF REGULATORY ANALYSIS IN THE FEDERAL BUREAUCRACY*, at xiv (1991) (describing the origins of the regulatory-reform movement as a “bold tactical stroke [by] regulated industries and their allies in academia”); Richard H. Pildes & Cass R. Sunstein, *Reinventing the Regulatory State*, 62 U. CHI. L. REV. 1, 45 (1995) (“[BCA] at times became a political tool for pursuit of an antiregulatory agenda based on something other than the actual numbers.”).

<sup>17</sup> On the substance of the regulatory-reform agenda, see generally Graham, *Agenda for Congress*, *supra* note 15, and CASS R. SUNSTEIN, *RISK AND REASON: SAFETY, LAW, AND THE ENVIRONMENT* 6 (2002), which argues that “the movement toward cost-benefit analysis should be seen as an effort to ensure, . . . not that regulation is ‘scaled back,’ but that regulation is undertaken with a firm sense of its consequences.”

<sup>18</sup> For an insightful philosophical inquiry into why rights-oriented thinking does not provide clear answers to risk questions, see Christopher H. Schroeder, *Rights Against Risks*, 86 COLUM. L. REV. 495 (1986).

<sup>19</sup> See, e.g., Shi-Ling Hsu, *Fairness Versus Efficiency in Environmental Law*, 31 *ECOLOGY L.Q.* 303, 309 (2004) (“Fundamentally, a shift towards efficiency-thinking means placing a greater emphasis on increasing total welfare than on upholding individual rights.”).

<sup>20</sup> See, e.g., CARNEGIE COMM’N ON SCI., TECH., & GOV’T, *RISK AND THE ENVIRONMENT: IMPROVING REGULATORY DECISION MAKING* 75 (1993) (advocating categorizing problems into “broad risk categories” and “address[ing] risks of high priority”).

<sup>21</sup> See generally VISCUSI, *supra* note 7; John F. Morrall III, *Saving Lives: A Review of the Record*, 27 *J. RISK & UNCERTAINTY* 221 (2003) (defending the use of BCA in rule-making and advocating improvements in its application).

and undue burdens<sup>23</sup> of regulation, and deploy market-oriented policy instruments that may stimulate innovation while minimizing costs.<sup>24</sup>

The legal obstacles to using BCA in the federal government are limited. On occasion, the legislation that underpins a regulator's authority prohibits consideration of BCA, but, more commonly, legislation is silent as to whether lifesaving rules may be informed by BCA and, if so, what role BCA should play.<sup>25</sup> In this legal vacuum, the reformers gained ground. Legal scholars refer to the emergence of the "cost-benefit state"<sup>26</sup> (or benefit-cost state) because lifesaving regulation is now routinely informed by insights from BCA<sup>27</sup> and related tools such as cost-effectiveness analysis (CEA),<sup>28</sup> quantitative risk assessment (QRA),<sup>29</sup> comparative risk assessment (CRA),<sup>30</sup> risk-tradeoff analysis (RTA),<sup>31</sup> and risk-benefit analysis (RBA).<sup>32</sup> In this Article,

<sup>22</sup> See generally RISK VERSUS RISK: TRADEOFFS IN PROTECTING HEALTH AND THE ENVIRONMENT (John D. Graham & Jonathan Baert Wiener eds., 1995).

<sup>23</sup> See THOMAS D. HOPKINS, CTR. FOR THE STUDY OF AM. BUSINESS, POLICY STUDY NO. 32, REGULATORY COSTS IN PROFILE (1996), available at <http://wc.wustl.edu/csab/regulation/ps132hopkins.pdf>.

<sup>24</sup> See, e.g., Bruce A. Ackerman & Richard B. Stewart, *Reforming Environmental Law*, 37 STAN. L. REV. 1333, 1341-51 (1985) (proposing a system of pollution regulations in which "polluters [could] buy and sell each other's permits—thereby creating a powerful financial incentive for those who can clean up most cheaply to sell their permits to those whose treatment costs are highest").

<sup>25</sup> Where statutory language is silent on the role of BCA, there has been a "quiet revolution" in favor of using BCA in lifesaving regulation. See SUNSTEIN, *supra* note 3, at 31-70.

<sup>26</sup> See, e.g., Thomas O. McGarity, *A Cost-Benefit State*, 50 ADMIN. L. REV. 7 (1998); Cass R. Sunstein, *Cost-Benefit Default Principles*, 99 MICH. L. REV. 1651, 1656-63 (2001) (describing the shift from the "apparently cost-blind" environmental regulations of the 1970s to a greater focus on BCA principles).

<sup>27</sup> For background on BCA's application, see generally ANTHONY E. BOARDMAN ET AL., COST-BENEFIT ANALYSIS (3d ed. 2006); EDWARD M. GRAMLICH, BENEFIT-COST ANALYSIS OF GOVERNMENT PROGRAMS (1981); E.J. MISHAN, COST-BENEFIT ANALYSIS (4th ed. 1988).

<sup>28</sup> See generally COST-EFFECTIVENESS IN HEALTH AND MEDICINE (Marthe R. Gold et al. eds., 1996).

<sup>29</sup> See generally YACOV Y. HAIMES, RISK MODELING, ASSESSMENT, AND MANAGEMENT (2d ed. 2004); HUMAN AND ECOLOGICAL RISK ASSESSMENT (Dennis J. Paustenbach ed., 2002).

<sup>30</sup> See generally J. Clarence Davies, *Comparative Risk Analysis in the 1990s: The State of the Art*, in COMPARING ENVIRONMENTAL RISKS: TOOLS FOR SETTING GOVERNMENT PRIORITIES I (J. Clarence Davies ed., 1996).

<sup>31</sup> See generally RISK VERSUS RISK, *supra* note 22 (analyzing various types of risk tradeoffs).

unless otherwise noted, I refer to BCA broadly to encompass this family of analytic tools.

There is dispute about how influential BCA has become at federal agencies,<sup>33</sup> but there is universal consensus that BCA plays a more significant role today than it did a generation ago.<sup>34</sup> In fact, benefit-cost thinking about regulation is also gaining ground in the fifty states,<sup>35</sup> in Canada<sup>36</sup> and the United Kingdom,<sup>37</sup> at the European Commission,<sup>38</sup>

<sup>32</sup> See generally RICHARD WILSON & EDMUND A.C. CROUCH, *RISK-BENEFIT ANALYSIS* (2d ed. 2001).

<sup>33</sup> See, e.g., Christopher H. Schroeder, *Prophets, Priests, and Pragmatists*, 87 MINN. L. REV. 1065, 1070 (2003) (noting that while regulatory reformers “have had some successes in altering some rules, regulations, and enforcement policies,” the “basic statutory structure has remained in place”); Amy Sinden, *Cass Sunstein’s Cost-Benefit Lite: Economics for Liberals*, 29 COLUM. J. ENVTL. L. 191, 239 (2004) (“Professor Sunstein’s claim of an emerging set of ‘cost-benefit default principles’ heralding the arrival of the Cost-Benefit State . . . seems . . . exaggerated.”).

<sup>34</sup> Both proponents and opponents of BCA acknowledge its growing influence in regulatory policy. See, e.g., Jane B. Baron & Jeffrey L. Dunoff, *Against Market Rationality: Moral Critiques of Economic Analysis in Legal Theory*, 17 CARDOZO L. REV. 431, 495 (1996) (“Cost-benefit analysis is enshrined as federal regulatory policy. . . . [W]ithin the academy cost-benefit analysis has become central to consideration of legal policy in a wide variety of fields.”); Jason Scott Johnston, *A Game Theoretic Analysis of Alternative Institutions for Regulatory Cost-Benefit Analysis*, 150 U. PA. L. REV. 1343, 1353 n.34 (2002) (sharing Sunstein’s view that courts generally allow an agency to consider costs of rules, in the absence of statutory language prohibiting such consideration); Richard W. Parker, *Grading the Government*, 70 U. CHI. L. REV. 1345, 1355 n.36 (2003) (“[F]or better or worse, cost-benefit analysis (with all of its built-in value assumptions) has been ratified by Congress—and applied to regulation . . . .”); Amy Sinden, *The Economics of Endangered Species: Why Less Is More in the Economic Analysis of Critical Habitat Designations*, 28 HARV. ENVTL. L. REV. 129, 184 (2004) (“Indeed, formal economic cost-benefit analysis now enjoys a level of acceptance and credibility in both academic and government circles that was unthinkable three decades ago.”); Sunstein, *supra* note 26, at 1654 (“Taken as a whole, the cost-benefit default principles are making a substantial difference to regulatory policy, both because of their effects in litigated cases and because of their systematic consequences for regulation.”).

<sup>35</sup> See Matthew D. Adler, *Risk, Death and Harm: The Normative Foundations of Risk Regulation*, 87 MINN. L. REV. 1293, 1392 (2003) (noting that over half of the states are using BCA in regulatory policymaking); Robert W. Hahn, *State and Federal Regulatory Reform: A Comparative Analysis*, 29 J. LEGAL STUD. 873 (2000) (discussing states’ use of tools such as BCA to improve regulations).

<sup>36</sup> GOV’T OF CAN., CABINET DIRECTIVE ON STREAMLINING REGULATION 8-9 (2007), available at <http://www.regulation.gc.ca/directive/directive-eng.pdf> (directing departments and agencies to “assess[] the costs and benefits of regulatory and non-regulatory measures”).

<sup>37</sup> The United Kingdom’s Department for Business, Enterprise and Regulatory Reform’s guidance document for regulatory analysts emphasizes BCA. See Impact Assessment Guidance paras. 26-34, <http://www.berr.gov.uk/files/file44544.pdf> (last visited Nov. 15, 2008).

and within international organizations such as the Organization for Economic Cooperation and Development (OECD).<sup>39</sup>

In this Article, I offer a broad assessment of federal lifesaving regulation informed by BCA. With the new Democratic administration, and with the increased Democratic majority in Congress, it is useful to examine how well the benefit-cost state is working and how the process of making lifesaving regulations can improve. My assessment is informed by seventeen years of faculty experience at Harvard, where I taught BCA to hundreds of public health and medical students and where I advanced through scholarship the application of BCA to lifesaving. I also draw on my experience from 2001 to 2006 as Administrator of the Office of Information and Regulatory Affairs (OIRA) in the White House Office of Management and Budget (OMB).

My central argument is that BCA, while easy to criticize because of its transparency,<sup>40</sup> has compelling philosophical and practical advantages over other suggested approaches to lifesaving regulation. In short, BCA is morally relevant and often helpful (“determinate”) in distinguishing good rules from bad rules, assuming that the analysis is conducted properly and that the findings are interpreted appropriately. Rather than seeking to replace BCA or diminish its role, future administrations should work with Congress and the judiciary to improve the benefit-cost state. Through targeted analytic innovations and institutional reforms, federal regulatory agencies can save more lives in the future, reduce the overall burdens of regulation, and attend to legitimate concerns about fairness to the poor.

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<sup>38</sup> See, e.g., Memorandum, European Comm’n, *Working to Ensure Better Quality of Commission Impact Assessments*, MEMO/06/427 (Nov. 14, 2006), available at [http://ec.europa.eu/enterprise/admin-burdens-reduction/news\\_en.htm#aa](http://ec.europa.eu/enterprise/admin-burdens-reduction/news_en.htm#aa) (announcing the creation of the Impact Assessment Board, a centralized unit dedicated to the review of impact assessments).

<sup>39</sup> For a survey of “regulatory-impact analysis” (RIA) practices in member countries of the OECD, see Secretariat, Pub. Governance & Territorial Directorate, OECD, *Regulatory Impact Analysis (RIA) Inventory*, OECD Doc. GOV/PGC/RD(2004) 1 (Apr. 15, 2004), available at <http://www.oecd.org/dataoecd/22/9/35258430.pdf>.

<sup>40</sup> The application of BCA to lifesaving regulation has always been controversial among proregulation advocates. See, e.g., SUSAN J. TOLCHIN & MARTIN TOLCHIN, *DISMANTLING AMERICA: THE RUSH TO DEREGULATE* ch. 4 (1983) (criticizing the use of BCA in policy determinations, in part because of its inadequacy and indeterminacy). More recently, the Center for Progressive Reform has helped stimulate a variety of books, law review articles, and position papers that criticize the growing role of BCA in lifesaving regulation.

A secondary theme of this Article is that much of the legal literature has an oversimplified view of the roles played by BCA and OIRA in federal lifesaving regulation.<sup>41</sup> Perhaps because of the stridently deregulatory stance taken by OIRA in the early years of the Reagan administration, a perception remains today that the exclusive role of OIRA is to foster deregulation or cost reduction.<sup>42</sup> Indeed, BCA counsels avoidance of inefficient lifesaving rules—but it also counsels acceleration of efficient investments in lifesaving. I shall illustrate, based on key rulemakings from the 2001–2006 period, that OIRA plays a much more complex role than legal scholars appreciate. Using findings from BCA, OIRA served as a crucial advocate of several lifesaving regulations that, in the absence of OIRA’s support, might not have survived White House oversight in a pro-business Republican administration.

The Article is organized in five parts. Part I examines the normative foundations of BCA, with an emphasis on lifesaving applications. Part II examines various benefit-cost decision rules and the main alternatives to BCA. Part III explores the reality of the benefit-cost state, with emphasis on OIRA review in the 2001 to 2006 period. Part IV, which may be skipped by readers without loss of continuity, examines the technical challenges of applying BCA to lifesaving. Part V concludes by charting some promising directions for lifesaving regulation that may be fruitful for future presidential administrations, Congress, and the federal judiciary.

## I. FOUNDATIONS OF BCA

Briefly, the normative perspective I advance is preconstitutional,<sup>43</sup> where citizens in an original position, with their own identities con-

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<sup>41</sup> There is a widespread misperception among prominent legal scholars that OIRA uses BCA only to oppose regulation or to reduce the economic burdens of regulation. See, e.g., Nicholas Bagley & Richard Revesz, *Centralized Oversight of the Regulatory State*, 106 COLUM. L. REV. 1260, 1267-70 (2006) (arguing that OIRA only “stands as a structural roadblock on the path of regulation, but not deregulation”); David M. Driesen, *Is Cost-Benefit Analysis Neutral?*, 77 U. COLO. L. REV. 335, 378-80 (2006) (stating that OIRA acts as a “one-way ratchet” by only weakening regulation); Lisa Heinzerling, *Risking It All*, 57 ALA. L. REV. 103, 113 (2005) (“[A]t OMB today, cost-benefit analysis continues to be what it has always been—a one-way street to deregulation.”).

<sup>42</sup> See, e.g., Sinden, *supra* note 33, at 199 (“After all, the widespread use of CBA in government decision-making began with Ronald Reagan, whose avowed mission was the dismantling of the regulatory state.”).

<sup>43</sup> By “preconstitutional,” I mean a hypothetical setting where citizens establish—or consent to—a social contract for a nation-state.

cealed by a veil of ignorance, establish principles for how resources are to be allocated for lifesaving purposes.<sup>44</sup> I favor an ex ante version of welfarism,<sup>45</sup> in which BCA is used as a surrogate for welfarism but is qualified by an equity-inspired concern for the welfare of society's poorest citizens.

#### A. Welfarism

Welfarism is a school of philosophical thought that is consequentialist and sensitive to utilitarian perspectives. Although there are many variants of welfarism, they share the premise that the welfare of society is determined by the well-being of its individual members. When lifesaving regulations make some citizens better off and others worse off, welfarists believe that it is feasible to make an overall determination as to whether society is better off or worse off as a result.<sup>46</sup>

Variants of welfarism differ in how much concern is given to addressing distributional inequities in society. For example, a simple (unweighted) approach to welfarism adds the utility of each citizen in society as the English philosopher Jeremy Bentham envisioned, thus treating each citizen equally in the calculation.<sup>47</sup> Even this simple approach is quite advantageous to the poor, assuming that a dollar of

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<sup>44</sup> See JOHN RAWLS, A THEORY OF JUSTICE 118-23 (rev. ed. 1999) (describing the "veil of ignorance," which prevents parties from knowing their own place in society or other facts of their own lives, thereby forcing them to make decisions based on their understanding of society as a whole); see also John C. Harsanyi, *Cardinal Welfare, Individualistic Ethics, and Interpersonal Comparisons of Utility*, 63 J. POL. ECON. 309, 316 (1955) ("[A]n individual's [policy] preferences satisfy [the requirement of impartiality] if they indicate what social situation he would choose if he did not know what his personal position would be in the new situation chosen . . .").

<sup>45</sup> See ROBERT CAMERON MITCHELL & RICHARD T. CARSON, USING SURVEYS TO VALUE PUBLIC GOODS: THE CONTINGENT VALUATION METHOD 29-30 (1989) ("For most welfare economic purposes, the ex ante perspective is generally considered to be the most appropriate one in situations where uncertainty about outcomes is involved."); John R. Hicks, *The Foundations of Welfare Economics*, 49 ECON. J. 696, 708 (1939) (arguing that wise economic policy can only secure ex ante optimality). *But see* Matthew D. Adler, *The Puzzle of "Ex Ante Efficiency": Does Rational Approvability Have Moral Weight?*, 151 U. PA. L. REV. 1255 (2003) (questioning the view that ex ante efficiency is morally relevant).

<sup>46</sup> For an excellent presentation of welfarism, see ADLER & POSNER, *supra* note 2, at 28-43.

<sup>47</sup> See THE OXFORD COMPANION TO PHILOSOPHY 85 (Ted Honderich ed., 1995) (explaining that Bentham viewed the principle of utility as the "only appropriate measure of value").

benefit to the poor produces more utility than a dollar of benefit to the rich.<sup>48</sup>

An alternative, weighted approach to welfarism gives more weight to the utility of some individuals than others, such as those who have low baseline levels of utility.<sup>49</sup> Thus, one of the interesting features of welfarism is that it is flexible enough to incorporate concerns about distributional equity, as well as allocative economic efficiency, into the overall social-welfare calculus.<sup>50</sup>

Welfarists envision what has been elusive since the days of Bentham: a cardinal measure of utility (or well-being) that is quantifiable and comparable across individuals.<sup>51</sup> Thus, just as the height and weight of individuals can be compared in units that have universal and objective meaning, proponents of cardinal utility envision a scale where a specific utility value for one person signifies the same degree of utility for any other person—or at least a system in which the two utility values can be related to one another in a mathematical way.<sup>52</sup>

Not surprisingly, there is some disagreement over how utility (or well-being) should be defined and measured.<sup>53</sup> One could examine the critical dimensions of life, each of which contributes to a person's overall well-being, and produce a weighted measure of these dimen-

<sup>48</sup> See Matthew D. Adler, *Beyond Efficiency and Procedure: A Welfarist Theory of Regulation*, 28 FLA. ST. U. L. REV. 241, 320-21 (2000) (noting that individuals may have different "monetary equivalents" for welfare changes due to their varying wealth levels).

<sup>49</sup> See, e.g., RICHARD LAYARD, HAPPINESS: LESSONS FROM A NEW SCIENCE 122 (2005) ("The impartial spectator would surely care more about what happened to the miserable person than to the person who was already happy. He would therefore give a different 'weight' to changes in happiness according to how happy the person was already."); Matthew D. Adler, *Risk Equity: A New Proposal*, 32 HARV. ENVT. L. REV. 1, 27 (2008) (explaining the Pigou-Dalton Principle, which "stipulates that shifting utility from someone at a higher utility level to someone at a lower level, without changing total utility, must increase the value of the [social welfare function]").

<sup>50</sup> See, e.g., Louis Kaplow & Steven Shavell, *Fairness Versus Welfare*, 114 HARV. L. REV. 961, 968 (2001) (defining welfare broadly to include levels of individual well-being and the distribution of well-being among citizens).

<sup>51</sup> Hicks provides an example that explains why this measure is difficult to create: "You cannot take a temperature when you have to use, not one thermometer, but an immense number of different thermometers, working on different principles, and with no necessary correlation between their registrations." Hicks, *supra* note 45, at 699.

<sup>52</sup> Strictly speaking, what is required is a scale richer than an ordinal one but weaker than an absolute one where there is one-to-one correspondence between people. For an enthusiastic defense of welfarism and cardinal utility, see YEW-KWANG NG, SOCIAL WELFARE AND ECONOMIC POLICY 12-17, 28-30, 38-39, 50-53 (1990).

<sup>53</sup> See ADLER & POSNER, *supra* note 2, at 28-35 (reviewing and evaluating three accounts of well-being: mental-state accounts, objective-good accounts, and preference-based accounts).

sions.<sup>54</sup> A more promising approach appears to be the direct measurement of happiness as a surrogate for well-being or utility.<sup>55</sup> An interesting finding from happiness research is that differences in income explain only a small proportion of the differences in happiness among persons.<sup>56</sup> This line of research, however, raises as many questions as answers.<sup>57</sup> Critics object that self-reported happiness (or other “mental-state” accounts of misery) may reflect the fact that many people—especially the poor and the disabled—become resigned to accepting their fate in life.<sup>58</sup>

In summary, the inability to resolve difficult conceptual and measurement issues impedes the direct implementation of welfarism. This stems from the lack of an established, validated scale to compare well-being across individuals. Until these difficulties are overcome, a direct welfarist analysis of lifesaving regulations cannot be undertaken.<sup>59</sup> Thus, proponents of welfarism have searched for surrogate measures of well-being that have practical utility, the most influential

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<sup>54</sup> See *id.* at 31-32 (describing potential dimensions of well-being proposed by various supporters of the objective-good account of well-being).

<sup>55</sup> There are, however, different constructs of utility, each of which is not necessarily synonymous with happiness. See Daniel Kahneman & Alan B. Krueger, *Developments in the Measurement of Subjective Well-Being*, J. ECON. PERSP., Winter 2006, at 3, 4 (“[I]t is fruitful to distinguish among different conceptions of utility rather than presume to measure a single, unifying concept that motivates all human choices and registers all relevant feelings and experiences.”).

<sup>56</sup> See David G. Blanchflower & Andrew J. Oswald, *Well-Being over Time in Britain and the USA*, 88 J. PUB. ECON. 1359, 1371-72 (2004) (“The amount of happiness bought by extra income is not as large as some would expect. . . . [T]he non-economic variables in happiness equations enter with large coefficients, relative to that on income.”); Daniel Kahneman et al., *Would You Be Happier if You Were Richer? A Focusing Illusion*, 312 SCIENCE 1908 (2006) (finding a “weak relation” between income and “experienced happiness”).

<sup>57</sup> See Kahneman & Krueger, *supra* note 55 at 18-19 (“One of the difficulties of using data on subjective well-being is that individuals may interpret and use the response categories differently. . . . [O]ne could legitimately question whether one should give a cardinal interpretation to the numeric values attached to individuals’ responses about their life satisfaction or emotional states because of the potential for personal use of scales.”).

<sup>58</sup> See Amartya Sen, *The Possibility of Social Choice*, 89 AM. ECON. REV. 349, 363 (1999) (“Mental reactions, the mainstay of classical utility, can be a very defective basis for the analysis of deprivation. Thus, in understanding poverty and inequality, there is a strong case for looking at real deprivation and not merely at mental reactions to that deprivation.”).

<sup>59</sup> Even proponents of welfarism acknowledge the measurement difficulties with cardinal utility. See NG, *supra* note 52, at 98 (“I do not attempt to deny that, despite the possibility of indirect measurement, the practical measurement and comparison of utility differences are still beset with many difficulties. But three hundred years ago, it was also difficult to measure the temperature of the atmosphere and to compare it with that of another area.”).

of which was advanced by European economists in the first half of the twentieth century.

### B. *The Pareto Criterion*

The normative rationale for BCA is found in a subfield of microeconomics called welfare economics. Welfare economics began with the bedrock principle that a regulation should be promulgated if at least one person will be made better off and nobody will be made worse off. Named for the Italian economist Vilfredo Pareto, the Pareto criterion is applied by reference to the preferences of each individual in society who might be affected by the rule.<sup>60</sup>

When applying the Pareto criterion, individual preferences are assumed to be based on full information about both the known and possible consequences of regulation. Furthermore, individuals are assumed to have the cognitive capacity and resources required to process such information and to rationally determine their preferences. The Pareto construct is an ideal and does not necessarily reflect the preferences of people as they are revealed on a day-to-day basis in marketplace decisions, since some revealed preferences are uninformed.<sup>61</sup>

Economists believe that lifesaving preferences based on actual decisions, where an informed consumer or worker faces real consequences from her choice, are more informative of genuine preferences than is idle speculation about what a person might do in the

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<sup>60</sup> The individuals who “count” in the analysis are all those whom the society determines should count (e.g., residents or citizens), and Pareto reasoning offers no view as to how the eligible pool of individuals should be determined. See generally Dale Whittington & Duncan MacRae, Jr., *The Issue of Standing in Cost-Benefit Analysis*, 5 J. POLY ANALYSIS & MGMT. 665 (1986) (exploring the difficulties of determining whether and how to count the preferences of various groups when conducting a BCA).

<sup>61</sup> Professors Matthew Adler and Eric Posner may have confused matters by insisting that welfare economics is interested in “preference” defined as “how people actually rank states of the world, not how they would rank states of the world if they were better informed, more enlightened, or otherwise different from the way they really are.” ADLER & POSNER, *supra* note 2, at 12. In fact, most welfare economists would object to their use of “preference.” See, e.g., A. MYRICK FREEMAN III, *THE MEASUREMENT OF ENVIRONMENTAL AND RESOURCE VALUES* 308 (2d ed. 2003) (arguing that using consumers’ safety decisions as the basis for valuation where consumer perceptions are not well informed is “problematic”); Mark V. Pauly, *Valuing Health Care Benefits in Money Terms*, in *VALUING HEALTH CARE: COSTS, BENEFITS, AND EFFECTIVENESS OF PHARMACEUTICALS AND OTHER MEDICAL TECHNOLOGIES* 99, 102 (Frank A. Sloan ed., 1995) (“In welfare economic theory, there is only one accepted way to measure the benefits an individual gets from a program. Benefit is defined as *the individual’s maximum willingness to pay for the program* when supplied with information as complete as it can be, given the scientific knowledge available at the time.”).

future. This respect for informed individual choice is called the principle of consumer sovereignty.<sup>62</sup>

In order to infer idealized preferences about lifesaving from day-to-day decisions, economists study decisions where people are well informed about risk or where their risk perceptions, even if biased, can be ascertained and related to choice. For example, Professor W. Kip Viscusi's pioneering studies of worker preferences for job safety did not assume full information in the labor market.<sup>63</sup> In fact, Viscusi sought to determine whether workers perceived risks, how workers learned about risks on the job, and whether perceived and actuarial risks impacted job choice, quit rates, and wages.<sup>64</sup> Viscusi found that hazardous jobs command significant wage premiums, even though employers have an incentive to find potential employees who are least averse to taking safety risks. As long as employers and employees negotiate in a well-informed, competitive market, there is no reason to believe that job-related dangers violate the interests of workers.<sup>65</sup> In short, ideal labor markets may satisfy the Pareto test.

Some concerns have been raised about the Pareto test.<sup>66</sup> Could use of this criterion justify more inequality? Could it cause more envy in society? Does it overemphasize private preferences, without authorizing a concept of the civic good? Although these are important questions, it is difficult to oppose a rule that saves lives without making anyone worse off! But if the Pareto test is unassailable as a sufficient condition for lifesaving regulation, should the test also be a necessary condition?

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<sup>62</sup> See LEE S. FRIEDMAN, *THE MICROECONOMICS OF PUBLIC POLICY ANALYSIS* 46 (2002) (defining "the principle of consumer sovereignty" as meaning that "each person is the sole judge of his or her own welfare").

<sup>63</sup> See W. KIP VISCUSI, *EMPLOYMENT HAZARDS: AN INVESTIGATION OF MARKET PERFORMANCE* 274-75 (1979) (stating that workers have imperfect information about the risks that they take on).

<sup>64</sup> *Id.* ch. 14; see also W. Kip Viscusi & Joseph E. Aldy, *The Value of a Statistical Life: A Critical Review of Market Estimates Throughout the World*, 27 *J. RISK & UNCERTAINTY* 5, 17 (2003) (reporting that the results from analysis of workers' perceptions of occupational hazards through labor-market models of wage determination are similar to the results from analysis of actuarial risks).

<sup>65</sup> For the classic analysis of whether there are sound rationales for government regulation to improve occupational safety, see generally W. KIP VISCUSI, *RATIONAL RISK POLICY* (1998); W. KIP VISCUSI, *RISK BY CHOICE: REGULATING HEALTH AND SAFETY IN THE WORKPLACE* ch. 5 (1983).

<sup>66</sup> See, e.g., AMARTYA SEN, *ON ETHICS AND ECONOMICS* 32 (1987) ("A state can be Pareto optimal with some people in extreme misery and others rolling in luxury, so long as the miserable cannot be made better off without cutting into the luxury of the rich.").

The most powerful objection to Pareto as a necessary test is simple: it is too stringent a hurdle for lifesaving regulators. If passing the Pareto test were a necessary criterion, there would be precious few lifesaving regulations because there are few rules that harm no member of society.<sup>67</sup>

### C. Kaldor-Hicks Efficiency

Recognizing that the Pareto test was too stringent, the “new welfare economics” was launched by an interesting alternative. In 1939, over thirty years after publication of Pareto’s *Manuale di economia politica*,<sup>68</sup> Cambridge economists Nicholas Kaldor and John Hicks (now a Nobel Laureate in Economics) proposed what has been called “the potential Pareto criterion,” or the Kaldor-Hicks (KH) efficiency test.<sup>69</sup>

In Kaldor’s analysis, a regulation is considered efficient (and thus potentially desirable) if those individuals who benefit from the rule would prefer the rule even if they were obliged to fully compensate all individuals made worse off by the rule. The “compensation,” a costless transfer from gainers to losers, is hypothetical and thus is not intended to occur on a rule-by-rule basis (or thereafter in any organized way).<sup>70</sup> The “surplus” in benefit that remains (after the hypothetical compensation of losers is carried out) is considered to be a measure of the net gain in social welfare from the regulation.<sup>71</sup>

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<sup>67</sup> See, e.g., NG, *supra* note 52, at 160 (“[M]ost, if not all, changes in the real world involve making some better off and some (no matter how small the number) worse off. Thus the Pareto criterion in itself is of little practical use.”); 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, 983 (2001) (“[I]t is almost impossible to imagine any regulatory program that would not make at least one person or group worse off.”); T. de Scitovszky, *A Note on Welfare Propositions in Economics*, 9 REV. ECON. STUD. 77, 79 (1941) (arguing that it is “doubtful” that any government policy would satisfy the Pareto test); Amy Sinden, *In Defense of Absolutes: Combating the Politics of Power in Environmental Law*, 90 IOWA L. REV. 1405, 1414 (2005) (“[I]t is very difficult to find a government action that does not cause harm to at least one person. Thus, virtually all government intervention would fail a Pareto-efficiency test.”).

<sup>68</sup> VILFREDO PARETO, *MANUAL OF POLITICAL ECONOMY* (Ann S. Schwier & Alfred N. Page eds., Ann S. Schwier trans., Augustus M. Kelley Publishers 1971) (1906).

<sup>69</sup> For a detailed explanation of the KH test, see RICHARD E. JUST ET AL., *THE WELFARE ECONOMICS OF PUBLIC POLICY* 32-48 (2004).

<sup>70</sup> Kaldor and Hicks were neutral as to whether compensation should be provided, believing that there could be no general economic principle to resolve that question. See, e.g., Hicks, *supra* note 45, at 711-12 (1939).

<sup>71</sup> What Richard Posner calls the “wealth maximization” principle is synonymous with the KH test. See Richard A. Posner, *Utilitarianism, Economics, and Legal Theory*, 8 J.

The Hicks version of the test is the flip side of the Kaldor version.<sup>72</sup> Hicks gives the presumption to the lifesaving regulation and asks whether the ex ante losers from the rule would be willing to compensate the ex ante beneficiaries for not having the rule.<sup>73</sup> Since in some situations the Kaldor and Hicks tests might give different answers, it has been suggested that a rule should have to pass both the Kaldor and Hicks tests in order to be considered efficient.<sup>74</sup>

Philosophically, the combined KH test has the following attractive features: the preferences of each individual in society are considered; the preferences of both winners and losers enter into a principled framework; the intensity of individual preferences counts; and the weighing of opposing preferences is explicit, calculable, and scrutable. If adequate information is available on the consequences of a rule and the preferences of each citizen, the KH test is also determinate (with regard to efficiency). Unlike Bentham's utilitarianism, no interpersonally comparable measure of utility is required for implementation of the KH test.<sup>75</sup>

#### D. From Kaldor-Hicks to BCA

KH reasoning is the original normative foundation of BCA.<sup>76</sup> It is implemented through use of "willingness to pay" (WTP) money as the measure of social benefit (*B*) and "willingness to accept" (WTA) money as the measure of social cost (*C*).<sup>77</sup> If an individual expects a

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LEGAL STUD. 103 (1979) (distinguishing Posner's wealth-maximization model from utilitarianism).

<sup>72</sup> See generally J.R. HICKS, VALUE AND CAPITAL: AN INQUIRY INTO SOME FUNDAMENTAL PRINCIPLES OF ECONOMIC THEORY (1939); Hicks, *supra* note 45.

<sup>73</sup> Cf. FREEMAN, *supra* note 61, at 61-63 (describing the difference between the Kaldor and Hicks tests and suggesting that the choice between the two tests may entail a value judgment about the underlying distribution of property rights).

<sup>74</sup> See de Scitovszky, *supra* note 67, at 88 (suggesting the need to use both the Kaldor and Hicks tests in order to avoid "absurd result[s]"). This suggestion is sometimes called the "double-compensation test" or the "Scitovsky test."

<sup>75</sup> See, e.g., Stephen Birch & Cam Donaldson, *Valuing the Benefits and Costs of Health Care Programmes: Where's the 'Extra' in Extra-Welfarism?*, 56 SOC. SCI. & MED. 1121, 1127 (2003) (U.K.) ("Under a [welfare-economic approach], interpersonal comparisons of utilities are not required to measure social welfare.").

<sup>76</sup> FRIEDMAN, *supra* note 62, at 169 (calling the compensation principle "the foundation" for BCA).

<sup>77</sup> Some authors perceive money as playing the role of cardinal utility when the KH test is implemented. See, e.g., John Broome, *Cost-Benefit Analysis and Population*, 29 J. LEGAL STUD. 953, 957 (2000) ("[WTP] is normally used in cost-benefit analysis to provide both a cardinal scale of value and a basis for interpersonal comparisons of

regulation to be beneficial to her, WTP is positive. If another individual expects to be harmed by regulation, her WTA will be positive. Citizens who are indifferent (or who perceive that gains equal losses) do not influence the benefit-cost calculation. When multiple regulatory alternatives are compared, the preferred alternative is the one that maximizes net benefits, defined as the sum of  $B$  minus the sum of  $C$  across all citizens in society.<sup>78</sup>

If lifesaving regulation is costless, there are no losers, and thus one could proceed on the basis of the Pareto principle without any appeal to KH reasoning. But lifesaving regulations typically have an opportunity cost: scarce labor and capital in the economy are drawn away from the production of other goods and services that consumers desire.<sup>79</sup> A dollar of scarce inputs devoted to lifesaving is a dollar of inputs that cannot be devoted to housing, education, transportation, national security, recreation, and other goods and services that citizens enjoy. These opportunity costs of lifesaving regulation usually underlie the need for the KH test and BCA.

Economic tools are used to measure the WTP and WTA values for regulatory consequences. Grounded in rational-choice theory, WTP and WTA values are inferred from observed transactions with known prices and risks.<sup>80</sup> When no relevant transactions can be found (or when market actors are ill informed), economists employ survey methods in which WTP and WTA values are derived from direct questioning of respondents. A series of validity and reliability tests are applied to such survey data (so-called "contingent valuation" techniques).<sup>81</sup> Since 1980, there has been an explosion of research in health and environmental economics that has made implementation

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value."). That may be true in monetary applications, but using money as a surrogate for utility is not the same as saying that the KH test presumes a cardinal, interpersonally comparable measure of utility. See KENNETH J. ARROW, SOCIAL CHOICE AND INDIVIDUAL VALUES 38-39 (2d ed. 1963) [hereinafter ARROW, SOCIAL CHOICE] (noting that the Kaldor compensation principle may be arbitrary and intransitive, but that it does not assume "interpersonal comparisons of utility").

<sup>78</sup> See FRIEDMAN, *supra* note 62, at 173 (explaining that the KH test measures "relative efficiency" and that "trying to maximize net benefits is . . . the same as trying to maximize relative efficiency").

<sup>79</sup> For an overview of opportunity cost, see MISHAN, *supra* note 27, ch. 11.

<sup>80</sup> See FREEMAN, *supra* note 61, ch. 4 (describing the basic theory of "revealed preference methods, which involves the estimation of value from observations of behavior").

<sup>81</sup> See *id.* ch. 6 (describing the "major types of [stated preference] question formats" and how to analyze responses "to obtain measures of welfare").

of the KH test far more feasible and precise today than it was a generation ago.<sup>82</sup>

Money is typically used as the metric to compare benefits and costs, but in theory other metrics could be used without discarding or modifying the KH test.<sup>83</sup> Nonmonetary metrics are rarely used in practice because money has practical advantages. Also, a common metric is crucial when comparing the consequences of different regulatory alternatives and when weighing the gains to beneficiaries against the losses realized by those made worse off.<sup>84</sup> Without such a metric, the task of making logical investments in lifesaving is far more challenging.

In conclusion, the KH test was offered as a normative standard—or at least as a useful surrogate for well-being (which cannot yet be measured). There is nothing in the KH test that presumes that markets function or work properly when lifesaving decisions are made. Indeed, KH reasoning is often employed to determine whether a lifesaving rule aimed at correcting market imperfections (e.g., externalities, inadequate information, or lack of competition among firms) should be promulgated.<sup>85</sup> Lifesaving regulations are often required because markets are failing or imperfect, which is why the KH test and BCA are useful to public decision makers. We now turn to whether the KH test can survive the many criticisms that have been launched against it, especially in the context of lifesaving opportunities.

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<sup>82</sup> See, e.g., Robert W. Hahn, *The Economic Analysis of Regulation: A Response to the Critics*, 71 U. CHI. L. REV. 1021, 1052 (2004) (“Scholars have made much progress over the past thirty years in understanding the economic impact of social regulation.”). For a broad overview of the field since 1980, see John D. Graham et al., *The Role of Efficiency in Risk Management*, in RISK ANALYSIS AND SOCIETY: AN INTERDISCIPLINARY CHARACTERIZATION OF THE FIELD 251 (Timothy McDaniels & Mitchell J. Small eds., 2004).

<sup>83</sup> See FREEMAN, *supra* note 61, at 9 (“WTP and WTA measures can be defined in terms of any good that the individual is willing to substitute for the good being valued.”).

<sup>84</sup> See James K. Hammitt, *QALYs Versus WTP*, 22 RISK ANALYSIS 985, 998 (2002) (arguing that an advantage of monetary BCA is that a common metric allows analysts to identify the regulatory option that maximizes net benefits for society).

<sup>85</sup> See ROBIN BOADWAY & NEIL BRUCE, WELFARE ECONOMICS 3 (1984) (“The study of welfare economics is useful in identifying [market failures] and in recommending and evaluating ‘corrective’ policies.”).

### E. Evaluating the Kaldor-Hicks Test

Numerous objections have been lodged against use of the KH test as a necessary or sufficient condition for regulatory policy.<sup>86</sup> In fact, Professor Adler has asserted that the KH test is flawed as a moral criterion and should no longer be taken seriously.<sup>87</sup>

I offer a more sympathetic analysis of the KH test and conclude that Kaldor-Hicks efficiency is a morally relevant, practical contribution to the evaluation of lifesaving regulation. But the KH test should not be considered a necessary or sufficient condition for issuing a life-saving rule.<sup>88</sup> Other distributional values, such as fairness to the poor, also require consideration.

Here the arguments are sketched briefly, with an emphasis on issues that arise in lifesaving regulation. I highlight why an impartial citizen who applies an ex ante constitutional perspective might favor Kaldor-Hicks reasoning, subject to some important qualifications.

#### 1. Single Versus Repeated Applications

One could consider the KH test in a single, isolated application.<sup>89</sup> Critics argue that such an isolated application of the KH test will create losers, possibly a large number of them, and maybe more losers than winners.

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<sup>86</sup> I do not address various theoretical arguments suggesting that the KH test is intransitive or circular. See, e.g., ARROW, *SOCIAL CHOICE*, *supra* note 77, at 42-45 (arguing that the Kaldor, Hicks, and Scitovsky tests do not satisfy the transitivity condition for a social welfare function).

<sup>87</sup> See, e.g., Matthew D. Adler, *QALYs and Policy Evaluation: A New Perspective*, 6 *YALE J. HEALTH POL'Y L. & ETHICS* 1, 16 (2006) ("Kaldor-Hicks efficiency itself lacks moral significance."). But Professor Adler's view is not characteristic of experts in the field. See, e.g., FRIEDMAN, *supra* note 62, at 178 (arguing that KH efficiency provides useful information to policymakers if it is accompanied by equity information).

<sup>88</sup> In the early history of modern welfare economics, between 1939 and 1959, the KH test was never suggested as a sufficient condition for policy choice, but some authors suggested it as a viable necessary condition. See, e.g., E.J. Mishan, *A Survey of Welfare Economics, 1939-59*, 70 *ECON. J.* 197, 237-38 (1960) (describing three possible ways of regarding compensation tests, one of which was as "necessary conditions for policy prescription"). The more recent view is that it establishes neither a necessary nor a sufficient condition. See, e.g., Kenneth J. Arrow et al., *Is There a Role for Benefit-Cost Analysis in Environmental, Health, and Safety Regulation?*, 272 *SCIENCE* 221, 222 (1996) ("Although formal benefit-cost analysis should not be viewed as either necessary or sufficient for designing sensible public policy, it can provide an exceptionally useful framework for consistently organizing disparate information . . .").

<sup>89</sup> See, e.g., Adler, *supra* note 48, at 252 (insisting on a rationale for why one-off Kaldor-Hicks changes are a good thing).

Moreover, in some situations, the costs of a lifesaving rule may also include a life-threatening side effect.<sup>90</sup> For example, stricter safety standards at nuclear power plants may cause some utilities to build coal plants instead, thereby imposing the burden of air pollution on the communities downwind of coal plants.<sup>91</sup> Thus, if the question is whether to apply the KH test in a single rulemaking, the test may not be persuasive, especially to those who experience economic harm or life-threatening risks and are not compensated accordingly.<sup>92</sup>

If the KH test must be defended in a single application, the best defense is that its average effect on citizens is to make them better off.<sup>93</sup> When citizens evaluate the test in the preconstitutional (original) position, behind a veil of ignorance, the case for KH is stronger. In this setting, one can argue that KH reasoning will enhance the expected value of the well-being of each citizen.<sup>94</sup> If everyone is expected (statistically) to be better off *ex ante*, the KH test is arguably consistent with the requirements of the Pareto test. But at the time any lifesaving regulation is adopted, when the veil has been removed, it will typically be apparent that there are losers as well as beneficiaries.<sup>95</sup>

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<sup>90</sup> The classic articles urging consideration of risks arising from decisions aimed at reducing risks are Chauncey Starr & Chris Whipple, *Risks of Risk Decisions*, 208 *SCIENCE* 1114 (1980), and Aaron Wildavsky, *No Risk Is the Highest Risk of All*, 67 *AM. SCIENTIST* 32 (1979).

<sup>91</sup> For an early legal analysis of risk/risk tradeoffs arising from differential treatment of new and existing sources of risk, see generally Peter Huber, *The Old-New Division in Risk Regulation*, 69 *VA. L. REV.* 1025 (1983).

<sup>92</sup> See Anthony J. Culyer & Robert G. Evans, *Mark Pauly on Welfare Economics: Normative Rabbits from Positive Hats*, 15 *J. HEALTH ECON.* 243, 247 (1996) ("But why the possibility of compensation that does not in fact take place should influence the ranking of different states has never been clear. It would certainly not be clear to the losers!").

<sup>93</sup> Notice that in a society where a small number of individuals reap most of the benefit (or incur most of the burden) from a regulation, the KH test does not necessarily protect the welfare of the median individual. It only assures that the average impact on individuals in society will be positive. The average impact on an individual in society may not correspond to the experience of any actual person, since the welfare change for the average person is simply a weighted average of the welfare change of each of the citizens in society.

<sup>94</sup> See, e.g., Pauly, *supra* note 61, at 101-02 ("The constitutional perspective . . . makes the potential compensation test more attractive. If society follows the cost-benefit rule, on average every person can expect to be better off; the chance that the person will win will more than offset, in expectational terms, the chance that the person will lose.").

<sup>95</sup> Uwe Reinhardt presents an entertaining account of how the KH efficiency test can be used to justify perverse outcomes. See Uwe E. Reinhardt, *Reflections on the Meaning of Efficiency: Can Efficiency Be Separated from Equity?*, 10 *YALE L. & POL'Y REV.* 302,

It is natural to be sympathetic to citizens who experience uncompensated harm due to a rulemaking decision, but the focus on a single rulemaking in societal analysis is misplaced.<sup>96</sup> The key question is whether to embed the KH test in a statute, an executive order, a judicial-review doctrine, an OMB directive, or in the standard operating procedures of agencies. In order to offer an informed assessment of the KH test in this larger context, the long-run properties of KH reasoning need to be considered.<sup>97</sup>

Viewed from an *ex ante*, long-run perspective, uncompensated harm from one rule does not necessarily raise deep philosophical problems. After all, limiting lifesaving rules to those that pass the Pareto test would compel society to forego many lifesaving regulations that would have a net positive impact on social welfare. It is these regulations that the KH test seeks to permit, even though some—possibly many—losers are expected to result from each individual rulemaking.<sup>98</sup>

If society applies the KH test in multiple rulemakings, and if there is considerable mixing of gainers and losers over time, we should expect most citizens in society to become better off than they would have been under the Pareto test.<sup>99</sup> The more widely the KH test is applied across rulemakings, programs, and agencies, and the more mobile citizens in society are, the more likely it is that different segments

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312-313 (1992) (proposing a scenario in which someone who has struck a bargain to punch another person in the nose, does punch that person, and then refuses to pay the person the agreed-upon sum will have created social welfare under a Kaldorian analysis).

<sup>96</sup> See, e.g., NG, *supra* note 52, at 52 (“We do not adopt [a social-welfare function] to guide our social choice for one particular known instance only. Rather, once [a social-welfare function] is adopted, it is used for all instances until, for some reason, it has been discarded in favour of another.”); Robert H. Frank, *Melding Sociology and Economics: James Coleman’s Foundations of Social Theory*, 30 J. ECON. LITERATURE 147, 160 (1992) (“[I]t is a mistake to evaluate the efficacy of cost-benefit analysis in terms of its effects on specific individuals in a single case. If the cost-benefit criterion is employed as a *policy* for resolving large numbers of social decisions, what is relevant is the *pattern* of decisions it produces.”).

<sup>97</sup> See, e.g., Frank, *supra* note 96, at 160 (“Though a person may suffer an uncompensated loss from many policy changes that pass a cost-benefit test, he will also reap an unencumbered benefit from many others. What matters is the net effect of the policies implemented under a cost-benefit criterion . . .”).

<sup>98</sup> Matthew D. Adler & Eric A. Posner, *Rethinking Cost-Benefit Analysis*, 109 YALE L.J. 165, 170 (1999).

<sup>99</sup> See J.R. Hicks, *The Rehabilitation of Consumers’ Surplus*, 8 REV. ECON. STUD. 108, 111 (1941) (contending that the effects of repeated social reorganizations based on Kaldor-Hicks efficiency would be to create many more overall gainers than losers).

of the public will be affected, which means that more mixing of gainers and losers would be likely to occur.<sup>100</sup> As more mixing occurs, a larger percentage of citizens, not just the average citizen, will experience net gains from repeated application of the KH test.<sup>101</sup>

But does this argument apply to life-threatening risks, where a person may be a casualty in one rulemaking, and thus unable to benefit from many future rulemakings that reduce risk?<sup>102</sup> As long as the lifesaving dilemma is analyzed from an *ex ante* perspective, and as long as the incremental change in probability of death to the average citizen is small, the multiple-application argument applies to lifesaving. For example, a citizen who incurs an annual mortality risk of 1 in 10,000 per year from one rule can experience a decline in yearly mortality risk of 1 in 10,000 from another rule. We shall explore this complication in more detail below, when we consider rational analysis of Russian Roulette.

Kaldor and Hicks did not claim that, in the long run, everyone will be better off under the Kaldor-Hicks test.<sup>103</sup> If that claim could have been established, proponents of the KH test could have argued that the Pareto test will be satisfied in the long run. Pareto reasoning has always had substantial moral appeal in both economics and philosophy.<sup>104</sup>

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<sup>100</sup> See MISHAN, *supra* note 27, at 171 (“[E]ven though it may be the case that for each change sanctioned by the [potential] Pareto criterion a number of people will be made worse off, a succession of such changes is not likely to inflict losses on the same group.”).

<sup>101</sup> See A. Mitchell Polinsky, *Probabilistic Compensation Criteria*, 86 Q. J. ECON. 407, 415 (1972) (“[I]f . . . there is sufficient geographic mobility, then, on balance, everyone is likely to be better off [under repeated application of the compensation principle].”). For the formal proof of the long-run power of Kaldor-Hicks efficiency in multiple applications, see *id.* at 412-23.

<sup>102</sup> A similar question has been raised by Ian Malcolm David Little:

It is clear that if we are considering the welfare of a changing group of real people over a long period, then we cannot literally deal with individuals [in part because many of them will be dead]. It becomes a question of whether we are better off than our fathers, or grandfathers.

I.M.D. LITTLE, A CRITIQUE OF WELFARE ECONOMICS 94 (retrospective reissue 2002).

<sup>103</sup> Some have argued that the repeated-application argument is compelling enough to create a “presumption that everyone or nearly everyone will be made better off by consistent application of the [potential] Pareto criterion.” MISHAN, *supra* note 27, at 171.

<sup>104</sup> See, e.g., ADLER & POSNER, *supra* note 2, at 25 (asserting that the criterion of Pareto superiority is “morally significant”).

But if a decision is to be made outside of the original position, with the veil removed, an appeal to the Pareto test<sup>105</sup> will not work as a defense of the KH test, even in the long run. Without complete compensation of each loser on a rule-by-rule basis, there is simply no way to know whether everyone will be better off in the long run.<sup>106</sup> Some citizens (e.g., those who are late in their life span) may not live long enough to experience enough gains to offset early losses. Moreover, whether because of chance or some systematic mechanism that creates repeated losses, it is possible that a single person or a group of persons will experience net losses after repeated application of the KH test.<sup>107</sup> Moreover, without knowing how long the long run will be, it is not clear how compelling the claim of long-run gain is.

The proper conclusion is that long-run use of the KH test may generate some losers. Fortunately, that conclusion is not necessarily a showstopper. When we rejected the strict Pareto test, we implicitly accepted a moral test that creates losers. Indeed, the Pareto test was rejected precisely because the no-loser stipulation was too stringent. Thus, the long-term application of the KH test may be defensible on its own terms (e.g., as an operational form of welfarism or preference-based utilitarianism), even if it does not satisfy the Pareto criterion.<sup>108</sup>

In order to complete a defense of the long-run KH test, we need a moral standard for judging when losses to some persons or communities are tolerable (e.g., because they were incurred knowingly by society, behind the veil, in pursuit of overall social welfare) and when such losses constitute a distributional injustice that should not be tolerated.<sup>109</sup> The answer that I shall sketch (in Part V) concerns situations

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<sup>105</sup> See, e.g., *id.* at 22 (“[T]he Kaldor-Hicks standard is sometimes defended by reference to the Pareto standard. Indeed, it is often called the ‘potential Pareto’ standard.”).

<sup>106</sup> See, e.g., FRIEDMAN, *supra* note 62, at 174 (arguing that one cannot assume that long-run application of the KH test will make everyone better off because no one knows whether the gains and losses from multiple policy decisions “are distributed randomly”).

<sup>107</sup> See LITTLE, *supra* note 102, at 113-14 (noting the difficulty of relying on an assumption of randomness of distribution effects).

<sup>108</sup> Professor Adler properly rejects as specious a long-run defense of the KH test based on the contention that it satisfies the Pareto test, but he says little about why a long-run KH policy should not be considered morally attractive in its own right. Adler, *supra* note 48, at 252-59.

<sup>109</sup> See, e.g., MISHAN, *supra* note 27, at 170 (“[I]t is not enough that the outcome of an ideal cost-benefit analysis be positive. It must be shown, among other things, that the resulting distributional changes are not perceptibly regressive and that no gross inequities are perpetrated.”).

where the losers have certain characteristics (e.g., they are poor) that raise justice-related concerns. There are creative amendments to the KH test that can address some concerns of injustice without losing all of the test's attractive properties.

The long-run KH argument is already influential in other public policy settings. Buttressed by the ex ante, constitutional perspective,<sup>110</sup> and the assurance of repeated application,<sup>111</sup> the KH test is routinely used in antitrust enforcement<sup>112</sup> and other forms of economic regulation (e.g., easing pricing and entry controls in the airline industry<sup>113</sup> and reducing tariffs against imported goods sold in the United States). Internationally, the case for liberalized trade policies has fairly broad acceptance on KH grounds, even though such policies do hurt some households and communities.<sup>114</sup>

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<sup>110</sup> See, e.g., Pauly, *supra* note 61, at 101-02 (asserting that a constitutional framework is likely to lead to the selection of an expected-utility standard); John W. Pratt & Richard J. Zeckhauser, *Willingness to Pay and the Distribution of Risk and Wealth*, 104 J. POL. ECON. 747, 757 (1996) ("Thinking about WTP before the whole process gets underway provides a helpful guideline in approaching these commitment and allocation issues.").

<sup>111</sup> See Polinsky, *supra* note 101, at 423 ("The reinterpretation of [the potential] Pareto[] criterion in terms of likelihood rather than certainty, and for many changes rather than one change, has greatly increased its usefulness for public sector allocative decision making, although at some cost in terms of guaranteeing that no one would actually be made worse off.").

<sup>112</sup> Even though monopolists are losers in antitrust regulation, the gains to consumers are estimated to be large enough to outweigh these losses. Monopolists are not typically compensated for their losses. See Jules L. Coleman, *Efficiency, Exchange, and Auction: Philosophic Aspects of the Economic Approach to Law*, 68 CAL. L. REV. 221, 247 (1980) (explaining that monopolists are not compensated because they are not thought to "deserve" such compensation after inhibiting free competition).

<sup>113</sup> See FRIEDMAN, *supra* note 62, at 169 (arguing that deregulation of the airlines passed by Congress in 1978 was based on Kaldor-Hicks reasoning, in that Congress knew that there would be winners and losers but sought to advance overall welfare and efficiency).

<sup>114</sup> When a country reduces tariffs on imported goods, harm is inflicted upon workers and investors in domestic industries subjected to intensified import competition. See WILLIAM J. BAUMOL & ALAN S. BLINDER, *ECONOMICS: PRINCIPLES AND POLICY* 722 (10th ed. 2006). But economic analysis suggests that these harms are typically more than offset by the widespread gains to consumers who can purchase tariff-free goods from importers. Free trade does not, however, necessarily satisfy the Pareto principle. Trade liberalization rarely proceeds with full compensation of displaced workers. In the final analysis, the KH argument for trade liberalization is that modest net benefits for the vast majority of the population are sufficient to justify concentrated—and sometimes severe—harms experienced by a relatively small number of people. See GRAMLICH, *supra* note 27, at 42-43 (using the Trade Readjustment Assistance Act, 19 U.S.C. § 2271-2321 (2006), which provides for payments to unemployed workers in industries harmed by rapid increases in imports, as an example of the im-

## 2. Unjust Distributions of Income and Wealth

When lifesaving opportunities are assessed using money as the metric, concerns about fairness arise because people with the same intensity of preference for lifesaving may have unequal access to money.<sup>115</sup> Thus, use of the monetary metric will reflect ability to pay as well as intensity of preference.<sup>116</sup> If the income distributions of those who gain and lose under a given rule are similar, this concern does not have policy relevance. However, it is quite possible that low-income citizens will be concentrated disproportionately among the gainers or among the losers.

A poor person may benefit enormously from a lifesaving rule, but the WTP value is constrained by his or her meager income and the corresponding need to preserve this income to meet pressing subsistence needs. Moreover, the WTA value for a poor person facing a life-threatening risk may be small relative to that of a rich person because a small amount of compensation appears more substantial to the poor, given their meager resources.

Insofar as a poor person's wealth position is viewed as unjust, and his or her WTP or WTA values would have been different under a just distribution of wealth, a more just distribution of income in society would justify more or less lifesaving regulation. Inescapably, the case for or against the KH test becomes embroiled in deeper debates about how wealth should be distributed in society.<sup>117</sup>

Proponents of the KH test make several arguments in response to distributional concerns. Some agree that society should address injustices but argue that the fixes should occur separately from the application of the KH test.<sup>118</sup> For example, tax and income-security programs

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plementation of Kaldor-Hicks principles—the gainers (consumer-taxpayers) compensate the losers (workers in domestic industries)).

<sup>115</sup> Even proponents of BCA acknowledge that in some situations a utility test will reach a different result than a monetary cost-benefit test. See, e.g., MISHAN, *supra* note 27, at 200 (“Clearly a cost-benefit criterion that is not met in money terms may be met when translated into utility terms, and vice versa.”).

<sup>116</sup> See ADLER & POSNER, *supra* note 2, at 18 (“CBA reflects both preference intensity, which we do care about, and wealth, which we do not care about . . .”).

<sup>117</sup> Cf. Jules Coleman, *Efficiency, Utility, and Wealth Maximization*, 8 HOFSTRA L. REV. 509, 524-25 (1980) (asserting that a set of initial entitlements, including wealth distribution, is necessary to get the KH system started, but that the KH test has no ability to define how initial entitlements should be allocated).

<sup>118</sup> See, e.g., Lewis A. Kornhauser, *On Justifying Cost-Benefit Analysis*, 29 J. LEGAL STUD. 1037, 1054 (2000) (“Cost-benefit analysis does in fact ignore distributional concerns, but one might argue that administrative agencies that regulate health and safety

are considered a more effective and efficient way to redistribute wealth than reconsidering each lifesaving regulation on grounds of unfair distribution.<sup>119</sup> Once a fair distribution of wealth is accomplished,<sup>120</sup> these scholars seek a separate screening of each regulation through an application of the KH test.<sup>121</sup> But politicians may choose not to use taxes and transfers appropriately to solve injustices in the distribution of income and wealth.<sup>122</sup> Until politicians correct the unjust wealth distribution, some will argue that each regulation should be evaluated on the basis of distributional justice as well as Kaldor-Hicks efficiency.<sup>123</sup>

An alternative analytic approach is to devise a weighted form of BCA in which the weights reflect various notions of distributional equity or justice.<sup>124</sup> For example, the WTP of the poor might be

ought not to take such distributional concerns into account; these concerns should be left to the relevant redistributive institutions in the society.” (footnote omitted); *see also* Robert H. Frank, *Why Is Cost-Benefit Analysis So Controversial?*, 29 J. LEGAL STUD. 913, 917 (2000) (“We can employ unweighted willingness-to-pay measures without apology, and use the welfare and tax system to compensate low-income families *ex ante* for the resulting injury.”).

<sup>119</sup> *See, e.g.*, Louis Kaplow & Steven Shavell, *Why the Legal System Is Less Efficient than the Income Tax in Redistributing Income*, 23 J. LEGAL STUD. 667, 674-75 (1994) (arguing that the income tax can accomplish redistribution more efficiently than legal rules and that, therefore, “normative economic analysis of legal rules should be primarily concerned with efficiency rather than the distribution of income”).

<sup>120</sup> Note that the KH test itself does not specify how, in seeking to achieve a fair distribution of wealth, the initial assignment of rights and wealth should be accomplished. *See* Ronald M. Dworkin, *Is Wealth a Value?*, 9 J. LEGAL STUD. 191, 193 (1980) (“It has often been pointed out that almost any widespread distribution of resources meets [the KH] test.”).

<sup>121</sup> *See* Frank, *supra* note 96, at 160 (“Once we focus on finding a general policy for making large numbers of social decisions and recognize that compensation for general biases is possible through the tax system, it becomes clear that we have had a perfectly good social choice mechanism all along, namely the cost-benefit criterion.”).

<sup>122</sup> There is a substantial body of literature objecting to any assumption that distributional injustices will be addressed appropriately through changes in taxes and transfers. *See, e.g.*, Dworkin, *supra* note 120, at 218 (“[I]f the familiar assumption is right, that optimal utility would require much more equality of wealth than now exists in our country, the hypothesis that the legislatures, federal and state, have been busy redistributing in search of utility seems embarrassingly disconfirmed.”); Yew-Kwang Ng, *Quasi-Pareto Social Improvements*, 74 AM. ECON. REV. 1033, 1040 (1984) (“The upper and middle classes will not only vote a government out of office for carrying out drastic changes in taxation but also for carrying out other drastic redistributive measures.”).

<sup>123</sup> *See* Kornhauser, *supra* note 118, at 1054 (“[T]he redistributive failings of cost-benefit analysis may seem more pressing if the redistributive institutions of society are inadequate . . .”).

<sup>124</sup> The myriad possible distributional weights raises a larger point: the KH test can be considered arbitrary, since there are infinite ways to weight the inputs.

weighted more than the WTP of the rich for the same lifesaving effect.<sup>125</sup> Although this approach has some intuitive appeal, it has proven to be difficult to implement.<sup>126</sup> There is no consensus about how the weights should be derived.<sup>127</sup>

Others concede that the distributional objection is valid and that a separate test of distributional fairness needs to accompany the Kaldor-Hicks test on a rule-by-rule basis. That is my position. In Part V, I recommend a distributional amendment to the KH test that protects the poor but retains many of the attractive aspects of the test.

In summary, the proper distribution of wealth in society is obviously an important issue, but the evaluation of a lifesaving rule is not always sensitive to distributional concerns.<sup>128</sup> When both gainers and losers from a lifesaving regulation comprise substantial numbers of poor and wealthy citizens, different wealth distributions may make little difference to the results of BCA.<sup>129</sup> Although some lifesaving rules may benefit (or harm) the poor disproportionately, few empirical studies address how the benefits and costs of lifesaving rules are distributed across income classes.<sup>130</sup> In Part V, I suggest how to set in motion these studies through institutional reform of the rulemaking process.

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<sup>125</sup> For a textbook treatment sympathetic to distributional weights, see TEVFIK F. NAS, *COST-BENEFIT ANALYSIS: THEORY AND APPLICATION* 151-53 (1996).

<sup>126</sup> See Matthew D. Adler & Eric A. Posner, *Implementing Cost-Benefit Analysis When Preferences Are Distorted*, 29 J. LEGAL STUD. 1105, 1144 (2000) (“[I]t is unclear whether the basic idea of distributive weighting is itself a feasible one.”); Jean Drèze, *Distribution Matters in Cost-Benefit Analysis: Comment on K.A. Brekke*, 70 J. PUB. ECON. 485, 486 (1998) (asserting that the oft-used aggregate benefit criterion, which does not use distributional weights, is theoretically flawed, and using the World Bank as an example of an institution that, “contrary to its own guidelines,” has nevertheless moved away from a weighted approach and toward an aggregate-benefit approach).

<sup>127</sup> See, e.g., JUST ET AL., *supra* note 69, at 41 (“Apparently, little hope exists for determining a social welfare function on which general agreement can be reached.”); Scott Farrow, *Environmental Equity and Sustainability: Rejecting the Kaldor-Hicks Criteria*, 27 ECOLOGICAL ECON. 183, 184 (1998) (“[Distributional weights] are often considered arbitrary by outside viewers and can add substantially to the effort involved in a benefit-cost analysis.”).

<sup>128</sup> See Kaplow & Shavell, *supra* note 50, at 993 (“If legal rules are likely to have little distributive effect, it will do little harm to ignore this effect in the analysis.”).

<sup>129</sup> See MISHAN, *supra* note 27, at 170 (“More often than not, the distributional effects [of a government project] on society as a whole are not large.”).

<sup>130</sup> On the case for treating high-income and low-income groups differently in BCA, see BOARDMAN ET AL., *supra* note 27, ch. 18.

### 3. Willingness to Pay or Willingness to Accept?

A variety of legal scholars are concerned that the Kaldor test, as implemented in BCA, constrains the measure of benefit by counting only the maximum WTP of those whose lives might be saved by a rule. Why not instead apply the Hicks rule, assessing what the lifesaving beneficiaries would have to be paid in compensation to forego the rule, and compare that amount to the WTP of losers to avoid the adverse impacts of the rule?<sup>131</sup> A lifesaving rule might be analyzed differently if the initial rights are assigned to the potential “victims” of risk rather than to the risk generators.<sup>132</sup> Thus, critics see the KH test as either indeterminate<sup>133</sup> or biased against the interests of lifesaving beneficiaries.<sup>134</sup>

When the probability of harm to life and limb is large, critics of the KH test have a valid point about indeterminacy. For example, it is hard to imagine that people would be willing to play a round of Russian Roulette, even if the revolver has only one out of six chambers filled with a deadly bullet, and even if an enormous financial offer is made to those who choose to play.<sup>135</sup> In this setting, most people presumably have a WTA value that is not just huge but infinite.<sup>136</sup>

Let us also consider the dilemma of those forced to play Russian Roulette—an admittedly hypothetical thought experiment. Their

<sup>131</sup> This is the question asked by Richard S. Markovits, *Legal Analysis and the Economic Analysis of Allocative Efficiency: A Response to Professor Posner's Reply*, 11 HOFSTRA L. REV. 667, 669-71 (1983), which argues that the former approach “bias[es] decision-making in favor of the status quo.” For an updated version of this perspective, see RICHARD S. MARKOVITS, TRUTH OR ECONOMICS: ON THE DEFINITION, PREDICTION, AND RELEVANCE OF ECONOMIC EFFICIENCY 51-53 (2008).

<sup>132</sup> See, e.g., Donald T. Hornstein, *Reclaiming Environmental Law: A Normative Critique of Comparative Risk Analysis*, 92 COLUM. L. REV. 562, 616-29 (1992) (emphasizing the importance of the initial allocation of property rights, which determines whether WTP or WTA measures are employed, and speculating that barriers to coal plants would be significant if the community, rather than the coal plant owners, had the initial property right).

<sup>133</sup> See, e.g., Sinden, *supra* note 67, at 1426 (“People generally demand more to give up an existing entitlement than they would be willing to pay to acquire that entitlement. Yet no one has been able to come up with a theoretically defensible basis on which to choose one value over the other.” (footnote omitted)).

<sup>134</sup> See, e.g., Thomas O. McGarity, *Professor Sunstein's Fuzzy Math*, 90 GEO. L.J. 2341, 2370 (2002) (“[T]he adoption of the willingness-to-pay test can (and usually does) bias the analysis against regulatory intervention.”).

<sup>135</sup> The Russian Roulette problem is analyzed in more detail in VISCUSI, *supra* note 7, at 151.

<sup>136</sup> See JOHANSSON, *supra* note 5, at 60 (concluding that an infinite WTA value may occur with certain death as well as “a range of probabilities” near certainty).

WTP for removing the lone bullet is constrained: it cannot exceed their wealth position. Thus, the WTP and WTA values for a single bullet in Russian Roulette must differ significantly, even though a single bullet carries the same probability of instant death: one in six, under both valuations.

A different result is obtained when the probability of harm is small.<sup>137</sup> Under this condition,<sup>138</sup> there are no obvious grounds (ex-

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<sup>137</sup> Professor Heinzerling interprets the writings of some economists as suggesting that higher valuations are properly assigned to identified people who face large or even certain risks of premature death than to one statistical death that comprises a large number of people incurring a small probability of premature death (a "statistical life"). Heinzerling then argues that there are no normative grounds for giving more priority to identified than to statistical lives: "[T]he rights of people not to be harmed should not depend on the identifiedness of the people who will be harmed." Lisa Heinzerling, *The Rights of Statistical People*, 24 HARV. ENVTL. L. REV. 189, 196 (2000). But from a strictly rational-choice perspective, there is no reason to expect that WTP to save an identified life will necessarily be greater than WTP to save a statistical life. See VISCUSI, *supra* note 7, at 21 (arguing that the WTP to save two identified lives should be the same as the WTP to save two statistical lives); Pratt & Zeckhauser, *supra* note 110, at 752-53, 753 n.9 (noting that while holding constant the expected risk, the WTP value may be greater for a community exposure than for an identified life because of the income constraint that the identified person faces, but that if the WTA measure is employed, the result flips, since the identified life at risk will presumably have infinite valuation). A more recent analysis concludes, based on rational-choice theory, that WTP to prevent identified deaths may be larger or smaller than WTP to prevent the same number of statistical deaths because there are opposing considerations that individuals may resolve differently. See Hammitt & Treich, *supra* note 6, at 62-63 (suggesting that political factors such as "responsibility, empathy, lobbying, and demagoguery," rather than BCA principles, help to explain the public bias towards spending more generously to save the lives of identified rather than statistical victims).

<sup>138</sup> Professor Driesen argues that this condition (small risks) never exists because, under the idealized and full-information assumptions of the Kaldor-Hicks test, the identity of those whose lives will be saved by regulation (or lost due to a decision not to regulate) are known with certainty. David M. Driesen, *The Societal Cost of Environmental Regulation: Beyond Administrative Cost-Benefit Analysis*, 24 ECOLOGY L.Q. 545, 588-90, 590 n.196 (1997). But Professor Driesen exaggerates what is meant by the idealized, full-information approach in welfare economics. "Full information" means that the potential beneficiaries of a regulation are entitled to know as much as can be known, given current science, but this does not imply access to a crystal ball that transcends the best current knowledge. Under a science-informed construct of perfect information, life-saving regulations will typically save anonymous, unidentified lives because current science is not advanced enough to determine which people in an exposed population will succumb to hazardous exposure and which will be saved by regulation. (If such knowledge existed, different policy options aimed at protecting those individuals would be worth considering.) Thus, the idealized and full-information assumptions of the Kaldor-Hicks test do not transform all statistical lives into identified lives. See Kenneth J. Arrow, *Behavior Under Uncertainty and its Implications for Policy*, in FOUNDATIONS OF UTILITY AND RISK THEORY WITH APPLICATIONS 19, 25-26 (B.P. Stigum & F. Wenstop eds., 1983).

cept for a tiny income effect) for expecting that a person's WTA value for risk imposition will exceed his or her WTP value for avoidance of the same risk. Thus, the minimum price reduction necessary to induce a consumer to purchase a somewhat smaller car with an incremental risk of death equal to 1 in 10,000 per year should be roughly equal to that same consumer's maximum WTP for an improved side-impact airbag that prevents an incremental annual risk of death of 1 in 10,000 per year.<sup>139</sup>

Most published surveys find that WTA values far exceed WTP values for the same good, though less so for ordinary private goods.<sup>140</sup> Only a limited number of surveys compare WTA and WTP values for changes in the risk of death, but those that do also find discrepancies.<sup>141</sup> Should these discrepancies be treated as informed departures from rational choice or do they reflect psychological foibles? Although the literature is not in consensus on this point,<sup>142</sup> the weight of

<sup>139</sup> Strictly speaking, there is a distinction between the WTA value for a risk increase and the WTA value for being deprived of a risk decrease of equal magnitude. Likewise, there is a difference between WTP for a risk reduction and WTP to avoid a risk increase of the same magnitude. In the small-risk range, one would not expect sharp kinks in the indifference curves relating wealth and risk (i.e., increases in risk should not be much more harmful than decreases in risk are beneficial). In the context of WTP, this simplification is similar to the approximation that WTP is nearly proportional to risk reduction for small risks. See, e.g., Hammitt & Treich, *supra* note 6, at 55-56.

<sup>140</sup> See John K. Horowitz & Kenneth E. McConnell, *A Review of WTA/WTP Studies*, 44 J. ENVTL. ECON. & MGMT. 426, 442 (2002) (explaining that an individual's WTA regarding the loss of a good is valued higher than her WTP regarding acquisition of the same good and that the "high observed WTA/WTP ratios do not appear to be experimental artifacts").

<sup>141</sup> The difference was first noted in a pilot study of emergency response for heart attack victims. JAN PAUL ACTON, *EVALUATING PUBLIC PROGRAMS TO SAVE LIVES: THE CASE OF HEART ATTACKS* (1973). The differences between WTA and WTP in the life-saving literature are "unexpectedly large," and there is no "simple and completely convincing explanation." JOHANSSON, *supra* note 5, at 38; see also W. Kip Viscusi et al., *An Investigation of the Rationality of Consumer Valuations of Multiple Health Risks*, 18 RAND J. ECON. 465, 469 (1987) ("Our hypothesis is that individuals exaggerate the magnitude of any increases in risk from levels to which they have become accustomed. . . . Even for very small changes in risk for which buying and selling prices for risk should be identical, the compensation required to accept an increase in risk will be much greater if there is a reference risk effect.").

<sup>142</sup> See FREEMAN, *supra* note 61, at 85-87 (stating that because the theory suggests that WTP and WTA values should be "approximately equal in most circumstances," the persistent differences found in the literature are "troubling").

the evidence suggests that the discrepancies do not always reflect informed rational choice.<sup>143</sup>

When subjects engage in repeated experiments with real monetary payoffs, some (but certainly not all) of the large differences between WTP and WTA values diminish, especially for private goods and services.<sup>144</sup> The convergence appears to be caused more by lowered WTA values than by larger WTP values; convergence may be nearly complete if subjects have clear incentives to be honest about their preferences.<sup>145</sup> Thus, more familiarity and experience with making WTP and WTA decisions may cause the two quantities to converge.<sup>146</sup>

Highly trained decision analysts who consider the risk-wealth dilemma for themselves report a large divergence between WTP and WTA, but not until the incremental risk of instantaneous death becomes quite high, greater than 1 in 1000.<sup>147</sup> Most life-threatening risks

<sup>143</sup> See VISCUSI, *supra* note 7, at 19 (“[T]here is often an alarmist reaction to increases in risk above the accustomed level so that willingness-to-accept amounts may dwarf the willingness-to-pay amounts if we respond irrationally to the risks.”).

<sup>144</sup> See Jason F. Shogren et al., *Resolving Differences in Willingness to Pay and Willingness to Accept*, 84 AM. ECON. REV. 255, 266 (1994) (explaining that for market goods with readily available substitutes, “WTA and WTP measures of value converge” in repeated experiments with real monetary payoffs, but that convergence does not occur with nonmarket goods, such as reduced health risks, “even with repeated market participation and full information on the nature of the good”).

<sup>145</sup> See David W. Harless, *More Laboratory Evidence on the Disparity Between Willingness to Pay and Compensation Demanded*, 11 J. ECON. BEHAV. & ORG. 359, 375-76 (1989) (discussing the results of a study that showed a decreased disparity between WTP and WTA when the truthful reporting of preferences is incentivized).

<sup>146</sup> See MITCHELL & CARSON, *supra* note 45, at 34-35 (citing a study suggesting that the more familiar a respondent is with the contingent-value scenario, the greater the convergence between WTP and WTA). *But see* Horowitz & McConnell, *supra* note 140, at 442 (“[F]amiliarity with the experiments does not uniformly lead to lower [WTA/WTP] ratios.”).

<sup>147</sup> See Ronald A. Howard, *On Fates Comparable to Death*, 30 MGMT. SCI. 407, 408 (1984) (defining a probability of death that is sufficiently large that no amount of money would induce a person to incur it, showing that WTP is equal to WTA for small incremental changes in the probability of death, and providing an example where WTP and WTA begin to diverge at probabilities of death near 1 in 1000); Ronald A. Howard, *On Making Life and Death Decisions*, in SOCIETAL RISK ASSESSMENT: HOW SAFE IS SAFE ENOUGH? 89, 92-101 (Richard C. Schwing & Walter A. Albers, Jr., eds., 1980); *see also* James E. Smith & Ralph L. Keeney, *Your Money or Your Life: A Prescriptive Model for Health, Safety, and Consumption Decisions*, 51 MGMT. SCI. 1309, 1319 (2005) (noting that for risks larger than 1 in 1000, “WTP and WTA amounts diverge”—at 1 in 1000 risk of death, WTA equals \$6,494 and WTP equals \$6,381, while for a risk of death greater than 0.057, WTA is infinite).

of concern to regulators are smaller than 1 in 1000, usually ranging from 1 in 10,000 to 1 in 10,000,000 on an annual basis.<sup>148</sup>

It is reasonable for a person's WTA value to exceed WTP when the good being valued is not fungible in markets (i.e., there is not much substitutability).<sup>149</sup> Decisions about small risks to life and limb are fairly common in daily life.<sup>150</sup> However imperfectly, people can equilibrate their WTP and WTA values for small risks when they make basic decisions about how large a car to drive (other things equal, a larger car is safer for the owner in crashes but costs more to purchase and operate), where to live (cleaner areas of Los Angeles tend to have higher apartment rents and housing prices), how many smoke detectors to install at home, how much to exercise each day, or what foods to eat. Even for apparently "involuntary" risks (e.g., increased exposure to outdoor air pollution), people can frequently substitute related risks (e.g., reduced exposure to indoor air pollutants) through personal actions.<sup>151</sup>

Even if the philosophical case is compelling that the initial entitlement should reside with the lifesaving beneficiaries from regulation, and thus the WTA value is normatively appropriate, measurement concerns may counsel against use of WTA. Scholars and practitioners of BCA argue for use of the WTP measure as a surrogate for the difficult-to-estimate WTA value.<sup>152</sup> The preference for the

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<sup>148</sup> On the levels of risk that typically concern federal regulatory agencies, see, for example, March Sadowitz & John D. Graham, *A Survey of Residual Cancer Risks Permitted by Health, Safety and Environmental Policy*, 6 RISK 17 (1995). Most average risks in life from specific technologies are smaller than the average risks of work, transportation, and recreation. For a statistical comparison of numerous risks in life, see WILSON & CROUCH, *supra* note 32, ch. 7.

<sup>149</sup> See W. Michael Hanemann, *Willingness to Pay and Willingness to Accept: How Much Can They Differ?*, 81 AM. ECON. REV. 635, 635 (1991) (arguing that the difference in value between WTP and WTA depends in part on "the ease with which other privately marketed commodities can be substituted for the given public good or fixed commodity, while maintaining the individual at a constant level of utility").

<sup>150</sup> See FREEMAN, *supra* note 61, at 299 (discussing the ways in which longevity is treated in making everyday decisions).

<sup>151</sup> See Hammitt, *supra* note 84, at 990 n.9 (explaining that individuals can purchase more or less of a private good to compensate for their exposure to more or less of a public good); see also ENVTL. ECON. ADVISORY COMM., EPA, AN SAB REPORT ON EPA'S WHITE PAPER *VALUING THE BENEFITS OF FATAL CANCER RISK REDUCTION* 17 (2000), available at <http://yosemite.epa.gov/sab/sabproduct.nsf/webReportsbyYearBOARD!OpenView> (click on "2000," then on report title) (listing various ways in which people can adapt to environmental exposures).

<sup>152</sup> See W. Kip Viscusi, *Economic and Psychological Aspects of Valuing Risk Reduction, in DETERMINING THE VALUE OF NON-MARKETED GOODS* 83, 93 (Raymond J. Kopp et al. eds., 1997) (noting that the disparity between WTA and WTP values may relate to re-

WTP metric partly reflects practical realities: the tools for measuring WTP values are better developed than the tools for measuring WTA values, especially in lifesaving applications, where an upward bias in WTA values has been detected.<sup>153</sup>

If the WTP and WTA values are obtained through surveys rather than revealed preferences,<sup>154</sup> the possibility of strategic behavior, including various forms of “protest” responses, needs to be considered.<sup>155</sup> A respondent may be tempted to exaggerate their WTP for safety improvement (in order to make it more likely to become reality), but there is a firm upper bound on their WTP rooted in their wealth position. In contrast, some subjects may respond to a WTA question by insisting that they would require infinite financial compensation to accept even tiny risks of premature death.<sup>156</sup> Practitioners have found that strategic responses are more common with WTA than WTP questions.<sup>157</sup>

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spondents’ “fundamental distrust of the veracity of the risk claims once having learned that their product has become riskier,” and concluding that it is “preferable to rely on willingness-to-pay amounts even if the appropriate policy measure pertains to a willingness-to-accept value”).

<sup>153</sup> See Hammitt, *supra* note 84, at 990 (“Estimated WTA is often viewed as implausibly large, and so attention has focused on estimating WTP even when WTA might seem conceptually more appropriate.”).

<sup>154</sup> It seems unlikely that the empirical discrepancy between WTP and WTA for the same risk change will be successfully estimated through studies of labor markets, since the wage determination may be viewed as a compromise between the two valuations. Well-designed stated-preference studies are the best hope for understanding the size of the differences between WTP and WTA, though progress is needed in the proper framing of the WTA questions. I thank Professor James Hammitt for making this point to me in personal communication.

<sup>155</sup> See generally John K. Horowitz & Kenneth E. McConnell, *Willingness to Accept, Willingness to Pay and the Income Effect*, 51 J. ECON. BEHAV. & ORG. 537, 544 (2003) (finding that persistently high WTA/WTP ratios extrapolated from surveys means either that the respondents do not have neoclassical preferences, or that—as an expert panel commissioned by the National Oceanic and Atmospheric Administration concluded—the WTP questions measure preferences, but the WTA questions do not).

<sup>156</sup> See, e.g., Thomas O. McGarity, *Media-Quality, Technology, and Cost-Benefit Balancing Strategies for Health and Environmental Regulation*, LAW & CONTEMP. PROBS., Summer 1983, at 159, 172 (contending that in environmental and occupational contexts, some “ideological holdouts” would not be willing to accept any price to surrender their rights); see also MITCHELL & CARSON, *supra* note 45, at 34 (pointing to surveys that found the rate of protest responses, a class that includes infinite responses, to be as high as fifty percent under the WTA format).

<sup>157</sup> See MITCHELL & CARSON, *supra* note 45, at 35 n.39 (“[I]t is unlikely that strategic behavior significantly influences WTP responses, although the same statement cannot be made about WTA responses.”).

When faced with possible strategic behavior, the analyst may be unsure whether a response is genuine or strategic.<sup>158</sup> If one protest response to a WTA question is misclassified as a genuine preference, the estimated benefits of a lifesaving rule under the WTA measure will be infinite. The ramifications of assigning infinite benefits to a small change in risk are far-reaching and potentially reckless in their policy implications for technologies (e.g., vaccines) that pose small risks. In contrast, there is an upper bound on the WTP value that is rooted in a citizen's wealth. Thus, the summation of WTP values across citizens is less sensitive to strategic behavior by respondents than the summation of WTA values.<sup>159</sup>

Surveys that generate protest responses are not uninformative. Protests may reflect a symbolic or ethical concern about a life-threatening risk.<sup>160</sup> These sentiments may reveal that normative evaluation is required from the perspective of justice, fairness, or efficiency, yet protest responses are not appropriate for inclusion in a monetary measurement of a person's preferences for lifesaving protection.<sup>161</sup> It is therefore important to make research investments in both WTA and WTP valuations, thereby helping regulators understand when and why the two measures of lifesaving value are likely to diverge.<sup>162</sup> In the future, there may be settings where policymakers

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<sup>158</sup> Cf. ADLER & POSNER, *supra* note 2, at 171 (arguing that analysts can reduce disparities between WTP and WTA and obtain more genuine responses by using research techniques "that are transparently incentive-compatible and that screen out protest votes, loss aversion, and other distortions").

<sup>159</sup> Even in the absence of strategic behavior, the WTP format may counteract an inherent upward bias in answers to hypothetical questions. See FREEMAN, *supra* note 61, at 176 (explaining that, compared to WTA responses, WTP responses have been found to require much smaller calibration adjustments to compensate for the hypothetical nature of the questions). Respondents may have a tendency to overstate their preferences since they do not have to pay money for safety or expose themselves to risk in exchange for money. *Id.* Experts in the field have generally recommended more conservative designs for the WTP method of valuation. See, e.g., Natural Resource Damage Assessments Under the Oil Pollution Act of 1990, 58 Fed. Reg. 4601, 4610 (Jan. 15, 1993) (recommending choices in formulating contingent-valuation instruments that offset the respondents' tendency to exaggerate WTP).

<sup>160</sup> See Lisa Heinzerling, *Knowing Killing and Environmental Law*, 14 N.Y.U. ENVTL. L.J. 521, 533-34 (2006) (arguing that when the WTA metric is employed, some people will not sell their entitlement to be free from imposed risks, suggesting that they may have moral reasons for refusing to participate in certain markets for risk).

<sup>161</sup> See ADLER & POSNER, *supra* note 2, at 170 ("WTP or WTA amounts that are substantially colored by moral views about the project . . . are irrelevant to CBA as we conceive it.").

<sup>162</sup> See *id.* at 173 (contending that indeterminacy due to discrepancies between WTP and WTA should decline "as preference-estimation techniques improve").

would prefer to see both WTP and WTA estimates, especially if the initial assignment of property rights is uncertain, controversial, or irresolvable.<sup>163</sup>

#### 4. Summary of KH Evaluation

From a philosophical perspective, there are at least three routes to a normative defense of the KH test: a claim that KH ultimately satisfies the Pareto test, where the Pareto test is understood to be the primitive moral standard; a claim that KH is a useful surrogate for welfare, since well-being—the proper moral standard—is not yet a practical, measurable construct; and a claim that the KH test is itself the primitive moral standard. Each of these claims has some merit.<sup>164</sup>

The second view is probably the best grounded in modern political philosophy. If this view has a weakness, it relates to ambiguity about how well-being should be defined and measured, or how WTP and WTA measures should be modified to serve as a useful surrogate for well-being. If a surrogate for well-being must be used, one also wonders whether BCA is the best available surrogate.

The first view is not tenable unless one is willing—as I am—to entertain a fairly sweeping veil of ignorance in the original position. Under those preconstitutional conditions, which I believe are consistent with the methodologies suggested by Harsanyi and Rawls,<sup>165</sup> one can make a strong argument that everyone is made better off by KH in an expectational sense.<sup>166</sup> The KH test becomes even more appealing when it is applied repeatedly in multiple rulemakings at different agencies, since the anticipated mixing of gainers and losers has the effect of producing more net winners, especially in a society that is geographically mobile.

The third view is rarely given serious consideration by philosophers, in part because they tend to focus on one-at-a-time applications

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<sup>163</sup> See Richard O. Zerbe, Jr., *Does Benefit Cost Analysis Stand Alone? Rights and Standing*, 10 J. POL'Y ANALYSIS & MGMT. 96, 102 (1991) (suggesting that both WTA and WTP values should be identified "where rights are unclear").

<sup>164</sup> For a contrary view, see Adler & Posner, *supra* note 98, at 187-194, which criticizes the conventional defenses of BCA, including the KH defense.

<sup>165</sup> See *supra* note 44 and accompanying text (describing Rawls's veil of ignorance and Harsanyi's requirement of impartiality).

<sup>166</sup> See generally Herman B. Leonard & Richard J. Zeckhauser, *Cost-Benefit Analysis Applied to Risks: Its Philosophy and Legitimacy*, in VALUES AT RISK 31, 47-48 (Douglas MacLean ed., 1986) (providing an ethical defense of "hypothetical consent" to BCA on the ground that "most individuals, in forming their social contracts," would accept society's need to make uncompensated transfers).

and in part because the proponents of the KH test have been weak in responding to the alleged distributional injustices that could be perpetrated by KH reasoning.<sup>167</sup> The real weakness in the long-run application of the KH test is the use of a monetary measure of preference satisfaction that is biased against the interests of the poor.<sup>168</sup> In Part V, I shall consider an amendment to the society-wide KH test that protects the interests of the poor without discarding the monetary measure.

In summary, we have examined two ways of thinking about when it is wise to impose a lifesaving regulation. Pure welfarism has the strongest appeal to theorists, in part because it is flexible enough to incorporate distributional concerns, but it has not yet overcome some major conceptual and measurement difficulties.<sup>169</sup> The KH test, though vulnerable to distributional criticisms, is a plausible surrogate for pure welfarism, satisfies an “expected” Pareto test, and, if modified to protect the least advantaged, may itself provide a normative foundation for BCA of lifesaving rules.<sup>170</sup>

## II. BCA AND ITS ALTERNATIVES

Regardless of which normative foundation is preferred, regulators must confront the question of how they should use BCA in regulatory decision making when lives are at stake. I thus turn to such an assessment. I also consider what the viable alternatives to BCA of lifesaving regulations might be.

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<sup>167</sup> The KH test does not suffer from a key philosophical conundrum that afflicts both utilitarianism and welfarism. The WTA measure in the KH test protects the rights of anyone whose life might be sacrificed with certainty in a society-wide deal aimed at promoting the utility or well-being of the rest of society. The sacrifice (or “knowing killing”) might pass a utility or welfarist test, but under the Kaldor test, the victims could block the action by expressing an infinite value for their loss under the WTA measure. In practice, this attractive feature of the Kaldor test is diminished because the tools of WTA measurement are poorly developed.

<sup>168</sup> See Farrow, *supra* note 127, at 183 (referring to “distributional issues” as “the Achilles’ heel of benefit-cost analysis”).

<sup>169</sup> Cf. RICHARD A. POSNER, *THE ECONOMICS OF JUSTICE* 79 (1981) (“It is easier to guess people’s market preferences in areas where the market cannot be made to work than to guess what policies will maximize happiness.”).

<sup>170</sup> See JUST ET AL., *supra* note 69, at 48 (calling the KH compensation principle “the most widely applicable, yet also empirically practical, criterion” for “aiding policy-makers in using resources optimally”).

### A. *How to Use BCA*

There are at least three distinct versions of the benefit-cost approach to regulatory decision making. I explore each version, emphasizing the practical ramifications for regulators and analysts.

#### 1. The “Hard” Test

The “hard” net-benefit test requires that the quantified benefits of a regulatory proposal exceed the quantified costs of the proposal.<sup>171</sup> Qualitative benefits or costs are irrelevant because they cannot be included in a net-benefit calculation.<sup>172</sup> Moreover, concerns about fairness in the distribution of costs and benefits are irrelevant,<sup>173</sup> at least until an accepted set of fairness weights are developed to apply to different people. Some critics of the benefit-cost approach assume (at least implicitly) that the “hard” version of the benefit-cost test is the

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<sup>171</sup> Some have argued that OIRA in the early Reagan years implemented a “hard” version of the cost-benefit test through Executive Order 12,291, 3 C.F.R. 127 (1982), reprinted in 5 U.S.C. § 601 note (1988). See, e.g., Christopher M. Heimann et al., *Project: The Impact of Cost-Benefit Analysis on Federal Administrative Law*, 42 ADMIN. L. REV. 545, 560 n.85 (1990) (describing an argument that the Reagan executive order focused exclusively on maximizing net social benefits, while disregarding “various intangible and distributional objectives”); Terry M. Moe & Scott A. Wilson, *President and the Politics of Structure*, LAW & CONTEMP. PROBS., Spring 1994, at 1, 38-39 (referring to the Reagan OIRA’s “rigorous” cost-benefit test, which “allowed agencies to issue rules only when the benefits could be shown to exceed the costs, and required them to choose among alternatives in such a way as to maximize the net benefits to society”). But see Richard B. Stewart, *A New Generation of Environmental Regulation?*, 29 CAP. U. L. REV. 21, 42 n.61 (2001) (asserting that the phrase “maximize[] net benefits” in the Reagan executive order did not specify how “net benefits” would be determined and thus “imposed little in the way of substantive constraints on agencies’ decisional discretion”).

<sup>172</sup> See Robert W. Hahn & Cass R. Sunstein, *A New Executive Order for Improving Federal Regulation? Deeper and Wider Cost-Benefit Analysis*, 150 U. PA. L. REV. 1489, 1525 (2002) (interpreting the original Reagan executive order as offering no authorization for agencies and the OMB to consider distributive effects); see also Frank Ackerman et al., *Applying Cost-Benefit to Past Decisions: Was Environmental Protection Ever a Good Idea?*, 57 ADMIN. L. REV. 155, 186 (2005) (“In the absence of hard estimates of the magnitudes involved, many benefits would typically be omitted from a cost-benefit analysis—in effect, valued at zero.”).

<sup>173</sup> Exclusion of equity considerations from regulatory deliberation often draws criticism from the environmental law community. See Hornstein, *supra* note 132, at 593-94 (arguing that regulatory decision making in any just system of environmental law “must account for equities and inequities in risk-bearing”).

only way to use BCA,<sup>174</sup> but there are few scholars or practitioners who actually recommend such a hard version of the test.<sup>175</sup>

## 2. The “Soft” Test

The “soft” benefit-cost test requires the regulator to show that the benefits of a proposal “justify” the costs. The word “justify,” instead of “exceeds,” is understood to mean that although some of the benefits and costs of a proposal may not be fully quantified or expressed in monetary units, they should nonetheless be considered by the regulator.<sup>176</sup> Thus, under a “soft” test, a regulator is permitted to promulgate a rule with quantified benefits that are less than quantified costs if a reasonable case is made that qualitative considerations are compelling enough to justify the proposal.<sup>177</sup> Likewise, “justify” is understood to mean that a nonefficiency claim (e.g., a fairness concern or equity consideration) can contribute to a determination that the benefits of a rule do, or do not, justify the costs.<sup>178</sup> Since the “soft” test does not require all impacts to be monetized, it also permits consideration of CEA based on quality-adjusted life-years (QALYs) as a supplement to BCA.<sup>179</sup>

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<sup>174</sup> Professor Sinden, for example, offers a definition of “formal economic cost-benefit analysis” that corresponds to what I have called the “hard” benefit-cost test. Sinden, *supra* note 34, at 135-36.

<sup>175</sup> Textbook treatments of the role of BCA in public policy virtually never defend the hard test. See, e.g., MISHAN, *supra* note 27, at 172 (indicating that a hard version of BCA is only one component of regulatory decision making).

<sup>176</sup> Robert W. Hahn & Patrick M. Dudley, *How Well Does the U.S. Government Do Cost-Benefit Analysis?*, 1 REV. ENVTL. ECON. & POL’Y 192, 195 (2007). Hahn notes that President Clinton’s Executive Order 12,866, 3 C.F.R. 638 (1994), *reprinted in* 5 U.S.C. § 601 (2000), “places more emphasis on distributional concerns” than does Reagan’s Executive Order 12,291, and also that the Clinton order required benefits to “justify” costs, while the Reagan order requires benefits to “outweigh” costs.

<sup>177</sup> See Hahn, *supra* note 82, at 1037 (explaining why a regulation that flunks a strict net-benefit test might pass “a more broadly defined cost-benefit test” that included consideration of nonquantifiable benefits).

<sup>178</sup> For a good discussion of a “soft” benefit-cost test that includes consideration of qualitative concerns, see Hahn & Sunstein, *supra* note 172, at 1498-1505.

<sup>179</sup> A “soft” benefit-cost test does not necessarily permit an agency to depart from established guidelines for doing BCA, at least not without careful peer review by relevant specialists in the field. For example, some of the modifications to BCA suggested by Professors Pildes and Sunstein (e.g., less reliance on monetization) and Revesz (e.g., adjustments to WTP for lifesaving based on sociological and psychological factors), see Pildes & Sunstein, *supra* note 16, at 9-10, 55; Richard L. Revesz, *Environmental Regulation, Cost-Benefit Analysis, and the Discounting of Human Lives*, 99 COLUM. L. REV. 941, 962-74 (1999), are either beyond what can be supported by valid empirical data or are outside the realm of welfarism. I share Professor McGarity’s concern that even some

For all of these reasons, the “soft” framework provides more discretion to both the analyst and the regulator than does the “hard” framework.<sup>180</sup> Nonetheless, the “soft” approach places the burden of explanation on the regulator.<sup>181</sup> If a regulation or deregulatory action is proposed despite poor benefit-cost numbers, the regulator must explain why the nonquantified benefits and costs are compelling enough to overrule the numeric results. If an equity consideration is overriding an efficiency determination, the equity claim must be explained.

### 3. The Procedural Requirement

The third approach, a procedural requirement for BCA, is conceptually different from a substantive benefit-cost test. A requirement to perform a BCA does not necessarily impose any substantive constraints on the regulator’s decision making.<sup>182</sup> Thus, under a procedural BCA mandate, the agency prepares a BCA of a proposal and the analysis is made available to inform the regulator’s decision and to inform other actors in the process (e.g., Congress, the judiciary, and the public). But no requirement is placed on the regulator to consider the results or explain why he or she did (or did not) use the results.<sup>183</sup>

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well-intended proponents of the benefit-cost state, including Professor Sunstein, may have a tendency to describe BCA as something different than what it is “commonly understood” to be. McGarity, *supra* note 26, at 63 n.284.

<sup>180</sup> Professor Driesen has expressed concern that while “[m]ost CBA proponents expect agencies to compare the non-quantified benefits to costs, not just the quantified ones[,] . . . they have nothing to say about how this could be done rationally.” David M. Driesen, *Distributing the Costs of Environmental, Health, and Safety Protection: The Feasibility Principle, Cost Benefit Analysis, and Regulatory Reform*, 32 B.C. ENVTL. AFF. L. REV. 1, 53 (2005). *But see* Hahn & Sunstein, *supra* note 172, at 1500 (interpreting the EPA’s 2001 decision to reduce the acceptable level of arsenic in drinking water as a case where “soft” considerations, including nonquantifiable benefits, were partly responsible for “tipp[ing] the balance” in favor of a stringent regulation).

<sup>181</sup> Some legal scholars fear that if the “soft” considerations are presented in conjunction with the “hard” cost-benefit numbers, the soft considerations will be short-changed. *See, e.g.*, McGarity, *supra* note 26, at 73 (“It is often difficult for decisionmakers to articulate in the lexicon of ‘rational’ analysis why a costly alternative that protects sensitive populations at the expense of all consumers is preferable to a less expensive alternative that protects most of the population.”). But my experience as OIRA administrator from 2001 to 2006 was that agency administrators were usually quite interested in qualitative considerations, sometimes to the point that they downplayed or ignored the benefit-cost numbers.

<sup>182</sup> *See* Hsu, *supra* note 19, at 396-97 (arguing that Congress should require BCA without making it “a determinative criterion or a prerequisite for regulatory action”).

<sup>183</sup> For a game-theoretic analysis supporting a procedural requirement, see Johnston, *supra* note 34, at 1354-55, 1378, 1386.

A procedural requirement is meaningful even if the substantive statute prohibits benefit-cost balancing. The analytic information may still have value to other actors, such as Congress. Some scholars contend that the mere presence of BCA in the rulemaking process influences the positions of stakeholders and the outcomes of rulemaking, even when the substantive statute does not compel (or even permit) consideration of BCA.<sup>184</sup>

#### 4. Evaluation of the BCA Approaches

Both legal and economic scholars, when considering the three approaches to BCA, are quite critical of the “hard” test, and for good reason.<sup>185</sup> A hard benefit-cost test is too restrictive for at least two independent reasons.

First, the available data may support a qualitative determination about certain costs and benefits but still be inadequate to support numeric or monetary estimates. For example, regulatory analysts may have information that indicates that reducing mercury pollution from coal plants is likely to offer some public health benefit, but, due to data gaps and modeling deficiencies, the analysts may be unable to make a meaningful numeric estimate. The hard test would appear to disqualify any qualitative information about benefits and costs, even if

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<sup>184</sup> See, e.g., Daniel A. Farber, *Revitalizing Regulation*, 91 MICH. L. REV. 1278, 1281 n.13 (1993) (book review) (noting that although EPA internal rules prohibit the agency from using BCA in determining air-quality standards under the Clean Air Act, Pub. L. No. 88-206, 77 Stat. 392 (1963) (codified as amended in scattered sections of 42 U.S.C.), the agency must conduct a Regulatory Impact Analysis, which is essentially a BCA, under Executive Order 12,291); Johnston, *supra* note 34, at 1386 (“Even though it is merely procedural . . . [, the National Environmental Policy Act’s BCA requirement] has had a surprisingly discernible impact on the behavior of federal project agencies.”).

<sup>185</sup> In personal communication, Professor Adler has suggested a more benign version of the hard test where qualitative considerations are counted in the calculus by making extensive use of subjective expert judgments about unknown physical quantities and unknown WTP values. According to his view, lifesaving regulators might be considered Bayesian decision makers who have prior numeric beliefs about all benefits and costs but use formal BCA as a procedure to update those prior beliefs based on new information. Without disputing the legitimacy of this view, I note that such widespread use of subjective probabilities and “prior beliefs” about WTP may not be compatible with the standards for information quality, sound science, and peer review that are increasingly applied by federal agencies. For textbook treatments of decision theory that are sympathetic to Adler’s view, see generally ROBERT T. CLEMEN, *MAKING HARD DECISIONS: AN INTRODUCTION TO DECISION ANALYSIS* (2d ed. 1996); HOWARD RAIFFA, *DECISION ANALYSIS: INTRODUCTORY LECTURES ON CHOICES UNDER UNCERTAINTY* (1968).

such information seems relevant to the ultimate goal of achieving Kaldor-Hicks efficiency or maximizing overall well-being. The perverse result may be blockage of promising lifesaving regulations.<sup>186</sup>

Second, the hard approach makes an incorrect assumption that KH efficiency is the only normative contribution to regulatory policy. Given our analysis of the philosophic considerations, it is apparent that other forms of normative argument (e.g., claims about distributional equity or justice) have a legitimate role in regulatory policy. That is one of the reasons that Professors Adler and Posner espouse “weak welfarism”<sup>187</sup> and why I support only a soft benefit-cost test.<sup>188</sup> Thus, the soft test is more defensible normatively because it permits consideration of equity as well as efficiency in lifesaving choices.<sup>189</sup>

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<sup>186</sup> Professor Ackerman and colleagues look retrospectively at several success stories in environmental policy (e.g., the phase-out of lead in gasoline) and determine that because these rules would not have passed a benefit-cost test at the time, BCA is unreliable as an evaluative analytic tool. See Ackerman et al., *supra* note 172. Although this is an insightful line of argument against the hard version of the benefit-cost test, the authors do not make the case that these policies would have been blocked by the soft version of the test. There are also some important weaknesses in their historical argument. They do not consider the possibility that had BCA been routine policy at the time, more effort would have been devoted to generating estimates of the benefits of these policies. See Jonathan B. Wiener, *Better Regulation in Europe*, in 59 CURRENT LEGAL PROBLEMS: 2006, at 447, 478 n.103 (Jane Holder & Colm O’Cinneide eds., 2006). The authors also do not consider any cases where promising lifesaving proposals (e.g., expansion of nuclear power instead of coal-fired power) were rejected, despite favorable benefit-cost evidence. See, e.g., PETER HUBER, *HARD GREEN: SAVING THE ENVIRONMENT FROM THE ENVIRONMENTALISTS* 20-21, 33, 189-90 (1999) (arguing that precautionary environmentalists “throttled nuclear power in the 1970s,” setting the stage for the growth of coal and global warming); Stephen Breyer, *Vermont Yankee and the Courts’ Role in the Nuclear Energy Controversy*, 91 HARV. L. REV. 1833, 1835 (1978) (citing studies suggesting that the likely alternative to expanded nuclear power is more coal-fired electricity, which is “likely to cause seven to twelve times as many deaths as nuclear plants, and four to six times as much sickness and injury”). Finally, the authors do not consider wasteful environmental policies that were implemented because of the failure to consider the results of BCA. See, e.g., JAMES T. HAMILTON & W. KIP VISCUSI, *CALCULATING RISKS? THE SPATIAL AND POLITICAL DIMENSIONS OF HAZARDOUS WASTE POLICY* 125 (1999) (citing EPA Superfund spending—a median of over \$6 billion per case of cancer prevented—as an example of potentially wasteful spending).

<sup>187</sup> ADLER & POSNER, *supra* note 2, at 26.

<sup>188</sup> See, e.g., Graham, *Legislative Approaches*, *supra* note 15, at 49 (advocating the adoption of a “benefits must justify the costs” test over a strict BCA). See generally Graham, *Agenda for Congress*, *supra* note 15.

<sup>189</sup> See FREEMAN, *supra* note 61, at 10 (arguing that it is not particularly useful to advocate BCA as a hard decision rule because decision makers also care about equity, social risk aversion, sustainability, and so forth); FRIEDMAN, *supra* note 62, at 172 (asserting that the KH compensation principle and BCA should not be considered sufficient conditions for policy choice, but rather should be considered “important” indicators of a policy’s worthiness). Related tools such as comparative risk analysis are also

If the soft test has a flaw, it is that it leaves some ambiguity about exactly how the soft considerations should be weighed in conjunction with the numbers.<sup>190</sup> Ambiguity may also be a strength, however, since regulators need discretion on a case-by-case basis to respond to the unique features of a lifesaving situation that are difficult or impossible to pre-specify by either a formula or a qualitative balancing standard. For example, risks that induce a geographic clustering of premature deaths in the same community (e.g., a nuclear meltdown, a dam that bursts, a terrorist attack similar to 9/11, or an accidental airplane crash into a neighborhood) may deserve a degree of regulatory priority greater than would be appropriate for the same number of deaths spread diffusely through the U.S. population. But it is difficult to determine the appropriate numeric weight for the prevention of clustered deaths.<sup>191</sup>

The procedural approach to BCA has merit because it brings analytic information into the process. If regulators are forced to generate such information, they may not devote the resources necessary to prepare careful, quality work (knowing that the analysis has no explicit role in the decision-making process).<sup>192</sup> The latter objection can be overcome to some extent if the procedural requirement is enforced with a combination of OIRA and judicial review.<sup>193</sup> But the procedural requirement is certainly superior to not mandating BCA at all.

In summary, the “soft” version of the benefit-cost test has been applied by the OMB and the regulatory agencies since 1993, has the

typically viewed as at most a partial contributor to policy deliberations. *See* Hornstein, *supra* note 132, at 615-16 (objecting to comparative risk analysis as the only contribution to decision making and seeking room for social discourse on relevant and important values that may not be captured in the formal analysis).

<sup>190</sup> *See* Mark Seidenfeld, *A Big Picture Approach to Presidential Influence on Agency Policy-Making*, 80 IOWA L. REV. 1, 43 (1994) (contending that President Clinton’s Executive Order 12,866 has “such a broad list of considerations [that it] does little to inform the agency as to what the President may desire concerning any particular regulation”).

<sup>191</sup> There have been tools developed to assess large, multiple-fatality events. *See, e.g.*, HAIMES, *supra* note 29, at 305-344 (providing textbook methods for the assessment of “extreme” events).

<sup>192</sup> *See* Sally Katzen, *Cost-Benefit Analysis: Where Should We Go from Here?*, 33 FORDHAM URB. L.J. 1313, 1318 (2006) (lamenting that BCA can become “simply a paper exercise that justifies the result reached rather than serving—as it should—in informing the decision-making”).

<sup>193</sup> Even in the presence of OMB oversight and possible use of cost-benefit information during judicial review of rules, there is plenty of evidence suggesting that the technical quality of agency analyses is uneven. *See* Hahn & Dudley, *supra* note 176 (examining seventy-four BCA calculations conducted by the EPA to determine the quality of the actual BCA being performed by federal agencies and finding no trend in quality).

broadest support among scholars in the field, and was almost codified by Congress in 1995.<sup>194</sup> Given that BCA is not cost-free (indeed, a complex BCA can be fairly information intensive and can be time consuming for agencies to produce), it is worth considering whether there are alternatives to BCA that can advance the cause of welfarism without creating unacceptable side effects.

### B. Alternatives to BCA

If BCA is not employed, how might regulators decide whether a lifesaving rule is appropriate and, if so, how stringent the rule should be? The legal literature identifies three classes of alternative approaches: the absolutist approach, the feasibility approach, and the intuitive balancing approach.<sup>195</sup> Each of these approaches, like BCA, has virtues and defects; no perfect approach to making lifesaving regulations has been devised.<sup>196</sup>

#### 1. Absolutism

An absolutist approach, in its simplest form, calls for complete safety, maximum lifesaving, or zero residual risk. The approach may also require protection of the public health with a margin of safety to account for scientific uncertainty and the susceptibilities of vulnerable subgroups (e.g., children, the elderly, or people with genetic predispositions to disease).<sup>197</sup> A characteristic feature of absolutist approaches is that the cost of protecting the public is not a legally permissible consideration.<sup>198</sup> In some cases, the absolutist approach is tempered with a presumption that a regulator is permitted to ignore tiny, negligible, or *de minimis* risks based on quantitative risk assessment.<sup>199</sup>

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<sup>194</sup> See Graham, *Legislative Approaches*, *supra* note 15, at 56-58 (discussing the politics of regulatory-reform legislation in the 104th Congress).

<sup>195</sup> See Sinden, *supra* note 33, at 226 (listing the three approaches).

<sup>196</sup> See Pauly, *supra* note 61, at 119 (“[T]he real test of the cost-benefit approach is not whether it is flawless when held up against some ideal standard but rather whether it is better than other feasible alternatives. Viewed in this light, the method holds up rather well.”).

<sup>197</sup> See LESTER B. LAVE, *THE STRATEGY OF SOCIAL REGULATION* 11-13 (1981) (illustrating examples of the “no-risk” approach to social regulation at the FDA and EPA).

<sup>198</sup> See Sinden, *supra* note 33, at 227 (“[A]bsolute standards . . . look only at impacts on human or ecological health and prohibit any consideration of costs.”).

<sup>199</sup> On the origins of the *de minimis* risk doctrine, see WILSON & CROUCH, *supra* note 32, at 164. The doctrine’s early use by federal agencies is traced by DE MINIMIS RISK (Chris Whipple ed., 1987).

The strength of the absolutist approach is its simplicity: it provides an unambiguous, unidimensional goal that can motivate staff and organize the regulator's thinking throughout a rulemaking.<sup>200</sup> This simple approach also allows the public, the Congress, and the courts to easily determine whether the regulator is doing her job. A related advantage is that the informational requirements in an absolutist rulemaking are minimal since the regulator only needs to make a factual claim that a lifesaving opportunity exists (or may exist) in order to regulate. No information about economics or engineering is necessary. It may not even be necessary to have numeric information about lifesaving, unless exemptions are provided for negligible risks. Additionally, the zero-risk position "sends a clear signal to markets that [lifesaving] innovation is needed."<sup>201</sup>

Some absolutist approaches to lifesaving regulation have been implemented by federal agencies and upheld by the federal courts, such as the national ambient air-quality standards set by the EPA to protect the public health with an adequate margin of safety. Costs of compliance are not a permissible consideration in setting air-quality standards, although costs may be considered when emissions limits are established for specific sources.<sup>202</sup>

Proponents of the absolutist approach do not necessarily expect that a zero-risk mandate will actually be implemented. Politics and economics may force compromises in the lifesaving rules that are issued.<sup>203</sup> An idealistic statutory criterion, absolutists argue, may help compensate for the fact that the beneficiaries of lifesaving regulation tend to be poorly organized in both politics and the marketplace. Thus, a defense of absolutist approaches may be launched on instrumental as well as intrinsic grounds.<sup>204</sup>

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<sup>200</sup> Cf. JOHN D. GRAHAM ET AL., IN SEARCH OF SAFETY: CHEMICALS AND CANCER RISK 97 (1988) ("Agreement on a simple moral principle such as health protection can help an organization sustain morale and recruit like-minded and effective employees.")

<sup>201</sup> Driesen, *supra* note 138, at 615.

<sup>202</sup> See generally Cass R. Sunstein, *Regulating Risks After ATA*, 2001 SUP. CT. REV. 1, 10-13 (discussing the Supreme Court's textualist approach to the Clean Air Act in *Whitman v. Am. Trucking Ass'n*, 531 U.S. 457 (2001), which prohibited, except in limited circumstances, the EPA from considering costs in setting air-quality standards).

<sup>203</sup> See Schroeder, *supra* note 18, at 556 ("Much environmental legislation is absolutist in language, but more lenient in administration."); Sinden, *supra* note 33, at 227-28 ("[Absolutist] standards are inevitably tempered by the political process and thus rarely deliver results that are actually absolute.")

<sup>204</sup> Professor Sinden sees her provocative instrumental defense of absolutism, which asserts that absolutism is needed to undo the power imbalances that skew rule-makers toward deregulation, as novel. Indeed, it may be novel in the legal literature.

The weaknesses of the absolutist approach also flow from its simplicity. One might wish that lifesaving could be pursued with no other social goal in mind, but there are no philosophical frameworks that assert that government's only purpose is to keep citizens alive. The good life is commonly understood to extend beyond health to include a citizen's overall level of utility or well-being.<sup>205</sup> Even those who want government to provide basic capabilities, primary goods, or fundamental rights do not restrict the mission of government to enhancing health and safety.<sup>206</sup>

In other words, regulators should consider a broad range of goods and services that can be provided with scarce resources: education, housing, transportation, recreation, health care, national security, and so forth. Protection against life-threatening risks is certainly a high priority among these goods, but it is not the only value of concern to society.

The absolutist approach is also indeterminate in cases where regulatory protection against one risk cannot be accomplished without creating other risks.<sup>207</sup> For example, if forcing cars to be more fuel efficient compromises the safety of motorists,<sup>208</sup> it is not obvious what a

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*See generally* Sinden, *supra* note 67. But her instrumental perspective has deep roots in the labor and environmental movements. *See, e.g.*, GRAHAM ET AL., *supra* note 200, at 98 (describing the argument that the nonbalancing interpretations of OSHA's and the EPA's statutes are appropriate ways to compensate for the political underrepresentation of workers and environmental groups, respectively).

<sup>205</sup> *See* W. Kip Viscusi, *Risk Equity*, 29 J. LEGAL STUD. 843, 862 (2000) ("The appropriate policy objective is maximization of expected individual welfare, not risk minimization.").

<sup>206</sup> The justice theories of Rawls and Dworkin do not provide a normative foundation for an absolute risk-protection standard. *See* Schroeder, *supra* note 18, at 535-48 (discussing Rawls and concluding that "no defense of an absolute right to freedom from risk can be built on the foundation of Rawls' ideas"); *id.* at 549-52 (discussing Dworkin, who "places questions of justice prior to questions of social welfare" but does not argue that "all abstract rights must be protected absolutely"); *id.* at 554 n.219 ("[T]he most careful environmentalists do not assert that the do-no-harm principle is an absolute.").

<sup>207</sup> The pervasiveness of risk/risk tradeoffs undermines the appeal of zero-risk thinking. *See generally* RISK VERSUS RISK: TRADEOFFS IN PROTECTING HEALTH AND THE ENVIRONMENT, *supra* note 22 (providing examples of risk tradeoffs and discussing how to resolve them). Some authors distinguish risk/risk frameworks that entail consideration of direct effects (e.g., sodium nitrate is a food additive that both causes cancer and prevents botulism) from broader risk/risk frameworks that permit consideration of indirect risk tradeoffs (e.g., cleaning up hazardous wastes may protect the public, but it exposes clean-up workers to risks from exposure during the cleanup process). *See, e.g.*, LAVE, *supra* note 197, at 15-17.

<sup>208</sup> The doubling of 1975 federal car mileage standards to almost 27.5 miles per gallon in 1990 saved fuel but at the expense of the lives of two thousand motorists per

regulator should do. Even legal scholars who resist the benefit-cost state have acknowledged that regulators should consider the unintended risks that may flow directly from their lifesaving actions.<sup>209</sup>

Excluding any consideration of the costs can lead to unwanted results. For example, in pursuit of lifesaving the regulator may issue expensive rules that hurt the poor. That may not only be unjust on its own terms but may also create indirect health and safety risks for poor households.<sup>210</sup> Whether lifesaving regulators should be permitted or required to consider indirect risk tradeoffs mediated by income loss is controversial,<sup>211</sup> but ignoring the costs of regulation is an invitation to perversity.<sup>212</sup>

Another objection to absolutism is that it is so impractical that regulators do not implement it.<sup>213</sup> In other words, absolutism does not necessarily accomplish much lifesaving!<sup>214</sup>

year. On the rise in fuel-economy standards, see Nat'l Highway Traffic Safety Admin., CAFE Overview, <http://www.nhtsa.dot.gov/cars/rules/CAFE/overview.htm> (last visited Nov. 15, 2008). On the deaths associated with these more stringent Corporate Average Fuel Economy (CAFE) standards, see COMM. ON THE EFFECTIVENESS AND IMPACT OF CORPORATE AVG. FUEL ECON. (CAFE) STANDARDS, NAT'L RESEARCH COUNCIL, EFFECTIVENESS AND IMPACT OF CORPORATE AVERAGE FUEL ECONOMY (CAFE) STANDARDS 111 (2002), available at [http://books.nap.edu/openbook.php?record\\_id=10172&page=1](http://books.nap.edu/openbook.php?record_id=10172&page=1).

<sup>209</sup> See, e.g., McGarity, *supra* note 26, at 41 ("There is a grain of truth in the proposition that single-minded regulation of some health and safety risks can increase others."); Schroeder, *supra* note 18, at 526-27 (arguing that any absolute risk-protection standard has difficulty with risk/risk tradeoffs).

<sup>210</sup> See, e.g., Ulf-G. Gerdtham & Magnus Johannesson, *Do Life-Saving Regulations Save Lives?*, 24 J. RISK & UNCERTAINTY 231 (showing that because reductions in income increase the number of fatalities, regulation that decreases income may indirectly increase fatalities).

<sup>211</sup> See, e.g., McGarity, *supra* note 26, at 42-49 (critiquing the hypothesis that "richer is safer" and that regulation makes the poor worse off and less healthy).

<sup>212</sup> See Schroeder, *supra* note 18, at 519 ("[A]ccording bodily integrity absolute status would virtually threaten to enslave everyone in the service of that single objective.").

<sup>213</sup> See John D. Graham, *The Failure of Agency Forcing: The Regulation of Airborne Carcinogens Under Section 112 of the Clean Air Act*, 1985 DUKE L.J. 100 (discussing the history of failure under an absolutist mandate to protect the public health from hazardous air pollution); Sinden, *supra* note 34, at 188-89 (noting that absolutist, health-based standards for toxic pollutants under the Clean Water Act proved to be "unworkable," causing them to be replaced with feasibility standards); Jay Michaelson, Note, *Rethinking Regulatory Reform: Toxics, Politics, and Ethics*, 105 YALE L.J. 1891, 1896 (1996) ("[T]he zero standard [for toxins] has proven all but impossible to institute.").

<sup>214</sup> Cf. Ackerman & Stewart, *supra* note 24, at 1360-62 (recommending fewer absolutist statutory mandates in environmental laws in order to reduce lethargy at regulatory agencies); Cass R. Sunstein, *Paradoxes of the Regulatory State*, 57 U. CHI. L. REV. 407, 416 (1990) (asserting that overly ambitious risk-protection statutes, such as those that forbid balancing of costs and benefits, make regulators "reluctant to act").

Even if regulators reluctantly decide (or are forced) to use an absolutist framework, they may do so in a way that undermines procedural values such as transparency and honesty in the public dialogue. When a rulemaking proceeds with dishonesty about regulatory rationales, it is difficult for public participation to proceed in a meaningful way, since the public does not know the real basis for the rulemaking. Although dishonesty can occur under any substantive standard of life-saving regulation, absolutism invites dishonesty because the consequences of pursuing zero risk, without regard to consequences, are reckless and politically untenable.<sup>215</sup>

In summary, moral absolutism about lifesaving may be symbolically appealing, but it is intellectually and practically unsatisfying. It has no normative foundation in welfarism (or otherwise), it discourages regulators from saving lives, and by encouraging dishonest behavior by regulators, it may undermine participatory values and accountability.

## 2. Feasibility

One of the most common approaches to lifesaving regulation might be called the “lowest feasible risk” or “feasibility analysis.”<sup>216</sup> This approach begins with the single social objective—lifesaving—but permits consideration of a practical constraint: the amount of lifesaving that is technologically and economically feasible.<sup>217</sup>

Technological feasibility typically refers to engineering limitations (e.g., do we have the technology to cut pollution by ninety percent from a factory?) whereas economic feasibility refers to affordability (e.g., would a mandate to reduce pollution by ninety percent be so expensive that it would lead to widespread economic dislocation among affected plants in an industry?). Thus, feasibility entails consideration of both engineering and industrial economics.<sup>218</sup>

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<sup>215</sup> McGarity, *supra* note 156, at 225 (noting that “administrative bodies apparently face irresistible pressures” to convert absolutist mandates into technology-based ones).

<sup>216</sup> For the political, economic, and legal history of the feasibility doctrine at the Occupational Safety and Health Administration, see GRAHAM ET AL., *supra* note 200, ch. 4. For a comparative analysis that favors the feasibility principle over BCA, see Driesen, *supra* note 180.

<sup>217</sup> See Driesen, *supra* note 180, at 3 (“[The feasibility principle] maximizes the protection of health, which is fundamental to welfare, in situations where doing so does not threaten welfare in a significant way.”).

<sup>218</sup> Another term used to describe feasibility-based standards is “technology-based.” This terminology is less precise because it is also used in contrast to market-based standards such as performance criteria, taxes, and cap-and-trade systems. If one favors technology-based standards, one still must decide whether to base them on feasibility

There are many variants of feasibility analysis. To specify technological feasibility, for example, the regulator might require each company to match the lifesaving accomplishment of the best firm, the average of the best performing firms, the firm at the ninetieth percentile of lifesaving accomplishment, or at least the average lifesaving performance in the industry. Some concepts of feasibility envision “technology forcing” rules that compel development and use of new lifesaving technologies, either those currently at the development stage (that are not yet commercialized) or, with adequate lead times, those that are only in the concept stage.<sup>219</sup>

The notion of economic feasibility is not a recognized term of art in economics, but it has a variety of meanings in the practice of regulation.<sup>220</sup> In a Supreme Court decision about OSHA regulation of chemical exposures, the Court drew a strong distinction between BCA and feasibility analysis.<sup>221</sup>

If a rule is anticipated to cause some economic dislocation, the extent of dislocation necessary to trigger an infeasibility determination is a matter of judgment.<sup>222</sup> In practice, regulators look at various financial measures to help make a feasibility determination: the projected compliance costs as a percentage of a firm’s annual profit or revenue, the number of companies expected to file for bankruptcy, and the number of jobs projected to be lost in the regulated sector. Even

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or on BCA. For a sympathetic view of technology-based standards that draws on feasibility analysis, see Sidney A. Shapiro & Thomas O. McGarity, *Not So Paradoxical: The Rationale for Technology-Based Regulation*, 1991 DUKE L.J. 729.

<sup>219</sup> California’s ambitious mandate of Zero-Emission Vehicles is an illustration of a technology-forcing mandate aimed at advancing technology beyond what is currently in significant commercial use. For a progress report on technology innovation under this mandate, see FRITZ KALHAMMER ET AL., STATUS AND PROSPECTS FOR ZERO EMISSIONS VEHICLE TECHNOLOGY: REPORT OF THE ARB INDEPENDENT EXPERT PANEL 2007 (2007).

<sup>220</sup> See Driesen, *supra* note 180, at 19 (noting that “technology-based standard setting” can appear incoherent because of “the sheer number of statutory provisions using this approach, the variability of language in these provisions, and the vagaries of implementation”).

<sup>221</sup> See *Am. Textile Mfrs. Inst., Inc. v. Donovan*, 452 U.S. 490, 506-13 (1981) (holding that a feasibility analysis and not a BCA is required under section 6(b)(5) of the Occupational Safety and Health Act of 1970, 29 U.S.C. § 655(b)(5) (2006)).

<sup>222</sup> See, e.g., Driesen, *supra* note 180, at 16 (noting that “feasibility” refers sometimes to “widespread plant closures” and other times to the point when “plant closures begin to occur”); *id.* at 41 (“The feasibility principle does not provide a ‘determinate criterion,’ a verbal formulation that tells an agency precisely what standard to set in every situation.” (footnote omitted)).

proponents of feasibility analysis acknowledge that it is not a determinative criterion.<sup>223</sup>

Of the two arms of the feasibility test (one relating to engineering, the other to affordability), the affordability arm is more influential. As a lifesaving rule is made more stringent, the affordability constraint is typically surpassed before the engineering constraint is reached. In other words, there are usually many feasible technologies that are not affordable.<sup>224</sup> Indeed, one can argue that it is always technologically feasible to make lifesaving rules more stringent, since more funds can be allocated by industry to research and development in order to discover even better lifesaving technology.<sup>225</sup> Thus, the “lowest feasible risk” test often collapses into an affordability test.

In theory, a feasibility approach is not very information intensive.<sup>226</sup> The regulatory analyst does not need to assess the size of the life-threatening risk to be regulated, the projected number of lives saved, or the monetary benefits.<sup>227</sup> But in practice it is common for the regulatory agency to undertake risk assessment prior to (or at the same time as) the feasibility analysis, in order to ensure that the regulation addresses a significant risk.<sup>228</sup> Only the monetization step in BCA is avoided by feasibility analysis, since risk and cost are usually assessed anyway.<sup>229</sup>

<sup>223</sup> In this respect, the ambiguity in feasibility analysis is similar to the ambiguity in the “soft” benefit-cost test. *See supra* Part II.A.2.

<sup>224</sup> *See* Ackerman & Stewart, *supra* note 24, at 1359 n.60 (noting that “[i]n many instances . . . technology is available . . . to eliminate pollution entirely” and that “most decisions about ‘available’ technology must—implicitly or explicitly—take costs into account”).

<sup>225</sup> *See* GRAHAM ET AL., *supra* note 200, at 98 (“What is feasible in the future is itself a function of how much manpower and resources are devoted to research and development.”).

<sup>226</sup> *See* Driesen, *supra* note 180, at 54 (“CBA is a much more complicated form of analysis than feasibility analysis. CBA involves all of the steps needed to perform a feasibility analysis and many additional, complicated, and controversial steps.” (footnote omitted)).

<sup>227</sup> *See id.* at 93-94 (arguing that the feasibility principle justifiably avoids calibrating risk to stringency because such efforts amount to a “huge waste of resources” and because the “huge error band in risk assessment” and the presence of important, unquantifiable risks “means that proportional calibration is impossible”).

<sup>228</sup> *See id.* at 26, 28 (noting that “government evaluation of risk to health and/or the environment generally accompanies or precedes application of the [feasibility] principle,” but that a significant-risk determination does not entail a monetary-benefits analysis or a formal cost-benefit determination).

<sup>229</sup> The monetization step of BCA is not very expensive, especially given the growing use of “benefit-transfer” techniques that reduce the costs of original data collection. *Cf.* ADLER & POSNER, *supra* note 2, at 80-88 (arguing that BCA’s costs are not

Feasibility tests are sometimes politically attractive,<sup>230</sup> but they are not necessarily wise regulatory policy.<sup>231</sup> The premise is that regulators should advance lifesaving goals up to the point where the financial viability of industry begins to be threatened or is crippled. Yet this apparently convenient stopping point has no normative foundation in either welfarism or rights-based thinking.<sup>232</sup>

Financial protection of a regulated industry is a fairly narrow balancing goal that overlooks important economic considerations. For example, the welfare of consumers, investors, and workers (short of impacts from widespread plant shutdowns) has no explicit place in feasibility analysis, even though concern for the overall well-being of the citizenry is widely considered an essential function of government.<sup>233</sup> Investors and workers gain some protection under feasibility analysis since their plants may not be shut down by lifesaving rules, but impacts on profits, prices, and wages are impermissible considerations (unless they relate to plant shutdowns). An economy with low wages, high prices, and low investment income will not produce much well-being, even if households manage to stay alive and healthy!

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high compared to those of alternative analytical methods); FREEMAN, *supra* note 61, at 453-56 (discussing the growing use of benefit-transfer techniques and their ability to lower analytical costs).

<sup>230</sup> From a political perspective, feasibility analysis has the potential to unite some diverse, yet powerful, forces. Regulation advocates (e.g., public health and environmental groups) may anticipate that a large amount of lifesaving can be accomplished by mandating the best technologies. Many business groups may accept feasibility analysis as long as they believe that they can pass on the costs of lifesaving rules to consumers. In some cases, business groups may have perverse reasons to support feasibility analysis (e.g., if the rules will act as a form of protection against import competition or raise entry barriers in the industry, making it harder for smaller businesses to form and grow). Thus, we may find a significant coalition of organized interests who will advocate, or at least accept, some form of feasibility analysis as an alternative to absolutist or benefit-cost approaches to lifesaving regulation.

<sup>231</sup> See Wiener, *supra* note 186, at 475 n.98 (summarizing key problems with a feasibility test).

<sup>232</sup> Cf. LAVE, *supra* note 197, at 15 (contending that technology-based definitions of feasibility are not really frameworks for reducing risk but instead are regulatory frameworks for “imposing costs arbitrarily among industries until all are at the same minimal level of profit”).

<sup>233</sup> Professor Driesen argues that the costs of feasible standards are distributed so widely among consumers, investors, and workers that “they have little real impact on human lives.” Driesen, *supra* note 180, at 36. But according to this argument, one can also dismiss the ex ante health benefits of rules because they are spread out over large numbers of consumers, workers, and motorists. Well-being depends not on the absolute size of costs per household or the absolute size of health benefits per household, but on the relative magnitude of the two quantities (benefits versus costs)—the exact inquiry that BCA addresses.

A more interesting objection to feasibility analysis is that it does not permit promising, but unaffordable, lifesaving regulations.<sup>234</sup> If the lifesaving consequences of a rule are sufficiently large and the adverse impacts of industrial dislocation are less compelling, why should a regulator not be permitted to issue an unaffordable lifesaving rule? In theory, either a benefit-cost or absolutist approach might permit regulators to authorize more stringent lifesaving rules than feasibility analysis will permit.<sup>235</sup> In short, there may be no rationale for the affordability constraint other than political convenience.<sup>236</sup>

Feasibility analysis is also incoherent in a world of multiple regulations of the same industry. Whenever the suite of all possible lifesaving rules is not affordable, it is not apparent how the regulator, guided by feasibility, is to decide which rules to forego. BCA urges that the rulemakings be ordered by net-benefit opportunity, but, by definition, feasibility analysis does not consider benefits and thus may disorder the priority of multiple lifesaving rules aimed at the same industrial sector.

In summary, unlike BCA, feasibility analysis does not entail any comparison of the benefits of lifesaving regulation against the costs. In fact, benefits analysis has no role to play in feasibility analysis.<sup>237</sup> Cost analysis is important, but only to determine whether the regulated industry can afford a lifesaving rule. Thus, feasibility standards uniformly applied to diverse plants or products are likely to produce a

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<sup>234</sup> See, e.g., Ackerman & Stewart, *supra* note 24, at 1342 n.20 (“[I]f the unemployment and dislocation caused by plant shutdowns due to pollution control programs are judged unacceptable, the appropriate response is not to weaken the program or impose disproportionate controls on new sources so as to throttle investment and productivity gains. The appropriate response is remedial: Compensation programs should be designed to deal with unemployment and dislocation.”).

<sup>235</sup> Some scholars are, however, under the misimpression that feasibility delivers more risk protection than BCA. See, e.g., SIDNEY A. SHAPIRO & ROBERT L. GLICKSMAN, RISK REGULATION AT RISK: RESTORING A PRAGMATIC APPROACH 37-38 (2003).

<sup>236</sup> See Hsu, *supra* note 19, at 346-47 (finding no normative foundation for the claim that worker health protections beyond what is “feasible” are unaffordable).

<sup>237</sup> Proponents of technology-based standards see this lack of benefits analysis as an advantage because a regulator’s informational costs are reduced. See Frank Ackerman & Lisa Heinzerling, *Pricing the Priceless: Cost-Benefit Analysis of Environmental Protection*, 150 U. PA. L. REV. 1553, 1581 (2002) (stating that a technology-based regulatory framework “avoids the massive research effort needed to quantify and monetize the precise harms caused by specific amounts of pollution”).

combination of overregulation and underregulation<sup>238</sup> compared to a framework that is sensitive to benefits and costs.<sup>239</sup>

### 3. Intuitive Balancing

Another way to address society's conflicting interests about lifesaving regulation is to instruct regulators to weigh the conflicting interests and choose the option that, holistically, best advances the welfare of society.<sup>240</sup> This so-called "intuitive balancing" approach is self-explanatory: it relies on the intuitive skills of the regulator to find the right answer.<sup>241</sup>

Under intuitive balancing, the projected consequences of regulatory options may be quantified in their natural units (e.g., the number of lives saved, the number of hospitalizations prevented, the amount of initial capital expenditures for compliance, and the amount of ongoing compliance expenditures), and there is no attempt to express the consequences in a common metric such as dollars or utility.<sup>242</sup> The regulator is expected to consider the diverse quantitative impacts and any qualitative considerations (e.g., any fairness concerns) in a holistic way.<sup>243</sup>

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<sup>238</sup> See Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613, 1694 (1995) (discussing how a technology-based approach will produce a mix of insufficient risk protection and tremendous cost inefficiencies).

<sup>239</sup> See Ackerman & Stewart, *supra* note 24, at 1335, 1340, 1354-55 (discussing inefficiencies of technology-based feasibility approaches); see also Sunstein, *supra* note 26, at 1701 ("[I]t would be wrong to think that cost-benefit analysis is more 'antiregulatory' than a feasibility constraint. We can easily imagine a regulation that might not be feasible, but that might satisfy a requirement of cost-benefit balancing.").

<sup>240</sup> See Lisa Heinzerling, *The Accidental Environmentalist*, 94 GEO. L. J. 833, 853 (2006) (book review) (defining the intuitive-balancing, or "holistic," approach).

<sup>241</sup> See ADLER & POSNER, *supra* note 2, at 78-79 (differentiating intuitive balancing from the more quantitative BCA).

<sup>242</sup> Fred Ackerman and Lisa Heinzerling perceive that BCA is a "complex, resource-intensive, and expert-driven process" and that "unpack[ing] even the simplest cost-benefit analysis" "requires a great deal of time and effort." Ackerman & Heinzerling, *supra* note 237, at 1577. But they acknowledge that their preferred framework, holistic balancing, would entail much of the same raw information that is produced to support BCA. Their approach does save the time and analytic costs associated with the monetization of benefits, but this is one of the least costly steps in BCA because the tools of "benefit transfer," now used widely in health and environmental economics, avoid the repeated costs of monetization in each rulemaking. See *supra* note 229.

<sup>243</sup> See Adler, *supra* note 35, at 1394 ("The nonmonetized version of CBA relies on intuition and judgment rather than formal commensuration to balance the divergent costs and benefits . . . . No attempt is made to reduce all these welfare impacts to a common scale, be it a dollar scale or some other.").

The advantages of intuitive balancing include the broad discretion to weigh numeric and qualitative factors in whatever way seems most likely to advance social welfare. No constraints are imposed by analytic procedures (e.g., monetization), which may have biases that mislead the regulator. And the informational costs of BCA are reduced, since the monetization in BCA is unnecessary.<sup>244</sup>

The main difficulties with intuitive balancing are that it is not guided by a normative framework and that it assumes a high degree of cognitive capacity and good motivation on the part of the regulator. For example, it is hard to imagine how intuitive regulators could pursue welfarism without BCA. The discipline provided by BCA helps avoid inconsistency over time and between regulators.<sup>245</sup> Intuitive balancing also removes many of the ground rules for OIRA and judicial review that have evolved through OIRA guidance and the judiciary's cost-benefit "default" principles under the Administrative Procedure Act.<sup>246</sup> Nor does intuitive balancing have the transparency required to implement a system of checks and balances on the regulator's discretion.<sup>247</sup>

In summary, there are alternatives to BCA of lifesaving regulation, but they are far from perfect and have little or no grounding in welfarism.<sup>248</sup> We therefore return to BCA and consider how the tool is currently applied to lifesaving opportunities in the federal government.

### III. THE REALITY OF THE BENEFIT-COST STATE

BCA is not very useful if its results do not help guide the lifesaving decisions of regulators. For almost thirty years, federal regulatory agencies have submitted their draft rules to the OMB for benefit-cost

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<sup>244</sup> See ADLER & POSNER, *supra* note 2, at 83 (noting that the costs of monetization studies are small and can be spread over multiple rulemakings due to numerous uses of the same values and benefit-transfer techniques).

<sup>245</sup> There is a strong literature in psychology and behavioral decision making exposing the weaknesses of human judgment when unaided by formal analysis. See generally, e.g., JONATHAN BARON, JUDGMENT MISGUIDED: INTUITION AND ERROR IN PUBLIC DECISION MAKING (1998) (examining how intuitive decision making can lead to unintended consequences and arguing that decisions affecting the common good should be made based on more quantifiable measures).

<sup>246</sup> Pub. L. No. 79-404, 60 Stat. 237 (1946) (codified in scattered sections of 5 U.S.C.).

<sup>247</sup> See Sunstein, *supra* note 1, at 292 (concluding that although intuitive benefit-cost balancing makes "a great deal of sense," the principal objection to qualitative balancing is that it is too open-ended).

<sup>248</sup> See ADLER & POSNER, *supra* note 2, at 80-100 (comparing BCA to alternative approaches, based on information costs and accuracy in advancing well-being).

review. In this Part, I explore how federal agencies and the OMB use BCA in the real world of regulatory policymaking.

From a political-economy perspective, centralized OMB oversight of regulators is expected to be responsive to broad national interests, such as those reflected in BCA, rather than to the narrow interests of specific industry or proregulation groups.<sup>249</sup> Given the policy-analytic training of the OMB's career professional staff, there is no reason to expect that they would be especially susceptible to "industry capture" as opposed to capture by any other organized interest. The OMB's dedication to exploring opportunities for cost reduction appears to compensate for a natural proregulation bias among staff at the regulatory agencies.<sup>250</sup> But, in principle, the OMB should be seeking both more beneficial and less costly lifesaving regulations.

In parts of the legal academy, there is a perception that OIRA, the unit in the OMB responsible for regulatory review, sees cost reduction as the only role for BCA.<sup>251</sup> A related perception, originating in the

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<sup>249</sup> See, e.g., Sally Katzen, *A Reality Check on an Empirical Study: Comments on "Inside the Administrative State,"* 105 MICH. L. REV. 1497, 1505 (2007) (finding that presidential control over administrative agencies is more complex and not as beholden to special interests as previously believed and that agencies do focus primarily on their statutory missions); James C. Miller III et al., *A Note on Centralized Regulatory Review,* 43 PUB. CHOICE 83, 86 (1984) ("[O]versight may dilute further the influence of concentrated-interest coalitions since there is no reason to believe that the reviewers will be captured by a particular industry; indeed, the reviewers must deal with a multitude of industries.").

<sup>250</sup> Though not always the case, federal regulatory agencies have a tendency to pursue costly regulations. One explanation is the natural tendency of project designers to be overly optimistic. See HER MAJESTY'S TREASURY, *THE GREEN BOOK: APPRAISAL AND EVALUATION IN CENTRAL GOVERNMENT* 29. Another contributing factor may be the culture of the mission-oriented regulatory agencies, including the worldviews of people who choose to work at regulatory agencies. See MCGARITY, *supra* note 16, at 8-10 (discussing "techno-bureaucratic" thinking in rulemaking agencies). Another explanation for the tendency of regulatory staff to overregulate is the desire of agencies to expand their power. See, e.g., Johnston, *supra* note 34, at 1356 ("[E]nvironmental regulators have an incentive to overstate the benefits of environmental regulation . . ."). Professor Stewart and others have observed that agencies may have a tendency to exaggerate benefits and minimize costs in order to pass OIRA review. See Stewart, *supra* note 171, at 46-47 & n.80.

<sup>251</sup> See MCGARITY, *supra* note 16, at 286-87 ("There are literally hundreds of cases of OMB intervention into agency rulemakings to urge less stringent regulations, and at most a handful of cases of OMB urging the agencies to regulate more stringently."); Lisa Schultz Bressman & Michael P. Vandenbergh, *Inside the Administrative State: A Critical Look at the Practice of Presidential Control,* 105 MICH. L. REV. 47, 96 (2006) (citing a perception among regulators that OIRA works to reduce costs of regulation but not to increase benefits); Driesen, *supra* note 41 (reviewing OIRA's use of BCA and concluding that BCA has almost always been used to impede environmental regulation); Lisa Heinzerling & Rena I. Steinzor, *A Perfect Storm: Mercury and the Bush Administration, Part II,* 34 ENVTL. L. REP. (Envtl. Law Inst.) 10,485, 10,488 (2004) ("In truth, cost-

early Reagan years,<sup>252</sup> is that industry representatives have privileged access to OIRA and that they exploit this privilege to weaken or block rules that agencies seek to clear through OIRA.<sup>253</sup> These perceptions continue even though the available literature finds no correlation between who meets with OIRA staff and who wins changes to rules during OIRA review.<sup>254</sup>

What is missing from the legal literature is recognition of OIRA's proregulation role, especially with regard to lifesaving. OIRA has enhanced the lifesaving impact of federal regulation through three mechanisms: improved methods of BCA; a transparent BCA process that stakeholders, judges, and the public can scrutinize; and intervention in specific rulemakings.

I begin with the methodological and process improvements and then explore some examples of OIRA's pro-lifesaving role in the 1981 to 2000 and 2001 to 2006 periods. Several in-depth case studies of OIRA's proregulation role are then presented based on my personal experience at OIRA. I conclude with a summary of the statistical evidence on benefits and costs, which indicates that the net benefits of major federal rules increased substantially from 2001 to 2006, a period when OIRA review of agencies was particularly vigorous.

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benefit analysis in the Bush Administration has been a one-way street—used to justify delaying or weakening regulation, not to strengthen it. When cost-benefit analysis almost certainly would justify strengthening regulation, especially environmental regulation, OIRA has kept it holstered in its belt.” (footnote omitted)); Sinden, *supra* note 67, at 1420 n.47 (“While some argue that, at least in theory, CBA has the capacity to spur as much regulation as it blocks, in practice CBA tends to be decidedly anti-regulatory.” (citation omitted)); *see also supra* note 41.

<sup>252</sup> *See* Seidenfeld, *supra* note 190, at 17 (“[A]lthough the ostensible goal of regulatory review by the Reagan OMB was efficiency, deregulation was clearly an unstated goal.”).

<sup>253</sup> *See* Bressman & Vandenberg, *supra* note 251, at 97 (stating that some EPA regulators perceive OIRA to have an institutional bias in favor of business interests).

<sup>254</sup> *See, e.g.,* Steven J. Balla et al., Outside Communications and OMB Review of Agency Regulations (unpublished manuscript, on file with author) (finding that outside communications by business firms and trade associations with OMB do not necessarily lead to deregulation). A similar study of OIRA during the Clinton administration found no evidence that meetings with industry parties led to changes in rules. *See* Steven Croley, *White House Review of Agency Rulemaking: An Empirical Investigation*, 70 U. CHI. L. REV. 821, 860 (2003) (“[T]he types of interests present at an OIRA meeting are not associated with a greater or lesser likelihood that OIRA will require a change in the rule . . .”).

### A. Methodological Advances in BCA

The key innovations in BCA since 1980 include the higher monetary valuation of lifesaving caused by the shift to WTP methods and the greater weight assigned to future lifesaving caused by the lowering of the rates of discount applied to future benefits and costs. Both of these methodological changes have had the practical effect of increasing the estimated benefits of lifesaving regulation, thereby making it easier for regulators to justify lifesaving rules. The central role of OIRA in promoting these analytical innovations is clear evidence that the members of OIRA's professional staff are dedicated to making sure BCA is done properly, even if the result is more regulation or more stringent and more costly regulations. Let us consider the numeric significance of these two improvements.

A generation ago, federal agency analysts used value-of-life estimates ranging from \$40,000 to \$300,000 per life saved. These figures were computed based on a person's foregone earnings attributable to premature death.<sup>255</sup> Adjusting for thirty years of inflation at 3% per year, \$250,000 in 1975 dollars is equivalent to \$607,000 in 2005 dollars. At the urging of OIRA, agencies gradually switched from the foregone-earnings method to the WTP method for valuing lifesaving impacts.<sup>256</sup> The result has been roughly a tenfold increase in the estimated benefits of lifesaving regulations.<sup>257</sup> OIRA now recommends that life valuations fall within the range of \$1 million to \$10 million, and the middle of the range is widely used. The WTP method has had an especially large effect on the values of saving the lives of senior citizens and children, whose lives were valued at disproportionately lower rates under the foregone-earnings method.<sup>258</sup>

Modernization of discounting practices has also had the practical effect of favoring the adoption of rules that impose immediate costs

<sup>255</sup> LAVE, *supra* note 197, at 40.

<sup>256</sup> See VISCUSI, *supra* note 7, at 74 (stating that the shift of agencies from the foregone-earnings method to the WTP method occurred "[i]n large part through the efforts of the U.S. Office of Management and Budget"); *id.* at 17-18 (discussing the shift from foregone earnings to WTP to reduce risk, and how, as a result, the controversy about research on the valuation of lifesaving has "diminished").

<sup>257</sup> See *id.* at 263 (estimating that WTP methodology boosted the monetized value of health benefits by "a factor of 10, which is approximately the ratio of the estimated implicit value of life to the present value of the earnings of workers for whom these values are estimated").

<sup>258</sup> See Steven E. Rhoads, *How Much Should We Spend to Save a Life?*, PUB. INT., Spring 1978, at 74, 78 (criticizing the foregone-earnings method for yielding "bizarre guideposts for policy," including relatively low valuations for children and women).

but save lives in the future. As recently as 1990, the OMB was instructing agencies to apply a 10% real rate of discount to future benefits and costs. As the perspectives of economists began to shift in the 1990s, the OMB lowered the rate to 7% and most recently to 3%, as a supplement to calculations based on 7%. The mathematical impact of a lower discount rate is so powerful that rules that save lives in the future are much more likely to pass a benefit-cost test under a 3% policy than a 10% policy.

For example, suppose the EPA proposes a rule that will cause immediate industrial investments in pollution prevention but will not reap benefits until thirty years from now, due to the long latency period between initial exposure and development of cancer. Saving 1000 lives thirty years from now is, assuming a 10% discount rate, equivalent to saving 57 lives today. But if the discount rate is 7% or 3%, the present value of lives saved is 131 and 412, respectively. Thus, the lower discount rates recommended by OIRA have a powerful pro-lifesaving impact in cases where rules produce deferred lifesaving benefits in exchange for immediate capital investments.

In summary, OIRA guidance has modernized the practice of BCA in ways that track the views of recognized scholars in the field of BCA.<sup>259</sup> OIRA has demonstrated its commitment to modernize the methodology of BCA even when better methodology leads to more regulation or more costly regulation of industry. The major methodological changes to BCA that have enhanced the estimated benefits of lifesaving rules are an unambiguous indication that OIRA is not a unit with a dominant deregulatory or pro-business ideology. OIRA is a proponent of BCA.

### B. *Early Examples of OIRA's Pro-Lifesaving Role*

In addition to improving agency practice of BCA, the OIRA review process can support or protect lifesaving regulations through direct

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<sup>259</sup> Both OMB Circular A-4 and the OMB's annual report to Congress on the costs and benefits of federal regulations are produced through a process that includes peer review by leading scholars in the fields of BCA and administrative law, as well as public comment. See OFFICE OF INFO. & REGULATORY AFFAIRS, OFFICE OF MGMT. & BUDGET, PROGRESS IN REGULATORY REFORM: 2004 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF FEDERAL REGULATIONS ON STATE, LOCAL AND TRIBAL ENTITIES 4 (2004) [hereinafter 2004 OIRA REGULATORY REPORT]; Office of Mgmt. & Budget, Executive Office of the President, OMB Circular A-4, at 1 (Sept. 17, 2003), available at <http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf> [hereinafter OMB Circular A-4] (listing peer reviewers).

OIRA intervention and more indirect mechanisms that result from making BCAs publicly available. I begin by considering some early examples of OIRA's pro-lifesaving rule.

The earliest documented case study where OIRA supported regulation due to BCA is the accelerated phase-out of leaded gasoline during President Reagan's first term. Soon after defeating President Carter in the November 1980 election, Reagan's new task force on "regulatory relief" targeted Carter's lead phase-down for reconsideration in conjunction with a suite of other relief initiatives.

But OIRA decided against deregulation. A high-quality BCA produced by the EPA and reviewed by OIRA persuaded the Reagan administration to reverse course.<sup>260</sup> The political leadership of the EPA and the Reagan White House ultimately approved an acceleration of the lead phase-out, an action that is now widely considered a success story in public health.<sup>261</sup>

Some scholars are under the misimpression that the lead phase-out is an isolated example, an aberration.<sup>262</sup> But there are other documented examples. For example, the phase-out of ozone-depleting chemicals by the EPA was assisted by careful BCA.<sup>263</sup>

Even when OIRA errs by ignoring or discounting favorable results in an agency's BCA, the formal process of producing the BCA can

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<sup>260</sup> See MCGARITY, *supra* note 16, at 44 (arguing that the EPA's regulatory analysis of the lead phase-down caused precisely the opposite regulatory outcome—an accelerated phase-out—than that which advocates of regulatory relief desired).

<sup>261</sup> See VISCUSI, *supra* note 7, at 14 ("[T]he improvements of lead pollution have been among the most dramatic of any class of pollutants. The reduction of lead pollution represents a remarkable success story in terms of the real achievements of environmental regulation in enhancing individual health."). *But see* Driesen, *supra* note 41, at 361-64 (disputing the lead example on the grounds that it has not been proven that BCA caused the EPA to promulgate a more stringent regulation of lead content, especially since the health benefits of the lead phase-out were not necessary to justify the rule).

<sup>262</sup> See Ackerman et al., *supra* note 172, at 171 ("[T]he story of cost-benefit analysis in supporting lead regulation stands almost alone: it is so universally cited that a skeptical observer might ask, is there a second example of cost-benefit methods being used to support environmental protection?").

<sup>263</sup> Cass R. Sunstein, *Is Cost-Benefit Analysis for Everyone?*, 53 ADMIN. L. REV. 299, 300 (2001). *But see* James K. Hammitt & Kimberly M. Thompson, *Protecting the Ozone Layer*, in *THE GREENING OF INDUSTRY: A RISK MANAGEMENT APPROACH* 43, 88-89 (John D. Graham & Jennifer Kassalow Hartwell eds., 1997) (concluding that the initial chlorofluorocarbon phase-out decision, applicable to aerosols, was based primarily on qualitative risk assessment but that BCA did play a modest role in the later phase-out of chlorofluorocarbon use from more valued applications). For a widely cited book of case studies on the role of BCA at the EPA, see *ECONOMIC ANALYSES AT EPA: ASSESSING REGULATORY IMPACT* (Richard D. Morgenstern ed., 1997).

cause other actors in the political process, such as the courts or the Congress, to protect lifesaving regulation. In recent years, the federal judiciary has become more aggressive about using the results of BCA—or omissions in BCA—to reach proregulation holdings under the “arbitrary and capricious” test.<sup>264</sup>

Consider the roles of OIRA and the judiciary in the evolution of the DOT’s mandatory airbag requirement. In this case study, which spans almost thirty years, OIRA—and the BCA process it oversees—had direct and indirect proregulatory influences.<sup>265</sup>

Issued originally in 1977, the DOT’s airbag rule was supported by BCA. But as the economy entered a severe recession and car sales plummeted, President Reagan entered office in 1981 on a campaign platform of regulatory relief for Detroit. Despite a favorable BCA of the airbag, officials at the DOT, OMB, and White House decided not to retain the rule in 1981.<sup>266</sup>

When the airbag rule was rescinded, without an assessment of airbags, the insurance industry challenged the decision and in 1983 won in a unanimous decision.<sup>267</sup> The *State Farm* Court made multiple references to findings from BCAs, including the National Highway Traffic Safety Administration’s (NHTSA) finding that airbags could save

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<sup>264</sup> For example, a federal appeals court ruled in 2003 that NHTSA, when selecting among regulatory options to reduce tire-safety problems, did not consider that its own BCA supported a more stringent regulatory alternative. *See Pub. Citizen, Inc. v. Mineta*, 340 F.3d 39, 56-58 (2d Cir. 2003) (explaining that the agency’s failure to consider the benefits revealed by its BCA was a “fundamental flaw” in the agency’s cost argument). Another appeals court, in reviewing NHTSA’s fuel-economy standards for light trucks, concluded that the standards should be reconsidered because “NHTSA fails to include in its analysis the benefit of carbon emissions reduction in either quantitative or qualitative form.” *Ctr. for Biological Diversity v. NHTSA*, 538 F.3d 1172, 1198 (9th Cir. 2008).

<sup>265</sup> For the political, economic, and regulatory history of the airbag rule, see generally JOHN D. GRAHAM, *AUTO SAFETY: ASSESSING AMERICA’S PERFORMANCE* (1989).

<sup>266</sup> Reagan’s regulatory relief package for the automotive industry was a deregulation effort aimed at slowing the escalation of regulatory costs on new-car production. Some of the items in the package were supportable by benefit-cost considerations, but others were not. *See VISCUSI, supra* note 7, at 266-69 & tbl.14-6 (detailing specific actions and savings claimed by the Reagan administration in Reagan’s reform package).

<sup>267</sup> *Motor Vehicle Manufacturers Ass’n v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29 (1983). The Court was unanimous in its view that NHTSA could not lawfully rescind the standard without an assessment of airbag technology. *Id.* at 44. The Court was splintered on a separate rationale involving NHTSA’s analysis of automatic safety belts. *See id.* at 58-59 (Rehnquist, J., concurring in part and dissenting in part) (rejecting the Court’s holding that the agency’s rescission of automatic-seatbelt requirements was arbitrary and capricious).

thousands of lives per year at reasonable cost to the consumer.<sup>268</sup> Thus, preparation of a written BCA, including review and clearance by OIRA, established a record that protects lifesaving rules from political shenanigans—even if OIRA errs in its review of the agency’s action.

Fifteen years later, after dozens of children were tragically killed by the deployment of passenger-side airbags, the DOT came under a different kind of political pressure: a public outcry to weaken the airbag rule by making the airbag an optional purchase or by requiring manufacturers to install a manual on-off switch in each new car equipped with the explosive device. Airbags did cause harm to children and adults with unexpected frequency—usually because the occupants were not properly belted—but the technology also saved many more lives, benefits that did not receive the same degree of publicity as the airbag-induced harms.<sup>269</sup>

The DOT proposed a rule to OIRA in the late 1990s that would have weakened the airbag mandate. During the OIRA review process, OIRA officials asked hard questions about whether making airbags optional (or requiring an airbag cut-off switch) would undercut the lifesaving benefits of the rule. After weighing the views of stakeholders and considering benefit-cost issues, it was OIRA, not the DOT, that insisted that the lifesaving impacts of the original rule be protected. At the insistence of OIRA, the DOT agreed to narrow the permission for airbag cutoff switches and instead redoubled its efforts to promote safety belt use and proper restraint of children in the rear seats of cars.

Validation studies have shown that while the ex ante estimates of the airbag’s safety benefits were overstated by the DOT,<sup>270</sup> the overall benefits of mandatory airbags, estimated after the rule was implemented, are greater than the costs.<sup>271</sup> Thus, OIRA played a critical role in protecting this promising lifesaving regulation from a hasty public protest.

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<sup>268</sup> *Id.* at 37-38.

<sup>269</sup> See John D. Graham, *Technological Danger Without Stigma: The Case of the Automobile Airbags*, in RISK, MEDIA AND STIGMA: UNDERSTANDING PUBLIC CHALLENGES TO MODERN SCIENCE AND TECHNOLOGY 241, 241 (James Flynn et al. eds., 2001).

<sup>270</sup> See Thompson et al., *supra* note 7, at 64-65. For a cost-effectiveness perspective, see generally John D. Graham et al., *The Cost-Effectiveness of Airbags by Seating Position*, 278 J. AM. MED. ASS’N 1418 (1997).

<sup>271</sup> See Kimberly M. Thompson et al., *Validating Benefit and Cost Estimates: The Case of Airbag Regulation*, 22 RISK ANALYSIS 803, 803 (2002) (“This case study . . . suggests that airbags are a reasonable investment in safety . . .”).

In summary, the pro-lifesaving role of OIRA should not be judged solely by the number of times OIRA forces an agency to adopt a more stringent or expensive lifesaving rule than that which agency proposed.<sup>272</sup> Scholars should also consider cases where OIRA encourages an agency to move forward with a lifesaving rule, prevents an agency from weakening a lifesaving rule, supports a lifesaving rule prepared by the agency, or helps establish a regulatory-analysis record that leads other policymakers (courts, legislators, or agency officials) to support lifesaving regulation.

The lead phase-down and airbag rules illustrate quite different pathways for BCAs to advance the cause of lifesaving regulation. Before offering some more recent examples from 2001 to 2006, I provide some perspective on what I was trying to accomplish as OIRA administrator during this period.

### C. OIRA's Strategy, 2001–2006

In order to succeed with a benefit-cost approach to regulatory oversight, I determined that OIRA needed to dispel some unfavorable perceptions that had developed during the early Reagan years. Those perceptions were that (1) OIRA's work was shrouded in secrecy;<sup>273</sup> (2)

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<sup>272</sup> Professor Driesen defines "neutral" behavior by OIRA as forcing an agency to make a rule more stringent as often as OIRA forces an agency to make a rule less stringent. He then selects a sample of rules examined by the General Accounting Office (GAO) and finds that OIRA is not neutral because OIRA, when it changed rules, always acted to make rules less stringent. See Driesen, *supra* note 41, at 394 ("CBA is generally not neutral. The forms of CBA most widely touted . . . benefit polluters by slowing down regulation and systematically reducing its stringency . . ."). This research design is rooted in the unverified assumption that agency proposals to OIRA are just as likely to be insufficiently stringent as overly stringent. It is certainly not a plausible premise if one believes that agencies have a tendency to submit overly stringent (and thus overly costly) proposals to OIRA for review. Moreover, the sample period for the selected rules excluded both the agency follow-up to OIRA's prompt letters and OIRA's participation in the case studies reviewed in this Article. (Professor Driesen offers a brief discussion of OIRA's prompt letters but—inexplicably—dismisses most of them as irrelevant to BCA and regulatory stringency, *id.* at 380-83.) In addition, the research design that Professor Driesen employs gives OIRA no credit for approving agency rules that are well supported by BCA, an outcome that was quite frequent in the sample of rules that he analyzed. Most importantly, Professor Driesen never examines the ultimate performance indicator: whether OIRA's actions increased or decreased the net benefits of rules. See ADLER & POSNER, *supra* note 2, at 121 ("Because Driesen does not show that agencies' regulations are just as often too weak as too strong, he fails to show that the OMB acted improperly.").

<sup>273</sup> See, e.g., Bagley & Revesz, *supra* note 41, at 1309 ("OIRA has a long and well-documented history of secrecy."); Bressman & Vandenberg, *supra* note 251, at 92-93

OIRA contributed to extensive delays in the rulemaking process;<sup>274</sup> (3) OIRA review was driven by an antiregulation or pro-business ideology, not the findings of BCA;<sup>275</sup> and (4) OIRA lacked the necessary scientific and technical expertise to contribute meaningful input to lifesaving rules.<sup>276</sup> Due to the perceived weaknesses of OIRA during the Clinton administration,<sup>277</sup> I also needed to establish quickly that OIRA was a strong, evidence-based force in the regulatory process. Fortunately, the White House empowered me to establish control over the flow of new regulations while beginning a long-overdue process of streamlining the sea of existing federal regulations.<sup>278</sup>

Before my confirmation by the Senate in July 2001, an inexperienced Bush administration mishandled several sensitive regulatory issues, including a decision to reopen the EPA's regulation of arsenic in drinking water and a decision not to regulate carbon dioxide emissions from electric utilities. When I was confirmed, I detected some relief among White House staff. They saw advantages in a stronger role for OIRA's professional orientation in the development of President Bush's regulatory policies. The tragic events of 9/11 enhanced OIRA's role. While much of the energy of the White House staff and

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(suggesting means by which OIRA could make its involvement in rulemaking more transparent).

<sup>274</sup> See, e.g., Robert V. Percival, *Checks Without Balance: Executive Office Oversight of the Environmental Protection Agency*, LAW & CONTEMP. PROBS., Autumn 1991, at 127, 156-61 (finding that OMB oversight has delayed EPA rulemaking); Wagner, *supra* note 238, at 1698-99 (expressing concern that regulatory analyses are "likely to increase regulatory delays substantially").

<sup>275</sup> See CORNELIUS M. KERWIN, RULEMAKING: HOW GOVERNMENT AGENCIES WRITE LAW AND MAKE POLICY 247 (1994) (noting that the perception among many Congressmen in the 1980s and 1990s was that OMB review was "little more than" a vehicle for powerful business interests to frustrate normal agency processes).

<sup>276</sup> See *id.* at 245 (suggesting that OMB staff are typically trained in "general policy analysis rather than the scientific and technical subjects that lie at the base of . . . contemporary rulemaking"); see also Bressman & Vandenberg, *supra* note 251, at 97-98 (noting that from 1989 to 2001 the perception among high-level EPA officials was that scientific issues were beyond OIRA's expertise and that OIRA was not well equipped to review an agency's scientific determinations); Driesen, *supra* note 180, at 93 (referring to "scientifically ignorant OMB economists").

<sup>277</sup> See Susan E. Dudley & Angela Antonelli, *Congress and the Clinton OMB: Unwilling Partners in Regulatory Oversight?*, REGULATION, Fall 1997, at 17-18 (observing that under the Clinton administration, OIRA's role changed from substantive review based on net-benefit maximization analyses to coordination amongst stakeholders, resulting in OIRA's failure to enforce the requirement that agencies analyze multiple regulatory alternatives); Johnston, *supra* note 34, at 1403 n.148 ("OMB played a very limited role in regulatory review during the Clinton administration.").

<sup>278</sup> For a summary of OIRA's efforts to modernize existing rules, see 2004 OIRA REGULATORY REPORT, *supra* note 259, at 47-131.

Congress turned to near-term homeland security issues, the regulatory agencies continued to produce rules on traditional issues, with the White House giving OIRA wide latitude to oversee regulatory policy.

In late 2001 and early 2002, we launched a series of procedural initiatives that put OIRA in an entirely new posture: OIRA went on the offense.

### 1. Unprecedented Openness

Beginning in 2001, OIRA established a stronger climate of openness by expanding public disclosure of OIRA activities and by making greater use of the OMB website (instead of OIRA's dusty public docket room) to make information available to the public.<sup>279</sup> On a day-to-day basis, anyone in the world could learn which rules had come to OIRA for review, which had been cleared or returned to the agency, and which interest groups had met with OIRA. This information included the names of participants, their institutional affiliations, and the rule under discussion.<sup>280</sup> OIRA also expanded the disclosure policy concerning meetings with outside groups by including the time period immediately prior to formal OMB review, a period when informal discussions typically occur between OIRA and agency staff and when many outside groups seek meetings at OIRA.<sup>281</sup>

Some critics argued that we should have been even more open about our communications with offices inside the executive branch,<sup>282</sup> but we jealously guarded our freedom to engage in candid, delibera-

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<sup>279</sup> See OFFICE OF INFO. & REGULATORY AFFAIRS, OFFICE OF MGMT. AND BUDGET, STIMULATING SMARTER REGULATION: 2002 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF REGULATIONS AND UNFUNDED MANDATES ON STATE, LOCAL, AND TRIBAL ENTITIES 11-13 (2002) [hereinafter 2002 OIRA REGULATORY REPORT] (describing initiatives to open OIRA to public scrutiny and "demystify" OIRA's role in the federal regulatory process).

<sup>280</sup> See Lisa Schultz Bressman, *Beyond Accountability: Arbitrariness and Legitimacy in the Administrative State*, 78 N.Y.U. L. REV. 461, 508 (2003) ("President Bush's 'regulatory czar' at OMB, John D. Graham, has elevated visibility to an art form. The White House website provides a log of his meetings, memoranda to agency heads, and general guidance on rulemaking.").

<sup>281</sup> See U.S. GEN. ACCOUNTING OFFICE, RULEMAKING: OMB'S ROLE IN REVIEWS OF AGENCIES' DRAFT RULES AND THE TRANSPARENCY OF THOSE REVIEWS 13 (2003).

<sup>282</sup> See, e.g., SHAPIRO & GLICKSMAN, *supra* note 235, at 185 (stating that OIRA "should be required to provide a written justification whenever they block an agency's issuance of a proposed or final rule" and that "agencies should be required to include in regulatory preambles a description of any significant changes that resulted from executive branch oversight"); Bagley & Revesz, *supra* note 41, at 1282 (observing that OIRA's disclosures are sometimes "sloppy" and often uninformative).

tive discussions with other agencies, including offices within the White House.<sup>283</sup> We did not publish minutes of our meetings with outside groups because we wanted our visitors to feel comfortable speaking with complete candor about their concerns regarding agency policy. When members of Congress asked for information about regulatory matters, we strived to be as open as possible without compromising the deliberative privilege.

## 2. Revival of the “Return Letter”

In the first year after my confirmation, we returned more than twenty rules to agencies for reconsideration, more than the total number of returns in the entire eight years of the Clinton administration.<sup>284</sup> This rate of return was lower than the return rate in the Reagan administration, but it was large enough to establish our credibility.<sup>285</sup> Each return letter (and the agency’s response) was posted on the OMB website so that the public could appreciate OIRA’s view of the technical shortcomings of the draft rule. In fact, once our power to return rules was demonstrated in the first year, we did not need to return many rules. Agencies respected our authority by following our instructions or persuading us that we should take their view. Rarely were disputes between OIRA and regulators taken to the OMB Director or the President for resolution.

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<sup>283</sup> Cf. Pildes & Sunstein, *supra* note 16, at 23-24 (explaining that disclosure of intra-executive branch communications is somewhat “troublesome” because it impedes the performance of executive agency functions and inhibits open communication); Seidenfeld, *supra* note 190, at 22 (“[I]n reality, unless every aspect of the OMB review process is thrown open to public scrutiny, secret channels for influencing OMB review will remain.” (footnote omitted)). However, as Sally Katzen, a former OIRA administrator from the Clinton administration, has discussed, openness does not necessarily lead to more accountability. See Katzen, *supra* note 249, at 1503 (“[I]t is the *product* of the decision-making, not the *process* of the decision-making, that is the key to accountability—however desirable it would be to know who said what to whom in the oval office (or in an office of a presidential aide).”).

<sup>284</sup> See U.S. GEN. ACCOUNTING OFFICE, *supra* note 281, at 41-43, 42 fig.5; 2002 OIRA REGULATORY REPORT, *supra* note 279, at 14 & tbl.2 (discussing the revival of the return letter and presenting data on the frequency of return letters from 1981 to 2000).

<sup>285</sup> See, e.g., Stephen Power & Jacob M. Schlesinger, *Bush’s Rules Czar Brings Long Knife to New Regulations*, WALL ST. J., June 12, 2002, at A1 (discussing how OIRA gained control over the federal regulatory process).

### 3. Invention of the “Prompt Letter”

To facilitate OIRA’s support of promising regulations, we invented a new tool called the “prompt letter.”<sup>286</sup> Unlike a presidential directive, which is a nondiscretionary order, a prompt letter is a public request by OIRA, to a regulator, that a rulemaking be initiated or completed,<sup>287</sup> that information relevant to a regulatory program be disclosed to the public,<sup>288</sup> or that a piece of research or analysis relevant to rulemaking be conducted.<sup>289</sup>

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<sup>286</sup> See generally 2002 OIRA REGULATORY REPORT, *supra* note 279, at 21-23 (discussing the rationale for the prompt letter and its early uses). The OIRA prompt letters are published at <http://www.reginfo.gov/public/jsp/EO/promptLetters.jsp>.

<sup>287</sup> Prompt letters do not exclusively serve proregulation purposes. It may on occasion be appropriate for OIRA to use a prompt letter to urge an agency to eliminate an outmoded or overly burdensome regulation.

<sup>288</sup> I was enthusiastic about OIRA’s effort to persuade the EPA, via prompt letter, to improve the operation of the Toxic Release Inventory (TRI) program. See Letter from John D. Graham, Adm’r, Office of Info. & Regulatory Affairs, to Kim T. Nelson, Assistant Adm’r, Office of Envtl. Info., U.S. Envtl. Prot. Agency (Mar. 4, 2002), *available at* [http://www.reginfo.gov/public/prompt/epa\\_tri3\\_prompt030402.html](http://www.reginfo.gov/public/prompt/epa_tri3_prompt030402.html). The improvements included greater use of electronic reporting of emissions and earlier public access to the electronic data supplied by industry. The prompt letter was spurred by a meeting at OIRA with an environmental advocacy group called Environmental Defense, and the EPA responded to the prompt letter by participating in a meeting with Environmental Defense representatives. When I left OIRA in 2006, my understanding was that the EPA had made some progress in this area but that more needed to be done. On the origins and success of the overall TRI program, see generally JAMES T. HAMILTON, REGULATION THROUGH REVELATION: THE ORIGIN, POLITICS, AND IMPACTS OF THE TOXICS RELEASE INVENTORY PROGRAM (2005).

<sup>289</sup> We issued two prompt letters that spurred interesting interagency discussions regarding priorities for research and analysis. We prompted the Energy Information Administration (EIA), an independent research arm of the Department of Energy, to treat hybrid engines and advanced diesel technology as compliance alternatives in models of industry response to tighter federal fuel-economy standards. See Letter from John D. Graham, Adm’r, Office of Info. & Regulatory Affairs, to Mary Hutzler, Dir., Office of Integrated Analysis & Forecasting, Energy Info. Admin., U.S. Dep’t of Energy (Feb. 24, 2003), *available at* [http://www.reginfo.gov/public/prompt/prompt-ltr\\_eia.pdf](http://www.reginfo.gov/public/prompt/prompt-ltr_eia.pdf). Prior to our prompt letter, the EIA included these technologies in purely market-based forecasts but, for some inexplicable reason, excluded them from the suite of compliance strategies that the EIA used to assess the future costs and benefits of federal fuel-economy standards. The EIA initially objected to our request, in part on the grounds that including these technologies would dampen its estimates of the economic harm of legislation to tighten mileage standards. See Letter from Mary J. Hutzler, Dir., Office of Integrated Analysis & Forecasting, Energy Info. Admin., U.S. Dep’t of Energy, to John D. Graham, Adm’r, Office of Info. & Regulatory Affairs (Mar. 17, 2003), *available at* [http://www.reginfo.gov/public/prompt/prompt\\_eia\\_response\\_ltr.pdf](http://www.reginfo.gov/public/prompt/prompt_eia_response_ltr.pdf). We argued that the EIA’s models should be made as realistic as possible, regardless of whether they make regulatory legislation appear to be more or less expensive. Professors Bagley and Revesz misinterpreted this prompt letter as an effort to as-

During my tenure, OIRA prompt letters were aimed at a broad range of purposes: to improve food labels, stimulate new dietary guidelines, promote use of lifesaving defibrillators in the workplace, protect motorists in “off-center” collisions, identify the most harmful particles in the air, protect beach goers from harmful bacteria, enhance community access to information about toxic industrial emissions, improve the designation of critical habitats under the Endangered Species Act,<sup>290</sup> and reduce taxpayer liability due to default rates on mortgages. In each case, we offered proactive, constructive suggestions about how public policy could be improved.

Our pioneering prompt requested that the FDA compel food companies to label foods for trans-fat content, a risk factor for coronary heart disease.<sup>291</sup> This rulemaking began during the Clinton administration but was moving at a snail’s pace until the OIRA prompt letter stimulated the FDA to move more expeditiously.<sup>292</sup> According

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sist the auto industry in its campaign against fuel-economy regulation. Bagley & Revesz, *supra* note 41, at 1279. To the contrary, inclusion of advanced diesels in EIA modeling provides another practical compliance alternative for industry, thereby supporting stricter fuel-economy standards. In fact, we urged diesel engine suppliers to meet with the EIA and explain the value of clean-diesel technology as a compliance option under federal fuel-economy standards. After careful review, the EIA revised its modeling along the lines that we requested.

The other example of a research-oriented prompt, where OIRA may have been less successful, concerned the EPA’s research strategy to clarify whether all fine particles are equally toxic. See Letter from John D. Graham, Adm’r, Office of Info. & Regulatory Affairs, to Christine Todd Whitman, Adm’r, U.S. Env’tl. Prot. Agency (Dec. 4, 2001), *available at* [http://www.reginfo.gov/public/prompt/epa\\_pm\\_research\\_prompt120401.html](http://www.reginfo.gov/public/prompt/epa_pm_research_prompt120401.html). We urged the EPA to give greater emphasis to large-scale epidemiological studies of different types of particles. Initially, I was pleased to learn that the Health Effects Institute, with funding from the EPA and the auto industry, moved some of its research in this direction. But I left OIRA in 2006 unconvinced that the EPA was exercising adequate scientific leadership. Several months after I left OIRA, on April 13, 2006, OIRA issued another prompt letter to the EPA urging the agency to give greater priority to research that will clarify whether it is true that all fine particles are equally toxic. See Letter from Donald R. Arbuckle, Acting Adm’r & Deputy Adm’r, Office of Info. & Regulatory Affairs, to Stephen L. Johnson, Adm’r, U.S. Env’tl. Prot. Agency (Apr. 13, 2006), *available at* [http://www.reginfo.gov/public/prompt/Prompt\\_Letter\\_to\\_EPA.pdf](http://www.reginfo.gov/public/prompt/Prompt_Letter_to_EPA.pdf). OIRA’s letter notes that the European Commission is already publishing sensitivity analyses that depart from this key assumption.

<sup>290</sup> See 16 U.S.C. § 1533(a)(3) (2006) (establishing procedures for the designation of critical habitats).

<sup>291</sup> See Letter from John D. Graham, Adm’r, Office of Info. & Regulatory Affairs, to Tommy G. Thompson, Sec’y, Dep’t of Health & Human Servs. (Sept. 18, 2001), *available at* [http://www.reginfo.gov/public/prompt/hhs\\_prompt\\_letter.html](http://www.reginfo.gov/public/prompt/hhs_prompt_letter.html).

<sup>292</sup> For a more detailed history of the prompt letter on the FDA’s trans-fats labeling rule, see John D. Graham, *The Evolving Regulatory Role of the U.S. Office of Management and Budget*, 1 REV. ENVTL. ECON. & POL’Y 171, 173-75 (2007).

to the FDA health economists, the benefits from reduced heart attacks from this rule (up to \$2.9 billion per year) will more than pay for the extra labeling and food-processing costs (up to \$275 million per year and declining after the third year of compliance).<sup>293</sup> The FDA's rule-making also helped stimulate a much broader movement in the United States and abroad to reduce the trans-fat content of foods offered everywhere from fast-food restaurants to grocery stores.<sup>294</sup>

OIRA also prompted OSHA to consider various policy options, including regulation, to promote the use of automated external defibrillators (AEDs) in the workplace.<sup>295</sup> AEDs are used to save lives during sudden cardiac arrest. In response to OIRA's request, OSHA worked with key outside groups (e.g., the American Heart Association and the National Safety Council) to promote wider use of AEDs at workplaces.

Interestingly, it was the lawyers in the Department of Labor who dug in their heels against a regulatory strategy on AEDs. They argued that since the deaths averted by AEDs are not caused by workplace exposures, OSHA lacks the authority to force employers to ensure that AEDs are made available at work. They also made a policy argument that such a rulemaking would set a precedent for a potentially infinite number of new employer obligations in the workplace (hypertension control, obesity prevention, smoking cessation, and so forth). I did not believe that these arguments were fully persuasive but was pleased that OSHA cooperated on an AED educational effort. If education fails to proliferate AED use, it may be appropriate for OSHA to pursue a regulatory strategy.

Prompt letters did not always lead to the policy outcome that OIRA initially anticipated and preferred,<sup>296</sup> but they were always aimed

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<sup>293</sup> For a summary of the FDA's trans-fat rule and for ranges of estimated benefits and costs of the rule, see 2004 OIRA REGULATORY REPORT, *supra* note 259, at 19 tbl.4.

<sup>294</sup> See, e.g., Ban Trans Fats: The Campaign to Ban Partially Hydrogenated Oils, <http://www.bantransfats.com/abouttransfat.html> (last visited Nov. 15, 2008).

<sup>295</sup> See Letter from John D. Graham, Adm'r, Office of Info. & Regulatory Affairs, to John Henshaw, Assistant Sec'y, Dep't of Labor (Sept. 18, 2001), *available at* [http://www.reginfo.gov/public/prompt/osha\\_prompt\\_letter.html](http://www.reginfo.gov/public/prompt/osha_prompt_letter.html). Professor Driesen asserts that "[n]one of the prompt letters addressing environmental, health, and safety regulation sought to initiate fresh regulation." Driesen, *supra* note 41, at 381. Yet rulemaking was one of the policy options that OIRA asked OSHA to consider in the AED prompt letter, and promotion of AED use in the workplace was certainly a fresh issue at OSHA.

<sup>296</sup> For example, OIRA suggested in a prompt letter that NHTSA consider initiating a new safety standard to protect motor-vehicle occupants in "off-center" frontal collisions. See Letter from John D. Graham, Adm'r, Office of Info. & Regulatory Affairs, to Michael P. Jackson, Deputy Sec'y, Dep't of Transp. (Dec. 7, 2001), *available at*

at promoting “smart” regulatory policy. A few scholars have downplayed or criticized this institutional innovation,<sup>297</sup> but I believe the grounds for opposing prompt letters are weak. The OIRA prompt letter has been praised by a variety of legal scholars.<sup>298</sup>

#### 4. Shorter OIRA Reviews

Timeliness in the OIRA review process is necessary in order for federal regulatory agencies to plan their work and allocate their resources wisely. To ensure promptness in OIRA reviews, I insisted on personally approving any OIRA review that was approaching more than three months in duration.<sup>299</sup>

The result of my focus on promptness was significant. Formal OIRA review times plummeted soon after I joined OIRA in July 2001.<sup>300</sup> Often, upon request, OIRA agreed to expedited considera-

[http://www.reginfo.gov/public/prompt/nhsta\\_prompt120701.html](http://www.reginfo.gov/public/prompt/nhsta_prompt120701.html). NHTSA was initially enthusiastic about the idea but later informed OIRA, based upon some experimental crash tests, that the addition of an off-center crash test might induce vehicle manufacturers to comply with stiffer exteriors. More stiffness might protect occupants in the striking vehicle, but the occupants in the struck vehicle could suffer more serious injuries. When I left OIRA in 2006, my understanding was that NHTSA remained concerned about whether a mandatory offset testing rule would have perverse safety impacts, especially in collisions between cars and light trucks.

<sup>297</sup> See, e.g., Heinzerling & Steinzor, *supra* note 251, at 10,488 n.36 (observing that “[n]o prompt letter suggesting tightened regulation has been issued” since the two most important prompts on trans-fats and AEDs were issued). But, in fact, subsequent OIRA prompt letters also influenced rulemakings by the U.S. Department of Agriculture (adding environmental-conservation criteria for the allocation of agricultural subsidies under the Environmental Quality Incentives Program in 2002), the Office of Federal Housing Enterprise Oversight (protecting the financial interests of taxpayers from the risk of defaults on mortgages in 2002), and the EPA’s Office of Water (protecting beach goers from harmful bacteria in 2004).

<sup>298</sup> See, e.g., Bagley & Revesz, *supra* note 41, at 1277 (referring to the prompt letter as “a salutary development” and implying that it should be incorporated into a reinvigorated executive order); Hahn & Sunstein, *supra* note 172, at 1522 (praising OIRA’s prompt-letter idea as a “striking, if overdue, innovation”); Parker, *supra* note 34, at 1417 n.260 (describing the prompt-letter initiative as “a start in the right direction”); Wiener, *supra* note 186, at 489-90 (declaring prompt letters to be a “pathbreaking innovation” and calling for the inclusion of prompt letters explicitly in the next revision to the executive order on regulatory review).

<sup>299</sup> See U.S. GEN. ACCOUNTING OFFICE, *supra* note 281, at 46-47 (“[I]n May 2002 the current OIRA Administrator said ‘. . . I have instructed my staff that no rule will stay longer than 90 days at OMB without my personal authorization.’”).

<sup>300</sup> See 2002 OIRA REGULATORY REPORT, *supra* note 279, 18 tbl.4 (demonstrating that the percentage of OIRA reviews taking longer than ninety days declined from 12% to 27% in 1999–2000 to less than 2% in 2001–2002).

tion of rules when the agency made a reasonable case. I received few complaints from agencies about the length of OIRA reviews.

### 5. Emphasis on Information Quality

The quality of BCA is only as good as the quality of the input data used to compute benefits and costs. OIRA engaged in a multiyear process to strengthen both the quality of OIRA's technical staffing and the information-quality policies that we applied to agency activities.<sup>301</sup>

During my tenure, OIRA hired its first toxicologist and first epidemiologist to assist in asking hard questions about public health risks and benefits. We also hired an engineer and a health-policy specialist, complementing OIRA's historic strengths in welfare economics, statistics, and policy analysis.<sup>302</sup> We modernized OIRA's guidance on BCA through a multiyear process involving expert peer review, interagency review, and public comment.<sup>303</sup> The National Academy of Sciences (NAS) was repeatedly consulted as an authoritative body to resolve technical disputes among agencies.<sup>304</sup> We also established new procedures for information quality, including peer review prior to agency release of scientific and technical information, and a new corrections process that the public could use if erroneous or misleading information was released by agencies.<sup>305</sup> One of my few disappointments at OIRA was that government-wide guidance on risk assessment was not finished before I left in early 2006.<sup>306</sup> But, after I left, my successor,

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<sup>301</sup> See generally James T. O'Reilly, *The 411 on 515: How OIRA's Expanded Information Roles in 2002 Will Impact Rulemaking and Agency Publicity Actions*, 54 ADMIN. L. REV. 835 (2002) (discussing changes to OIRA's role in reviewing agency information dissemination).

<sup>302</sup> See John D. Graham et al., *Managing the Regulatory State: The Experience of the Bush Administration*, 33 FORDHAM URB. L.J. 953, 968-69 (2006) (discussing the rationale for changing the OIRA staff mix).

<sup>303</sup> See, e.g., OMB Circular A-4, *supra* note 259, at 1 ("In developing this Circular, OMB first developed a draft that was subject to public comment, interagency review, and peer review.").

<sup>304</sup> For an example of the NAS serving in its technical-dispute-resolution role, see NATIONAL RESEARCH COUNCIL, NAS, HEALTH IMPLICATIONS OF PERCHLORATE INGESTION (2005), available at [http://dels.nas.edu/dels/rpt\\_briefs/perchlorate\\_brief\\_final.pdf](http://dels.nas.edu/dels/rpt_briefs/perchlorate_brief_final.pdf), in which the NAS provided an independent assessment of the risks of perchlorate ingestion, when critics alleged that the EPA's risk assessments were flawed.

<sup>305</sup> On OIRA's information-quality initiative, see 2005 OIRA REGULATORY REPORT, *supra* note 8, ch. IV; 2002 OIRA REGULATORY REPORT, *supra* note 279, at 24-30.

<sup>306</sup> During my tenure, we submitted for peer review a draft bulletin on risk assessment by a committee assembled by the National Academy of Sciences. The committee raised a variety of technical concerns about the draft and suggested an alternative process—principles instead of technical guidance—for OIRA to pursue in its effort to

Susan Dudley, worked with OIRA staff to modernize OIRA's principles for sound risk-assessment practice in a memorandum to federal agencies.

All of these steps send a clear message to regulators: OIRA cares about the quality of the science and economics that inform and justify regulatory decisions.

#### D. *OIRA as an Advocate of Lifesaving Regulation, 2001–2006*

The portrait of OIRA as an ardent, ideological force for deregulation was not the OIRA that I experienced during the George W. Bush administration. As I served in a pro-business Republican presidency, OIRA frequently supported lifesaving regulations of business activity. The OIRA position did not always prevail, but OIRA was certainly not, as some legal scholars perceive, a knee-jerk voice against regulation of business. In this section I offer several examples of this phenomenon based on personal experience, including three in-depth case studies of large rulemakings by the EPA and DOT. Before turning to the cases, I must describe some of the complexity of the Executive Office of the President (EOP).

Until very recently, centralized White House oversight of regulation had been viewed as a bilateral model, where OIRA and the regulatory agency negotiated the terms of a regulation. OIRA's role is modest and complicated due to the large number of actors inside the executive branch (including various offices inside the White House) with interests in regulatory policy.<sup>307</sup> Other interested EOP units include the White House policy offices (domestic and economic policy), the White House communications and political offices, the Vice President's office, the Council of Economic Advisers, and the Council on Environmental Quality.

In the George W. Bush administration, OIRA provided a distinctive perspective because it was often the only office inside the Execu-

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enhance the quality of agency risk assessments. See COMM. TO REVIEW THE OMB RISK ASSESSMENT BULLETIN, NAT'L RESEARCH COUNCIL, SCIENTIFIC REVIEW OF THE PROPOSED RISK ASSESSMENT BULLETIN FROM THE OFFICE OF MANAGEMENT AND BUDGET (2007). After my departure, OIRA followed the National Academy of Sciences's advice.

<sup>307</sup> See, e.g., Bressman & Vandenberg, *supra* note 251, at 93 (describing EPA survey respondents' impressions that "presidential control was not a unified enterprise but coalitions of different offices competing for influence over EPA rulemaking," and that "OIRA often was in the middle, brokering regulatory bargains in some cases and used by certain White House offices to combat other White House offices in other cases").

tive Office of the President (with the possible exception of the Council of Economic Advisers) that was primarily interested in a benefit-cost perspective on rulemakings and legislation.<sup>308</sup> Other offices were concerned with matters such as White House relations with stakeholders, communications, congressional affairs, intergovernmental affairs, and the President's political priorities.

As one of the few EOP units with a well-trained career staff, OIRA is generally respected throughout the EOP as a unit that uses its professional expertise to form policy positions. Since OIRA is perceived inside the EOP as an apolitical, professional organization, it also is well placed to coordinate the views of multiple agencies and EOP offices on rulemaking proposals. It is also OIRA's role to help communicate conflicting views throughout the White House and to help seek resolution without elevation to the President.

When OIRA emerged as a proregulation advocate of lifesaving investments, it did so in various ways. Sometimes OIRA played a pro-lifesaving role by trying to persuade the regulator to take a more aggressive regulatory position (e.g., a rule with broader scope or greater stringency). But more often, OIRA, in an alliance with the regulator, worked inside the EOP on behalf of lifesaving regulation. OIRA often countered the skeptical or opposing views of other agencies or EOP units.

Thus, OIRA was not reluctant to take a proregulation position, but it often did so in complex situations where factions inside and outside the administration were competing for policy influence. I turn to three in-depth case studies of OIRA's pro-lifesaving role in the George W. Bush administration.

### 1. Reducing Diesel-Engine Exhaust

The first case study concerns the air pollution from diesel engines used to power heavy trucks on the highway and the many off-road engines used in construction, agriculture, and mining.<sup>309</sup> In this case, BCA produced a determinate result, and thus the EPA and OIRA

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<sup>308</sup> See Stewart, *supra* note 171, at 179 ("There is a strong ideological constituency within the West Wing and the Executive Office of the President—exemplified by the Council of Economic Advisers, OMB, and the Treasury—that is committed to promoting economic efficiency and the soundness of the economy.").

<sup>309</sup> For a more in-depth version of this case study, see Graham, *supra* note 292, at 175-77.

joined forces to protect an existing rule and to bring to fruition a new major lifesaving regulation.<sup>310</sup>

The story begins in 2000, near the end of the Clinton administration, when the EPA issued a multibillion-dollar regulation of refiners and engine suppliers. The aim was to slash by 90% the amount of diesel exhaust from heavy trucks on the highway. Although engine suppliers were expected to incur some of the costs, the bigger investments were to be made at refineries, where the sulfur content of diesel fuel was to be reduced dramatically. The rule was a bitter pill for the refining industry, which had struggled financially through much of the 1980–2000 period.<sup>311</sup>

Soon after President Bush took office, conservative think tanks and industry representatives requested that the EPA's 2000 highway diesel rule be reconsidered. The Mercatus Center of George Mason University argued in a comment to OIRA that the EPA had not prepared an adequate BCA to support the 2000 highway diesel rule. And since OIRA had requested nominations of rules for reconsideration, the Mercatus suggestion to reconsider the highway diesel rule came at an opportune time.<sup>312</sup>

OIRA reviewed the highway diesel rule, but came to a different conclusion from the Mercatus Center. The rule was certainly expensive, as it was projected to cost about \$4.3 billion per year in 2030. However, the EPA also estimated that the rule would prevent 8300 cases of premature death, 5500 cases of chronic bronchitis, and 361,400 asthma attacks each year. The estimated benefits in 2030 were huge—about \$70.4 billion per year, or a ratio of benefit to cost of about 16 to 1.

Based on the benefit-cost results, OIRA decided to support the EPA in opposition to any reopening of the highway diesel rule. This decision, which created an unusual OIRA-EPA alliance, caused con-

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<sup>310</sup> In 2007, the EPA extended similar requirements to diesel locomotives and marine vessels. Control of Emissions of Air Pollution from Locomotive Engines and Marine Compression-Ignition Engines Less Than 30 Liters per Cylinder, 72 Fed. Reg. 15,938 (proposed Apr. 3, 2007) (codified in scattered parts of 40 C.F.R.).

<sup>311</sup> See Ana Campoy, *Refiners Cash In on High Gasoline Prices*, WALL ST. J., May 18, 2007, at A10 (“For decades, there was too much refining capacity in the U.S., margins were crummy and many companies were closing or selling off refineries.”).

<sup>312</sup> See OFFICE OF INFO. & REGULATORY AFFAIRS, OFFICE OF MGMT. & BUDGET, MAKING SENSE OF REGULATION: 2001 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF REGULATIONS AND UNFUNDED MANDATES ON STATE, LOCAL, AND TRIBAL ENTITIES 105 (2001) (summarizing the regulatory-reform nomination on the highway diesel rule submitted to OIRA by the Mercatus Center).

sternation among some White House offices that felt OIRA should be working aggressively to reduce the cost burdens of regulation on business. When explaining this decision to senior administration officials, OIRA made effective use of the findings from BCA.

Rather than delay or weaken the highway diesel rule, OIRA began to consider whether the same fumes should be reduced from the large number of off-road diesel engines used in construction, agriculture, and mining. OIRA staff believed that the EPA possessed the legal authority to regulate these off-road engines. But there was no statutory requirement or deadline to do so, and the Clinton EPA had not covered this sector in the 2000 rule.

In 2002, OIRA began to draft a prompt letter requesting that the EPA regulate off-road diesel engines.<sup>313</sup> When we met informally with the EPA to discuss the prompt, EPA staff insisted that the rulemaking was already a priority. We therefore agreed to undertake an unprecedented EPA-OMB rulemaking collaboration, which was announced in 2002 via press release.<sup>314</sup>

To make a long story short, the EPA issued an ambitious rule in 2004 calling for a 90% reduction in the exhaust from diesel engines used in the nonroad sector.<sup>315</sup> Although the rule was costly, the estimated ratio of benefits to costs was roughly 40 to 1 by 2030.<sup>316</sup> Despite large scientific uncertainties, the agency's probability analysis showed a very high likelihood (over 90%) that the benefits of the rule would exceed the significant costs.<sup>317</sup>

Aided by this impressive benefit-cost case, OIRA helped the EPA persuade other federal agencies and the White House that another multibillion-dollar regulation of the refining industry was worthwhile. The rule was issued without any court order, with no statutory deadline in the Clean Air Act, and with no commitment made by the President during the 2000 campaign. In the absence of the favorable

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<sup>313</sup> See Graham, *supra* note 292, at 175.

<sup>314</sup> See Press Release, U.S. Envtl. Prot. Agency, EPA and OMB Working to Speed the Reduction of Pollution from Nonroad Diesel Engines (June 7, 2002), available at <http://www.epa.gov/otaq/press2002.htm> (follow link for press release).

<sup>315</sup> Control of Emissions of Air Pollution from Nonroad Diesel Engines and Fuel, 69 Fed. Reg. 38,958 (June 29, 2004) (codified in scattered parts of 40 C.F.R.).

<sup>316</sup> 2005 OIRA REGULATORY REPORT, *supra* note 8, at 98 tbl.A-1 (estimating benefits of \$83 billion and annual costs of \$2.1 billion in 2030).

<sup>317</sup> See EPA, FINAL REGULATORY ANALYSIS: CONTROL OF EMISSIONS FROM NONROAD DIESEL ENGINES, at ES-2 (2004) ("Despite the uncertainty inherent in the benefit-cost analysis for this rule, the results strongly support a conclusion that the benefits will substantially exceed costs.").

information on benefits and costs and the support from OIRA, I doubt whether the EPA would have issued this rule promptly, if at all.

During this same time frame, a controversy erupted over whether the EPA should penalize engine manufacturers that did not comply with the accelerated 2004 deadline for introduction of cleaner engines under the 2000 highway diesel rule. While some manufacturers were ready to comply, others sought delay or small noncompliance penalties. In order to ensure a strong signal favoring environmental innovators in the business sector, OIRA joined the EPA in persuading the Bush administration to support a strong noncompliance penalty formula.<sup>318</sup>

In summary, OIRA's proregulation approach to diesel-engine exhaust is a clear illustration of OIRA responding to an ideology of BCA, not an ideology against regulation or in favor of business interests. In some respects, the tale is reminiscent of OIRA's role in the accelerated phase-out of lead in gasoline in the early 1980s.

## 2. Reducing Sulfur and Nitrogen Oxides from Coal Plants

The second case study concerns a major rule issued by the EPA in 2005 to reduce sulfur dioxide and nitrogen emissions from coal-fired power plants. BCA again reached a determinative result, but this time the sulfur portion of the rule, even though it called for a 70% reduction in emissions, was not as stringent as OIRA believed was justified by BCA. This is an interesting case where the EPA and OIRA joined forces in advocating a rule that was more stringent than the administration could support.

Beginning in 2001, OIRA worked closely with the EPA and other agencies on the President's Clear Skies initiative, an ambitious legislative proposal to rewrite the Clean Air Act.<sup>319</sup> Even though then-Governor Bush had campaigned in favor of the idea in the 2000 presidential contest against Vice President Gore, by 2001 Bush's advisors were split on whether Clear Skies should be proposed.

A significant faction in the administration argued that proposing Clear Skies would serve no constructive purpose. With the Democrats controlling the Senate Committee on Environment and Public Works, skeptics argued that either (a) the Committee would block considera-

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<sup>318</sup> See Control of Air Pollution from New Motor Vehicles and New Motor Vehicle Engines, 67 Fed. Reg. 2159 (Jan. 16, 2002) (to be codified at 40 C.F.R. pt. 86).

<sup>319</sup> S. 485, 108th Cong. (2003). For a more in-depth version of this case study, see Graham, *supra* note 292, at 181-86.

tion of Clear Skies, making the President look ineffective, or (b) the Committee would insist upon so many draconian changes to Clear Skies that the bill would not be worth passing.

OIRA joined the White House Council on Environmental Quality and the EPA in the prolegislation camp, but hindsight reveals considerable merit in the skeptical view. Clear Skies was proposed by President Bush but was never considered on the Senate floor, even when the Republicans acquired a 55-45 majority after the 2004 election.<sup>320</sup> A key factor in the defeat of Clear Skies was the President's decision to exclude carbon dioxide from the legislation. He reversed his 2000 campaign pledge to include it along with three other pollutants: sulfur dioxide, nitrogen dioxide, and mercury.<sup>321</sup>

In the course of helping to prepare the Clear Skies proposal, I learned why it can be difficult for benefit-cost insights to determine the content of a legislative proposal, especially when complex regional and partisan politics are in play. Clear Skies called for a uniform, nationwide 70% reduction in three pollutants (sulfur dioxide, nitrogen dioxide, and mercury). From a benefit-cost perspective, OIRA lost its arguments that the sulfur cap should be more stringent (a 90% rather than a 70% reduction) while the mercury cap should be less stringent (than a 70% reduction). What carried the day were arguments that the President's initial proposal to Congress should (1) be easy to explain (e.g., a uniform 70% control for all three pollutants) and (2) leave some room for additional stringency on sulfur in the event that a realistic chance of compromise with Senate Democrats could be found.

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<sup>320</sup> See Catherine Hunter, *Fall Agenda: "Clear Skies" Emissions Controls*, 63 CQ WKLY. 2313, 2314 (2005) ("[T]he Senate Environment and Public Works Committee deadlocked 9-9, essentially defeating the bill in March."); Shankar Vedantam, *Senate Impasse Stops 'Clear Skies' Measure*, WASH. POST, Mar. 10, 2005, at A4 ("President Bush's bid to rewrite federal air pollution laws ground to a halt in Congress yesterday when Republicans were unable to overcome objections in the Senate Environment and Public Works Committee that the bill would weaken the central pillars of the nation's environmental protection framework.").

<sup>321</sup> See Seth Borenstein, *Bush Changes Pledge on Emissions*, PHILA. INQUIRER, Mar. 14, 2001, at A2 ("Reversing a campaign pledge he made in September, President Bush announced yesterday that he would not regulate power plants' emissions of carbon dioxide, which scientists say contributes to global warming."); Press Release, The White House, Text of a Letter from the President to Senators Hagel, Helms, Craig, and Roberts (Mar. 13, 2001), available at <http://www.whitehouse.gov/news/releases/2001/03/20010314.html> ("I do not believe, however, that the government should impose on power plants mandatory emissions reductions for carbon dioxide, which is not a 'pollutant' under the Clean Air Act.").

In the course of collaborating with the EPA on Clear Skies, I became aware that some senior Bush administration officials were skeptical of the accuracy of the EPA's large benefit estimates for sulfur control. OIRA concluded, given the uncertainties in the EPA's primary estimates, that the EPA should also prepare an alternative set of benefit estimates that were plausible but not as optimistic as the agency's primary estimates.<sup>322</sup> I instructed my staff to ensure that the EPA's alternative benefit estimates<sup>323</sup> account for two plausible possibilities: that sulfates do not cause as many premature deaths as the EPA predicted, and that the proper monetary valuation of avoided deaths is not as large as the EPA predicted.<sup>324</sup>

The alternative benefit estimate, to which some EPA staff objected strenuously, was almost ten times smaller than the EPA's primary estimate.<sup>325</sup> Yet even the alternative benefit estimate was large enough

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<sup>322</sup> See NAT'L RESEARCH COUNCIL, ESTIMATING THE PUBLIC HEALTH BENEFITS OF PROPOSED AIR POLLUTION REGULATIONS 43 tbl.2-2, 46 tbl.2-3 (2002) (summarizing health-benefit estimates for gasoline and highway diesel sulfur-control requirements).

<sup>323</sup> I was aware that, during the Clinton administration, the EPA presented "alternative" (as well as "primary") benefit estimates in support of the 2000 highway diesel rule. See EPA, REGULATORY IMPACT ANALYSIS: HEAVY-DUTY ENGINE AND VEHICLE STANDARDS AND HIGHWAY DIESEL SULFUR CONTROL REQUIREMENTS, at xvii tbl.ES-6 (2000).

<sup>324</sup> For an extensive critique of the alternative benefit estimates on the grounds that the estimates are inconsistent with economic theory and are too low, see Laura J. Lowenstein & Richard L. Revesz, *Anti-Regulation Under the Guise of Rational Regulation: The Bush Administration's Approaches to Valuing Human Lives in Environmental Cost-Benefit Analyses* 64-66 (N.Y. Univ. Law & Econ. Research Paper Series, Working Paper No. 04-014, Mar. 12, 2004), available at <http://ssrn.com/abstract=556721> (showing that four questionable techniques led to "an inappropriate undervaluation of environmental benefits of over 85%"). But even with the alleged "undervaluation," the estimated benefits of the Clear Skies proposal exceeded the estimated costs! The alternative estimate was not designed to provide a best estimate; it was intended as a low-bounding estimate that would balance the more optimistic estimate that EPA staff favored. The presentation of the alternative estimate (as well as the larger, primary benefit estimate) helped to generate consensus in the White House for a multibillion-dollar lifesaving proposal. By attacking the alternative benefit estimate as if it stood alone (rather than as a supplement to the primary estimate), the critique by Lowenstein and Revesz misses the point of the alternative analysis.

<sup>325</sup> The senior discount originated during the Clinton administration in an alternative benefit analysis supporting the 2000 highway diesel rule, even though Laura Lowenstein and Professor Revesz attribute the analytic practice to the George W. Bush administration. See *id.* at 8-9 ("[T]he Bush administration began including alternative benefit estimates in cost-benefit analyses of proposed environmental regulations."); see also EPA, *supra* note 323, at xvii tbl.ES-6 (noting that two discounts were used based on different surveys from the United Kingdom, one of -10% and another -41%). My staff at OIRA was (understandably) frustrated that critics of the senior discount did not appreciate (or acknowledge) the fact that, under the alternative estimate, the average

to support stricter sulfur limits than were contained in the Clear Skies proposal, a point that I made repeatedly to skeptical officials from the Department of Energy (DOE) and the White House.

In 2003, as it became increasingly certain that Congress would not pass Clear Skies, the President instructed OIRA to begin working with the EPA on rulemakings that would accomplish as much of the administration's agenda as possible under existing Clean Air Act authority. In March 2005, when the Senate failed in a last-ditch effort to move Clear Skies, the EPA issued a final rule on sulfur and nitrogen control. Called the Clean Air Interstate Rule (CAIR),<sup>326</sup> the measure was justified as a tool to prevent the interstate transport of pollution. It was the most expensive new regulation of business that I cleared during my tenure at OIRA.<sup>327</sup>

CAIR compelled a 60% to 70% reduction in emissions of sulfur dioxide and nitrogen dioxide from coal-fired power plants located east of the Mississippi River. The economic case for the rule is impressive, since the estimated ratio of benefits to costs is roughly 30 to

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year of life saved for a senior citizen was valued at a premium compared to the average year of life saved for a middle-aged adult. In particular, the alternative estimate placed the average value of a life-year at \$172,000 for those under age 65 and \$434,000 for those over age 65. Cass R. Sunstein, Essay, *Lives, Life-Years, and Willingness to Pay*, 104 COLUM. L. REV. 205, 208 n.18 (2004). See generally James K. Hammitt, *Valuing Mortality Risk: Theory and Practice*, 34 ENVTL. SCI. & TECH. 1396, 1399 (2000) (noting that empirical studies suggest that the value of a statistical life (VSL) is not constant but increasing with age). Under a nonconstant VSL method, the overall valuation of life for seniors could be higher or lower than the preferred VSL figure for middle-aged adults, depending upon how many years of life are at risk. See Lisa A. Robinson, *How US Government Agencies Value Mortality Risk Reductions*, 1 REV. ENVTL. ECON. & POL'Y 283, 287 (2007) (discussing the controversy surrounding the "senior discount implicit in age-adjusted VSL estimates used by the EPA").

<sup>326</sup> 70 Fed. Reg. 25,162 (May 12, 2005) (codified in scattered parts of 40 C.F.R.). In 2008, the D.C. Circuit vacated CAIR on statutory grounds that were not directly related to benefit-cost considerations. See *North Carolina v. EPA*, 531 F.3d 896, 929 (D.C. Cir. 2008). It is not yet clear whether CAIR will be redone or whether Congress will seek to accomplish similar goals through legislative action. Either way, it is likely that the policy outcome will move even more strongly in the direction favored by OIRA, which was stricter control of sulfur dioxide (and to a lesser extent nitrogen dioxide). Legislative action would be the best approach to achieving a national cap-and-trade program, including the possible inclusion of carbon dioxide as another tradable pollutant.

<sup>327</sup> The EPA estimated the social costs of CAIR to be \$1.9 billion in 2010 and \$2.6 billion in 2015 (using a 3% discount rate), or \$2.1 billion in 2010 and \$3.1 billion in 2015 (at a 7% discount rate). Clean Air Interstate Rule, 70 Fed. Reg. at 25,305.

1.<sup>328</sup> The alternative benefit estimate, if it had been presented, would have exceeded costs by more than 3 to 1.<sup>329</sup>

By 2015 the sulfur controls in CAIR are projected to prevent 17,000 premature deaths, 8700 cases of chronic bronchitis, 22,000 nonfatal heart attacks, 10,500 hospitalizations, 1.7 million lost work days, and 9.9 million days of restricted physical activity.<sup>330</sup> The health gains from the nitrogen controls were much smaller but significant: 2800 fewer hospital admissions for respiratory illnesses, 280 fewer emergency room visits for asthma, 690,000 fewer days with restricted activity, and 510,000 fewer days when children are absent from school due to illness. The number of premature deaths prevented by the nitrogen controls could be as large as 17,000 per year.

CAIR covered only power plants. OIRA tried to persuade the administration that a supplemental rule should be issued to cover industrial boilers and other stationary sources of sulfur emissions not included in CAIR. OIRA also met with some representatives of industrial sources and environmental groups interested in such a rulemaking. Even though the benefit-cost case for extension of the rule to other stationary sources would probably have been powerful, OIRA was not successful in building consensus on this issue.

In summary, CAIR salvaged most of the sulfur- and nitrogen-control benefits that were contained in the failed Clear Skies proposal. With projected benefits exceeding \$100 billion per year, CAIR is one of the most beneficial rules in the history of OIRA.<sup>331</sup> Due to the complex congressional and regional politics, BCA exerted less in-

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<sup>328</sup> OFFICE OF MGMT. & BUDGET, 2006 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF FEDERAL REGULATION AND UNFUNDED MANDATES ON STATE, LOCAL, AND TRIBAL ENTITIES 61 tbl.A-1 (2006) (illustrating that in 2015 the benefits and costs of CAIR were projected by the EPA to be \$101 billion and \$3.1 billion respectively, suggesting a benefit-cost ratio of 32.6).

<sup>329</sup> The alternative estimates were used by the EPA and OMB during internal administration discussions of Clear Skies in 2002, but were not published in conjunction with CAIR in 2005. However, a formal probability analysis published as an appendix to the RIA of the CAIR rule also shows that the benefits of the CAIR rule, especially the sulfur cap, are highly likely to exceed the costs. See EPA, DOC. NO. EPA-452/R-05-002, REGULATORY IMPACT ANALYSIS FOR THE FINAL CLEAN AIR INTERSTATE RULE, at B-11 (2005).

<sup>330</sup> Clean Air Interstate Rule, 70 Fed. Reg. at 25,307 tbl.X-1.

<sup>331</sup> The only two federal rulemakings that may have equal or larger benefits are the EPA's 1993 program to control acid rain and the EPA's 2000 highway diesel rule. However, the EPA's published benefit estimates for these rules are not comparable to the CAIR benefit estimates because the available data and EPA methods of benefit assessment for particulate control have changed since the 1990s.

fluence on this issue than I would have preferred (e.g., BCA supported even stricter sulfur limits than CAIR required, and BCA probably would have supported inclusion of industrial plants as well as power plants). Although the CAIR rule did not go as far as OIRA advocated, the CAIR rule is another illustration of OIRA's playing a proregulation, pro-lifesaving role in collaboration with the EPA.

### 3. Increasing the Fuel Efficiency of Cars and Light Trucks

The final case study examines reform of federal fuel economy standards for passenger cars and "light trucks" (SUVs, pickups, and vans). This case study challenges two myths in the legal literature: the notion that risk-tradeoff analysis, a variant of BCA, is only a tool of deregulation;<sup>332</sup> and the notion that BCA necessarily leads to less stringent standards than feasibility analysis.<sup>333</sup> The reform of most concern to OIRA—adjusting mileage standards for cars and trucks based on vehicle size to protect safety—was adopted, affirmed by the federal judiciary, and codified in energy legislation passed in late 2007.<sup>334</sup> Although other aspects of this case study are still not fully resolved due to litigation and new legislation, it is a powerful illustration of the role of OIRA in regulatory policy.<sup>335</sup>

At the beginning of the Bush administration, the federal Corporate Average Fuel Economy (CAFE) program, which sets mileage rules for new cars and light trucks, was moribund. Congress had granted DOT authority in 1974 to set mileage rules, but in 1996 a bipartisan coalition in Congress began adding "riders" to DOT appropriations bills that froze the standards at 27.5 miles per gallon (mpg) for cars and 20.7 mpg for light trucks.<sup>336</sup> As a result, the combined fuel-

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<sup>332</sup> 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, 1793 (2002) ("Risk tradeoff analysis began as a tool of deregulation. . . . The emergence and ascendancy of risk tradeoff analysis is closely linked to the rise of [BCA] during two antiregulatory 'moments' in recent American political history: President Reagan's election in 1980, and the 1994 legislative elections that . . . produced Republican majorities in both houses.").

<sup>333</sup> See, e.g., Driesen, *supra* note 180, at 3 ("[B]y demanding stringent regulation where such regulation does not threaten widespread shutdowns, [feasibility analysis] maximizes the protection of health . . .").

<sup>334</sup> Energy Independence and Security Act of 2007, Pub. L. No. 110-140, § 102, 121 Stat. 1492, 1498-1501 (to be codified at 49 U.S.C. § 39202).

<sup>335</sup> This case study draws from but elaborates upon Graham, *supra* note 292, at 177-81.

<sup>336</sup> ROBERT BAMBERGER, CONG. RESEARCH SERV., AUTOMOBILE AND LIGHT TRUCK FUEL ECONOMY: THE CAFE STANDARDS (2002).

economy of new “light-duty” vehicles (cars and light trucks) was about 21 mpg in model year 2006, unchanged from twelve years earlier.<sup>337</sup>

Nor had the EPA established any limits on the carbon dioxide emissions by cars and light trucks, even though the Clinton administration negotiated an international treaty to reduce carbon dioxide emissions and slow the pace of global climate change.<sup>338</sup> A petition was filed with the EPA in 1999 requesting that the EPA regulate carbon dioxide emissions from motor vehicles as an air pollutant under the Clean Air Act.<sup>339</sup> The Clinton administration was slow to respond to the petition and effectively handed the issue to the incoming Bush administration.

Due to the slow pace of deliberations in Washington, D.C., the California legislature, with encouragement from organized environmental groups, began to consider a bill that would authorize the California Air Resources Board (CARB) to establish carbon-emission rules for new cars and light trucks sold in California. Vehicle manufacturers opposed the effort to regulate cars through state legislative action.<sup>340</sup>

Recognizing that CAFE was at the heart of both energy-policy and climate-policy debates, the President’s energy task force recommended in May 2001 that the DOT determine whether CAFE should be revitalized or replaced with more market-based policies.<sup>341</sup> The task force also recommended that Congress authorize tax credits for consumers who purchased vehicles with innovative fuel-saving tech-

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<sup>337</sup> EPA, DOC. NO. EPA420-R-011, LIGHT-DUTY AUTOMOTIVE TECHNOLOGY AND FUEL ECONOMY TRENDS: 1975 THROUGH 2006, at 7 (2006), available at <http://permanent.access.gpo.gov/lps73194/420r06011.pdf> (“The average fuel economy for all model year 2006 light-duty vehicles is estimated to be 21.0 mpg—the same value as achieved in 1994.”).

<sup>338</sup> Kyoto Protocol to the United Nations Framework Convention on Climate Change, Dec. 10, 1997, 37 I.L.M. 22.

<sup>339</sup> See Control of Emissions from New and In-Use Highway Vehicles and Engines, 66 Fed. Reg. 7486 (Jan. 23, 2001) (soliciting public comments regarding the 1999 petition submitted by the International Center for Technology Assessment and other groups).

<sup>340</sup> See Jeffrey Ball & Jim Carlton, *California Pact Would Place Cap on Emissions*, WALL ST. J., Aug. 31, 2006, at A1 (reporting that the auto industry sued to stop a measure mandating a decrease of emissions by 2016 from cars and light trucks sold in California).

<sup>341</sup> One of the market-based reforms favored by economists was an increase in the federal gasoline tax. See U.S. CONG. BUDGET OFFICE, REDUCING GASOLINE CONSUMPTION: THREE POLICY OPTIONS 15 (2002), available at <http://www.cbo.gov/ftpdocs/39xx/doc3991/11-21-GasolineStudy.pdf> (“A well-designed increase in the federal tax on gasoline would give consumers a direct incentive to reduce gasoline consumption.”).

nology such as hybrid engines.<sup>342</sup> A window of opportunity to reform CAFE occurred in the summer of 2001 when the National Academy of Sciences released a comprehensive assessment of the CAFE program.

Using information from RTA,<sup>343</sup> the NAS concluded that while CAFE rules do reduce fuel consumption, they also create safety risks. The NAS found that the doubling of car-mileage rules from 14 to 28 mpg between 1975 and 1985 contributed to 2000 excess fatalities per year as carmakers downsized their fleets to save fuel. Instead of scrapping CAFE, the NAS suggested that the CAFE program be reformed to account for vehicle attributes (e.g., weight or size) and thereby minimize adverse safety impacts. The NAS also called for a variety of market-based reforms of the program (e.g., permission for companies to trade CAFE compliance credits and consolidation of the separate programs for imported cars, domestic cars, and light trucks).<sup>344</sup>

Impressed with the NAS recommendations, the Bush administration requested that Congress provide new legislative authority to reform CAFE. However, that idea went nowhere because none of the key stakeholders (the auto industry, the United Auto Workers, or environmental and consumer groups) supported giving the DOT broad authority to reform CAFE.

On the heels of this legislative drubbing, the President instructed OIRA to work with the DOT and other agencies to reform CAFE as much as possible in response to the NAS report, using existing legal authority.<sup>345</sup> The President hoped that, if the stakeholders learned more specifics about how CAFE could be improved, they might be persuaded to support (or tolerate) legislative reform at a later date.

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<sup>342</sup> See NAT'L ENERGY POLICY DEV. GROUP, NATIONAL ENERGY POLICY ch. 4 (2001) (detailing recommendations to increase energy conservation and efficiency).

<sup>343</sup> One of the earliest RTAs to expose the safety risks of CAFE regulation was Robert W. Crandall & John D. Graham, *The Effect of Fuel Economy Standards on Automobile Safety*, 32 J.L. & ECON. 97, 98 (1989) (estimating the effects of CAFE and concluding that "the real social cost of [CAFE] is much greater than is commonly believed"). But the crucial study that laid the groundwork for the NAS's determination was CHARLES J. KAHANE, NAT'L HIGHWAY TRAFFIC SAFETY ADMIN., DOT HS 809 662, VEHICLE WEIGHT, FATALITY RISK AND CRASH COMPATIBILITY OF MODEL YEAR 1991-99 PASSENGER CARS AND LIGHT TRUCKS (2003), available at <http://www.nhtsa.dot.gov/cars/rules/regrev/evaluate/pdf/809662.pdf>, which expanded upon past analyses of vehicle weight and fatality risk of 100-pound reductions in light trucks and vans and in passenger cars.

<sup>344</sup> COMM. ON THE EFFECTIVENESS AND IMPACT OF CORPORATE AVG. FUEL ECON. (CAFE) STANDARDS, *supra* note 208, at 114.

<sup>345</sup> Request for Comments; National Academy of Sciences Study and Future Fuel Economy Improvements, Model Years 2005-2010, 67 Fed. Reg. 5767 (Feb. 7, 2002).

In 2002 the California legislature enacted Assembly Bill 1493, which authorized CARB to reduce greenhouse gas emissions from new vehicles sold in California.<sup>346</sup> Recognizing the danger of California rules, the industry and the United Auto Workers persuaded Congress to lift the freeze on federal CAFE standards, setting the stage for complex litigation about whether federal CAFE standards preempt state carbon standards.

From model years 2005 to 2011, the DOT gradually raised the light-truck mileage requirements by about 16%, from 20.7 mpg to 24.0 mpg.<sup>347</sup> The new rules were projected to save more fuel (in excess of 10 billion gallons per year, once fully implemented) than any previous rulemaking in the twenty-year history of the light-truck CAFE program.<sup>348</sup> In these rulemakings, the DOT took the legal position that these rules preempted any related state rules, such as California's carbon plan.

The fuel savings in 2011 are mandated under a reformed regulatory structure that sets different mileage requirements for each vehicle based on its size (defined as "footprint," roughly the area between the four wheels).<sup>349</sup> The size-based reform, which was championed by an OIRA-DOT alliance, is projected to enhance safety for two independent reasons. First, the size-adjusted mileage rules encourage vehicle manufacturers to enhance fuel efficiency by implementing new fuel-saving technology (e.g., hybrid-electric engines or advanced diesel technology) rather than by downsizing vehicles. The NAS had documented the safety risks of downsizing vehicles. Second, the reform accomplished roughly equal stringency in mileage requirements for smaller SUVs and large sedans and station wagons.<sup>350</sup> Consequently,

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<sup>346</sup> CAL. HEALTH & SAFETY CODE §§ 42823, 43018.5 (West 2006).

<sup>347</sup> Light Truck Average Fuel Economy Standards Model Years 2005–2007, 68 Fed. Reg. 16,868 (Apr. 7, 2003) (codified at 49 C.F.R. pt. 553); Average Fuel Economy Standards for Light Trucks Model Years 2008–2011, 71 Fed. Reg. 17,566 (Apr. 6, 2006) (codified at 49 C.F.R. pts. 523, 533, 537).

<sup>348</sup> See NAT'L HIGHWAY TRAFFIC SAFETY ADMIN., U.S. DEP'T OF TRANSP., STUDY OF FEASIBILITY AND EFFECTS OF REDUCING USE OF FUEL FOR AUTOMOBILES 13 (2006) ("We estimated that the 2008–2011 light truck standards could save up to 10.7 billion gallons of fuel over the lifetime of the vehicles sold during those model years . . ."); Laura Meckler, *Fuel Standards Set for Auto Makers*, WALL ST. J., Mar. 30, 2006, at A2.

<sup>349</sup> The DOT showcased the "footprint" reform plan in a proposed rulemaking. See Average Fuel Economy Standards for Light Trucks; Model Years 2008–2011, 70 Fed. Reg. 51,414 (Aug. 30, 2005) (codified at 49 C.F.R. pts. 523, 533, 537).

<sup>350</sup> See Average Fuel Economy Standards for Light Trucks Model Years 2008–2011, 71 Fed. Reg. at 17,619 (detailing reduced incentives to participate in the CAFE program because of safety concerns).

vehicle manufacturers no longer have a perverse incentive to raise the center of gravity of passenger vehicles in order to obtain the more lenient "light-truck" classification in the CAFE program. A higher center of gravity in vehicle design contributes to a vehicle's tendency to roll over when it strikes a roadside tripping mechanism. For these two independent reasons, size-adjusted CAFE standards are expected to pose fewer safety risks than application of a uniform MPG standard to all manufacturers.

The setting of the stringency of the mileage rules for model year 2011 illustrates how a benefit-cost approach can lead to more stringent rules than a feasibility analysis. Historically, NHTSA set mileage rules based on affordability, a form of feasibility analysis. Since the two firms producing a majority of new light trucks (Ford Motor Company and General Motors Corporation) were under serious financial strain (including possible bankruptcy), some officials in the Bush administration argued that tighter mileage rules for light trucks were not affordable.<sup>351</sup> OIRA countered that feasibility, as defined for CAFE purposes, should ignore the financial condition of individual companies. Instead, BCA should be employed to set feasible mileage standards that maximize net social welfare for the nation as a whole.<sup>352</sup> Overall, the 2011 standards are projected to generate an increasing amount from \$1 billion to \$3 billion per year in benefits, with a benefit-cost ratio averaging 1.25 (excluding benefits from diminished carbon dioxide emissions, which were quantified but not monetized).<sup>353</sup>

With encouragement from OIRA, CAFE rules were also extended to include large passenger SUVs (e.g., the Hummer), but OIRA did not prevail in the effort to include large pickup trucks that weigh between 8500 and 10,000 pounds.<sup>354</sup> This is another example where

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<sup>351</sup> Cf., e.g., Sholnn Freeman, *Truck and SUV Sales Plunge as Gas Prices Rise*, WASH. POST, Oct. 4, 2005, at D1 (reporting that from September 2004 to September 2005, General Motors saw a 24.1% drop in auto sales in the United States, while Ford experienced a 20.1% drop).

<sup>352</sup> Average Fuel Economy Standards for Light Trucks 2008–2011, 71 Fed. Reg. at 17,588.

<sup>353</sup> *Id.* at 17,622–23.

<sup>354</sup> The administration was concerned that Congress was on record against the inclusion of large pickup trucks. In 2002, an energy bill amendment that was sponsored by Senator Zell Miller and aimed at exempting pickup trucks from CAFE regulation passed the Senate 56 to 44 with the support of seventeen Democratic senators (including then–Majority Leader Tom Daschle). 58 CQ ALMANAC, at S-13 (2002) (reporting that numerous Democratic senators supported Miller's amendment).

benefit-cost considerations caused OIRA to argue for a more expansive regulatory program.

When the DOT, with OIRA support, sought to move forward with the CAFE reform plan, some offices in the EOP objected. The OIRA-DOT alliance prevailed on CAFE reform only after President Bush resolved an internal dispute in the Oval Office in 2005. But environmental groups sued the DOT on the grounds that the reformed mileage rules did not save enough fuel.

In early 2007, President Bush went further and called for new legislation to raise the mileage standards for light trucks while extending the size-based reforms to passenger cars. Overall, Bush called for a 4% per year gain in overall fuel economy (cars and light trucks) through 2017. Later in the year, when the Supreme Court ruled that the EPA already had the necessary authority to achieve fuel-economy gains and carbon-emission control under the Clean Air Act,<sup>355</sup> President Bush instructed the EPA and the DOT to work together on an administrative plan to achieve his legislative goal of 4% per year.<sup>356</sup>

In late 2007, a federal appeals court remanded the 2008–2011 CAFE rules to NHTSA for reconsideration on the grounds that some of NHTSA's reasoning was arbitrary and capricious.<sup>357</sup> Interestingly, two of the reasons for the remand are consistent with OIRA's views (i.e., the need to include a monetized value of carbon dioxide in the benefit calculation and the need to extend the program to include large pickup trucks).<sup>358</sup> Importantly, the court upheld NHTSA's new benefit-cost approach to feasibility analysis and did not object to the size-based reforms.<sup>359</sup>

The auto industry lost the initial rounds of litigation against state carbon plans in Vermont and California. Although they appealed these decisions, they also intensified efforts to enact national legislation. In late 2007 Congress responded by passing legislation aimed at

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<sup>355</sup> *Massachusetts v. EPA*, 127 S. Ct. 1438, 1459-62 (2007).

<sup>356</sup> See John D. McKinnon et al., *Bush Orders Stricter Rules on Auto Mileage*, WALL ST. J., May 15, 2007, at A1.

<sup>357</sup> *Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin.*, 508 F.3d 508, 514 (9th Cir. 2007) (ordering NHTSA to revise its average fuel-economy standards for 2008–2011), *vacated on other grounds*, No. 06-71891, 2008 WL 3822966 (9th Cir. Aug. 18, 2008).

<sup>358</sup> *Id.* at 524.

<sup>359</sup> *Id.* at 530.

achieving 35 mpg by 2020 using a reformed system that adjusts mileage rules based on vehicle size, weight, and other attributes.<sup>360</sup>

The practical importance of national CAFE reform will be diminished if California and more than twelve other states proceed with their ambitious regulatory programs to reduce carbon emissions from new cars and light trucks. The California plan, finalized in 2004, has the practical effect of compelling mpg gains that are larger and take effect sooner than the 35 mpg mandate recently stipulated by Congress.<sup>361</sup> But the California plan is risky because it does not contain the safer size-based reforms. The multiple state-level plans are so stringent and inflexible that substantial economic upheaval in Michigan and other automotive-dependent states could result. In late 2007 the EPA denied California's request for a waiver, but the EPA's decision could be overturned by Congress or the courts.<sup>362</sup> Or California and other states could use other policy instruments (e.g., "feebates") to force large increases in the fuel economy of new cars and light trucks.

In summary, CAFE reform is a fascinating case where a life-threatening regulatory program was not repealed but redesigned to prevent adverse safety effects. The RTA summarized by the NAS led to an improved regulatory design rather than deregulation.<sup>363</sup> BCA also led to more stringent rules than would have resulted from feasibility analysis. Inside the Bush administration, OIRA had a decidedly pro-lifesaving, proregulation influence on federal fuel-economy policy—precisely the opposite of what some critics of RTA, BCA, and OIRA might have predicted.<sup>364</sup>

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<sup>360</sup> Energy Independence and Security Act of 2007, Pub. L. No. 110-140, § 102, 121 Stat. 1492, 1498-1501 (to be codified at 49 U.S.C. § 39202).

<sup>361</sup> See MICHAEL BENJAMIN ET AL., CAL. AIR RES. BD., COMPARISON OF GREENHOUSE GAS REDUCTIONS UNDER CAFE STANDARDS AND ARB REGULATIONS ADOPTED PURSUANT TO AB1493 (2008), available at [http://www.arb.ca.gov/cc/ccms/reports/ab1493\\_v\\_cafe\\_study.pdf](http://www.arb.ca.gov/cc/ccms/reports/ab1493_v_cafe_study.pdf) (finding that, in a technical evaluation, California state standards would reduce greenhouse gas emissions and increase vehicle efficiency more extensively than federal CAFE standards).

<sup>362</sup> See Juliet Eilperin, *EPA Chief Denies Calif. Limit on Auto Emissions*, WASH. POST, Dec. 20, 2007, at A1 (noting that environmentalists and state officials promised to sue to overturn the EPA's decision).

<sup>363</sup> Proponents of RTA stressed from the outset that RTA is not necessarily an anti-regulation tool. It can also lead to improved regulations. See generally Graham & Wiener, *supra* note 22, at 37 (discussing how "risk-superior" choices can result from the identification of risk tradeoffs).

<sup>364</sup> Samuel Rascoff and Professor Revesz, for example, state that RTA is simply another conservative political tool for OIRA to use in its deregulation campaign. See Ras-

E. *The Benefits and Costs of Federal Rules, 1981–2006*

From 1981—when OIRA began to keep records—through 2006, OIRA cleared 259 final rules that were judged to be “major” due to a projected economic impact on the private sector or state and local governments of at least \$100 million per year.<sup>365</sup> Based on preregulation (ex ante) estimates at the time the rules were issued, these 259 rules added about \$126.9 billion of annual costs to the federal regulatory burden,<sup>366</sup> on top of the hundreds of billions of dollars of costs associated with the myriad federal regulations already in place prior to 1981.<sup>367</sup> In other words, from 1981 to 2006, these rules added an average of almost \$5 billion per year to the regulatory burdens on the private sector and state and local governments.<sup>368</sup>

The rate of new cost burdens from major rules was not uniform throughout the twenty-six-year period. It was quite low during President Reagan’s first term but grew rapidly during his second term. That growth accelerated under the tenure of President George H.W. Bush, but declined steadily from 1992 to 1997. The last three years of the Clinton administration, however, saw a burst of new regulatory burdens. In 2000, the new regulatory cost burdens skyrocketed to a record high of \$18 billion, more than three times as large as the twenty-six-year annual average. From 2001 to 2006, under the George W. Bush administration, the rate of costly new regulations declined sharply, down 47% compared to the annual average from 1981 to 2000, and down 59% compared to 1993 to 2000.<sup>369</sup>

These trends are consistent with a commonly held perception that OIRA engaged in a systematic campaign against regulation from 2001 to 2006.<sup>370</sup> Adherents to this position point to the declining numbers

coff & Revesz, *supra* note 332 at 1793-94 (“[R]isk tradeoff analysis was developed and took shape at two crucial moments of heightened antiregulatory sentiment. This conservative pedigree of risk tradeoff analysis is responsible for its incompleteness.”).

<sup>365</sup> U.S. OFFICE OF MGMT. & BUDGET, DRAFT 2007 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF FEDERAL REGULATION 33-36 (2007) [hereinafter 2007 DRAFT OIRA REGULATORY REPORT].

<sup>366</sup> *Id.* at 34.

<sup>367</sup> See Thomas D. Hopkins, *The Costs of Federal Regulation*, 2 J. REG. & SOC. COSTS 5 (1992) (summarizing the annual cost of federal regulation for 1977 through 2000).

<sup>368</sup> 2007 DRAFT OIRA REGULATORY REPORT, *supra* note 365, at 34.

<sup>369</sup> *Id.* at 34-36, 35 fig.2-1, 36 fig.2-2.

<sup>370</sup> The legal literature contains numerous references to the antiregulation agenda of the George W. Bush administration. See, e.g., Robert R.M. Verchick, *The Case Against Cost-Benefit Analysis*, 32 ECOLOGY L.Q. 349, 354 (2005) (book review) (“President

of entries in the regulatory agendas of federal agencies and declines in the sheer number of rules issued.<sup>371</sup>

A careful look at the data on regulatory benefits tells a different story. Unfortunately, OIRA has not been able to assemble benefit estimates for all of the 259 major rules with cost estimates. In fact, for most of the Ronald Reagan and George H.W. Bush years, from 1981 to 1991, OMB's 2007 report to Congress discloses no benefit information. Nevertheless, a careful look at the data on projected regulatory benefits tells a powerful story. For the fifteen years from 1992 to 2006 (the last year of the George H.W. Bush administration through the Clinton years and the sixth year of George W. Bush administration), OMB reports information for a subsample of 134 major rules where agencies reported at least some estimates of benefits and costs.<sup>372</sup>

In each year from 1992 through 2006, the estimated benefits of major rules exceeded the estimated costs. The total benefits of major rules during this period exceeded the total costs by more than 300%. And from 2001 to 2006, the average annual benefits from major rules were more than double the rate of the previous eight years.<sup>373</sup> If these ex ante estimates are accurate, they suggest that new federal regulations have contributed to a substantial improvement in social welfare in the United States.

Measured by net benefits, the regulatory policies of the 2001 to 2006 period have also made a significant contribution. By enlarging regulatory benefits and reducing costs, the net benefits from major rules grew significantly during the 2001–2006 period. The average annual rate of net benefits was 262% larger from 2001 to 2006 compared to the previous eight years.<sup>374</sup>

The comparison across the Clinton and Bush administrations suggests a simple explanation: OIRA did not clear a large number of costly major rules from 2001 to 2006, but the ones cleared tended (on average) to have impressively large benefits. As a result, the net benefits of federal rulemakings in the 2001–2006 period were strikingly positive, with lifesaving rules by the EPA's clean air office accounting

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George W. Bush is now using the Clinton executive order in much the same way that Reagan did, as an anti-regulatory tool.”).

<sup>371</sup> See, e.g., Joel Brinkley, *Out of Spotlight, Bush Overhauls U.S. Regulations*, N.Y. TIMES, Aug. 14, 2004, at A1 (reporting that some commentators believe that the Bush administration's agency regulations cater to business interests).

<sup>372</sup> 2007 DRAFT OIRA REGULATORY REPORT, *supra* note 365, at 36 & fig.2-2.

<sup>373</sup> *Id.* at 2-3, 36 & fig.2-2.

<sup>374</sup> *Id.* at 36.

for the majority of the estimated benefits and net benefits of federal regulation during this period.

#### IV. TECHNICAL CHALLENGES IN BCA OF LIFESAVING RULES

When a BCA of a lifesaving regulation is undertaken, a variety of technical challenges must be overcome in order to perform the analysis and produce useful results. In this Part, I describe those challenges and some of the analytic approaches that have been taken. I seek to dispel some of the confusion in the legal literature about how BCA of lifesaving regulation is performed, how analysts address possible biases, and why the results may be more objective and determinative than critics realize. Then, I turn in Part V to a menu of suggested reforms to improve federal lifesaving regulation. For readers less interested in the technical issues, this Part can be skipped without loss of continuity.

##### A. *Are Life-Threatening Hazards Quantifiable?*

The benefits of a lifesaving regulation cannot be computed unless the number of lives at risk from a hazard can be quantified. Critics argue that BCA of lifesaving rules is often impractical because the number of lives at risk is unknown and cannot even be estimated.<sup>375</sup>

The field of quantitative risk assessment, which originated with applications to food, transport, and nuclear safety, is dedicated to quantifying risks to human health, safety, and the environment.<sup>376</sup> Due to progress in risk assessment, regulators are now able to obtain quantified estimates of many risks that previously could be identified only qualitatively.<sup>377</sup>

Litigation over federal lifesaving regulation helped stimulate the field of QRA. In the 1970s, industry challenged a new benzene-exposure limit aimed at reducing the risk of workers contracting leukemia from exposure to the chemical. Risk assessors ultimately demonstrated that the risk of a worker contracting leukemia from benzene at an exposure level of 10 parts per million of air was greater than 1 in

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<sup>375</sup> See, e.g., Heinzerling, *supra* note 240, at 850 (“[S]cientific uncertainty, in particular the frequent inability of science to produce numerical estimates of likely environmental harm, makes the number-hungry cost-benefit analyst starve.”).

<sup>376</sup> One of the classic texts in QRA is HUMAN AND ECOLOGICAL RISK ASSESSMENT, *supra* note 29.

<sup>377</sup> See generally RISK ANALYSIS AND SOCIETY: AN INTERDISCIPLINARY CHARACTERIZATION OF THE FIELD (Timothy McDaniel & Mitchell J. Small eds., 2004).

1000 for a working lifetime, and thus OSHA tightened the permissible exposure limit.<sup>378</sup> Although the litigation on this issue dealt only with OSHA, the reasoning of a highly splintered Supreme Court spurred greater use of QRA throughout the federal government.<sup>379</sup>

More recently, progress in epidemiology and risk assessment has made it feasible to detect even smaller probabilities of death—about 1 to 3 in 10,000 per year for the average American—from public exposures to particulate air pollution.<sup>380</sup> This probability is far from trivial. The average American's annual probability of dying in a traffic crash is of the same order of magnitude. More importantly, individual risks of this magnitude can produce a major public health problem when large numbers of people are exposed on a daily basis. For example, if 300 million Americans are each exposed to an annual risk of 2 in 10,000 from breathing particulate air pollution, the expected number of excess deaths is 60,000 per year.<sup>381</sup> That is more than the number of people who die from AIDS or traffic crashes each year in the United States.<sup>382</sup>

Even if there are insufficient human data to determine risk, regulators can commission risk assessors to estimate human risk based on toxicity data from laboratory animal experiments. For example, the CPSC, OSHA, and the EPA have used tumor data from animal experiments to inform rulemakings that compelled a reduction in human exposure to formaldehyde.<sup>383</sup> Animal experiments have revealed

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<sup>378</sup> GRAHAM ET AL., *supra* note 200, at 80-114.

<sup>379</sup> See *Indus. Union Dep't v. Am. Petroleum Inst.*, 448 U.S. 607, 662 (1980) (holding that an agency's action based on an "absolute, no-risk policy" was invalid for lack of "findings of a significant risk of harm required by the Act").

<sup>380</sup> For a provocative account of how environmental epidemiology produced findings that challenged conventional wisdoms in government, industry, and academia, see DEVRA DAVIS, *WHEN SMOKE RAN LIKE WATER: TALES OF ENVIRONMENTAL DECEPTION AND THE BATTLE AGAINST POLLUTION* ch. 5 (2002), which describes systematic efforts to discredit environmental epidemiologists who found that breathing particulate matter increases the risk of premature death.

<sup>381</sup> In round numbers, these statistics are the basis for the claims by environmental advocacy groups that particulate air pollution kills 64,000 people each year in the United States. See, e.g., NRDC: Breath-Taking, <http://www.nrdc.org/air/pollution/bt/btinx.asp> (last visited Nov. 15, 2008).

<sup>382</sup> In 2000, the number of deaths attributable to AIDS and traffic crashes in the United States was 14,370 and 41,804, respectively. U.S. CENSUS BUREAU, *STATISTICAL ABSTRACT OF THE UNITED STATES* 80 tbl.101 (2002), available at <http://www.census.gov/prod/2003pubs/02statab/vitstat.pdf>.

<sup>383</sup> For a review of how the CPSC, OSHA, and the EPA originally used animal data to estimate cancer risk and regulate formaldehyde, see GRAHAM ET AL., *supra* note 200, at 12-34.

that chemicals vary enormously in their inherent toxicity and in their ability to cause cancer and reproductive abnormalities.<sup>384</sup>

Most recently, risk-assessment models have been extended from the traditional fields of application (food and transport safety, nuclear plant safety, and occupational and environmental health) to homeland security. The DHS is now in the process of improving its analytic capabilities so that future rulemakings will be supported by BCA whenever feasible. A recently enacted DHS rule, supported by a rudimentary QRA and BCA, requires travelers to show identification on the Canadian and Mexican borders.<sup>385</sup>

The growing acceptance of QRA, which is often based on plausible assumptions and expert judgment rather than on hard data, reflects a theoretical shift in how the terms “risk” and “uncertainty” are understood. Before the modern advances in QRA and the related field of statistical decision theory,<sup>386</sup> theorists drew a distinction between risk—where the probabilities of adverse events are known based on historical data—and uncertainty, where the probabilities of future adverse events are unknown. Some critics of BCA perceive that QRA is not feasible when life-threatening hazards are uncertain, since the probability of death cannot be ascertained.<sup>387</sup>

The emergence of subjective probability, coupled with Bayesian statistics and modern decision theory, has largely obliterated the distinction between risk and uncertainty.<sup>388</sup> A subjective probability assessment can be provided even when actuarial data are unavailable. When actuarial data about risk are available, some form of scientific

<sup>384</sup> See generally JOSEPH V. RODRICKS, *THE TOXICITY AND HUMAN HEALTH RISKS OF CHEMICALS IN OUR ENVIRONMENT* (1992).

<sup>385</sup> See generally Tom LaTourrette & Henry H. Willis, *Using Probabilistic Terrorism Risk Modeling for Regulatory Benefit-Cost Analysis: Application to the Western Hemisphere Travel Initiative Implemented in the Land Environment* (RAND Ctr. for Terrorism Risk Mgmt., Working Paper No. WR-487-IEC, May 2007) (performing probabilistic risk modeling on the proposed policy, but concluding that the high level of uncertainty limits the usefulness of the analysis).

<sup>386</sup> A classic text is JOHN W. PRATT ET AL., *INTRODUCTION TO STATISTICAL DECISION THEORY* (1965).

<sup>387</sup> This is a standard line of argument used to justify highly risk-averse policies: since we cannot discern how likely the hazard is or how bad it might be, we should adopt a highly risk-averse policy to protect ourselves. See, e.g., RAWLS, *supra* note 44, at 130-68 (using such an argument to further justify his adoption of the liberty and difference principles).

<sup>388</sup> See Kenneth J. Arrow, *Some Ordinalist-Utilitarian Notes on Rawls's Theory of Justice*, 70 J. PHIL. 245, 251 (1973) (arguing that, although Rawls presumes that probabilities are unknown in the original position, he neglects the subjectivist and axiomatic argument that all uncertainties are expressible as probabilities).

judgment about probability is also required to determine whether future risks will track historical experience. Even without extensive historical data about life-threatening hazards, risk assessors can often estimate risks based on a combination of theory, models, experiments, fragmentary actuarial evidence, and scientific judgment.<sup>389</sup> These Bayesian methods, already used widely in engineering, business, and medicine, are now appearing in BCAs of federal lifesaving regulations.<sup>390</sup>

The dilemma of uncertain risk has garnered a great deal of public attention in recent years due to public concerns about genetically modified foods, toxic chemicals, and global warming. Some critics see a BCA requirement as a barrier to promulgating precautionary regulations that protect the public from serious, potentially irreversible harms that are not yet fully understood by science.<sup>391</sup> These critics sometimes favor the “precautionary principle” as an alternative—or at least a partial alternative—to QRA and BCA.<sup>392</sup>

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<sup>389</sup> The development of tools for eliciting meaningful judgments from experts about unknown probabilities has itself become a burgeoning field in QRA. See, e.g., ROGER M. COOKE, EXPERTS IN UNCERTAINTY: OPINION AND SUBJECTIVE PROBABILITY IN SCIENCE (1991) (developing several models for evaluating and combining expert opinions, while proposing several guidelines as to what form those opinions should take).

<sup>390</sup> For a textbook on these tools, see M. GRANGER MORGAN & MAX HENRION, UNCERTAINTY: A GUIDE TO DEALING WITH UNCERTAINTY IN QUANTITATIVE RISK AND POLICY ANALYSIS (1990). During my tenure at OIRA, we persuaded analysts at the EPA and the DOT to begin using formal probabilistic tools in the preparation of RIAs. The EPA demonstrated the feasibility of these tools in its rulemakings on off-road diesel-engine exhaust and coal-plant air pollution. See EPA, DOC. NO. EPA420-R-04-007, FINAL REGULATORY ANALYSIS: CONTROL OF EMISSIONS FROM NONROAD DIESEL ENGINES, at 9-213 to -235 (2004) (discussing the results of a pilot program that used expert expectation to characterize some uncertainties); EPA, *supra* note 329, at 4-77 to -83 (same). The DOT also demonstrated the feasibility of the tools in its rulemaking on federal fuel-economy standards for light trucks. U.S. DEP'T OF TRANSP., FINAL REGULATORY IMPACT ANALYSIS: CORPORATE AVERAGE FUEL ECONOMY STANDARDS AND CAFE REFORM FOR MY 2008–2011 LIGHT TRUCKS, at X-23 tbl.X-5 (2006) (finding that the probability that the benefits exceed costs for each model year covered by the rule is at least 68%, assuming a 7% discount rate is applied to future benefits and costs).

<sup>391</sup> In support of this view, see Douglas A. Kysar, *It Might Have Been: Risk, Precaution and Opportunity Costs*, 22 J. LAND USE & ENVTL. L. 1 (2006), which criticizes BCA as fundamentally amoral and argues that the precautionary principle is therefore superior.

<sup>392</sup> Works advocating the precautionary principle include INTERPRETING THE PRECAUTIONARY PRINCIPLE (Tim O'Riordan & James Cameron eds., 1994); PRECAUTION: ENVIRONMENTAL SCIENCE AND PREVENTIVE PUBLIC POLICY (Joel A. Tickner ed., 2003); THE PRECAUTIONARY PRINCIPLE IN THE 20TH CENTURY: LATE LESSONS FROM EARLY WARNINGS (Poul Harremoës et al. eds., 2002); PROTECTING PUBLIC HEALTH AND THE ENVIRONMENT: IMPLEMENTING THE PRECAUTIONARY PRINCIPLE (Carolyn Raffensperger & Joel A. Tickner eds., 1999).

In reality, precaution and BCA are compatible. Even the European Commission, a champion of the precautionary principle, has stipulated that rules based on precaution should also be accompanied by an analysis of benefits and costs whenever feasible.<sup>393</sup> In fact, some of the most exciting advances in BCA over the last generation have clarified how analysts can apply benefit-cost tools under conditions of incomplete data and scientific uncertainty about potentially irreversible consequences.<sup>394</sup> Those tools are now being employed to produce benefit and cost estimates for a wide range of uncertain hazards, including global climate change.<sup>395</sup>

Even with the guidance of subjective-decision theory, it will sometimes be impossible or impractical to prepare a QRA of a suspected hazard. The absence of a QRA does not necessarily block a precautionary regulation under a “soft” benefit-cost test. A qualitative determination of hazard (or even of a possible hazard) may be sufficient to justify a lifesaving regulation, especially if the costs and risks of the regulation are small.

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<sup>393</sup> *Communication from the Commission on the Precautionary Principle*, at 19, COM (2000) 1 final (Feb. 2, 2000) (“[E]xamination of the pros and cons should include an economic cost-benefit analysis where this is appropriate and possible.”).

<sup>394</sup> Even if the numeric uncertainties in a BCA are so large that the net-benefit determination is ambiguous, such a finding is useful. It suggests that “value of information” (VOI) analysis may be informative. A VOI analysis is a formal analytic approach for determining whether a lifesaving rule should proceed based on imperfect information, or whether the rulemaking decision should be delayed until more or better scientific information is acquired. VOI analysis is really an advanced form of BCA where awaiting better data is one of the regulator’s decision options. A textbook account of VOI analysis is presented in CLEMEN, *supra* note 185, at 352-56. One of the pioneering applications of VOI analysis to lifesaving regulation is Adam M. Finkel & John S. Evans, *Evaluating the Benefits of Uncertainty Reduction in Environmental Health Risk Management*, 37 J. AIR POLLUTION CONTROL ASS’N 1164 (1987).

<sup>395</sup> See, e.g., WILLIAM D. NORDHAUS, *MANAGING THE GLOBAL COMMONS: THE ECONOMICS OF CLIMATE CHANGE* 101-35 (1994) (analyzing “the impact of uncertainty about the underlying parameters and models on the uncertainty about the overall projections of the pace of climate change, on the impact on the economy, and on the optimal policies that we should follow today”); MORT D. WEBSTER ET AL., *MIT JOINT PROGRAM ON THE SCI. AND POLICY OF GLOBAL CHANGE, UNCERTAINTY ANALYSIS OF GLOBAL CLIMATE CHANGE PROJECTIONS* (2001) (providing estimates for future climate change that include probabilities of their own accuracy).

B. *Are Lifesaving Benefits and Monetary Costs Commensurate?*

Some critics argue that BCA is impractical because it is not feasible to express costs and benefits in a single metric.<sup>396</sup> For example, some argue that human life is priceless, that any human action that knowingly leads to the death of another human being is equivalent to murder, and that no person would willingly accept certain death for any amount of monetary compensation.<sup>397</sup> To attempt monetization, they argue, is to cheapen the value of life in our society.<sup>398</sup>

Similar arguments against monetary valuation of lifesaving regulations were expressed decades ago, both in the economics literature and in other disciplines, and have recently been addressed by Professors Adler and Posner.<sup>399</sup> I do not address here the philosophical aspects of the issue, but I do note three analytic developments that have increased the acceptability of an economic approach to valuing the benefits of lifesaving regulations.<sup>400</sup>

First, the analytic practice shifted from a direct economic valuation of premature death to an estimation of the public's WTP for reducing risks to life and limb. A risk-prevention framework based on WTP, where regulators are seen as investors of society's resources in lifesaving opportunities, better reflects the ex ante dilemma faced by regulators than does a rights-oriented approach that treats each anonymous death from a technological hazard as a potential victim of

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<sup>396</sup> See, e.g., Lynn E. Blais, *Beyond Cost/Benefit: The Maturation of Economic Analysis of the Law and Its Consequences for Environmental Policymaking*, 2000 U. ILL. L. REV. 237, 249-50 (arguing that the value of environmental protection cannot be measured in economic terms); Heinzerling, *supra* note 240, at 849 (“[T]he benefits of environmental protection—especially the protection of human health and life—cannot meaningfully be monetized.”).

<sup>397</sup> See, e.g., Heinzerling, *supra* note 137, at 192 (advancing the proposition that monetizing the saving of human lives “is equivalent to saying that a person can kill another person if it would cost too much to avoid killing her” and calling this “a striking proposition, and so far one that has been applied only to lives described in statistical terms”).

<sup>398</sup> See, e.g., Verchick, *supra* note 370, at 363 (“CBA threatens to change our concept of what is just and good by making incommensurable and unique values seem fungible.”).

<sup>399</sup> See ADLER & POSNER, *supra* note 2, at 158-66 (acknowledging that while CBA is inherently limited in its inability to precisely value intangibles, it is nonetheless a valuable test).

<sup>400</sup> As economics research progresses, what was once thought to be intangible becomes susceptible to economic measurement. See FREEMAN, *supra* note 61, at 3 (“What were once considered unquantifiable and perhaps relatively unimportant intangibles such as improved recreation and visual amenities are now recognized as significant sources of value and are thought to be susceptible to economic measurement.”).

murder.<sup>401</sup> As a result of the shift from an ex post, rights-infringement framework to an ex ante investment perspective, the economic valuation of lifesaving has become more widely accepted. All federal regulatory agencies in the United States and the European Commission now employ WTP approaches to the valuation of lifesaving.<sup>402</sup>

Second, the soft BCA perspective acknowledges that there may be qualitative aspects of lifesaving that cannot be fully captured by monetary figures.<sup>403</sup> Some studies have sought to estimate WTP premiums for various attributes (e.g., whether there is a higher WTP to prevent a cancer death than a traumatic death caused by an accident), but at this stage it is probably best for qualitative concerns about the lifesaving context to be presented to regulators separately from, though at the same time as, the monetary estimates. Thus, a soft benefit-cost test does not preclude—and in fact encourages—consideration of intangible, moral, or qualitative concerns that are not captured by the monetary metric.<sup>404</sup>

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<sup>401</sup> Professor Heinzerling strives to show “how common it has become to strip statistical lives of rights against harm enjoyed by those whose lives are not described in statistical terms.” Heinzerling, *supra* note 137, at 191. But Heinzerling does not grapple with the scholarship that precedes her showing that a rights-oriented approach to public protection from small technological risks is not logically or philosophically defensible. See, e.g., Schroeder, *supra* note 18, at 495, 498, 501 (arguing that such an approach fails to account for the interests of all those involved).

<sup>402</sup> See Adler, *supra* note 87, at 15 (“Federal agencies have published numerous cost-benefit analyses incorporating an explicit, monetary valuation of human life.”); DIRECTORATE GENERAL FOR RESEARCH, EUROPEAN COMM’N, EUR 21951, EXTERNE: EXTERNALITIES OF ENERGY: METHODOLOGY 2005 UPDATE 4 (Peter Bickel & Rainer Friedrich eds., 2005) (stating that the European Commission’s analysis “requires an estimation of the impacts in physical terms and then a valuation of these impacts based on the preferences of the individuals affected”).

<sup>403</sup> There is a substantial psychological literature on qualitative attributes of hazards that appear to trigger media attention, public concern, and political action. See, e.g., PAUL SLOVIC, *THE PERCEPTION OF RISK* (2000). It is not obvious which of these risk-perception factors (e.g., dread, controllability, voluntariness, familiarity) have normative significance for BCA, though they are clearly relevant for how businesses and politicians should think about the public’s likely reaction to a hazard. Professor Sunstein has offered much thoughtful analysis of whether and how these factors might be incorporated into BCA. See Cass R. Sunstein, *Which Risks First?*, 1997 U. CHI. LEGAL F. 101, 105 [hereinafter Sunstein, *Which Risks First?*] (proposing the use of “lay judgments to the extent that these are based on reasonable judgments of value rather than factual error or selective attention”); see also Cass R. Sunstein, *The Laws of Fear*, 115 HARV. L. REV. 1119, 1168 (2002) (reviewing SLOVIC, *supra*) (“For purposes of policy, however, what is most important is actual risk rather than perceived risk.”).

<sup>404</sup> There is a difference of opinion among analysts about whether contextual factors in lifesaving (e.g., whether a risk is perceived to be involuntary, dreadful, or associated with an especially feared cause of death) should be quantified in monetary measures of benefit or treated as an intangible factor by regulators under a soft bene-

Finally, no monetization of lifesaving is necessary with CEA, although the decisions that regulators make will implicitly reveal value judgments about how much was invested to save lives.<sup>405</sup> Thus, even if some regulators have doubts about the WTP approach, they can garner significant insight about lifesaving investments from CEA. OIRA now requires federal agencies to prepare both a BCA and a CEA in support of a lifesaving regulation.<sup>406</sup>

### C. *Are the Results of BCA Indeterminate?*

Critics also claim that BCA is indeterminate, meaning that the range of possible costs and benefits is so large as to preclude any policy determination.<sup>407</sup> The alleged indeterminacy arises from a combination of uncertainties about how many premature deaths and illnesses will be averted by a rule, what monetary value should be assigned to lifesaving, when the lives will be saved, what discount rate should be assigned to future lifesaving, and what the long-run costs of the rule will be.<sup>408</sup>

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fit-cost test. As analytic progress is made in measuring the relative importance of contextual factors, it may be feasible to capture more of the contextual variation in the value of lifesaving from one rulemaking to the next. For an optimistic view of what can currently be done to quantify and monetize contextual factors in lifesaving, see SUNSTEIN, *supra* note 17, at 174-75. Until more analytic progress is made, regulators should be encouraged to consider contextual factors among the soft BCA considerations in regulatory deliberation. See, e.g., ENVTL. ECON. ADVISORY COMM., *supra* note 151, at 1 (recommending that the EPA retain the uniform VSL approach for primary estimates because the literature on contextual factors is too limited to support adjustments).

<sup>405</sup> Professor Adler offers a nonstandard view of how QALYs, coupled with a dollar-per-QALY conversion ratio, could be used to implement BCA rather than traditional CBA. See Adler, *supra* note 88, at 17 (urging use of a QALY-to-dollar conversion ratio as a supplement to WTP/WTA measures and calling it a “hybrid cost-benefit technique”); *id.* at 62 (proposing that the setting of the QALY-dollar conversion ratio is “a problem at the level of system design”).

<sup>406</sup> OMB Circular A-4, *supra* note 259, at 9.

<sup>407</sup> See, e.g., Baron & Dunoff, *supra* note 34, at 438 (“The indeterminacy of shadow pricing means that cost-benefit analyses are circular . . . The talented economist can thus justify virtually any policy, which . . . severely limits the effectiveness of cost-benefit analysis as a guide to public policy.”); Farber, *supra* note 184, at 1282 (“Except in extreme cases, the result of cost-benefit analysis often turns on a series of discretionary judgments; competent, reasonable analysts can come up with quite different but equally defensible answers.”).

<sup>408</sup> See Sinden, *supra* note 67, at 1409 (“CBA is indeterminate, both because of intractable theoretical difficulties . . . and because of practical problems . . . This indeterminacy renders CBA not only ineffectual, but also endlessly manipulable.”).

Critics of BCA are surely correct that there are multiple, often significant, technical uncertainties in BCA. But even highly uncertain benefit and cost estimates may have useful policy implications.

The EPA's analysis of the 2001 arsenic rule<sup>409</sup> is commonly touted as an example of indeterminacy.<sup>410</sup> The projected costs of reducing arsenic levels in drinking water from 50 to 10 parts per billion (ppb) are about \$210 million per year,<sup>411</sup> but the benefits are highly uncertain. Professor Sunstein, for example, reports that the benefits could be anywhere from \$0 to \$3.8 billion per year, based on a series of pessimistic and optimistic inputs to the benefit calculation.<sup>412</sup>

I shall consider this example in some depth, since it is apparently a poster child for indeterminacy in the legal literature. Sunstein's range of benefit estimates, computed based on a method called sensitivity analysis, does reveal a large degree of uncertainty, but his analysis is incomplete. He does not indicate the relative credibility or likelihood of specific benefit estimates within the wide range of numbers that he reports. It would be a mistake to assume that each estimate within his wide range of possible benefits is equally likely to be accurate.<sup>413</sup>

To offer a deeper level of insight, I commissioned a doctoral fellow at Pardee RAND Graduate School to conduct a simple probability analysis of the four key inputs that Sunstein uses based upon the assumption that some input values are more credible than others. We assumed, for example, that input values toward the middle of a range are more plausible than input values at the extremes. We also as-

<sup>409</sup> EPA, ARSENIC IN DRINKING WATER RULE: ECONOMIC ANALYSIS (2000), available at [http://www.epa.gov/ogwdw/arsenic/pdfs/econ\\_analysis.pdf](http://www.epa.gov/ogwdw/arsenic/pdfs/econ_analysis.pdf).

<sup>410</sup> See, e.g., Hsu, *supra* note 19, at 352 ("The arsenic case presents a problem for advocates of cost-benefit analysis because the benefits and costs of the proposed policy are so close, and the uncertainties so great, that the cost-benefit analysis itself does not tell the policymaker clearly what to do.").

<sup>411</sup> *Id.*

<sup>412</sup> Cass R. Sunstein, *The Arithmetic of Arsenic*, 90 GEO. L.J. 2255, 2288 tbl.6 (2002).

<sup>413</sup> Professor Sunstein acknowledges that "[w]hen the underlying science and economics allow analysts to come up with a 'best estimate' and to assign probabilities to the alternative outcomes, this indeed should be done. . . . But with respect to health benefits, science does not allow best estimates to be provided here." *Id.* at 2289. My experience at OIRA is that some working scientists at federal agencies share Professor Sunstein's view that it is often not feasible to develop probability distributions and expected values because of the limits of science and economics. But the validity of the tools is clearly demonstrated in the peer-reviewed literature, and the tools have been recommended for use by the National Academy of Sciences. See, e.g., NAT'L RESEARCH COUNCIL, *supra* note 322, ch. 5 (recommending that the EPA improve the probabilistic uncertainty assessments of its health-benefits analyses).

sumed that a discount rate of 3% is more plausible than 7%. A more detailed analysis, which we have not conducted, would construct a probability distribution for each input based on opinions elicited from qualified experts in relevant fields.<sup>414</sup>

Based on a simulation with 2500 runs, we found that the benefits of the 10 ppb rule exceed the costs (assumed to be equal to the EPA's \$210 million estimate) in 64% of the runs. In the other 36% of the runs, costs exceeded benefits. More importantly, the expected value of benefits is \$382 million, which produces expected net benefits of \$172 million per year, or an expected benefit-cost ratio of 1.8 to 1.<sup>415</sup> A more in-depth probability analysis of net benefits would explore setting the arsenic standard at levels somewhat higher and lower than 10 ppb, rather than simply comparing 10 to 50 (as Professor Sunstein and we have done).<sup>416</sup>

When regulators face uncertainty about benefits and costs, a strong theoretical case has been made that policy determinations should be based on the expected value of net benefits (rather than the wide range of results that Sunstein reports or the "most probable" estimate of net benefits<sup>417</sup>). The expected value is the key summary

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<sup>414</sup> This decision-analytic approach to expressing uncertainty was pioneered by RAIFFA, *supra* note 185. A useful textbook on this approach is MORGAN & HENRION, *supra* note 390.

<sup>415</sup> Meena Fernandez, a doctoral fellow in policy analysis at the Pardee RAND Graduate School, performed this simulation. The inputs to the calculation are the annual number of lives saved (5.5, 28, 112); the annual number of morbidity cases saved (0, 12.95, 25.9); the monetary value, in millions, of saving a life (\$0.7, \$6.7, \$33); the monetary value, in millions, of preventing a case of morbidity (\$0.607, \$1.5, \$3.6); the discount rate (0.02, 0.03, 0.07); and the latency period, in years (0, 20, 40).

<sup>416</sup> Given the inherent uncertainties in BCA of lifesaving, results are likely to be more determinative for larger policy changes (e.g., 10 versus 50 ppb arsenic in water) than smaller policy changes (e.g., 9.5 versus 10.0 ppb arsenic in water). If the policy changes are extremely large, thereby requiring the use of general equilibrium models, the inherent uncertainties in BCA may be so large that results are likely to be indeterminate. But in the range of the incremental policy changes that characterize America's pluralistic democracy, BCA may often have insights to offer. See John D. Graham, *Valuing the Future: OMB's Refined Position*, 74 U. CHI. L. REV. 51, 54-55 (2007) (speculating that the U.S. climate policies that are politically feasible are unlikely to require general-equilibrium—as opposed to partial-equilibrium—methods of economic modeling).

<sup>417</sup> A point of technical imprecision in Professor Sunstein's position is that he appears to favor use of the "most probable" estimate of net benefits rather than the expected value. Sunstein, *supra* note 412, at 2288-89. In the case of the EPA's arsenic rule, the expected value of benefits is likely to exceed the "most probable" (modal) estimate of benefits because the probability distribution over benefits is skewed to the right (suggesting a small probability of very large benefits). If we assume (as standard theory does) that individual risk aversion is accounted for in the monetary valuations of life and morbidity, then the regulator should typically prefer the regulatory option

statistic in the lifesaving context as long as individual attitudes toward risk are accounted for in the monetization procedures—a standard assumption in either a stated-preference or revealed-preference study of WTP.

I did not participate in the Bush administration's decision to reopen the EPA's arsenic rulemaking in early 2001, but at the final rule stage I did participate in deliberations and was not concerned about reinstatement of the 10 ppb rule. In fact, I argued for a reduction in the drinking water standard from 50 to 8 ppb arsenic, combined with more flexible affordability guidance for small communities. The EPA decided instead to retain the 10 ppb rule without any new flexibility for small communities.<sup>418</sup>

In summary, even in the case of arsenic, where there are large uncertainties about benefits, Professors Sunstein, Heinzerling, Hsu, McGarity, and Sinden may have prematurely concluded that a proper BCA of the EPA's arsenic dilemma is necessarily indeterminate.<sup>419</sup> More generally, the claims in the legal literature about the indeterminacy of BCA are far too sweeping. For sure, the results of some BCAs

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that achieves the highest expected value of net benefits. See Kenneth J. Arrow & Robert C. Lind, *Uncertainty and the Evaluation of Public Investment Decisions*, 60 AM. ECON. REV. 364, 366 (1970) (arguing that, to maximize public investment returns, "the government should behave as an expected-value decision maker and use a discount rate appropriate for investments with certain returns").

<sup>418</sup> OIRA ultimately did persuade the EPA to propose new guidance about what is an affordable cost impact on small, largely rural water systems. If the EPA finalizes more realistic affordability guidance under the Safe Drinking Water Act, 42 U.S.C. §§ 300f–300j-26 (2000), the agency may confront diminished opposition from small communities to future national standards. See generally Small Drinking Water Systems Variances, 71 Fed. Reg. 10,671 (Mar. 2, 2006) (seeking comment on the EPA's methodology for determining whether technologies are available that would allow small public water systems to affordably achieve compliance with the Safe Drinking Water Act).

<sup>419</sup> See Lisa Heinzerling, *Markets for Arsenic*, 90 GEO. L.J. 2311, 2338 (2002) ("To his credit, Professor Sunstein does not flinch from admitting that, based on assumptions that he believes to be credible, the benefits of reducing arsenic in drinking water to 10 ppb range from zero to over half a billion dollars."); Hsu, *supra* note 19, at 352 (assuming a great degree of uncertainty in the EPA's arsenic BCA); McGarity, *supra* note 134, at 2366 (expressing surprise that Sunstein could believe that "all of this occasionally comprehensible, but frequently preposterous and always manipulable number spinning, could possibly lead to better decisionmaking in the real world"); Sinden, *supra* note 33, at 194 ("[In his case study of arsenic, Professor Sunstein] stumbles upon the inescapable conclusion that CBA is indeterminate. Indeed, in this instance, it is wildly indeterminate."); *id.* at 241 ("But when [Sunstein's] case study of the arsenic CBA reveals indeterminacy of such an astonishing magnitude that we cannot say whether the benefits are \$13 million or \$3.4 billion, one has to wonder whether CBA can provide any meaningful information at all.").

are ambiguous.<sup>420</sup> But other results are quite robust, even accounting for the substantial uncertainties about benefits and costs.<sup>421</sup> An assessment of whether or not the results of BCA are determinate needs to occur on a case-by-case basis.

#### D. *Are the Results of BCA Biased Against Lifesaving?*

Even when BCA produces results that are determinate, critics argue that the results are likely to be biased. A common allegation in the legal literature is that efforts at quantification are inevitably skewed to understate benefits and overstate costs.<sup>422</sup> If these concerns are valid, they certainly should cause one to caution regulators against relying on the findings of BCA. But I shall demonstrate that the evidence for systematic bias in BCA is weak.

##### 1. The Amount of Lifesaving

When analysts err in estimating the lifesaving impacts of a rule-making, there are two possible directions of error: the number of lives saved is either underestimated or overestimated. Both types of error occur and are of concern, but there is no empirical evidence demonstrating systematic bias.

Consider the 1984 estimate by the DOT that installation of frontal airbag systems in new cars and light trucks would save 9000 lives per year, once the entire fleet was equipped. That preregulation estimate was based on a combination of injury epidemiology, crash testing with dummies and cadavers, and engineering judgment. After millions of airbag systems were installed in vehicles in the 1990s, it became apparent that the DOT had overstated the airbag's lifesaving impact. The best current estimates, based on real-world experience, are that airbags save about one-third as many lives as the DOT initially

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<sup>420</sup> See Arrow et al., *supra* note 88, at 221 (“In some cases, however, benefit-cost analysis cannot be used to conclude that the economic benefits of a decision will exceed or fall short of its costs, because there is simply too much uncertainty.”).

<sup>421</sup> See Hahn, *supra* note 82, at 1034-35 tbls.1-2 (showing that net-benefit results in most regulatory analyses are robust with respect to plausible changes in the values of uncertain inputs, including the discount rate and the monetary value of a statistical life).

<sup>422</sup> See, e.g., SHAPIRO & GLICKSMAN, *supra* note 235, at 97 (“The use of revealed preferences to estimate individuals’ willingness to pay for more protection and less risk is subject to a number of potential errors, which cause regulatory benefits to be understated.”); *id.* at 118 (observing that studies that ignore the psychological benefits of health regulations understate the value of those regulations).

thought.<sup>423</sup> Fortunately, the actual amount of lifesaving is sufficient to justify our nation's multibillion-dollar investment in airbag technology for frontal-crash protection.<sup>424</sup>

When two or more errors occur in a lifesaving estimate, they may reinforce each other or act in opposite directions—one error causing overstatement, another causing understatement. There is no evidence that reinforcing errors are more common or more serious than errors that cancel each other out.

Consider the challenge of making lifesaving estimates for clean-air rules. The analyst must project both the “baseline” risks from pollution (i.e., the lives lost without the rule) and the amount of risk reduction (i.e., the number of lives saved) that will occur due to the changes in business practices that improve air quality.<sup>425</sup> Errors of underestimation or overestimation can occur at each stage of the analysis.

The EPA currently assumes that all fine particles in the air are equally toxic, regardless of their chemical composition. If it turns out that carbon-containing particles are more toxic than sulfates and nitrates, then the EPA will have underestimated the benefits of rules aimed at reducing diesel-engine exhaust (a significant source of carbon-containing particles) and overestimated the benefits of rules aimed at reducing air pollution from coal plants and industrial boilers (a significant source of sulfates and nitrates).<sup>426</sup>

There is a substantial body of technical opinion that the EPA's risk-assessment procedures for cancer tend to overestimate baseline and residual risks (i.e., risks remaining after regulation) because they are based on conservative (i.e., likely to overstate true risk), default assumptions about chemical emissions, human exposure, and toxicity.<sup>427</sup>

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<sup>423</sup> See Thompson et al., *supra* note 7, at 64-66 (describing the significant sources of error that led to the DOT's overestimation of the number of lives airbags would save).

<sup>424</sup> See Graham et al., *supra* note 270, at 1422-1424 (presenting the results of a cost-effectiveness study showing that the DOT's airbag requirement is cost justified).

<sup>425</sup> For a rigorous examination of the analytic challenges in projecting the health benefits of air-quality rules, see NAT'L RESEARCH COUNCIL, *supra* note 322.

<sup>426</sup> See *id.* at 89-93 (explaining the EPA's “total mortality” approach to analyzing the health effects of air pollution, given the current levels of uncertainty as to “all relevant pathways and mechanisms of health effects”).

<sup>427</sup> See ENVTL. ECON. ADVISORY COMM. *supra* note 151, at 15 (pinpointing the “conservative” elements of EPA cancer-risk assessments that cause estimates of cancer risk to be unrealistically large); HAMILTON & VISCUSI, *supra* note 186, at 90 (“The current [EPA] approach [to risk assessment at hazardous waste sites] leads to an unpredictable and quite extreme level of conservatism in risk estimation because of the compounding of the varying conservatism adjustments.”); Albert L. Nichols & Richard J. Zeckhauser, *The Perils of Prudence: How Conservative Risk Assessments Distort Regulation*, REGU-

In the case of the artificial sweetener saccharin, recent evidence suggests that saccharin is a less significant risk of human cancer than originally predicted and may not even be a human carcinogen.<sup>428</sup> But a growing body of evidence suggests that another chemical carcinogen, formaldehyde, may be more potent—and cause different types of tumors—than the EPA previously estimated.<sup>429</sup>

Although some of the default assumptions in chemical-risk assessment are “conservative,” other assumptions may lead to underestimation of risk. For example, risk assessors do not always account for the existence and size of sensitive subpopulations, the adverse health effects other than cancer that a chemical may cause, or the total number of emissions sources and exposure pathways.<sup>430</sup> Sometimes a toxin is shown to be lethal at low doses, even though it was thought only to cause nonfatal illnesses. For example, recent studies of community exposure to ozone (smog) have caused scientists to realize that low-level ozone exposures may be associated with premature death as well as various nonfatal illnesses.<sup>431</sup>

Thus, the multiple sources of possible bias in lifesaving estimates need to be examined on a rule-by-rule basis.<sup>432</sup> Readers should be skeptical of sweeping claims that lifesaving opportunities are persistently understated (or overstated). The truth is that lifesaving estimates can be too large or too small, and there is no clear evidence as to which form of error in QRA is more common or more severe.<sup>433</sup>

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LATION, Nov./Dec. 1986, at 13, 13 (“The cumulative effect of using . . . a long series of conservative assumptions[] can be monumental overestimates of health risks.”).

<sup>428</sup> See U.S. DEP’T OF HEALTH & HUMAN SERVS., ELEVENTH REPORT ON CARCINOGENS (2005) (omitting saccharin from a list of chemicals known or reasonably believed to be carcinogens).

<sup>429</sup> See, e.g., Michael Hauptmann et al., *Mortality from Solid Cancers Among Workers in Formaldehyde Industries*, 159 AM. J. EPIDEMIOLOGY 1117 (2004) (finding a possible causal connection between the exposure of industrial workers to formaldehyde and certain cancers).

<sup>430</sup> See COMM. TO REVIEW THE OMB RISK ASSESSMENT BULLETIN, *supra* note 306, ch. 5 (discussing several omissions that limit the utility of the OMB risk-assessment guidelines and suggesting that federal agencies would be best served by “develop[ing] individual guidelines tailored to their own needs and practices”).

<sup>431</sup> See, e.g., Kazuhiko Ito et al., *Associations Between Ozone and Daily Mortality: Analysis and Meta-Analysis*, 16 EPIDEMIOLOGY 446 (2005).

<sup>432</sup> Parker, *supra* note 34, at 1368 n.80 (arguing that the “net effect of these opposing biases [in risk assessment] may well depend on the facts of each case”).

<sup>433</sup> For two quite different views, compare AARON WILDAVSKY, BUT IS IT TRUE? A CITIZEN’S GUIDE TO ENVIRONMENTAL HEALTH AND SAFETY ISSUES (1995), which uses multiple case studies to question whether hazards are really as bad as activists allege, with THE PRECAUTIONARY PRINCIPLE IN THE 20TH CENTURY, *supra* note 392, which uses

## 2. The Monetary Value of Lifesaving

When federal agencies estimate WTP for small risk reductions, they use a summary statistic called the “value of statistical life” (VSL). If 100,000 people are each exposed to a mortality risk of 1 in 100,000, then one statistical death is expected. If the average WTP to prevent the risk is \$50 per person, then the VSL for the population is \$5 million.

Federal agencies do not use the same VSL figures. The 2003 OIRA guidance to federal agencies is to value each statistical life saved at anywhere from \$1 million to \$10 million.<sup>434</sup> The EPA often emphasizes a point estimate of \$6 million while other federal agencies (the DOT and the Department of Health and Human Services) tend to use somewhat smaller point estimates, in the range from \$3 million to \$5 million.<sup>435</sup>

Professor Heinzerling questions the practice of applying the same VSL in the following two situations: 1000 people each face a mortality risk of 1 in 1000, and 1,000,000 people each face a mortality risk of 1 in 1,000,000. In both cases, the expected number of lives lost is equal to one. Should the same VSL be applied in both cases, thereby producing identical monetary measures of welfare change?<sup>2</sup>

Technically speaking, the answer is no, since the VSL is an approximation derived from small risks that does not necessarily apply to larger risks.<sup>436</sup> The direction and size of error caused by applying the same VSL to risks of 1 in 1000 and 1 in 1,000,000 is an empirical question. An indifference curve for wealth and survival probability may be roughly linear in the “small-risk” range,<sup>437</sup> and thus the approximation that Professor Heinzerling criticizes may not be unreasonable.<sup>438</sup>

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multiple case studies to suggest that hazards often prove to be more serious than originally thought.

<sup>434</sup> OMB Circular A-4, *supra* note 259, at 30.

<sup>435</sup> Robinson, *supra* note 325, at 294-95.

<sup>436</sup> See VISCUSI, *supra* note 65, at 94-95 (considering “what value we should place on small reductions in the probabilities of . . . outcomes for large” groups).

<sup>437</sup> See generally James K. Hammitt & John D. Graham, *Willingness to Pay for Health Protection: Inadequate Sensitivity to Probability?*, 18 J. RISK & UNCERTAINTY 33 (1999) (discussing the failure of contingent-valuation surveys to produce the expected theoretical correlation between WTP and reduced “small-risk” probabilities).

<sup>438</sup> Welfare economics does not assume that all population risk distributions that produce the same number of expected deaths are equally onerous. The answer to Professor Heinzerling’s question may depend upon whether the WTA or WTP metric is employed. A 1 in 1000 risk is more likely to trigger an extreme WTA value than a 1 in 1,000,000 risk. Thus, on a population-wide basis, the sum of the WTA values for 1000 people each facing a risk of death of 1 in 1000 may exceed the sum of the WTA values

Some critics object that the value of lifesaving should include the ex post losses when the premature death occurs as well as the ex ante WTP for risk reduction. If a person is insured against lost earnings from premature death and other death-related costs, the individual will presumably fail to include those costs in her ex ante private WTP for safety. Although these external costs of premature death are believed to be small relative to ex ante WTP, they should, strictly speaking, be included in an agency's overall VSL figure.<sup>439</sup>

Is the EPA's \$6 million VSL figure too low or too high? It is based primarily on data from real-world labor markets where employers offer workers wage premiums (and other noncash benefits) in order to induce them to accept and retain hazardous jobs.<sup>440</sup>

More than twenty studies in the United States and abroad, each using somewhat different data sets and econometric methods, have

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for 1,000,000 people each facing a risk of death of 1 in 1,000,000. The opposite is true for the WTP values (because of the wealth constraint's influence). The size of the error in applying the same VSL at different levels of risk should diminish as the risk levels diminish. *See generally* Hammitt & Treich, *supra* note 6, at 45-66 (showing that usually if "one aggregates individuals' willingness to pay . . . for a project that reduces risk, information about heterogeneity of risk change decreases the value of the project").

<sup>439</sup> Professors Ackerman and Heinzerling argue that the WTP procedure values the statistical life saved but not the value of life itself. Ackerman & Heinzerling, *supra* note 237, at 1564-65. But when WTP is used to value risk reduction, it is based on a person's ex ante evaluation of both the severity of the adverse effect and the corresponding probability reduction. When the adverse effect is less severe than death, the WTP for risk reduction is typically much smaller. *See, e.g.*, Michael W. Jones-Lee et al., *Valuing the Prevention of Non-Fatal Road Injuries: Contingent Valuation Versus Standard Gambles*, 47 OXFORD ECON. PAPERS 676, 692-93 (1995) (U.K.) ("[T]he prevention of the typical serious non-fatal injury should be accorded approximately one-tenth the value placed upon the prevention of a fatality . . ."). The only aspects of premature death that are not included in an informed private WTP value are the "externalities": the adverse spillovers from premature death that impact persons other than the lifesaving beneficiary—effects that are not included in private WTP. These external benefits from lifesaving should be added to the private WTP for lifesaving. The externalities associated with premature death are likely to be larger in Sweden than in the United States since foregone earnings in Sweden are replaced by social insurance while health costs are fully socialized. Thus, Swedish economists argue that the full valuation of lifesaving should include the private WTP for risk reduction plus all of the adverse financial costs of death itself. MAGNUS JOHANNESSON, *THEORY AND METHODS OF ECONOMIC EVALUATION OF HEALTH CARE* 47-64 (1996) (comparing the proper valuation of lifesaving in "private" versus "public" systems).

<sup>440</sup> Values of lifesaving derived from wage premiums for hazardous jobs might seem like a WTA measure, but they are actually a hybrid of WTA and WTP values. *See* Hammitt, *supra* note 84, at 998 (noting that when a worker retains a job rather than taking other offers, the worker's WTA compensation to bear additional risk is larger than the incremental pay offered by more dangerous jobs, and the WTP for risk reduction is smaller than the pay cut the worker would face by choosing a safer job).

explored the magnitude of wage premiums for hazardous employment. How analysts combine or weight the results of these studies is somewhat important. One review of these studies generally supports the EPA's position.<sup>441</sup> Another review suggests that the EPA's value is too high and should be closer to the values used by other federal agencies.<sup>442</sup>

The estimated VSL from the workplace studies, which is usually based on traumatic injuries to middle-aged workers, is not directly relevant to reducing mortality risks from chronic disease in the community through EPA regulation. The transfer of a VSL from the workplace setting to the community setting could generate an upward or downward bias.<sup>443</sup> Despite the differences in lifesaving context, the EPA and its science advisors believe that a "benefit transfer"<sup>444</sup> from workplace safety to environmental protection is a defensible procedure until more relevant data are available.<sup>445</sup>

Recent stated-preference surveys suggest that the EPA's \$6 million figure may be somewhat on the high side.<sup>446</sup> But stated-preference studies suffer from the problem that WTP values are often unresponsive to the probability of death.<sup>447</sup> More valuation studies based on

<sup>441</sup> W. Kip Viscusi, *Monetizing the Benefits of Risk and Environmental Regulation* 9 (AEI-Brookings Joint Ctr. for Reg. Stud., Working Paper 06-09, Apr. 2006) (reporting a comprehensive study showing the median value of a statistical life at \$6.7 million).

<sup>442</sup> See Janusz R. Mrozek & Laura O. Taylor, *What Determines the Value of Life? A Meta-Analysis*, 21 J. POL'Y ANALYSIS & MGMT. 253, 253 (2002) (reviewing labor market VSL studies using "'best practices' assumptions" to find an appropriate range of \$1.5 million to \$2.5 million).

<sup>443</sup> See generally W. Kip Viscusi & Joseph. E. Aldy, *Labor Market Estimates of the Senior Discount for the Value of Statistical Life*, 53 J. ENVTL. ECON. & MGMT. 377, 377 (2007) (showing that estimates of the value of statistical life approximate a bell curve, peaking at \$9 million for ages 35 to 44).

<sup>444</sup> See FREEMAN, *supra* note 61, at 453-56 (defining "benefits transfer" and describing its increasing use in regulatory analysis).

<sup>445</sup> EPA, GUIDELINES FOR PREPARING ECONOMIC ANALYSES 76 (2000) ("Environmental benefits assessments can draw upon [hedonic wage] studies to estimate the value of reductions in environmental mortality risks.").

<sup>446</sup> See Alan Krupnick, *Mortality-Risk Valuation and Age: Stated Preference Evidence*, 1 REV. ENVTL. ECON. & POL'Y 261 (2007) (cataloguing studies).

<sup>447</sup> The available survey-based studies do not confirm sensitivity to the size of risk reduction unless careful efforts are made to help respondents understand the magnitude of the risk changes. See Phaedra S. Corso et al., *Valuing Mortality-Risk Reduction: Using Visual Aids to Improve the Validity of Contingent Valuation*, 23 J. RISK & UNCERTAINTY 165 app. (2001) (employing visual aids to communicate risk to survey respondents); Hammitt & Graham, *supra* note 437, at 58 (reviewing poor risk sensitivity in many studies and recommending additional methodological research).

well-informed respondents who address chronic diseases or pollution-related risks specifically are needed.<sup>448</sup>

An important unanswered question is how much VSL figures should vary depending on the preferences of the target population of beneficiaries. Federal agencies have tended to prefer a constant VSL figure, but rational-choice theory predicts unequal lifesaving preferences. In other words, it is expected that VSLs will vary for different target populations.<sup>449</sup>

The most obvious reason to expect such heterogeneity in VSL is that people vary widely in their ability to pay (i.e., income and assets). Each 10% increase in household income appears to be associated with about a 5% to 6% increase in WTP for risk reduction.<sup>450</sup> On this basis, some economists have recommended that wealthy airline passengers be assigned a larger VSL than automotive occupants and pedestrians. As long as wealthy airline passengers are expected to incur the costs of safety rules through larger fares, a case can be made that their preferences should be considered on the benefit side of the ledger. The DOT has been reluctant to take this step,<sup>451</sup> presumably due to political sensitivities, even though it is well grounded in Kaldor-Hicks reasoning.<sup>452</sup> An expert advisory group to the EPA has recommended against making adjustments based on the income of the target population due to the “sensitivity of making such distinctions.”<sup>453</sup>

An even more complicated case concerns the lifesaving preferences of the young versus the old, where the young face a loss of more healthy life-years than do seniors. From a welfarist perspective, it is both efficient and fair to value lives based on the number of years that

<sup>448</sup> Graham, *supra* note 292, at 189 (urging less reliance on benefit transfer and more targeted research into the economic value of enhanced air quality).

<sup>449</sup> See, e.g., ADLER & POSNER, *supra* note 2, at 178-82 (arguing for variation in VSL based on factors that reflect well-being, but objecting to the KH perspective, which causes inflated VSL figures for seniors and the affluent).

<sup>450</sup> Viscusi & Aldy, *supra* note 64, at 63.

<sup>451</sup> Viscusi, *supra* note 205, at 858 (discussing the Secretary of Transportation’s decision not to value the lives of airline passengers at a premium, even though airline passengers are wealthier than the average citizen and presumably pay the costs of airline safety rules in the form of higher fares).

<sup>452</sup> See Viscusi, *supra* note 441, at 18 (discussing the DOT’s refusal to raise the VSL figure for wealthy airline passengers); see also Viscusi & Aldy, *supra* note 64, at 54 (observing that the DOT “has continued to lag behind the estimates in the literature”).

<sup>453</sup> ENVTL. ECON. ADVISORY COMM., *supra* note 151, at 5.

are lost, possibly adjusted for their quality.<sup>454</sup> But the Kaldor-Hicks perspective, when implemented via a monetary WTP measure, does not necessarily produce this result because older persons tend to be wealthier than young people (due to a lifetime of savings), and seniors tend to be more concerned about health issues because they have relatively few remaining life-years.<sup>455</sup> In other words, the WTP of seniors for lifesaving may be inflated because their opportunity costs of spending money are low (unless they have strong bequest motives). This has been called the “dead-anyway” effect.<sup>456</sup> Thus, from a Kaldor-Hicks perspective, it is not clear whether old age should produce a larger or smaller WTP for lifesaving.<sup>457</sup> The most recent empirical evidence suggests that VSL does decline at older ages but not in the dramatic way that some originally suspected.<sup>458</sup>

Even for citizens of the same age and ability to pay, preferences for lifesaving may vary considerably.<sup>459</sup> For example, WTP for safety tends to be smaller for those who smoke and do not wear safety belts,

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<sup>454</sup> See generally Sunstein, *supra* note 325, at 216-19 (rejecting claims of age discrimination and arguing that consideration of life-years is exactly what a welfarist perspective would support).

<sup>455</sup> See Yew-Kwang Ng, *The Older the More Valuable: Divergence Between Utility and Dollar Values of Life as One Ages*, 55 J. ECON. 1, 1 (1992) (“[W]hile the utility value of life may decrease monotonically with age, the dollar value may increase dramatically until a fairly old age . . .”).

<sup>456</sup> See Pratt & Zeckhauser, *supra* note 110, at 752-56 (offering a theoretical derivation of the “dead-anyway” effect).

<sup>457</sup> See Mary F. Evans & V. Kerry Smith, *Do We Really Understand the Age-VSL Relationship?*, 28 RESOURCE & ENERGY ECON. 242, 259 (2006) (“In our opinion, the conclusion that VSL declines with age is not supported by either the theoretical or empirical literatures.”); James K. Hammitt, *supra* note 84, at 993 (noting that the effect of age on WTP for lifesaving is ambiguous due to opposing effects); Per-Olov Johansson, *On the Definition and Age-Dependency of the Value of a Statistical Life*, 25 J. RISK & UNCERTAINTY 251, 260 (“[T]he claim that there are strong theoretical grounds for the view that the VSL declines with age . . . seem [sic] premature.” (emphasis omitted)).

<sup>458</sup> See Joseph E. Aldy & W. Kip Viscusi, *Age Differences in the Value of Statistical Life: Revealed Preference Evidence*, 1 REV. ENVTL. ECON. & POL’Y 241, 257 (2007) (“[T]he popular perception that the VSL must be less for a 60-year-old than for a 20-year-old . . . is not borne out.”); Krupnick, *supra* note 446, at 274-76 (discussing ambiguity in the literature on the relationship between age and VSL).

<sup>459</sup> See, e.g., JOHANSSON, *supra* note 5, at 93 (noting that VSL is “expected to vary with the type of risk (e.g., voluntary versus involuntary), the initial risk level, the size of the risk change, age, and income”); VISCUSI, *supra* note 7, at 43 tbl.3-3, 46 tbls.3-4 & 3-5, 47 tbl.3-6 (demonstrating large heterogeneity in the value of lifesaving among workers).

after other personal characteristics are controlled statistically.<sup>460</sup> There is limited evidence that WTP valuations also vary by cause of death, with cancer deaths commanding a premium.<sup>461</sup> Some scholars suggest that the VSL values should be highly contextual, floating upward or downward depending upon whether the risk is voluntary or involuntary,<sup>462</sup> whether the potential victims have dependents, whether the risk triggers dread, and whether the people at risk have contributed to their vulnerability through personally unhealthy behaviors.<sup>463</sup> Agencies do not currently make such adjustments in WTP for lifesaving,<sup>464</sup> in part because the literature supporting such adjustments is quite limited,<sup>465</sup> but such adjustments are the next frontier in WTP research.<sup>466</sup>

In summary, there is little support for the allegation that the VSL values now in widespread use are too low.<sup>467</sup> A case can be made that the difference in VSL values between agencies and rulemakings are inconsistent or unsupported. The FDA has been influenced by the life-year approach, while the EPA has tended to assign the same VSL,

<sup>460</sup> See, e.g., W. Kip Viscusi & Joni Hersch, *Cigarette Smokers as Job Risk Takers*, 83 REV. ECON. STAT. 269 (2001) (finding a lower WTP for reduced risk on the part of individuals who engage in risky behaviors such as smoking).

<sup>461</sup> See generally Viscusi, *supra* note 441, at 10 (asserting that “one would expect” people to value death by cancer lower than death by other causes).

<sup>462</sup> See generally COMM. TO EVALUATE MEASURES OF HEALTH BENEFITS FOR ENVTL., HEALTH, AND SAFETY REGULATION, INST. OF MED. OF THE NAT’L ACADS., VALUING HEALTH FOR REGULATORY COST-EFFECTIVENESS ANALYSIS 140-43 (Wilhelmine Miller, Lisa A. Robinson & Robert S. Lawrence eds., 2006) (discussing “ethical, distributional, and other factors,” such as dread and degree of personal control, that change the valuation of risk but are not captured by quantitative measures of risk).

<sup>463</sup> See Paul Dolan et al., *QALY Maximization and People’s Preferences: A Methodological Review of the Literature*, 14 HEALTH ECON. 197, 202-03 (2005) (reviewing studies that suggest that respondents want to give less weight to people who have not cared for their own health, although in some surveys a majority of respondents do not take that view).

<sup>464</sup> See Viscusi, *supra* note 205, at 857 (observing that agencies do not recognize “legitimate sources of heterogeneity” in the monetary value of lifesaving).

<sup>465</sup> See, e.g., Letter from Morton Lipmann, Interim Chair, Sci. Advisory Bd., & Robert N. Stavins, Chair, Envtl. Econ. Advisory Comm., to Carol Browner, Adm’r, U.S. Envtl. Prot. Agency 1 (July 20, 2000), in ENVTL. ECON. ADVISORY COMM., *supra* note 151 (concluding that, although VSL estimates based on wage-risk tradeoffs are imprecise, the agency lacks “theoretical and empirical” grounds for adjusting the estimate to correct for risk and population characteristics); EPA, *supra* note 445, at 92-94 (recognizing the limitations of a generalized VSL, but suggesting that “[a]nalysts should exercise caution in accounting for . . . risk and population characteristics”).

<sup>466</sup> See Viscusi, *supra* note 205, at 870 (arguing for refinements in VSL valuation based on a variety of factors).

<sup>467</sup> But see Parker, *supra* note 34, at 1416 (“[T]he life and health values in current use are empirically questionable, and probably too low.”).

regardless of the number of life-years saved or their quality. The EPA-FDA difference in VSLs may reflect the deeper unresolved question as to whether welfarism or Kaldor-Hicks efficiency should be the foundation of BCA. Nonetheless, the analytic approaches of each agency are currently within a zone of reasonableness and are consistent with OIRA guidance and the available empirical evidence. Given the political sensitivity of departing from the assumption that each life saved is equally valuable, it is likely that substantial data will be necessary to persuade agencies and the OMB to embrace more heterogeneity in safety preferences across people and hazards.

### 3. Time Preferences for Lifesaving

Most lifesaving rules entail some immediate cost in exchange for deferred lifesaving benefits. When comparing immediate costs to future health gains, it is common practice in BCA to discount the future health gains to present value using a real discount rate (e.g., 3% per year). This is the same procedure used to express a regular car or mortgage payment in present value. At a 3% discount rate, saving 1000 lives 30 years from now is equivalent to saving 412 lives today.

This discounting procedure obviously penalizes rules that save lives in the future, after the costs of lifesaving have been incurred, and favors rules that save lives today at costs that are not incurred until the future. Critics argue that this procedure is inappropriate because the investment analogy does not apply to lifesaving—one cannot “invest” a life-year in the bank today and earn more than one life-year in the future.<sup>468</sup> Moreover, critics argue that there are no compelling grounds for preferring present to future life-years. In some situations, citizens might prefer to experience an adverse health effect sooner rather than later if it must be experienced at all.<sup>469</sup> Based on these considerations, some critics argue that future lifesaving should not be discounted.<sup>470</sup>

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<sup>468</sup> See Lisa Heinzerling, *Discounting Life*, 108 YALE L.J. 1911, 1913 (1999) (“Lives do not compound the way money does.”).

<sup>469</sup> See Heinzerling, *supra* note 41, at 108 (questioning whether people always prefer distant harms to immediate harms).

<sup>470</sup> See, e.g., Lisa Heinzerling, *Discounting Our Future*, 34 LAND & WATER L. REV. 39, 40-41 (1999) (“[D]iscounting should be abandoned as a way of evaluating the wisdom of life-saving regulations.”); Parker, *supra* note 34, at 1416 (arguing that “agencies should cease the semantically misleading practice of discounting the number of lives saved” when conducting CEA).

Critics are correct that many past BCAs have used discount rates (e.g., 7% or 10% per year) for future health benefits that we now realize are too high.<sup>471</sup> But there is no case for a zero discount rate, at least for current investments that generate health gains within a generation.<sup>472</sup> A rule that saves lives primarily in future generations is a more complicated case that I do not address here.<sup>473</sup>

In 2003, OIRA changed the government's discounting policy in regulatory analysis. Agencies were instructed to present benefit-cost results using discount rates of 3% and 7% rather than only 7%. By moving the federal government toward stronger consideration of the 3% rate, OIRA affirmed a position that the EPA has taken for a number of years.<sup>474</sup> The result should be that more future-oriented lifesaving rules will pass a "hard" benefit-cost test than otherwise would have occurred.

The central rationale for discounting future lifesaving is the opportunity cost of investing resources now—since lifesaving may not occur for many years, or possibly decades.<sup>475</sup> If instead of expending \$1 billion today to save 1000 lives ten years from now, we invest the \$1 billion for ten years at a 3% real rate of interest, we will accumulate \$1.34 billion to invest in lifesaving (or other purposes) ten years from now. If the marginal (inflation-adjusted) cost of saving lives is the same ten years from now as it is today, investing the resources will enable us to save 1340 lives ten years from now—340 more than we will save by making the immediate lifesaving expenditure.<sup>476</sup>

When my faculty colleagues and I taught this same logic at the Harvard School of Public Health, we found it useful to offer several reaffirming paradoxes: the delay paradox, the time-inconsistency

<sup>471</sup> See FREEMAN, *supra* note 61, at 199 (supporting EPA-recommended discount rates of 2% to 3%, but suggesting that OMB's 7% figure is too high).

<sup>472</sup> See *id.* at 320-21 (explaining the strong case for discounting future lives saved).

<sup>473</sup> For OIRA's position on intergenerational discounting, see Graham, *supra* note 416, at 54.

<sup>474</sup> EPA, *supra* note 445, at 48 (recommending intragenerational discount rates of 2% to 3%).

<sup>475</sup> See, e.g., JUST ET AL., *supra* note 69, at 579 ("In practice, the most widely accepted approach to choice of a discount rate is the opportunity cost approach, particularly for projects of less than 100 years."). There is no necessary assumption that future lifesaving is morally or hedonistically less appealing than lifesaving that occurs now.

<sup>476</sup> For a three-variable approach, see Hugh Gravelle & Dave Smith, *Discounting for Health Effects in Cost-Benefit and Cost-Effectiveness Analysis* (Ctr. For Health Econ., Univ. of York, CHE Technical Paper Series, Paper No. 20, Oct. 2000).

paradox, and horizontal-inequity paradox. Each of the paradoxes offers a different perspective but leads to the same conclusion.

The paradox of delayed lifesaving, also named the “Keeler-Cretin paradox,” starts with the seemingly innocuous assumption that the analyst assigns a lower discount rate (possibly zero) to lives saved than is assigned to dollars.<sup>477</sup> But then the analyst is asked to compare a promising lifesaving rule to the same rule delayed for a year. Under certain conditions, Keeler and Cretin show that the rule is a better investment if it is delayed because future lives saved have been discounted at a lower rate than future costs. By the same logic, it can be shown that the lifesaving regulation should be delayed indefinitely, which Keeler and Cretin argue is perverse.<sup>478</sup> The Centers for Disease Control and Prevention, which includes the delay paradox in its guidance document on economic evaluation, instructs analysts to apply the same rate of discount to benefits and costs.<sup>479</sup>

The time-inconsistency paradox builds on the idea that the optimal tradeoff between wealth and health should not necessarily be changing over time.<sup>480</sup> But a violation of time consistency can be shown if lifesaving is discounted at a lower rate than costs. The reason for discounting future lives is precisely because they are being valued relative to dollars and, since a dollar in the future is discounted relative to a present dollar, so must a life saved in the future be dis-

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<sup>477</sup> See Emmett B. Keeler & Shan Cretin, *Discounting of Life-Saving and Other Non-monetary Effects*, 29 MGMT. SCI. 300, 306 (1983) (arguing that “any cost-effectiveness analysis using lower discount rates for benefits than costs is difficult to justify”).

<sup>478</sup> For a criticism of one of the premises of the Keeler-Cretin paradox, see Heinzerling, *supra* note 470, at 72, arguing that if the lifesaving program addresses environmental pollution, and if the program is delayed, then the environmental damages will grow and the solution will become more costly. But if Professor Heinzerling’s argument is correct, the number of lives saved should be adjusted to reflect a worsening baseline condition. Once that adjustment is made, the paradox will remain operative. See Revesz, *supra* note 179, at 990-92 (disputing the Keeler-Cretin paradox partly on the grounds that there are “difficulties concerning the transfer of resources across projects”). But disputing the transferability of resources does not deny the logic of the paradox. In Part V, I argue that institutional reforms should be taken to make lifesaving resources more transferable in society.

<sup>479</sup> U.S. CTRS. FOR DISEASE CONTROL & PREVENTION, A PRACTICAL GUIDE TO PREVENTION EFFECTIVENESS: DECISION AND ECONOMIC ANALYSES (1994).

<sup>480</sup> If wealth is projected to increase over time, a good case can be made for adjusting the VSL value upward over time, since the demand for lifesaving surely rises with income. But changing levels of wealth should not affect the real discount rate. See ENVTL. ECON. ADVISORY COMM., *supra* note 151, at 5 (“[T]he Committee believes that it is appropriate to adjust the value of projected statistical lives saved in future years to reflect higher incomes in those years . . .”).

counted relative to a present dollar. "It is the discounting of [future] dollar costs, and the assumed constant steady-state relation" between health benefits and dollar costs, that "mandates the discounting of health benefits . . . as well as dollar health costs."<sup>481</sup>

The horizontal-inequity paradox arises when we consider two groups of lifesaving beneficiaries who are identical in every respect except for their positions in time relative to the moment at which the regulator must act. If discount rates for dollar costs and lives saved are not constrained to be equal, it can be shown that these identical beneficiaries will be assigned unequal cost-effectiveness ratios (once the present-value calculations are executed), which means that investment on behalf of one group will be preferred to investment on behalf of the other (identical) group. An extension of this same argument, which proceeds from an original position where citizens make constitutional choices behind a veil of ignorance, leads to a fairness conclusion: future lifesaving and future dollar costs must be discounted at the same rate.<sup>482</sup>

A more subtle, science-based argument has been made against the practice of discounting future deaths from chronic diseases that occur only after a long period of time, called a "latency period." The process of chronic disease occurs in stages. Sometimes a death will occur earlier and sometimes later in the disease process, depending upon the individual.

A lifesaving rule that prevents the development of chronic disease will produce a continuum of health benefits that begins (at least) from the moment a person develops the disease and includes the period of increasing pain and suffering prior to eventual death. In fact, some benefit may occur from the moment a risky exposure (e.g., to a chemical pollutant) is reduced, since a person will not experience the stress that may be associated with knowing that she has been ex-

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<sup>481</sup> Milton C. Weinstein & William B. Stason, *Foundations of Cost-Effectiveness Analysis for Health and Medical Practices*, 296 *NEW ENG. J. MED.* 716, 720 (1977). To apply a zero discount rate to future lives saved but not to future dollars would create a time inconsistency in the health/wealth tradeoff—an inconsistency that has spurred objections from analysts who take either a societal or individualistic view of health investment. A hypothetical example of time inconsistency in lifesaving is published in a guidance document on CEA prepared by an expert panel for the U.S. Department of Health and Human Services. J. Lipscomb et al., *Time Preference*, in *COST-EFFECTIVENESS IN HEALTH AND MEDICINE*, *supra* note 28, at 214, 220 fig.7.1.

<sup>482</sup> See Lipscomb et al., *supra* note 481, at 221 (outlining the horizontal-equity argument).

posed.<sup>483</sup> Given all these complications, it has been suggested that a zero discount rate should be assigned in BCA to premature deaths from chronic disease.<sup>484</sup>

Agencies have developed analytic practices that are more appropriate to biological complexity than simply assigning a zero discount rate. The EPA, for example, recognizes that some diseases have longer latency periods than others and adjusts the latency period depending upon the disease.<sup>485</sup> The EPA also recognizes that, for the same disease, some people will die with a shorter latency period than others. The EPA accounts for this complexity with a percentage distribution of latencies, with part of the distribution reflecting the near-term mortality impacts of pollution exposure and part of the distribution reflecting progressively longer latency periods after a period of chronic exposures.<sup>486</sup>

The period of morbidity prior to death can be handled in several ways. If the monetary value of life is derived through a procedure that accounts for the period of pain and suffering prior to death, then no adjustment for morbidity is required.<sup>487</sup> If lifesaving has been valued through benefit transfer, where WTP to prevent the risk of sudden death is transferred to WTP to prevent a slow, painful death, then an adjustment to the benefit transfer is appropriate. When a separate analysis addresses morbidity reduction, including the WTP to avoid pain and suffering associated with morbidity prior to death, the amounts should be discounted based on when the pain and suffering are expected to occur.

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<sup>483</sup> See Lisa Heinzerling, *The Temporal Dimension in Environmental Law*, 31 ENVTL. L. REP. (Envtl. Law Inst.) 11,055, 11,056-57, 11,060 (2001) (observing that reduction of environmental risks may bring psychological benefits for individuals).

<sup>484</sup> *Id.* at 11,070 (arguing that latent health effects should not be discounted because the appropriate point in time cannot be marked precisely).

<sup>485</sup> See EPA, *supra* note 317, at 9-148 to -149 (noting a "potential time lag" between exposure to particulate matter and changes in the premature mortality rate, the length of which may depend on the type of exposure).

<sup>486</sup> See *id.* at 9-255 tbl.9C-1 (reporting a sensitivity analysis of premature deaths from particle exposure where the distribution of latency periods is 20% in the first year, 50% in years two through five, and 30% in years six through twenty).

<sup>487</sup> A complication arises when the WTP to prevent death is derived from a procedure that accounts for the period of morbidity preceding death. If a standard discount rate is applied to the full WTP value, it will apply too much discounting to the pain and suffering, which occurs prior to the death. In settings where the most severe pain and suffering occurs close to the point of death, however, the overestimation will not be large.

If a lifesaving rule reduces emotional stress about toxic exposures, that psychic benefit should be measured directly by analysts (or treated as an intangible benefit for consideration by regulators).<sup>488</sup> Analysts should also consider the timing of the stress reduction, as the time profile of stress reduction may be very different (i.e., with much less discounting) than the time profile of lives saved.<sup>489</sup> However, I have seen no evidence that federal lifesaving rules have a discernible impact on levels of stress or dread in American society.

In summary, there is a fairly strong analytic case for discounting future lives saved and costs at the same rate. I do not address here the more complex case of intergenerational lifesaving.<sup>490</sup>

#### 4. Respect for Altruistic Sentiments

Some legal scholars are under the impression that BCA has no place for altruism as a human value; they perceive that BCA considers only hedonistic preferences.<sup>491</sup> For example, critics argue that the monetary value of lifesaving should consider both the WTP of lifesaving beneficiaries as well as the WTP of other people who care about the well-being of lifesaving beneficiaries. If altruistic preferences were counted, critics predict that more lifesaving policies would pass a benefit-cost test.

Economists have long been intrigued about altruistic preferences toward lifesaving.<sup>492</sup> Some estimates of altruistic lifesaving preferences

<sup>488</sup> The possibility of WTP to avoid emotional stress was of interest to the pioneers of the WTP approach to lifesaving. But there was early recognition that distress may not be proportional to actual risk. See M.W. JONES-LEE, *THE VALUE OF LIFE: AN ECONOMIC ANALYSIS* 32 (1976) (“[A]nxiety is probably a *discontinuous* function of risk, becoming apparent only if risk exceeds some ‘threshold level’ . . .”).

<sup>489</sup> Heinzerling, *supra* note 483, at 11,055-60 (arguing that because exposure to toxic substances induces stress and dread, there may be an immediate social benefit from reducing exposure).

<sup>490</sup> For a discussion of why intergenerational discounting raises more complex issues, see Douglas A. Kysar, *Discounting . . . on Stilts*, 74 U. CHI. L. REV. 119, 138 (2007), which discusses policy concerns associated with intergenerational discounting in light of future concerns such as climate change.

<sup>491</sup> See Ackerman & Heinzerling, *supra* note 237, at 1566 (expressing concern that altruism is not reflected in the monetary value of lifesaving); see also Adam F. Scales, *How Much Is that Doggy in the Window? The Inevitably Unsatisfying Duty to Monetize*, 33 *FORDHAM URB. L.J.* 1045, 1050-51 (2006) (noting that WTP valuations that include altruism are “several times higher than self-regarding WTP” but that altruism is nevertheless “mysteriously underemphasized” in BCA).

<sup>492</sup> See, e.g., M.W. Jones-Lee et al., *The Value of Safety: Results of a National Sample Survey*, 95 *ECON. J.* 49, 69 (1985) (attempting to quantify people’s WTP for others).

have already been published,<sup>493</sup> but they are not used in BCA because they will have no net effect.

If citizens are concerned generally for the well-being of others (i.e., for the overall well-being of others rather than merely their own health), inclusion of altruistic preferences is still expected to have no net effect on policy choice. That is because both the benefits and costs of regulatory policy, which impact general well-being, will be augmented by the same amount because of generalized altruism.<sup>494</sup> Thus, the effects of general altruism are expected to be symmetric on the benefit and cost sides of the ledger and thus can safely be ignored in BCA.<sup>495</sup>

It is hard to imagine a person caring about another person's health status without caring about other aspects of her well-being, but it is certainly possible. If altruism is exclusively directed at health status or longevity, then there are grounds for including altruistic preferences in BCA and, as mentioned above, the literature already contains some rough estimates of what those adjustments might be.<sup>496</sup>

### 5. Accurate Estimates of Regulatory Costs

One of the most common criticisms of BCA is that the estimated costs of regulations are routinely and greatly overestimated.<sup>497</sup> Critics argue that information on costs must come from the businesses that

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<sup>493</sup> Early estimates of the altruistic value of lifesaving were made in Lionel Needleman, *Valuing Other People's Lives*, 44 MANCHESTER SCH. ECON. & SOC. STUD. 309 (1976). See also W. Kip Viscusi et al., *Altruistic and Private Valuations of Risk Reduction*, 7 J. POL'Y ANALYSIS & MGMT. 227, 243-44 (1988) (quantifying the altruistic value of lifesaving).

<sup>494</sup> On the conceptual rationale for excluding general altruism from BCA, see M.W. Jones-Lee, *Altruism and the Value of Other People's Safety*, 4 J. RISK & UNCERTAINTY 213, 217-18 (1991), which argues that incorporating altruism in BCA will "result in an overprovision of safety."

<sup>495</sup> The first author to highlight this point was T.C. Bergstrom, *When Is a Man's Life Worth More Than His Human Capital?*, in THE VALUE OF LIFE AND SAFETY, *supra* note 4, at 3, 16-18, which stated that the effects of "benevolence" balance themselves out.

<sup>496</sup> I do not address here an alternative rationale for excluding altruistic preferences from BCA that is advanced by ADLER & POSNER, *supra* note 2, 133-36. Adler and Posner argued that all "disinterested preferences," including altruism, should be excluded from BCA.

<sup>497</sup> See, e.g., David M. Driesen, *The Economic Dynamics of Environmental Law: Cost-Benefit Analysis, Emissions Trading, and Priority-Setting*, 31 B.C. ENVTL. AFF. L. REV. 501, 516 (2004) (observing that "regulators almost always overestimate costs").

will be regulated.<sup>498</sup> Firms that would be adversely affected by a proposed regulation certainly have an incentive to overstate costs (assuming that cost information will be used to set the stringency of the rule).<sup>499</sup> There are well-documented cases where such overstatement has occurred.<sup>500</sup> I shall argue that, although bias in cost estimation is an important issue, the phenomenon is more complex and diverse than critics realize, and critics understate the solutions available to regulatory analysts.

Compliance-cost estimates may be exaggerated when confidentiality agreements protect the estimates submitted by regulated companies, rendering the estimates immune from inspection and critique by outside parties. The public-comment process for the projected costs of a rule is likely to be more meaningful if all commenters can scrutinize and critique the cost estimates supplied by companies, including the itemization that supports the overall estimates.<sup>501</sup>

On the other hand, regulatory analysts may gain more insight into costs from proprietary information when the regulated firms are diverse.<sup>502</sup> Some companies typically face higher compliance costs than

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<sup>498</sup> See McGarity, *supra* note 26, at 55 n.243 (“Agencies have no effective way of gathering cost data other than by asking industry to submit it.” (quoting *Regulatory Reform: Hearing on S. 343 Before the S. Comm. on Governmental Affairs*, 104th Cong. 495 (1995) (statement of David C. Vladeck, Public Citizen Litigation Group))).

<sup>499</sup> See Ackerman & Heinzerling, *supra* note 237, at 1580 (observing that regulatory-cost estimates are usually provided by the regulated industry, which has “an obvious incentive to offer high estimates” as a way to ward off new regulatory requirements); see also SHAPIRO & GLICKSMAN, *supra* note 235, at 105 (“[R]egulated firms have an incentive to overstate such costs in order to persuade agencies to weaken proposed regulations.”).

<sup>500</sup> For example, OSHA’s 1980 cotton-dust standard was subjected to a thorough validation study after the rule was implemented. OSHA overestimated the costs of the standard, in part because of excessive reliance on industry-based compliance-cost estimates. See VISCUSI, *supra* note 7, at 173-77 (analyzing the cost and efficacy of OSHA’s cotton-dust regulation).

<sup>501</sup> One argument in favor of confidentiality is that companies are unlikely to disclose trade secrets or meaningful information about a sensitive, cost-competitive issue if such information will be made available to their competitors, suppliers, and purchasers. Additionally, if the government releases proprietary information about lifesaving technology, the inventor of the technology will have difficulty capturing financial rewards for the innovation. This in turn will undermine the incentive for lifesaving innovation. When a firm knows that its costs or lifesaving information may be released to the public, the firm may be inclined to submit information through an industry-wide trade association, thereby ensuring that firm-specific information is concealed in industry-wide averages.

<sup>502</sup> One of the complexities for regulated firms is that they may not know their cost position relative to other firms in their industry, especially when production processes are changing rapidly.

others.<sup>503</sup> If a rule is promulgated, companies facing low costs of compliance will gain a competitive advantage over companies facing high costs. Thus, companies facing low compliance costs will have an incentive to understate their compliance costs, thereby inducing the agency to impose an industry-wide regulation that favors them. Moreover, if the compliance costs pose a barrier to entry for new firms, existing firms may not be averse to an expensive regulation. Thus, existing firms may behave strategically by submitting low estimates of their compliance costs. Given the possibility of strategic behavior, a range of proprietary cost estimates prepared by individual companies may provide more useful information for an agency than a single estimate from a trade association.

Suppliers to regulated firms are another source of information for regulatory analysts. The regulated industry is often supplied by companies that produce or distribute lifesaving equipment or services (e.g., airbag suppliers or inventors of pollution-control equipment). If these companies have an incentive to bias their figures, it favors understating costs, since understatement may enhance the chances of a rule passing a benefit-cost test. The suppliers, however, need to be careful that they do not provide cost estimates to regulators that are grossly different from the bids that they make (or prices that they charge) to their customers. Thus, information from suppliers may serve as a useful check on information supplied by trade associations representing regulated firms.

If companies are making a one-time estimate of cost to a regulator, the incentive to exaggerate may be pronounced. But companies and their suppliers often deal with the same regulatory agency on multiple issues over time. The credibility of regulated companies is not enhanced by submitting cost information with significant technical biases. Regulated entities benefit by building a reputation for technical competence and honesty when dealing with regulators. Some regulatory agencies have developed their own engineering and economics teams that, over time, learn a great deal about regulated companies, including which companies tend to submit accurate information.<sup>504</sup>

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<sup>503</sup> See, e.g., Thomas O. McGarity & Ruth Ruttenger, *Counting the Cost of Health, Safety and Environmental Regulation*, 80 TEX. L. REV. 1997, 2056 (2002) (noting that “companies that delay in installing [technology that complies with regulatory requirements] wind up at an undeserved competitive advantage”).

<sup>504</sup> For example, when faced with wildly varying airbag-cost estimates from vehicle manufacturers and suppliers, NHTSA employed tear-down methodology to construct

Another source of bias occurs when regulatory analysts assume that a rule will achieve 100% compliance. Analysts may also assume that the enforcement arm of an agency will issue no waivers, variances, or technical modifications to a rule to curb compliance costs. Several critics have speculated that these assumptions lead to cost overestimation.<sup>505</sup> Noncompliance rates, including agency flexibility about noncompliance, may be higher when compliance costs are relatively high than when compliance costs are relatively low.<sup>506</sup> But noncompliance and waivers reduce benefits as well as costs. If both benefits and costs are reduced by the same amount, then there is no net bias in an assumption of 100% compliance.

Critics make a key assumption that plants or companies facing high costs and low benefits may be particularly likely to violate the rule or benefit from agency flexibility.<sup>507</sup> Research is needed on the benefits and costs of noncompliance and variances,<sup>508</sup> since there are numerous factors that may predict noncompliance and waivers. Some of the factors that influence agency enforcement or firm compliance may be unrelated to BCA (e.g., the financial condition of a plant or company, or the extent of preexisting relationships between regulators and regulatees). Since agency personnel do not have firm-specific data on benefits and costs when they issue variances and exercise enforcement discretion (because no such data are prepared by

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cost estimates from the original materials and labor inputs. Validation studies indicate that NHTSA's airbag-cost estimates proved to be quite accurate, except for the replacement cost after an airbag had deployed—a cost that was underestimated. See Kimberly M. Thompson et al., *Validating Benefit and Cost Estimates: The Case of Airbag Regulation*, 22 RISK ANALYSIS 803 (2002).

<sup>505</sup> See, e.g., SHAPIRO & GLICKSMAN, *supra* note 235, at 158-64 (arguing that instead of doing extensive BCA before rules are adopted, regulators should rely on “back-end adjustments” during the implementation and enforcement processes to make sure compliance costs are not excessive).

<sup>506</sup> See, e.g., Daniel A. Farber, *Taking Slippage Seriously: Noncompliance and Creative Compliance in Environmental Law*, 23 HARV. ENVTL. L. REV. 297, 301-11 (1999) (discussing “negative” and “positive” slippage, where the real-world behavior of regulatees falls behind or moves ahead of formal regulatory requirements).

<sup>507</sup> Farber speculates that

in at least some settings, [slippage] might significantly undermine the standard economic critiques of federal “command and control” regulation. The reason is simple: in those settings, command and control regulation does not really exist in the first place. Instead, what looks like a regulatory command is only one stage in a larger and more flexible process.

*Id.* at 317-18 (footnote omitted).

<sup>508</sup> *Id.* at 325 (acknowledging that “[t]he hardest question of all . . . is whether slippage is good or bad”).

the agency), one should not assume that such decisions are based on BCA.

Research also needs to examine whether agencies use discretion during the implementation process to *expand* the scope and stringency of regulations, without any guidance from BCA or OIRA review. We should not make a naïve assumption that post-rulemaking flexibility by regulators always results in lower compliance costs. Indeed, agencies often use “soft law” (e.g., guidance documents and enforcement notices) to expand the scope and stringency of a rule, thereby potentially increasing compliance costs (and benefits). Since OIRA reviews rules but not guidance or enforcement policies, agencies have an opportunity to conceal compliance costs from OIRA by leaving some key issues unresolved in a final rule and then making postrule decisions to accomplish their compliance objectives. OIRA is at the early stages of a more disciplined effort to oversee the guidance practices of regulatory agencies.<sup>509</sup>

The pace of learning and innovation may also reduce compliance costs over time. In some cases, companies are able to develop low-cost ways to comply with agency rules. Some EPA offices have introduced a time-dependent adjustment factor that accounts for projected cost savings.<sup>510</sup> In the 2000 highway diesel rulemaking, EPA assumed that regulated companies would experience a downward trend in compliance costs from the levels experienced soon after the rule was adopted. The more predictable such cost savings are, the more feasible it is for regulatory analysts to account for them in preregulation cost estimates.<sup>511</sup> However, more research is needed to determine whether such adjustments are unique to particular industries or types of compliance expenditures.

Although compliance costs will sometimes be overstated, in other cases they may be understated. For instance, there are well-documented examples of regulators overestimating the effectiveness and operational lifetime of lifesaving technologies while underestimating their actual costs. In some cases, this error occurs because an

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<sup>509</sup> See Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. 3432 (Jan. 25, 2007) (establishing “guidance practices” to assist with “overseeing and coordinating . . . regulatory policy”).

<sup>510</sup> See, e.g., EPA, *supra* note 323, at vi-vii (estimating the reduction over time in the cost of producing cleaner engines).

<sup>511</sup> See McGarity & Ruttenberg, *supra* note 503, at 2052-53 (encouraging regulatory analysts to use a discount factor representing the probability of unanticipated technological improvements).

agency relies too heavily on the optimistic projections of the suppliers of lifesaving technology, leading the agency to adopt an overly favorable view of the technology.<sup>512</sup>

Critics of BCA allege that occurrences of cost-underestimation are less common than instances of cost-overestimation.<sup>513</sup> A related perception in the legal literature is that it is easier to estimate the costs of regulation than to estimate the lifesaving benefits.<sup>514</sup> But these views reflect an overly simplified view of the costs of lifesaving regulation, where costs are seen only as direct compliance costs incurred by companies. A more complete view of regulatory costs accounts for a wide range of direct and indirect considerations, including possible life-threatening risks *created* by regulations. These indirect costs and risks of lifesaving regulations are sometimes very difficult to identify and quantify, just as some of the benefit calculations defy simple quantification and monetization.

Overall, the impression I received from my experience at OIRA was that agencies should not—and typically do not—blindly accept every cost estimate that regulated companies submit to them. Rather, they thoroughly evaluate and verify this information so that the regulatory agency's official cost estimates may widely depart from (and are frequently lower than) the estimates submitted by the regulated industry. Although agencies still occasionally overestimate compliance costs,<sup>515</sup> the most egregious examples of this phenomenon occurred decades ago,<sup>516</sup> before regulators and OMB developed experience with—and analytic guidance for—the craft of cost estimation.

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<sup>512</sup> For a case study where vendors' inflated claims to the EPA were ultimately revealed to the public, see John D. Graham & David R. Holtgrave, *Coke Oven Emissions: A Case Study of Technology-Based Regulation*, 1 RISK 243 (1990).

<sup>513</sup> See, e.g., Katzen, *supra* note 192, at 1315 (“[T]he costs in [agency] CBA are almost always overstated.”); McGarity & Ruttenberg, *supra* note 503, at 1998 (“[E]x ante cost estimates have usually been high, sometimes by orders of magnitude, when compared to actual costs incurred.”).

<sup>514</sup> See McGarity, *supra* note 26, at 58 (arguing that costs are easier to compute than benefits, in part because “the cost side of the equation implicates fewer ‘soft’ considerations”—considerations like “fairness, dignity, and intrinsic beauty”).

<sup>515</sup> In the legal literature assessing BCA, some of the criticism is aimed at cost estimates prepared by companies or industry, not the official cost estimates published by federal regulatory agencies. See, e.g., McGarity & Ruttenberg, *supra* note 503 (examining, in detail, both industry and agency estimates of compliance costs).

<sup>516</sup> For some of the most egregious examples of cost overestimation, see *id.* at 2031, which lists several examples of OSHA regulations the costs of which grossly overestimated by the agency.

In summary, there are widespread claims in the legal literature that the analytic procedures of BCA produce numeric estimates that are systematically biased against the enactment of lifesaving rules. I have countered that the practice of BCA is more complex than critics realize, and that regulatory analysts have creative tools at their disposal to identify and correct biases. There is no empirical foundation for the claim that agencies' official estimates of the benefits and costs of lifesaving regulations are routinely biased against lifesaving.

#### E. *Validation of BCA*

The accuracy of BCA should be judged by whether the ex ante predictions of benefit and cost are validated by real-world experience with the regulation, assuming the rule is implemented and enforced as the analyst assumed. Regrettably, there is no systematic process in place for making this assessment, but the modest amount of information that we do have on validation is encouraging.

The most comprehensive validation study of BCA examined benefit-cost ratios for sixty-one federal rules where ex ante and ex post ratios were compared.<sup>517</sup> The ratios were judged to be accurate (plus or minus 30%) in only sixteen cases. In twenty-one cases, the benefit-cost ratios were overestimated, suggesting that the rule was less worthwhile than projected. In twenty-four cases, the benefit-cost ratios were underestimated, meaning that the rule was more worthwhile than expected. After excluding sixteen rules that were not reviewed by OIRA, however, the number of overestimated ratios (eighteen) slightly exceeds the number of underestimated ratios (fifteen). Based on these findings, the author concludes that there is simply "no bias in estimates of benefit-cost ratios."<sup>518</sup>

Federal regulatory agencies have been using BCA of lifesaving regulations for almost thirty years. The practices of both benefit and cost estimation have matured as the underlying theory of BCA has been clarified. Moreover, agency analysts have developed practical experience collecting data, managing contractors, scrutinizing claims by industry and other stakeholders, developing quality-assurance practices, and subjecting their own work to criticism by peer reviewers,

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<sup>517</sup> See Winston Harrington, *Grading Estimates of the Benefits and Costs of Federal Regulation: A Review of Reviews* 33 tbl.7 (Res. For the Future, Discussion Paper No. RFF DP 06-39, Sept. 2006), available at <http://ssrn.com/abstract=937357>.

<sup>518</sup> *Id.* at 34.

stakeholders, OMB, and the courts.<sup>519</sup> Although BCA is far from perfect and the progress is not as rapid as some specialists in BCA expect,<sup>520</sup> there is no empirical foundation for the claim that BCA is generally biased against—or in favor of—lifesaving regulation.<sup>521</sup>

#### V. FUTURE DIRECTIONS FOR LIFESAVING REGULATION

Despite the progress that has been made by the “benefit-cost state,” there is much more that can and should be done to improve federal lifesaving regulation. I conclude this Article with a survey of promising directions for improvement.

Based on my experience at OIRA, I have come to appreciate—even more so than I did as a Harvard professor teaching BCA—that there are shortcomings in the benefit-cost approach to lifesaving regulation. But I am confident that these shortcomings can be overcome. In this Part, I highlight eight promising innovations—some addressing analytic practice, others addressing institutional design—that will lead to better lifesaving rules. My hope is that these eight proposals will be considered in 2009, when a new presidential administration and a new Congress take office.

##### A. *Ensure the Poor Are Treated Fairly*

One of the longest-standing criticisms of KH efficiency concerns its indifference to the distribution of benefits and costs.<sup>522</sup> For exam-

<sup>519</sup> The improvements in the quality of BCA reflect, in part, a response to the critiques of the initial assessments in the 1980s. See, e.g., MCGARITY, *supra* note 16, at 306 (arguing that bias in regulatory analysis can be reduced by “(1) consulting . . . multiple sources of information in preparing regulatory analysis documents; (2) carefully citing all information upon which the analysis draws and making the information available for public scrutiny . . . ; and (3) subjecting critical studies to review by acknowledged experts”).

<sup>520</sup> See Hahn & Dudley, *supra* note 176, at 205-06 (analyzing agency use of BCA and concluding that agencies are not as thorough as they should be).

<sup>521</sup> See Wiener, *supra* note 186, at 477 (“[R]etrospective analyses of a variety of policies do not bear out the concern that BCA is biased toward overstating costs and understating benefits.”).

<sup>522</sup> Professors Nicholas Bagley and Richard Revesz suggest that distributional analysis should become “a core feature of [OIRA’s] agenda” because “the often unseen distributional consequences of our regulatory state [have been] largely unexamined.” Bagley & Revesz, *supra* note 41, at 1329. But Bagley and Revesz offer no guidance as to how distributional injustice should be defined. Basic arithmetic reveals that the dimensions of distributional analysis explode quickly: (3 income groups) × (3 wealth groups) × (5 race groups) × (3 age groups) × (2 genders) = 270 possible distributional subanalyses that need to be performed. In order for distributional analysis to be con-

ple, a lifesaving regulation may have positive net benefits for society as a whole but make the poorest citizens in society worse off. Some have suggested that the EPA's 2001 arsenic rule might be an illustration of this perverse phenomenon.<sup>523</sup>

There is already a fairly broad consensus that regulators should consider equity as well as efficiency,<sup>524</sup> but confusion exists as to how equity should be defined, measured, and nurtured.<sup>525</sup> Which groups in society deserve special consideration, beyond their contribution to the social benefit-cost calculus?

During my tenure at OIRA, I heard arguments that each of the following groups deserve special protection: farmers, small business owners, women, racial and ethnic minorities, workers, senior citizens, children, disabled individuals, people with chronic illnesses, uninsured individuals, migrants (legal and illegal), and people who lack English proficiency.<sup>526</sup> If the regulator considered the impact of each

structive, tractable, and practical, more thought needs to be given to which specific forms of distributional injustice are most urgent.

<sup>523</sup> See Sunstein, *supra* note 412, at 2257-58 ("In its voluminous materials on the effects of the new arsenic rule . . . the EPA does not say a word about whether poor people would bear the sometimes significant costs of the regulation."). *But see* Matthew E. Kahn, *The Beneficiaries of Clean Air Act Regulation*, REGULATION, Spring 2001, at 34, 36 tbl.2 (displaying that from 1980 to 1998, the benefits of clean-air regulation were not disproportionately felt by households with incomes under \$30,000 per year).

<sup>524</sup> See, e.g., Sunstein, *supra* note 412, at 2257 (arguing that "EPA should be required to provide, if feasible, a *distributional* analysis showing exactly who would be helped and hurt by regulation"). *But see* FRIEDMAN, *supra* note 62, at 174 (explaining the "controversy" over whether or not the potential compensation principle should account for equity).

<sup>525</sup> See, e.g., FRIEDMAN, *supra* note 62, at 58 (defining equity as "fairness in the distribution of goods and services among the people in an economy," but acknowledging that "no unique concept of equity is widely regarded as definitive for public policymaking" (emphasis omitted)); *id.* at 125 (distinguishing "two broad categories of equity concepts: those that relate to [the distribution of decisions'] outcomes and those that relate to [the decision-making] process"); Hsu, *supra* note 19, at 313-20 (explaining various definitions of fairness applied in environmental lawmaking and concluding that "fairness" is "incoherent as applied"); Viscusi, *supra* note 205, at 844 ("Fairness has no well-defined guidelines, and as a result . . . there are quite diverse views as to what does in fact constitute an equitable risk policy").

<sup>526</sup> The legal literature has also suggested that numerous groups deserve special protection on grounds of justice or fairness. See, e.g., SHAPIRO & GLICKSMAN, *supra* note 235, at 58 ("The current approach to risk regulation is . . . more protective of the . . . entities least able to protect themselves."); Shapiro & McGarity, *supra* note 218, at 740 (using equitable standards to argue that workers should receive more protection from health and safety risks than BCA would justify); *id.* at 742 (arguing that "preventable occupational diseases are not merely inefficient—they are *wrong*"); *id.* at 751 (noting that "one can make a moral case for the proposition that society should do the best it can to protect workers," even if the cost exceeds what WTP measures will support).

lifesaving regulation on each of these subgroups, the analytic burden would mushroom. What legal scholars now call “ossification” in rule-making would be magnified many times over.<sup>527</sup> In short, there is serious concern that equity considerations, if they became too diffuse and numerous, would cause regulatory policy to degenerate into a proliferation of special-interest favors rather than good public policy.<sup>528</sup>

Since modern theories of justice urge us to focus more rigorously on society’s least advantaged group, I recommend that a new equity test be devised to protect this group. The corresponding modification of the KH test should be designed to ensure that lifesaving rules do not harm the least advantaged group.<sup>529</sup>

To illustrate how such a test might work, I shall define the worst-off group using the official U.S. poverty line.<sup>530</sup> A similar approach

Professor Sinden sees the most vulnerable groups as “the aged, the sick, the disabled, and children.” Sinden, *supra* note 67, at 1453; *see also* Sunstein, *supra* note 412, at 2260 (claiming that “it would be highly desirable to know whether poor people are mostly helped or mostly hurt” by regulations, but not specifying how many distinct minority groups should be analyzed for disparate impact).

<sup>527</sup> The concern about ossification is that procedural requirements are slowing down agency production of new rules. *See generally* Thomas O. McGarity, *Some Thoughts on “Deossifying” the Rulemaking Process*, 41 DUKE L.J. 1385 (1992).

<sup>528</sup> Even scholars who advocate fairness as a central consideration in public policy acknowledge that self-interested parties are inclined to frame personal losses as issues of fairness. *See* Christine Jolls et al., *A Behavioral Approach to Law and Economics*, 50 STAN. L. REV. 1471, 1501 (1998) (“[O]ften there will be room for disagreement about what is fair . . . and thus there will be the opportunity for manipulation by self-interested parties. . . . [W]hile people care about fairness, their assessments of fairness are distorted by their own self-interest.”).

<sup>529</sup> The pioneers of the WTP approach to lifesaving were concerned with ensuring that lifesaving not be biased in favor of the wealthy at the expense of the poor. But they did not propose a specific resolution to address this, other than the need to consider distributional aspects. For example, M.W. Jones-Lee claimed that

a conventional cost-benefit analysis (narrowly conceived to eschew the evaluation of distributional effects) will tend to recommend the utilisation of scarce safety-improvement resources in *relatively* high-income, high-risk areas. Lest [this] be misinterpreted or adduced as evidence of the moral poverty of cost-benefit analysis, it must be stressed that a responsible social decision-maker would normally be expected to consider distributional effects *together with* the results of a cost-benefit analysis and not to base allocative decisions on the latter alone.

JONES-LEE, *supra* note 488, at 103.

<sup>530</sup> I acknowledge that one of the drawbacks of my income-based standard is that income, including a state of poverty, is “an imperfect measure of ‘deservingness’” because income is endogenous, meaning that people can change their income via work and investment. *See* Ng, *supra* note 122, at 1042. A conceptually better construct

could be devised with an alternative (broader or narrower) definition of the worst-off group.<sup>531</sup> Over time, I would like to see a multi-attribute measure of the least advantaged group that includes information on consumption, permanent income, wealth, health status, and overall risk of premature death or injury (from all causes).<sup>532</sup>

A lifesaving regulation should be considered presumptively desirable if it passes *both* the KH test for society as a whole *and* the KH test for the least advantaged (e.g., the poor).<sup>533</sup> A poverty-focused KH test assures that the WTP of the gainers among the poor is equal to or greater than the WTA of the losers among the poor.<sup>534</sup> Unless a lifesaving rule is neutral or yields a net gain for the poor as a group, it should not be promulgated, regardless of its consequences for society as a whole.<sup>535</sup>

As a practical matter, the application of this test should create incentives for regulators and proregulation lobbies to find ways to compensate the poor for any losses that they might experience from a lifesaving regulation. Opponents and proponents of regulation should also be encouraged to gather and present data on how rules impact

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would target citizens who lack basic capabilities to pursue a good life, who lack primary goods, or who have been deprived of the central entitlements that define humanity in a modern, civilized society. My guess, however, is that poverty is a fairly good surrogate for these difficult-to-measure constructs.

<sup>531</sup> The roots of this idea appear in Arnold C. Harberger, *On the Use of Distributional Weights in Social Cost-Benefit Analysis*, 86 J. POL. ECON. S87, S110-11 (1978) (contending that the policy implications of using distributional weights that decline with income “turn out to be quite disturbing”); *id.* at S117 (“All of this leads to a robust and . . . appealing simplification—to work with standard (unweighted) cost-benefit criteria in general, but to calculate also a net change (plus or minus) in surplus for the group below the poverty line.”).

<sup>532</sup> But if such a credible measure were developed, it might be feasible to work with an interpersonally comparable measure of cardinal utility instead of monetary BCA, thus pursuing welfarism instead of KH efficiency. See generally Adler, *supra* note 49, at 4 (suggesting that “health and safety agencies might evaluate the equity impacts of their policies by applying a variety of plausible utility functions and equity-regarding social welfare functions”).

<sup>533</sup> I am adapting here Professor Ng’s idea that the KH test should be applied within income classes as well as within society as a whole. He contends that this analysis should be applied to “each and every (usually income) group of individuals,” Ng, *supra* note 122, at 1033, but I believe a more limited application designed to protect the low-income group is sufficient.

<sup>534</sup> Ng’s quasi-Pareto improvement test can be considered “an acceptable middle ground between the Pareto criterion that is almost never satisfied, and the ordinary compensation principle that may make a whole group of individuals (for example, the poor) significantly worse off.” NG, *supra* note 52, at 166.

<sup>535</sup> Like Professor Ng, I believe that this amendment rids the KH test of “its main objection on the ground of distributional considerations.” *Id.* at 160.

the poor. The EPA's regulation of arsenic in drinking water is a rule that might not have survived a poverty-focused distributional test.<sup>536</sup>

The Kaldor-Hicks modification that I am proposing is preferable to alternative suggestions that have been made. One such alternative relies on the restrictive assumption that the poor have the same life-saving preferences as the middle class; another relies on the even more restrictive assumption that everyone in society values lifesaving to the same degree.<sup>537</sup> Distributional weights by income have a respectable theoretical foundation, but they are impractical, complex, and lacking broad consensus.<sup>538</sup>

One could instead allow regulators to consider impact on the poor without specifying how that information should be considered or weighed.<sup>539</sup> But without a specific definition of the distributional test, my fear is that regulators will not seriously consider the impact on a group that is so poorly organized in the regulatory process.

A reflection on my OIRA experience underscores why we should be determined to protect and advance the interests of the poor in life-saving regulation. I do not recall a single rulemaking from 2001 to 2006 in which an outside group lobbied OIRA primarily on the grounds that a regulation was good, or bad, for the poor. Yet we were lobbied to advance the interests of virtually every other group in society, including labor unions, consumer advocates, public health associations, medical providers, farmers, manufacturers, electric utilities, title insurers, bankers, realtors, environmental advocacy groups, and academic institutions. It is time for OIRA and the agencies to add a poverty-oriented distributional test to BCA.

How many federal lifesaving rules would be impacted by this distributional amendment to the KH test? I don't know. There is a small but growing literature that low-income populations incur disproportional

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<sup>536</sup> See Hahn & Sunstein, *supra* note 172, at 1527 (“Consider also the fact that the burdens of stringent regulation of arsenic in drinking water are likely to be borne disproportionately by those who are relatively less well off.”).

<sup>537</sup> See Revesz, *supra* note 179, at 967-68 (arguing for upward adjustments to valuations of lifesaving beneficiaries with “relatively low incomes”).

<sup>538</sup> See, e.g., Sunstein, *supra* note 263, at 307 (proposing that BCA may be able to adjust for socioeconomic differences, “perhaps by using a uniform number for valuing benefits, a number that will not go down when poor people are being counted, or up when rich people are being counted”).

<sup>539</sup> See Sunstein, *supra* note 26, at 1710 (suggesting that an agency should be permitted to go forward with a rule “[i]f, for example, the benefits are \$800 million, but enjoyed mostly by low-income workers, whereas the costs are \$900 million, but faced mostly by consumers generally”).

tionate risks from hazardous exposures to some products, technologies, and production facilities.<sup>540</sup> But there is also a literature suggesting that low-income households bear a disproportionate share of the costs of environmental regulation.<sup>541</sup>

One of the drawbacks of the new distributional test is that it will require agencies to prepare more analysis to support a lifesaving regulation than is currently required. Fortunately, the informational burdens of a poverty test are smaller than the complex weighting schemes for income and wealth that have been suggested by Professors Adler and Sunstein but rejected by most practitioners.<sup>542</sup> Moreover, the United States already has an established system for collecting information about poverty, and it is fairly easy to link poverty data with a variety of other data sets that are routinely employed in economic analysis.<sup>543</sup> The refinement to the KH test that I have offered is admittedly modest compared to the grand redistributionist visions<sup>544</sup> of some welfarists.

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<sup>540</sup> See, e.g., ROBERT D. BULLARD, *DUMPING IN DIXIE: RACE, CLASS, AND ENVIRONMENTAL QUALITY I* (1990) (“[D]ocumentation shows blacks, lower-income groups, and working-class persons are subjected to a disproportionately large amount of pollution and other environmental stressors . . .”); MICHAEL R. GREENBERG & DONA SCHNEIDER, *ENVIRONMENTALLY DEVASTATED NEIGHBORHOODS* 188-96 (1996) (arguing that “massive technology sites” are a relatively small concern to people in bad neighborhoods, compared to day-to-day concerns about “crime, other behavioural risks, and blight”).

<sup>541</sup> See Ian W.H. Parry et al., *The Incidence of Pollution Control Policies*, in *THE INTERNATIONAL YEARBOOK OF ENVIRONMENTAL AND RESOURCE ECONOMICS 2006/2007*, at 1, 19, 31 (Tom Tietenberg & Henk Folmer eds., 2006) (asserting that a disproportionate share of the “costs of environmental policies” falls on “poorer groups” with increased prices of necessities).

<sup>542</sup> See, e.g., Farrow, *supra* note 127, at 186 (suggesting that a simpler alternative is to apply the KH test within groups).

<sup>543</sup> I acknowledge conceptual ambiguities and flaws in the U.S. definition of income as well as imperfections in the ways the U.S. poverty line is determined. The Census Bureau and the National Academy of Sciences are investigating alternative methods of measuring poverty. See *PANEL ON POVERTY & FAMILY ASSISTANCE: CONCEPTS, INFO. NEEDS, & MEASUREMENT METHODS*, NAT’L RESEARCH COUNCIL, *MEASURING POVERTY* 19 (Constance F. Citro & Robert T. Michael eds., 1995) (recommending a new measure based on “scientific evidence” and “judgment”); KATHLEEN SHORT ET AL., *DEP’T OF COMMERCE, EXPERIMENTAL POVERTY MEASURES, 1990 TO 1997*, at 4-23 (1999) (exploring the implications of several alternative measures suggested by the NAS).

<sup>544</sup> See Matthew D. Adler & Chris William Sanchirico, *Inequality and Uncertainty: Theory and Legal Applications*, 155 U. PA. L. REV. 279, 304 (2006) (“Poverty line views are more plausible, but fail to account for equalizing transfers from the wealthiest to those who are much less well off, and yet not impoverished.”); Louis Kaplow, *Why Measure Inequality?*, 3 J. ECON. INEQUALITY 65, 73 (2005) (“[P]overty measures have the added problem of being arbitrary: [t]hey ignore most of the income distribution and often give substantial weight to an individual being at or just below the poverty line whereas no weight is given to those slightly above the poverty line.” (footnote omitted)).

A poverty test will not simply provide equity-based grounds for OIRA to reject or modify a proposed lifesaving regulation. It will also cause agencies to generate an increasing volume of data on how risks and regulatory costs impact the poor. With such data in hand, agencies and Congress will become more informed about fundamental steps that can be taken to advance the interests of the poor in society.

Some critics of BCA are less concerned about the poor and more concerned about a different form of injustice: when the risks of business activity are incurred by people other than those who benefit from that activity.<sup>545</sup> Toxic fumes emitted into a community by a factory are a prototypical example. Investors in the factory (and consumers of the factory's production) may reap the benefits while nearby residents, unless compensated by lower apartment rents and initial housing prices, incur the risks.

According to this different view of justice, residents who incur involuntary risks—especially risks with relatively high probability and severe impacts—deserve a special measure of protection from regulators on grounds of equity. Some have suggested that people subject to the largest life-threatening risks from production activities should be assured that such risks will not be raised above a certain ceiling, regardless of what it costs other members of society to achieve that ceiling on individual risk.<sup>546</sup>

At first glance, special protection for those at the highest individual risk might seem to be demanded by modern theories of justice, since those theories seek to protect the worst-off segments of society. It is certainly plausible to consider good health, including protection against risk, as a primary good or basic capability that merits consideration in a justice-based analysis.<sup>547</sup>

But a closer look at modern theories of justice reveals that they identify the worst-off group through a much broader inquiry than an assessment of the degree of incremental risk from a technology,

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<sup>545</sup> See McGarity, *supra* note 26, at 68 (“A fundamental assumption underlying most health and environmental legislation is that each individual is entitled to some minimal level of security from risks posed by others . . .”).

<sup>546</sup> See, e.g., M. Granger Morgan, *Risk Management Should Be About Efficiency and Equity*, 34 ENVTL. SCI. & TECH. 32A (2000) (“[T]his formulation . . . says there is a level of risk above which we will not allow *anybody* in our society to be exposed.”). For a view that ceilings on individual risk are not justified by an ex post, welfarist perspective, see Matthew D. Adler, *Against “Individual Risk”: A Sympathetic Critique of Risk Assessment*, 153 U. PA. L. REV. 1121, 1246-50 (2005).

<sup>547</sup> See Schroeder, *supra* note 18, at 538 (“Avoidance of exposure to risk of serious harm or death can plausibly be considered a primary good [in the Rawlsian sense].”).

product, or production facility.<sup>548</sup> In fact, the worst-off group is typically defined in terms of overall capabilities, primary goods, income, or wealth. Even if protection against technological risk is one of the primary goods, the justice inquiry should focus on the least-advantaged group considering *all* the primary goods.<sup>549</sup> In other words, a risk-based approach to justice would cover all sources of risk, not just the incremental risk from each product, technology, or facility one at a time.<sup>550</sup>

Under the KH test, although some citizens will incur risks from specific man-made sources that are outside their control, they will also experience unexpected benefits from man-made technologies.<sup>551</sup> In my view, an equity concern about small life-threatening risks is compelling only when the uncompensated risk is incurred by poor citizens; the poor as a group are not made better off by the absence of a lifesaving regulation. Those who are most exposed to particular risks, and who know who they are *ex post*, will object to this criterion, but citizens would likely consent in a preconstitutional setting, where the veil of ignorance conceals the distribution of exposure to risk.

To ensure that protection of the poor is taken seriously, Congress should incorporate a distributional amendment, coupled with a soft benefit-cost test, into the APA or, if that is not feasible, into a modified presidential executive order. OMB Circular A-4 should also be updated to provide guidance on how poverty is defined and how impacts on the poor should be identified, quantified, and monetized.

In summary, the soft benefit-cost test should be modified to include a distributional test in the evaluation of lifesaving rules. The poor should not be made worse off so that other groups in society can

<sup>548</sup> See, e.g., Adler, *supra* note 49, at 11-12 (maintaining that the incremental individual risks from man-made technologies are not relevant to equity analysis); P Anand, *Capabilities and Health*, 31 J. MED. ETHICS 299, 302 (2005) (arguing that “one has to look at the inequalities in the round, not just in the health arena” in judging whether women are disadvantaged).

<sup>549</sup> Being high on one of the technological risks does not necessarily demonstrate membership in the worst-off class. See Schroeder, *supra* note 18, at 545 (noting that the presence of multiple primary goods can raise the indexing problem when one good “do[es] not vary with [the] other primary social goods sufficiently”).

<sup>550</sup> See Viscusi, *supra* note 205, at 862 (“Any meaningful notion of risk equity, however, presumably should be grounded in the absolute risk level of the individual rather than focusing on incremental risks since otherwise there will be clear-cut inequities in what is of consequence to people’s lives, which is the total risk they face.”).

<sup>551</sup> Cf. Schroeder, *supra* note 18, at 547 (“Situations where those benefited and disadvantaged are different subgroups of the worst-off class are complicated to resolve [using modern theories of justice].”).

live longer, healthier lives. Since it is well known that the poor suffer elevated rates of most diseases and premature death, the new distributional test may also serve a constructive, priority-setting function. The test will highlight data showing how risks and costs impact the poor and what public-policy priorities might advance the overall interests of the poor.

### B. *Weigh Nonquantified Benefits and Costs*

What should a regulatory analyst do with benefits (and costs) that either cannot be quantified in physical units or cannot be translated into dollars? Critics of BCA contend that regulatory analysts routinely omit from their assessment benefits that cannot be easily quantified and monetized, such as the prevention of nonfatal injuries and diseases and the mitigation of adverse impacts on wildlife and ecosystems.<sup>552</sup> A similar criticism is applicable on the cost side of the ledger, where analysts may identify possible risks or costs of a regulation that cannot be quantified or monetized.<sup>553</sup>

Nonquantified benefits and costs are a legitimate concern, and there is no scientific basis for assuming that nonquantified benefits are always balanced out by nonquantified costs.<sup>554</sup> Even if a rough balance exists on average, the nonquantified benefits may be larger in some rulemakings while the nonquantified costs may be larger in others. Thus, it is important that analysts provide regulators with as much information as possible about nonquantified impacts, especially those items that could be important enough to tip the scales in favor of one regulatory option over another.<sup>555</sup>

OMB guidance in Circular A-4 already urges regulatory analysts to report any benefit and cost items that could not be quantified or

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<sup>552</sup> See, e.g., Lisa Heinzerling & Frank Ackerman, *The Humbugs of the Anti-Regulatory Movement*, 87 CORNELL L. REV. 648, 652-55 (2002) (claiming that many analysts “ignore[] nonfatal harms to human health as well as harms to ecosystems”).

<sup>553</sup> See Freeman, *supra* note 61, at 37 (characterizing the common perception that “the costs of environmental regulations are relatively easy to measure” as “optimistic” and consistent with “a naive theory of cost”).

<sup>554</sup> See Richard W. Parker, *The Empirical Roots of the “Regulatory Reform” Movement: A Critical Appraisal*, 58 ADMIN. L. REV. 359, 381 (2006) (“[T]wo biases of unknown magnitude and opposite signs cannot be assumed to cancel each other out.”).

<sup>555</sup> See, e.g., Parker, *supra* note 34, at 1416 (“[A]gencies need to do a much better job of narratively explaining the significance of costs and benefits . . . and the reasons underlying the agency’s determination that the benefits justify the costs.”).

monetized.<sup>556</sup> Yet critics fear that some regulators will focus on the numeric calculation of net benefits, ignoring any qualitative presentation of nonquantified benefits and costs. On the other hand, some analysts may construct such a long list of nonquantified benefits and costs that it is difficult for the regulator and OIRA to appreciate the relative importance of the nonquantified items.<sup>557</sup>

More innovative approaches are needed to highlight the most important nonquantified (and nonmonetized) items. Agency analysts, subject to review by peers and OIRA, should exercise more professional judgment in deciding which nonquantified items to highlight for consideration by regulators.

The European Commission uses a multistar rating system where the more important qualitative items are assigned more stars than the less important items.<sup>558</sup> If a BCA successfully quantifies the most important benefits and costs, then few of the nonquantified items receive multiple stars. But if analysts believe that the most important items in the analysis have been left nonquantified, those items are highlighted with multiple stars. Agency analysts in the United States should begin to experiment with the multistar system in consultation with regulators, peer reviewers, and OIRA.

Periodically, a multiagency analysis should be undertaken to identify the most commonly encountered nonquantified (and nonmonetized) benefits and costs. The agencies, under OIRA oversight, should develop a tracking system to determine which nonquantified benefit and cost items are appearing repeatedly in rulemakings. Some items that do not appear repeatedly at one agency may recur at other agencies. For example, reduced emissions of carbon dioxide were cited as a nonmonetized benefit in the DOT's fuel-economy rulemakings for new light trucks.<sup>559</sup> But carbon emissions are also an issue

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<sup>556</sup> See OMB Circular A-4, *supra* note 259, at 2 (“[Y]ou should indicate, where possible, which non-quantified effects are most important and why.”).

<sup>557</sup> In support of its off-road diesel rule, the EPA lists fifty-two nonmonetized benefits of reducing diesel-engine exhaust, without any indication of the relative importance of the fifty-two items or how important they might be compared to the items that were quantified. Control of Emissions of Air Pollution from Nonroad Engines and Fuel, 69 Fed. Reg. 38,958, 39,139 tbl.VI.E-6 (June 29, 2004) (codified in scattered parts of 40 C.F.R.).

<sup>558</sup> For an illustration of the multistar system, see *Commission Staff Working Paper: Annex to: The Communication on Thematic Strategy on Air Pollution and “The Directive on Ambient Air Quality and Cleaner Air for Europe,”* at SEC (2005) 1133 (Sept. 21, 2005).

<sup>559</sup> See Average Fuel Economy Standards for Light Trucks Model Years 2008–2011, 71 Fed. Reg. 17,566, 17,589 (Apr. 6, 2006) (codified at 49 C.F.R. pts. 523, 533, 537)

at the DOE, the EPA, and other agencies where regulations impact federal climate policy.

Using an integrated tracking system, OIRA and an interagency team of analysts could identify the nonquantified benefit or cost items that, across the government, are in urgent need of additional research in order to enable quantification and monetization in future rulemakings. The OMB and the agencies should ensure that BCA-related research needs find their way into the administration's annual research budgets that are submitted to Congress. Finally, OIRA should coordinate with the U.S. National Science Foundation (NSF) and other research-funding agencies to ensure that scarce research dollars are targeted at uncertain benefit and cost items that recur in federal rulemakings.

### C. *Validate Benefit and Cost Estimates*

Thousands of federal regulations have been issued since 1980, but there is a remarkably small literature comparing the actual ex post benefits and costs of rules to the ex ante predictions published by the agency at the point of promulgation.<sup>560</sup> The most careful study, undertaken by analysts at Resources for the Future (RFF), reviewed several dozen rules where ex ante and ex post information about benefits and costs is now available.<sup>561</sup> While the RFF results, reviewed above,<sup>562</sup> are encouraging because they find no systematic bias, they cover only a tiny fraction of federal regulations.

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(noting "a variety of benefits and costs that either could not be monetized or could not be quantified," including "a significant reduction in carbon dioxide emissions").

<sup>560</sup> See, e.g., McGarity & Ruttenberg, *supra* note 503, at 2036 (noting that "of the 101 economically significant regulations that EPA issued between 1981 and 1998, only five had been the subject of any retrospective studies" (citing U.S. GEN. ACCOUNTING OFFICE, ENVIRONMENTAL PROTECTION: ASSESSING THE IMPACTS OF EPA'S REGULATIONS THROUGH RETROSPECTIVE STUDIES 2 (1999))).

<sup>561</sup> Harrington, *supra* note 517, at 20-36.

<sup>562</sup> See *supra* Part IV.E.

A more robust validation literature is urgently needed.<sup>563</sup> If life-saving rules are to be modernized periodically based on real-world implementation, accurate information will be needed on how many lives were saved, what the overall benefits were, and how much the rules cost society.<sup>564</sup> Moreover, any systematic biases of BCA will be disclosed in a persuasive way only with a more comprehensive program of validation research. Without validation, proregulation activists will continue to assert that BCA is biased against lifesaving rules, while antiregulation activists will continue to assert that regulators “cook the numbers” to justify more regulation.<sup>565</sup>

From an analytic perspective, validation studies also help to pinpoint systematic weak points in assumptions and data, thereby targeting efforts aimed at improving data systems and analytic procedures. Continuous improvement in BCA requires ongoing validation efforts.

The value of validation research to the benefit-cost state is so great that Congress and the President should take explicit steps to stimulate it. Congress should authorize a validation research program at NSF in collaboration with the interested regulatory agencies. Using NSF’s competitive, investigator-initiated model of research funding, independent researchers should be commissioned to develop better

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<sup>563</sup> See U.S. GOV’T ACCOUNTABILITY OFFICE, REGULATORY REFORM: PRIOR REVIEWS OF FEDERAL REGULATORY PROCESS INITIATIVES REVEAL OPPORTUNITIES FOR IMPROVEMENTS 1 (2005) (suggesting more retrospective evaluations of existing regulations to gauge their “actual benefits and costs”); Lori Snyder Bennear & Cary Coglianese, *Measuring Progress: Program Evaluation of Environmental Policies*, ENVIRONMENT, Mar. 2005, at 22, 35 (urging more systematic program evaluation of environmental policies, including regulations); Calandrillo, *supra* note 67, at 1006-07 (urging a more concerted effort to measure and evaluate the consequences of rules *ex post*); Katzen, *supra* note 192, at 1316 (arguing for “serious systematic empirical research of the *ex post* costs and benefits of major regulations from various agencies”); McGarity & Ruttenberg, *supra* note 503, at 1999 (“[N]o important economic actor has an incentive to find out how much regulations actually did cost once the strategic battle over the proposed regulation has ended and the companies and the agency have moved on to other things.”); *id.* at 2053 (“Probably the single most important step that agencies could undertake to enhance the robustness of the empirical basis for regulatory cost assessment would be for agencies to commission more retrospective evaluations of past prospective cost assessments.”); Wiener, *supra* note 186, at 513-16 (urging more *ex post* evaluation of regulatory policies as part of a larger process of “adaptive management,” including collaboration between the United States and EU).

<sup>564</sup> See Parker, *supra* note 34, at 1417 (“Retrospective studies, though difficult, are indispensable . . .”).

<sup>565</sup> See, e.g., MCGARITY, *supra* note 16, at 308 (“Only if beneficiaries become convinced that analysis is being used fairly in support of protective regulation as well as against it will they begin to accept it as a legitimate decisionmaking tool.”).

methods of validation research and undertake innovative applications using the best available data.

The President, for his part, should issue an executive order requiring that all new rules with billion-dollar impacts (benefits or costs) be accompanied by a plan for the agency to collect and analyze postregulation information about benefits and costs.<sup>566</sup> Following the executive order, OMB Circular A-4 should be expanded to include analytic guidance on how validation studies should be conducted. Additionally, the OMB should encourage agencies to use external committees and other procedural devices to ensure appropriate scientific peer review and stakeholder participation in validation studies.

#### D. *Create Authoritative Blueprints of Lifesaving Opportunities*

Agencies overregulate some tiny risks while neglecting some big hazards.<sup>567</sup> This syndrome of “paranoia and neglect”<sup>568</sup> has been well documented for years<sup>569</sup> but is not easy to prevent or reduce.<sup>570</sup> What is missing is a rational process in the federal government for setting lifesaving priorities in the first place.<sup>571</sup>

Agencies draft lifesaving rules, and OIRA decides whether to return them, clear them, or suggest modifications. OIRA has little formal role in shaping rulemaking priorities.<sup>572</sup> Critics argue that BCA,

<sup>566</sup> See Hahn & Sunstein, *supra* note 172, at 1531 (“[A] process should be instituted by each agency to give a retrospective analysis of some of its most costly regulations to see what kinds of effects they are having in actual process.”).

<sup>567</sup> *Id.* at 1490 (noting “exceptionally poor priority-setting, with substantial resources sometimes going to small problems, and with little attention being paid to some serious problems”).

<sup>568</sup> *Id.* at 1540.

<sup>569</sup> See generally Tim Kuran & Cass R. Sunstein, *Availability Cascades and Risk Regulation*, 51 STAN. L. REV. 683, 691-703 (1999) (giving examples of regulation and policy-making stemming from exaggerated fears, and suggesting reforms to alleviate the potential hazards of availability cascades); Richard J. Zeckhauser & W. Kip Viscusi, *Risk Within Reason*, 248 SCIENCE 559, 559 (1990) (arguing that efficient risk management requires decisions about the division of labor among regulators).

<sup>570</sup> See VISCUSI, *supra* note 7, at 10 (referring to pressures for bias in regulatory efforts, which lead to “the extremes of excessive complacency to inordinate attention”).

<sup>571</sup> See generally STEPHEN G. BREYER, *BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION* 76 (1993) (pointing out the need for more centralized coordination within the executive branch); SUNSTEIN, *supra* note 17, at 110 (suggesting that the government should engage in BCA before addressing problems).

<sup>572</sup> See, e.g., Bagley & Revesz, *supra* note 41, at 1274 (“An even more profound objection to OIRA review is that it is almost wholly reactive: An agency submits a proposed rule to OIRA, and OIRA reviews it to ensure that it passes cost-benefit muster and is in line with the President’s priorities.”).

as overseen by OIRA, acts primarily as a constraint on overly burdensome regulation<sup>573</sup> or as a filter to make sure such rules are consistent with presidential priorities. Although a proactive OIRA can have a key priority-setting influence on a handful of rules per year, I share the view that there is a need for a stronger priority-setting force in the regulatory process, a force that highlights opportunities to implement promising yet neglected lifesaving interventions.<sup>574</sup>

The requirements for BCA and OIRA review have some salutary effect on the syndrome because they gear agencies toward rulemakings with a potential to increase social welfare.<sup>575</sup> Unfortunately, BCA and OIRA review occur far too late in the rulemaking process to ensure that agencies focus on the most promising lifesaving endeavors.<sup>576</sup>

There are subtle yet profound forces at work that shape the agendas of regulators—forces that are less sensitive to social-welfare considerations and more responsive to the popular psychology of risk perception and interest-group politics.<sup>577</sup> While special interests abound, there is no credible, well-informed agent in the regulatory process producing the “friendly facts”: a comprehensive ordering of lifesaving opportunities by cost-effectiveness ratio, including key qualitative insights about each lifesaving opportunity (e.g., whether it will benefit or hurt the poor).<sup>578</sup>

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<sup>573</sup> See, e.g., Heinzerling & Steinzor, *supra* note 251, at 10,488 (“In truth, cost-benefit analysis in the Bush Administration has been a one-way street—used to justify delaying or weakening regulation, not to strengthen it.”). But see Graham, *supra* note 448, at 172 (providing examples of several rules in the George W. Bush administration that were advocated and promulgated with the support of BCA).

<sup>574</sup> See, e.g., Hahn & Sunstein, *supra* note 172, at 1540 (“[T]he system for OIRA review has not succeeded in fundamentally redirecting regulation toward areas where it would do the most good.”).

<sup>575</sup> Presidential Executive Order 12,498 sought to insert OMB review into a disciplined process where agencies would submit formal regulatory agendas for review. Exec. Order No. 12,498, 3 C.F.R. 323 (1985), *reprinted in* 5 U.S.C. § 601 (2000). But these agendas are no more than “thumbnail sketches” of an agency’s intentions, and OIRA lacks the leverage to engage at such an ambiguous, information-poor stage of the priority-setting process. See VISCUSI, *supra* note 7, at 260.

<sup>576</sup> See, e.g., Bressman & Vandenbergh, *supra* note 251, at 95 (stating that the perception at the EPA is that OIRA review occurs too late in the process, since earlier interaction would prevent wasting of time on both sides).

<sup>577</sup> See HOWARD MARGOLIS, *DEALING WITH RISK: WHY THE PUBLIC AND THE EXPERTS DISAGREE ON ENVIRONMENTAL ISSUES* 193 (1996) (explaining how normal habits of the mind cause ordinary people to develop distorted views of risk); Sunstein, *Which Risks First?*, *supra* note 403, at 103 (discussing how the phenomenon of selective attention leads to distorted regulatory priorities).

<sup>578</sup> The most comprehensive account is Morrall, *supra* note 21, at 230 tbl.2 (presenting a league table of seventy-six federal lifesaving regulations from 1967 to 2001,

Justice Stephen Breyer has suggested that a small cadre of lifesaving specialists be housed inside the Executive Office of the President and granted vast priority-setting powers.<sup>579</sup> Professor Sunstein has advocated that OIRA become more involved in priority setting.<sup>580</sup> Although these ideas are certainly worth exploring, I believe that part of the solution must come from a credible source outside of government.

I have in mind a team of health scientists, statisticians, economists, and other specialists housed at the Institute of Medicine (IOM) or one of the other operating units of the National Academy of Sciences. This outside group would have legal responsibility from Congress for using the best available knowledge to identify and publicize lifesaving opportunities, without being constrained by concerns about agency jurisdiction, popular opinion, electoral pressures, or interest-group politics. Stakeholders could use the periodic findings of this group to lobby Congress and the executive branch, and OIRA could use these findings to issue prompt letters to agencies that do not follow up on IOM's most promising lifesaving ideas.

Under this scheme, a standing committee of the IOM would have the responsibility for publishing periodically a "league table" of lifesaving opportunities based on CEA, perhaps using a consistent effectiveness metric such as the quality-adjusted life-year.<sup>581</sup> At OIRA's request, IOM has already issued a report describing a consistent methodology that could be used by future IOM committees, OIRA, and federal agencies.<sup>582</sup> Even some critics of BCA acknowledge that CEA based on QALYs could play a stronger role in priority setting.<sup>583</sup>

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including several potential regulations that could have saved lives more cost-effectively than those issued).

<sup>579</sup> See BREYER, *supra* note 571, at 59-61 (stating that such a group should have a specific mission, interagency jurisdiction, political insulation, prestige, and authority).

<sup>580</sup> See generally Pildes & Sunstein, *supra* note 16, at 125 (offering various proposals for beneficial federal regulatory reforms).

<sup>581</sup> See Parker, *supra* note 34, at 1356 ("Scorecards cannot be salvaged. They should simply be abandoned."). *But see* Hahn, *supra* note 82, at 1023 ("The solution to the legitimate concerns raised by the critics is not to eliminate quantitative analysis [league tables], but to gain a deeper insight into its strengths and weaknesses, and to use it wisely.").

<sup>582</sup> COMM. TO EVALUATE MEASURES OF HEALTH BENEFITS FOR ENVTL., HEALTH, AND SAFETY REGULATION, *supra* note 462, at 130.

<sup>583</sup> See McGarity, *supra* note 26, at 70-71 (acknowledging that QALYs "could be useful in setting agency priorities" and that it might be feasible for an agency to prepare "dense" league tables "once every five years or so to guide the agency in setting its regulatory priorities").

Unlike the league tables that rank English soccer teams, the life-saving league tables prepared by the IOM should include both numeric estimates of lifesaving payoffs<sup>584</sup> and qualitative information about relevant factors that could not be quantified or monetized.<sup>585</sup> Since the IOM already has an excellent peer-review process and a strong reputation for producing quality work, the league tables produced by the IOM should be objective and credible.<sup>586</sup> IOM could be

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<sup>584</sup> Professor Driesen has suggested that priority setting should be based not on BCA or CEA but on a ranking of the most serious hazards. Driesen, *supra* note 497, at 506. But the relevant metric for social-welfare purposes must include both the risk-reduction potential for each hazard and the costs and risks of implementing the risk-reduction measure. See John D. Graham & James K. Hammitt, *Refining the Comparative Risk Analysis Framework*, in *COMPARING ENVIRONMENTAL RISKS: TOOLS FOR SETTING GOVERNMENT PRIORITIES* 93, 97-101 (J. Clarence Davies ed., 1996) (explaining why risk-reduction potential as well as baseline risk needs to be considered in priority setting).

<sup>585</sup> Professor Parker objects to several published league tables on the grounds that they omit qualitative information about benefits that could not be quantified. Parker, *supra* note 554, at 389. But OIRA already includes a qualitative column of information (next to benefits and costs) on each major rule included in its annual report to Congress. Instead of insisting that lifesaving league tables be abandoned, Professor Parker should reconsider the informational value of lifesaving league tables prepared by IOM that have key cost-effectiveness data as well as significant qualitative information. Professor Driesen has argued that priority setting based on league tables of lifesaving interventions is "deeply problematic" because "many environmental regulations aim to address widespread illness and ecological damage as well as, or rather than, death." Driesen, *supra* note 497, at 503. But the QALY metric used in CEA accounts for illnesses as well as deaths. If ecological damage can be quantified and expressed in monetary units, it should be included in the numerator of the cost-effectiveness ratio. If the ecological damages cannot be monetized, they should be included as qualitative factors in the lifesaving league table. On the feasibility of CEA as applied to lifesaving, see *COMM. TO EVALUATE MEASURES OF HEALTH BENEFITS FOR ENVTL., HEALTH, AND SAFETY REGULATION*, *supra* note 462.

<sup>586</sup> There is much confusion in the legal literature about whether lifesaving league tables, assuming they are to be generated, should include measures that are already implemented (partially or fully), or whether they should be restricted to lifesaving opportunities that are not yet implemented. Professor Driesen makes the point that some lifesaving league tables focus on implemented regulations that may appear to be overly stringent. See David M. Driesen, *Getting Our Priorities Straight: One Strand of the Regulatory Reform Debate*, 31 *ENVTL. L. REP.* (Envtl. Law Inst.) 10,003, 10,014 (2001) (referring to a widely cited league table published by Dr. John Morrall of the OMB). Professor Lisa Heinzerling has expressed concern about a large lifesaving league table that I helped prepare that includes some interventions and regulations that were not promulgated or implemented. See Heinzerling & Ackerman, *supra* note 552, at 652. Professor Parker, though certainly not an advocate of lifesaving league tables, has clarified the confusion. If lifesaving resources are to be reallocated in ways to save more lives, the league table *must* include at least some measures that are currently being implemented and some that are not yet fully implemented. If none of the measures is currently being implemented, there are no resources to reallocate. If all the included measures are fully implemented, there is no unexplored opportunity available for life-

charged by Congress with updating the league tables periodically as new information becomes available.

Subcommittees of the IOM's new standing committee on lifesaving should be organized in the major fields of lifesaving regulation: food safety, lifestyle and nutrition, environmental pollution and radiation protection, worker safety and health, consumer-product safety, transport safety, natural hazards management, and homeland security. It may also be advisable to assemble a separate subcommittee on lifesaving opportunities for the poor. The subcommittees should produce the specialized information necessary for the standing committee to construct the IOM's official, standardized league tables.

The role of the IOM should be to highlight promising, cost-effective ways for lives to be saved in America while also indicating which lifesaving efforts are not likely to be cost-effective at the present time. The IOM's role should not be to compare different regulatory instruments, to perform full-blown benefit-cost studies of rules, or to draft regulatory language.<sup>587</sup> Those responsibilities should remain with the federal agencies under OIRA, congressional, and judicial oversight.

#### E. Codify OIRA and Citizen-Prompt Letters

In order to accelerate the promulgation of promising lifesaving rules, OIRA's authority to issue prompt letters should be codified by legislative action and/or presidential executive order. Prompt letters should be understood as the analogue to the OIRA return letter, which seeks to stop an agency from issuing a rule or seeks to encourage reconsideration of a rule. The OIRA prompt is intended to nudge a reluctant or negligent agency in the direction of a good lifesaving rule. Codification of the prompt would reinforce OIRA's authority to say "yes" as well as "no."<sup>588</sup>

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saving. See Parker, *supra* note 34, at 1378 n.123 (suggesting ways to improve the evaluation of individual rules and government regulation in general).

<sup>587</sup> Driesen, *supra* note 497, at 506 (stating that it is not practical for agencies to perform all of the analyses at the priority-setting stage that will later be needed at the standard-setting stage).

<sup>588</sup> See Wiener, *supra* note 186, at 489-90 (describing OIRA's invention of the prompt letter as a "pathbreaking innovation" that should be codified in the next presidential executive order on regulatory review).

I also support an idea suggested by Professor Hsu: the citizen prompt letter.<sup>589</sup> Like citizen suits against agencies for inaction or arbitrary actions, the citizen prompt letter is intended to give a voice to otherwise unrepresented beneficiaries of a potential lifesaving intervention.<sup>590</sup> In order to discourage spurious requests that might squander valuable agency and OIRA resources, a citizen prompt letter must be accompanied by a new CEA or BCA, or be supported by a well-done BCA or CEA already available in the peer-reviewed literature.<sup>591</sup> Alternatively, the prompt letter could cite a promising lifesaving measure contained in a recent IOM league table.

Agencies should be required to respond to citizen-prompt letters within a specified period of time,<sup>592</sup> and OIRA should be required to monitor agency responses to citizen prompt letters and report to Congress each year on their resolution.<sup>593</sup> Agencies and OIRA should ensure that successful prompts are supported by information that meets OIRA and agency information-quality standards.

Legal scholars need to consider whether it is necessary and appropriate to accompany the citizen prompt with a threat of judicial review in the event that an agency does not respond at all or responds in an arbitrary manner. I would lean in favor of a limited judicial review opportunity to ensure that agencies consider prompts seriously. If judicial review is not provided, citizens should be provided an opportunity to submit their idea directly to OIRA as part of the OMB's annual regulatory-reform process and the OMB's annual report to Congress on the costs and benefits of federal regulation.<sup>594</sup>

#### F. Codify Default Benefit-Cost Principles

The benefit-cost state, as defined by Professor Sunstein and others, is a loose collection of default rules that courts have injected into

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<sup>589</sup> Shi-Ling Hsu, *The Identifiability Bias in Environmental Law*, 35 FLA. ST. U. L. REV. 433, 497 (2008).

<sup>590</sup> *Id.*

<sup>591</sup> *Id.* at 498.

<sup>592</sup> *Id.*

<sup>593</sup> An interesting suggestion has recently been made that OIRA be empowered to review agency responses to citizen petitions for rulemaking, using benefit-cost criteria. See RICHARD L. REVESZ & MICHAEL A. LIVERMORE, RETAKING RATIONALITY: HOW COST-BENEFIT ANALYSIS CAN BETTER PROTECT THE ENVIRONMENT AND OUR HEALTH 173-74 (2008).

<sup>594</sup> See Wiener, *supra* note 186, at 490 (suggesting that OIRA might solicit ideas for promising prompt letters each year from the public).

rulemaking through application of judicial-review authority under the Administrative Procedure Act. Elsewhere, I have made the case that a soft benefit-cost test should become a cross-cutting statutory criterion for rules issued by federal health, safety, and environmental agencies.<sup>595</sup> Congress came close to passing such a requirement in 1995 as part of a comprehensive regulatory-reform bill.<sup>596</sup> Given agencies' substantial experience with default principles of BCA, it makes sense to codify them in an omnibus regulatory statute or an amendment to the APA. Even better would be a move by Congress to subject new regulatory legislation to BCA by the Congressional Budget Office or the Government Accountability Office.<sup>597</sup>

If a broad-based approach to codifying BCA is not feasible, then it makes sense to include a soft benefit-cost test in each organic statute as it is reauthorized by the Congress. In the Safe Drinking Water Act Amendments of 1996, for example, Congress added a benefit-cost test to the feasibility criterion that had previously governed the setting of national drinking-water standards for specific contaminants.<sup>598</sup>

### G. Authorize "Risk Trading"

A more ambitious approach to legislative reform would incorporate "risk trading" into our health, safety, and environmental laws.<sup>599</sup>

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<sup>595</sup> See Graham, *supra* note 15 (discussing how Congress can help minimize the "paranoia and neglect" that the American people feel about dangers to their health).

<sup>596</sup> Comprehensive Regulatory Reform Act of 1995, S. 343, 104th Cong. § 625.

<sup>597</sup> See Wiener, *supra* note 186, at 490-91 (noting that the European Community applies RIA to all primary legislation and arguing that the United States could do something similar by making better use of the Congressional Budget Office and the GAO).

<sup>598</sup> See Sunstein, *supra* note 412, at 2267 (noting that the Safe Drinking Water Act goes as far as any other lifesaving statute in requiring consideration of benefits and costs). *But cf.* McGarity, *supra* note 134, at 2377 (expressing concern that the new cost-benefit authority under the Safe Drinking Water Act Amendments of 1996 "may have guaranteed that the standard-setting process will be much more difficult, much more controversial, and much easier to manipulate in advancing the policy agendas of the regulated entities").

<sup>599</sup> Professor McGarity criticizes Professor Sunstein and others for failing to "devote some of their considerable intellectual firepower to coming up with ways (other than blind reliance on the market) to guarantee" that the "resources saved through the application of cost-benefit analysis are channeled into other socially desirable uses." McGarity, *supra* note 26, at 78. For a concrete proposal on how funding should be reallocated to save more lives under the Superfund program, see John D. Graham & March Sadowitz, *Superfund Reform: Reducing Risk Through Community Choice*, ISSUES SCI. & TECH., Summer 1994, at 35 (proposing that those living near hazardous sites be

Under this trading authority, any regulated entity would be entitled to petition the regulator for approval to implement an alternative risk-reduction plan that would achieve more lifesaving than would be accomplished by compliance with existing legal obligations. This more flexible approach to saving lives would need to be accompanied by rigorous monitoring and evaluation requirements, including limited immunity for regulatees who pursue approved risk-trading plans.

Trading could be either expansive or restricted to lifesaving measures within the jurisdiction of a single program or agency.<sup>600</sup> The lifesaving league tables produced by the Institute of Medicine are a possible menu of lifesaving opportunities that might be used by regulatees in their risk-trading plans.

A limited form of risk-trading is authorized in the 1996 amendments to the Safe Drinking Water Act.<sup>601</sup> States were allowed to tolerate some residual cancer risks from radon in drinking water in exchange for larger reductions in cancer risks from radon in indoor air.<sup>602</sup> Unfortunately, the EPA has been slow to implement this innovative regulatory scheme.

The case for new trading authority does not rest on a premise that most current lifesaving regulations are ineffective or overly costly. The estimated benefits of lifesaving regulation, measured over the last fifteen years, are certainly large enough to justify the overall costs. But a small number of rules (e.g., those reducing particulate pollution under the Clean Air Act) account for a majority of the benefits of federal rulemaking activity since 1993.<sup>603</sup>

Risk trading is especially promising when rules have a marginal or poor benefit-cost result and where most of the costs of compliance are expenditures by regulatees instead of budgetary expenditures by the

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given the flexibility to use funds for cleanup to address other costs, such as health and environmental problems).

<sup>600</sup> An expansive version of trading is suggested by Graham, *Legislative Approaches*, *supra* note 15, at 46, which discusses a flexible agency authorization to maximize aggregate risk reduction. For a restricted version of trading, see Sunstein, *supra* note 1, at 297, which cites examples of environmental contracting in Europe and Japan and the EPA-Amoco pollution prevention project.

<sup>601</sup> See 42 U.S.C. § 300g-1 (2000) (instituting risk analysis and management into the administration of the Safe Drinking Water Act).

<sup>602</sup> See *id.* § 300g-1(b)(13).

<sup>603</sup> See Parker, *supra* note 554, at 398 (“The majority of these numerically measured benefits derive from a relative handful of very large rules . . .”).

federal government.<sup>604</sup> If the same private-sector compliance resources were devoted to more efficient lifesaving opportunities, the number of lives saved could be much larger.<sup>605</sup>

Some legal critics acknowledge the theoretical possibility of resource reallocation but insist that private-sector resources expended on regulatory compliance are not “fungible” with investments in lifesaving outside of an agency’s jurisdiction.<sup>606</sup> This view may be an accurate view of current “tunnel-vision” law,<sup>607</sup> but Congress needs to provide federal regulators and regulatees more authority to engage in creative reallocations of compliance resources toward lifesaving opportunities that better maximize social welfare.<sup>608</sup> The United Kingdom recently created formal regulatory-budget authority for all rules

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<sup>604</sup> See Jonathan Bender, *Societal Risk Reduction: Promise and Pitfalls*, 3 N.Y.U. ENVTL. L.J. 255, 257 (1994) (“Private-sector spending on regulatory compliance tends to far exceed government spending on regulation . . .”). Permission to trade federal appropriations raises a more complex set of political and legal issues.

<sup>605</sup> A good candidate for risk trading is the mandatory cleanup expenditures under federal hazardous-waste laws. For example, at a majority of studied Superfund sites, the estimated cost per case of cancer prevented exceeds \$100 million. See HAMILTON & VISCUSI, *supra* note 186, at 127 (summarizing a review of 145 Superfund sites where only 44 had an estimated cost-effectiveness ratio less than \$100 million).

<sup>606</sup> See, e.g., Driesen, *supra* note 497, at 515-21 (discussing how risk-trading advocates assume that all resources are “fungible,” but noting that the budgetary resources expended by federal agencies are not fungible with the private money used to comply with lifesaving rules); Parker, *supra* note 554, at 368 (“Without such a (currently non-existent) reallocation mechanism, no additional lives could be saved.”); Verchick, *supra* note 370, at 357 (“[I]f insurance companies spend too little on flu vaccines, it is hardly because chemical companies spend too much cleaning up Superfund sites.”).

<sup>607</sup> See McGarity, *supra* note 26, at 34 (“Even under the highly contestable assumption that a cost-benefit decision criterion would eliminate waste, no vehicle exists for channeling the savings to the most deserving social programs.”).

<sup>608</sup> Professor Parker, in a comment on my service as OIRA Administrator, emphasizes that I have never “proposed establishing such a reallocation mechanism in [my] capacity as President Bush’s regulatory czar.” Parker, *supra* note 34, at 1375 n.109. He then proceeds to explain how implementation of a “formal regulatory budget” that includes private-sector compliance costs would create a de facto reallocation mechanism, since “a dollar spent on Risk A necessarily would be subtracted from Risk B. Congress and agencies would be forced into a painful triage, with lives at stake, which might produce more ‘efficiency.’” *Id.* (italics added). Professor Parker’s observation is more interesting than he may realize. In testimony before OIRA’s House government reform committee, I argued in favor of a pilot project to determine the workability of the regulatory budget concept, which I have always regarded as a promising reform. *Paperwork and Regulatory Improvements Act of 2003: Hearing Before the H. Comm. on Government Reform*, 108th Cong. 16 (2003) (statement of John D. Graham, Adm’r, Office of Info. & Reg. Affairs). As Professor Parker indicates, a regulatory budget is another route to risk trading. See Graham, *Legislative Approaches*, *supra* note 15, at 51-52 (proposing a mandatory congressional budget for risk-regulating activities).

(except those that address global climate change), which sets the stage for formal risk trading in the United Kingdom.<sup>609</sup> Various forms of risk trading, both within and across regulatory jurisdictions, should be launched in pursuit of larger lifesaving payoffs. Such programs are already being created at the state and local levels of government, where the rigidity of federal law is not so constraining.<sup>610</sup>

There is a wide range of steps that Congress could take to encourage risk trading, but the misperception that risk trading equates to complete deregulation needs to be dispelled.<sup>611</sup> Limited experiments or pilot projects with trading might serve a useful educational function in the near term. If trading reforms are designed creatively and monitored with care,<sup>612</sup> they have the potential to save many more lives than we are currently saving at less overall cost to society.<sup>613</sup>

The opportunity to trade will not be of much use if each trade must pass the Pareto test; instead the objective should be to pass the Kaldor-Hicks test for society as a whole, and among the poor.<sup>614</sup> For people in poor neighborhoods, the opportunity to reallocate resources from presumed threats to real threats has enormous promise.<sup>615</sup> If Congress moves in this direction, the executive branch should be compelled to undertake rigorous ex post evaluation of risk-

<sup>609</sup> DEP'T FOR BUSINESS, ENTERPRISE & REGULATORY REFORM, HER MAJESTY'S GOVERNMENT, REGULATORY BUDGETS: A CONSULTATION DOCUMENT (2008), available at <http://www.berr.gov.uk/files/file47129.pdf>

<sup>610</sup> See, e.g., Charisse Jones, *Activists Use Research to Win Pollution Battles*, USA TODAY, Dec. 6, 2006, at 13A (citing an example of activists extracting concessions and services from corporations based on risk-assessment findings).

<sup>611</sup> See Bender, *supra* note 604, at 259 (arguing that the risk-trading concept is "prone to abuse as a cover for mere deregulation").

<sup>612</sup> See *id.* at 285 ("Probably the most fundamental criterion . . . is that the money for the trade must come from somewhere specific and be directed to somewhere else specific.").

<sup>613</sup> See Calandrillo, *supra* note 67, at 1028 (urging permission for regulatees to transfer resources from wasteful efforts to deserving social programs, such as free vaccinations and cost-effective health care). *But see* Bender, *supra* note 604, at 291-92 (discussing how the cost savings from trading can create difficult conflicts about how savings induced by trading will be divided among interested stakeholders).

<sup>614</sup> Jonathan Bender goes too far—discarding much of the benefit of the Kaldor-Hicks approach—when he insists that all trading must require that (1) "all beneficiaries of the pre-trade state of affairs . . . be identified," and (2) "all pre-trade beneficiaries should benefit at least as much from the trade as they did from the pre-trade state of affairs." Bender, *supra* note 604, at 287.

<sup>615</sup> See GREENBERG & SCHNEIDER, *supra* note 540, at 207 ("Our research supports . . . reallocating funds from existing narrowly focused national or state programs to broader local environmental concerns in multiple-hazard neighborhoods.").

trading programs to ensure that alternative investments in lifesaving are productive.<sup>616</sup>

Legal scholars can play a key role in the future of risk trading by designing enforceable legal regimes that authorize regulators and regulatees to ignore small risks in exchange for alternative investments in risk prevention that save more lives.<sup>617</sup> Environmental programs are already moving in this direction by allowing polluters to trade emissions permits. The “cap and trade” regimes that have been applied to sulfur air pollution in the United States, and to carbon dioxide in Europe, are microcosms of a much more dramatic change in the way lifesaving investments should be made. But we will not be able to move rapidly in this direction until the “tunnel vision” in current federal regulatory statutes is reformed. Instead of simply enacting more laws in response to the latest “risk of the month,” Congress should modernize risk-protection statutes in a general way that allows BCA to expand social welfare through creative investments in alternative lifesaving opportunities.<sup>618</sup> Even modest pilot projects aimed at helping devastated neighborhoods would be a huge step in the correct direction.<sup>619</sup>

#### H. *Coordinate U.S. and European Union Regulators*

When I joined OIRA in 2001, relations between the United States government and European Union (EU) officials on regulatory issues were poor. Both sides of the Atlantic had reason to complain.

The United States felt the EU was using regulatory policy as a device to block importation of American products and technologies. Trade-policy officials were in persistent controversy over the future of hormone-treated beef and crops grown from genetically modified seeds. The EU’s overt promotion of the precautionary principle

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<sup>616</sup> See Bender, *supra* note 604, at 273-75 (urging that alternative investments in vaccination, education, and crime prevention be analyzed carefully to ensure that speculative claims of cost-effectiveness are well grounded).

<sup>617</sup> See *id.* at 293 (arguing that Congress would need to give the executive branch broad legal authority to oversee risk trading, possibly including a new risk-management oversight body along the lines suggested by Justice Breyer).

<sup>618</sup> See Calandrillo, *supra* note 67, at 1011-17 (urging that Congress rewrite legislative mandates of federal regulators to permit use of BCA and RTA).

<sup>619</sup> See GREENBERG & SCHNEIDER, *supra* note 540, at 208-30 (suggesting a “target-of-opportunity” approach to overcome the formidable political obstacles to community risk trading).

seemed to be a signal of more protectionist rules from the EU in the years ahead.

The EU was objecting to the slow pace at which the United States was developing a regulatory program to slow global climate change. President Bush's 2001 decision not to seek ratification of the Kyoto Protocol exacerbated already poor relations with the EU on the climate issue.<sup>620</sup> The EU also began to register complaints about the unintended side effects of the Sarbanes-Oxley antifraud legislation and the slew of new homeland security regulations issued soon after 9/11.

In order to prevent future regulatory disputes, officials in both the United States and the EU should recognize that more dialogue needs to occur when legislation or regulation is in the developmental stages. In the period from 2001 to 2004, OIRA made an aggressive effort to enhance communication between the European Commission and United States regulators. OIRA actually encouraged the Commission's better-regulation agenda.<sup>621</sup> The coordination efforts accelerated in the period from 2005 to 2007, especially when the Commission created a centralized Impact Assessment Board with responsibility for reviewing the quality of impact assessments prepared by the Commission.<sup>622</sup>

To build on the improving regulatory relationships, the United States government and the Commission should develop mutual "early warning" systems about lifesaving regulations that are under development. A lifesaving rule that is promising on one side of the Atlantic is likely to have application on the other side as well. If these rules have trade implications, the early warning may facilitate discussions and fixes that can avoid long, arduous, and expensive trade disputes.

To overcome gridlock at regulatory agencies, OIRA and the Secretary General's Office in the European Commission need to nudge regulators in the direction of harmonizing a suite of existing rules that currently complicate trade between the United States and the EU.

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<sup>620</sup> See Wiener, *supra* note 186, at 457 (discussing the European negotiators' criticisms of United States greenhouse-gas-emissions proposals).

<sup>621</sup> See *Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions, A Strategic Review of Better Regulation in the European Union*, at 10-12, COM (2006) 689 final (Nov. 14, 2006) (establishing goals for progress in the EU's better-regulation program). OIRA also urged the Commission to create an OIRA-like unit, in part to facilitate such dialogue.

<sup>622</sup> See Memorandum, European Comm'n, *supra* note 38, at 1-2 (notifying that the quality control work of the Impact Assessment Board will begin "immediately"). On the history and details of the EU's Better Regulation program, see generally Wiener, *supra* note 186, at 448-518.

Without nudges from centralized oversight units, regulators on both sides of the Atlantic are likely to dig in, defend their turf, and resist more harmonization of conflicting rules. The more the United States and EU can find consensus on lifesaving regulations, the more likely it is that the rapidly growing economies of the developing world will cooperate in a consistent approach that facilitates world trade and global prosperity, as well as lifesaving.