

May 10, 2012

#### VIA ELECTRONIC COMMUNICATION

Cass Sunstein, Administrator Office of Information and Regulatory Affairs

<u>Subject</u>: <u>Recommendations to Promote Interagency Coordination</u>

Dear Administrator Sunstein.

The Institute for Policy Integrity respectfully submits the following recommendations on steps that the Office of Information and Regulatory Affairs (OIRA) should take to promote interagency coordination.

The Institute for Policy Integrity (Policy Integrity) is a non-partisan think tank dedicated to improving the quality of government decisionmaking through advocacy and scholarship in the fields of administrative law, economics, and public policy.

OIRA holds a unique position at the center of the regulatory state. Since 1981, it has overseen the quality of significant executive rulemakings and brought rules in line with Presidential priorities.<sup>1</sup> Not as well appreciated, however, is the role that OIRA can and has played in interagency coordination and system harmonization. Although OIRA has already done a great deal despite its limited resources, there are other actions OIRA should take to improve the efficiency, efficacy, and coherence of the federal government.

OIRA should take these actions as soon as is feasible:

- I. <u>Address claims of regulatory conflict and incoherence.</u> OIRA should investigate criticism alleging that federal agencies promulgate conflicting and incoherent regulations. An empirical analysis of the problem would be especially useful.
- II. Improve interagency coordination by standardizing methodological practices. OIRA should work towards standardizing methodological practices and, where appropriate, convene interagency working groups to forward that goal. There are many areas where coordination would be beneficial, including:
  - (a) harmonizing the Value of a Statistical Life;
  - (b) requiring and establishing best practices for distributional analysis;
  - (c) establishing best practices for labeling rules; and
  - (d) standardizing agency cancer risk assessment practices.

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<sup>&</sup>lt;sup>1</sup> Exec. Order No. 12,291, 46 Fed. Reg. 13,193 (1981).

#### I. ADDRESS CLAIMS OF REGULATORY CONFLICT AND INCOHERENCE IN THE ANNUAL REPORT

Each year in its annual report to Congress,<sup>2</sup> OIRA highlights several potential reforms to the regulatory process.<sup>3</sup> In the next report, OIRA should investigate one of the most common criticisms about the regulatory system—that the large number of rules results in conflicting or incoherent burdens on regulated entities. Many academics and political actors have warned about the dangers of regulatory conflict and incoherence. However, to date there has been no systematic analysis of the extent of the problem. It is important for OIRA to determine the seriousness of this issue and to identify any conflicting rules in need of reconciliation.

To prepare for the annual report, OIRA should survey the existing literature, consult with agencies, and solicit public comments —making use of the "dispersed knowledge"<sup>4</sup> of the public—to identify instances of regulatory conflict and incoherence.<sup>5</sup> Analysis of the results in the annual report will either facilitate improvements to the regulatory system by identifying problematic rules or focus the discourse surrounding the regulatory system on more pressing problems.

# Many Academic Commentators and Political Actors Have Warned About Regulatory Conflict

Many academic scholars have warned about regulatory conflict and incoherence.<sup>6</sup> Some scholars argue that the problem is so prevalent that the government should be reformed to avoid conflicting regulations.<sup>7</sup> Others have argued that the fear of inconsistent regulations has already influenced the shape of government by leading to more centralized review.<sup>8</sup>

<sup>&</sup>lt;sup>2</sup> Under the Regulatory Right-to-Know Act, the OMB Director is required to publish an annual report accompanying the budget that analyzes the impacts of federal regulation on targeted constituencies and makes recommendation for reform after giving an opportunity for notice and comment. Regulatory Right-to-Know Act, § 624, Pub. L. No. 106-554, 114 Stat. 2763 (2000) (codified at 31 U.S.C. § 1105 (note)).

<sup>&</sup>lt;sup>3</sup> See, e.g., Office of Information and Regulatory Affairs, 2011 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities 75–76 (2011) (regulatory cooperation on trade); Office of Information and Regulatory Affairs, 2009 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities 42–44 (2010) (transparency).

<sup>&</sup>lt;sup>4</sup> Office of Information and Regulatory Affairs, 2010 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities 43 (2010) (discussing the value of public comments).

<sup>&</sup>lt;sup>5</sup> A comprehensive investigation may not be justified by the limited evidence of this problem but a limited survey could yield valuable information.

<sup>&</sup>lt;sup>6</sup> See, e.g., Robert B. Ahdieh, Dialectical Regulation, 38 Conn. L. Rev. 863, 864–65 (2006) (describing the conventional view that the existence of regulatory overlap will create bad results, such as conflicting rules); Lisa Schultz Bressman & Michael P. Vanderburgh, Inside the Administrative State: A Critical Look at the Practice of Presidential Control, 105 Mich. L. Rev. 47, 50 (2006) ("OIRA review appears to . . . minimiz[e] overlaps and conflicts between or among the regulations of different federal agencies. But OIRA review does not achieve what might be called 'intra-agency coherence,' which includes reducing redundancies, avoiding inconsistencies, and eliminating unintended consequences between or among the regulations of a particular agency.").

<sup>&</sup>lt;sup>7</sup> See, e.g., Jerry Brito & Veronique de Rugy, *Midnight Regulations and Regulatory Review*, 61 Admin. L. Rev. 163, 193 (2009) ("We need a regulatory budget in order to reduce the impact of unnecessary, excessive and conflicting Government regulations." (quoting 125 Cong. Rec. 3817 (1979) (statement of Sen. Lloyd Bentsen))); Sidney A. Shapiro, *Political Oversight and the Deterioration of Regulatory Policy*, 46 Admin. L. Rev. 1, 31 (1994) (recommending that the creation of "minicabinets" to handle "conflicts between agencies that regulate in the same or similar areas or otherwise have the potential of establishing conflicting regulatory policies").

<sup>&</sup>lt;sup>8</sup> See, e.g., Richard H. Pildes & Cass R. Sunstein, *Reinventing the Regulatory State*, 62 U. Chi. L. Rev. 1, 39 (1995) ("[T]he sense of inconsistent, duplicative, and cumulatively burdensome regulation leads to demands for more centralized national control, especially at the presidential level.").

Like academics, political actors have also criticized the regulatory system for producing conflicting or incoherent rules. Members of Congress on both sides of the aisle, as well as business lobbyists, consistently discuss the difficulty of complying with conflicting regulations. Several presidential administrations have also tried to curtail conflicting regulations. For instance, the Clinton Administration promulgated Executive Order 12,866, which orders agencies to avoid inconsistent regulations. More recently, President Obama wrote in his announcement of retrospective review of regulations that his Administration's mission is "to root out regulations that conflict, that are not worth the cost, or are just plain dumb." 11

This criticism of the regulatory system appears to be based on the number of rules and regulators. It is well known that government programs have inefficient overlaps<sup>12</sup> and that administrative agencies have overlapping delegations of regulatory authority.<sup>13</sup> Moreover, there are some examples of directly conflicting rules—two rules that were impossible to comply with simultaneously—but they are often decades old. For example, in the early 1980s, certain chocolate manufacturers faced a situation in which OSHA rules required the use of porous insulation that could not be kept clean enough to meet FDA standards.<sup>14</sup> Another past example

<sup>&</sup>lt;sup>9</sup> See, e.g., 157 Cong. Rec. H7994 (daily ed. Nov. 30, 2011) (statement of Rep. Steve King) ("There are floors and floors of lawyers and administrative experts whose job it is to try to keep those companies from avoiding the conflict that comes from Federal regulations and, of course, our State regulations that are part of that as well."); 157 Cong. Rec. H2087 (daily ed. Mar. 30, 2011) (statement of Rep. Tim Bishop) ("I believe a more prudent course would be to take the time necessary and work together to address the concerns of both sides in a manner that minimizes regulatory duplication ...."); CTR. FOR CAPITAL MARKETS, U.S. CHAMBER OF COMMERCE, U.S. CAPITAL MARKETS COMPETITIVENESS: THE Unfinished Agenda 4 (2011) (asserting that there are "egregious conflicts and duplication among the maze of existing regulators" in the finance sector); John Allison & Sen. Ron Johnson, Regulations Stifle Economic Growth, Politico (Oct. 4, 2011) (asserting that there are an "an endless number of rules — often arcane, arbitrary and contradictory" that "crush[] the creative spirit"); Sen. Mark Warner, To Revive the Economy, Pull Back the Red Tape, Wash. Post, Dec. 13, 2010, http://www.washingtonpost.com/wp-dyn/content/article/2010/12/12/AR2010121202639.html (proposing a system that "would discourage agencies from continually adding new rules because they would be required to eliminate one outdated or duplicative regulation of the same approximate economic impact for each new rule they want to enact").

<sup>&</sup>lt;sup>10</sup> Exec. Order No. 12,866 § 1(b)(10), 58 Fed. Reg. 51,735 (1993). ("Each agency shall avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations or those of other Federal agencies.").

<sup>&</sup>lt;sup>11</sup> Barack Obama, *Toward a 21st-Century Regulatory System*, WALL St. J., Jan. 18, 2011, at A17 (emphasis added); *see also Eliminating Job-Sapping Federal Rules through Retrospective Reviews: Hearing Before the H. Comm. on Small Business* (statement of Cass Sunstein, Adm'r, OIRA), *available at* 

http://smbiz.house.gov/UploadedFiles/Sunstein\_Testimony.pdf ("[Agencies' regulatory review plans] include over 500 initiatives that will reduce costs, simplify the regulatory system, and eliminate redundancy and inconsistency."). Obama Administration officials also express concern about the possibility of conflicting regulation, such as in testimony before Congress. See, e.g., Reviewing the President's Fiscal Year 2013 Budget Proposal for the U.S. Department of Labor: Hearing Before the H. Comm. on Educ. & the Workforce (statement of Hilda L. Solis, Sec'y of Labor), available at http://edworkforce.house.gov/UploadedFiles/03.21.12\_solis.pdf ("Under the Standards Improvement Project, OSHA reviews and eliminates outdated and duplicative regulations."); Continued Oversight of the Implementation of the Wall Street Reform Act: Hearing Before the S. Comm. on Banking & Urban Affairs (statement of Neal S. Wolin, Deputy Sec'y of the Treasury), available at

 $http://banking.senate.gov/public/index.cfm? Fuse Action = Hearings. Hearing \& Hearing\_ID = 77971a67-b8f7-4e14-a837-892a065b7201 (arguing that coordination in implementing Dodd-Frank "is also important to avoid overlapping or conflicting regulations").$ 

<sup>&</sup>lt;sup>12</sup> GAO, More Efficient and Effective Government: Opportunities to Reduce Duplication, Overlap and Fragmentation, Achieve Savings, and Enhance Revenue (2012).

<sup>&</sup>lt;sup>13</sup> See generally Jason Marisam, Duplicative Delegations, 63 ADMIN. L. REV. 181 (2011); see also J.R. DeShazo & Jody Freeman, Public Agencies as Lobbyists, 105 COLUM. L. REV. 2217 (2005).

<sup>&</sup>lt;sup>14</sup> Office of the Vice President, Accompanying Report of the National Performance Review (1993), *available at* http://clinton6.nara.gov/1994/09/1994-09-01-npr-monograph-7-on-regulatory-systems-part.html (recommending the creation of "an interagency regulatory coordinating group").

was that the Bureau of Tobacco and Firearms (BATF) and FDA had conflicting regulations on alcohol bottle labeling in 1976. Among other things, in their regulations, the two agencies required the volume of each container to be measured at different temperatures and had differing requirements "with respect to the size of the declaration of contents required." More recently, the Nuclear Regulatory Commission Assistant Inspector General found that NRC regulations and guidance regarding reporting defective components were "contradictory" because they stated that certain defects did not have to be reported even though a statute required them to be. 17

However, when the academics and political actors discussed above assert that such conflicts persist, they either lack ready examples or only give examples of burdensome regulations or programmatic issues. <sup>18</sup> Therefore, this problem may be overstated. <sup>19</sup> Critics may be correct that regulations create significant burdens and that agency jurisdictions often overlap but may be wrong that these overlaps actually create burdens through conflict or incoherence. Alternatively, it may be that identified conflicts are quickly resolved and therefore need no additional attention. If the problem is genuinely overstated, then regulators and regulated entities can work together on more substantial concerns about regulation, such as cost-effectiveness. If conflicting rules are still a problem, then soliciting comments would be a low-cost way to find existing conflicts, which is the only way to resolve them.

# Survey the Academic Literature, Consult with Agencies, and Solicit Comments to Ascertain the True Extent of the Problem

To uncover the severity of the problem of conflicting and incoherent regulations, OIRA should survey academic literature, consult with agencies, and solicit and analyze comments from the public. Regulated entities are interested in reducing their regulatory burdens. Therefore, they are likely to participate in a comment process that would eliminate rules that are impossible to comply with. Regulated entities' desire to ease regulatory burden may also mean that they may incorrectly claim that rules conflict because they consider the rules onerous.<sup>20</sup>

<sup>&</sup>lt;sup>15</sup> See Brown-Forman Distillers Corp. v. Mathews, 435 F. Supp. 5 (W.D. Ky. 1976).

<sup>&</sup>lt;sup>16</sup> *Brown-Forman*, 435 F. Supp. at 14–15.

 $<sup>^{17}\,</sup>$  Office of Inspector General, Nuclear Regulatory Comm'n, Audit of NRC's Implementation of 10 CFR Part 21, Reporting of Defects and Noncompliance (2011), http://www.nrc.gov/reading-rm/doc-collections/insp-gen/2011/oig-11-a-08.pdf

<sup>&</sup>lt;sup>18</sup> See, e.g., Robert Gombar et al., OSHA and EPA: Redundancy at the Employer's Expense, 58 Occupational Hazards 63 (1996) (criticizing EPA and OSHA's overlapping enforcement authority); Karen Nash, Conflicting, Ambiguous Federal Rules Create Biggest Headaches for Urologists, Urology Times, July 1, 2011, available at http://www.modernmedicine.com/modernmedicine/Modern+Medicine+Now/Conflicting-ambiguous-federal-rules-create-biggest/ArticleStandard/Article/detail/730465 (reporting comments from an unscientific survey of urologists including complaints about the burden of "conflicting regulations," but citing only examples of ambiguous or burdensome programmatic requirements); see also sources listed supra notes 6–7.

<sup>&</sup>lt;sup>19</sup> See Binyamin Applebaum & Edward Wyatt, Obama May Find Useless Regulations Are Scarcer Than Thought, N.Y. TIMES (Jan. 21, 2011), http://www.nytimes.com/2011/01/22/business/22regulate.html (arguing that duplicative regulations are rarer than many think).

<sup>&</sup>lt;sup>20</sup> See Citizens Coal Council v. U.S. EPA, 447 F.3d 879, 903–04 (6th Cir. 2006) (en banc) (denying petitioners' claim that EPA's more stringent regulations under the Clean Water Act conflicted with another statute that petitioners thought had a lower standard); cf. Interview of Bob Lutz, Vice Chairman, Gen. Motors, with Alexis Glick, Fox Business News Anchor (Dec. 9, 2008) (asserting that "federal fuel economy regulations" and "California fuel economy regulations" were "conflicting regulations," even though a manufacturer could meet both); John D. Graham, Op-Ed., Steer a Smarter Course than Specific Mileage Goals, Detroit Free Press, Mar. 16, 2007, at 10 (similar).

Therefore, OIRA will have to develop a clear definition of "regulatory conflict" and "regulatory incoherence" and use these definitions to analyze conflicts reported in the comment process. There does not appear to be an agreed upon definition of regulatory conflict.<sup>21</sup> It may make sense to apply the definition used to determine when laws "actually conflict[]" for the purposes of preemption.<sup>22</sup> There have been several proposed definitions to test for coherence or consistency.<sup>23</sup> Settling on definitions of these terms will require thoughtful consideration, since "[c]oherence can be understood and incoherence can be tested in many different ways."24 OIRA should consult literature and develop its own definition.

After OIRA reviews the comments, it should publish a full report counting and describing actual conflicts and incoherence in OMB's annual report. This report will identify conflicting and incoherent rules in need of reconciliation and give regulators and regulated entities a better sense of the scope of the problem. Moreover, publication should allow for more targeted implementation of the retroactive review and cumulative burdens review processes that OIRA has recently commenced and will also allow agencies to address existing conflicts.

#### II. IMPROVE INTERAGENCY COORDINATION BY STANDARDIZING METHODOLOGICAL PRACTICES

Rule development frequently requires multiple agencies to confront a similar set of methodological issues. If agencies do not coordinate on common issues, they will be unable to use the accumulated knowledge of other agencies, and systematic inefficiencies will result. Methodological standardization makes it easier to compare the effects of regulations across agencies, and it equalizes the marginal costs of regulation, leading to a more efficient regulatory system.

For complex issues, particularly where agencies have important subject matter expertise that will help shape a more accurate result, interagency groups may be the most appropriate vehicle to achieve harmonization. Interagency groups may also be superior where agencies are hesitant to change their established practices—agencies may comply with the result more readily where they had a role in its creation.<sup>25</sup> The Social Cost of Carbon (SCC) working group succeeded in

<sup>&</sup>lt;sup>21</sup> See, e.g., Exec. Order No. 12,866 §§ 2(b), 4, 6(b), 7 (repeatedly referring to "conflict" without defining the term); Neil R. Eisner & Judit S. Kaleta, Federal Agency Reviews of Existing Regulations, 48 ADMIN. L. REV. 139, (1996) (arguing that "conflicts or inconsistencies between an agency's rules and those of another" are a justification for reviewing and existing regulations but not defining either term); 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, 1542-52 (2002) (proposing a new executive order that uses the term "conflict" without defining it); Sidney A. Shapiro, Political Oversight and the Deterioration of the Regulatory Policy, (arguing that the White House could "reduce conflicts between agencies that regulate in the same or similar areas or otherwise have the potential of establishing conflicting regulatory policies" but not defining that conflict).

<sup>&</sup>lt;sup>22</sup> Fidelity Fed. Savings & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 153 (1982) ("Such a conflict arises when 'compliance with both federal and state regulations is a physical impossibility[,]' or when state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," (quoting Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142-143 (1963), and Hines v. Davidowitz, 312 U.S. 52, 67 (1941)).

<sup>&</sup>lt;sup>23</sup> See, e.g., Thomas O. McGarity, Presidential Control of Regulatory Agency Decisionmaking, 36 Am. U. L. Rev. 443, 447 (1987) (defining "inconsistency" as "when one agency's unconstrained pursuit of its statutory goals clashes with another agency's similar pursuit of conflicting goals"); Cass Sunstein et al., Predictably Incoherent Judgments, 54 STAN. L. Rev. 1153, 1154 (2002) (using the question "[w]hen two or more judgments have been made separately, and each seems to make sense on its own, do they still make sense when considered together?" to test for coherence).

<sup>&</sup>lt;sup>24</sup> Sunstein et al., *supra* note 23 at 1154.

<sup>&</sup>lt;sup>25</sup> C.f. Michael R. Cooper & Michael T. Wood, Effects of Member Participation and Commitment in Group Decision Making On Influence, Satisfaction, and Decision Riskiness, 59 J. of Applied Psychology 2127 (1974).

altering the way agencies do regulatory impact analysis,<sup>26</sup> in part because it came about through an interagency process.

OIRA should continue to standardize aspects of agency rulemaking through interagency working groups. While there are many areas where standardization would be highly beneficial, OIRA and the regulatory agencies do not have the resources to approach all important issues at once. High-impact issues that OIRA should consider include:

- (a) harmonizing the Value of a Statistical Life;
- (b) requiring and establishing best practices for distributional analysis;
- (c) establishing best practices for labeling rules; and
- (d) standardizing agency cancer risk assessment practices.

#### Harmonizing the Value of a Statistical Life

The monetized value of incremental mortality risk reduction, often referred to as the Value of a Statistical Life (VSL), is one of the most important numbers in cost-benefit analysis. Circular A-4 requires that, where possible, benefits and costs are to be quantified and expressed in monetary units.<sup>27</sup> Establishing a common unit enables comparison between the benefit and costs. Monetized VSL is derived from individuals' willingness to pay to avoid a particular risk.<sup>28</sup> This monetized value then determines the monetary benefit of expected lives saved by a rule, so an increase or decrease in the VSL will often determine whether a regulation is cost justified or how stringently a regulatory standard should be set. This is particularly true for rules for which the primary benefit is lives saved, including many environmental, health, and safety rules.<sup>29</sup>

VSL Harmonization Will Facilitate Comparisons of Rules and Promote a More Efficient Regulatory System

Agencies use disparate VSLs.<sup>30</sup> For example, in rules published last year, the Federal Motor Carrier Safety Administration (FMSCA) set the VSL at \$6 million,<sup>31</sup> the Food and Drug Administration (FDA) at \$7.9 million,<sup>32</sup> and the Environmental Protection Agency (EPA) at \$8.7

<sup>&</sup>lt;sup>26</sup> Agencies are already incorporating the harmonized SCC in their new rules. *See* Michael Greenstone et al., *Estimating the Social Cost of Carbon for Use in U.S. Federal Rulemakings: A Summary and Interpretation* 22–23 (Mass. Inst. of Tech. Dep't of Econ. Working Paper No. 11-04, 2011), *available at* 

http://papers.ssrn.com/sol3/papers.cfm?abstract\_id=1793366 ("[T]he monetized benefits of CO<sub>2</sub> emission reductions have been included in at least 7 major rules . . . across three Federal departments and agencies.").

<sup>&</sup>lt;sup>27</sup> U.S. Office of Mgmt. & Budget, Exec. Office of the President, OMB Circular A-4, Regulatory Analysis 2 (2003). <sup>28</sup> *Id* at 29.

<sup>&</sup>lt;sup>29</sup> See Richard L. Revesz & Michael A. Livermore, Retaking Rationality 33 (2008) (describing VSL as "particularly important for environmental regulation" because the main benefits of environmental rules are reductions in mortality risk).

<sup>&</sup>lt;sup>30</sup> 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 1, 118 (2003); Gabriel Nelson, *EPA Plans to Revisit a Touchy Topic—The Value of Saved Lives*, N.Y. TIMES (Jan. 18, 2011), http://www.nytimes.com/gwire/2011/01/18/18greenwire-epa-plans-to-revisit-a-touchy-topic-the-value-75301.htm (noting that agencies value a statistical life at between \$5 and \$8 million).

<sup>&</sup>lt;sup>31</sup> U.S. Federal Motor Carrier Safety Administration, Hours of Service of Drivers, 76 Fed. Reg. 81,134, 81,176 (Dec. 27, 2011).

<sup>&</sup>lt;sup>32</sup> U.S. Food and Drug Administration, Labeling for Bronchodilators To Treat Asthma, 76 Fed. Reg. 44,475, 44,482 (July 26, 2011).

million.<sup>33</sup> While this range is smaller than it once was,<sup>34</sup> it still represents an unexplained 45% variance—large enough to have significant practical implications.<sup>35</sup>

Any significant disparity in agencies' VSLs without a unifying rationale suggests that agencies may be approving or rejecting regulatory alternatives when another agency's methodological assumptions would result in the opposite outcome.<sup>36</sup> This methodological divergence also makes it difficult to compare the value of life-saving regulations across agencies.<sup>37</sup> Dissonant agency VSLs may account in part for the dramatic variation in the cost effectiveness of final rules<sup>38</sup> and may contribute to a regulatory system that, on the whole, "devote[s] too many resources to regulations that have small net benefits and not enough to regulations with big net benefits."<sup>39</sup>

## Steps Toward Harmonization

An interagency working group could be especially useful in harmonizing the VSL. The simplest approach would be to establish a single federal VSL. This is possible given that each agency that has approached the issue has established a single VSL across all of their rules.<sup>40</sup> Alternatively, the working group might find it desirable to allow for multiple VSLs, in which case the group could either create a set of acceptable values based on willingness to pay variations (discussed in more detail below) or it could create a guidance document for determining the VSL akin to Circular A-4. Any of these approaches would facilitate more accurate comparison of rules across agencies and would equalize the marginal costs of regulation, resulting in a more harmonious regulatory system.

Leading experts have argued for the use of multiple VSLs because people value different mortality risks differently.<sup>41</sup> The VSL is derived from the willingness to pay to avoid a particular risk,<sup>42</sup> so the value of reducing a mortality risk may differ by type of risk ("risk variables").

<sup>&</sup>lt;sup>33</sup> U.S. Environmental Protection Agency, Federal Implementation Plans: Interstate Transport of Fine Particulate Matter and Ozone, 76 Fed. Reg. 48,208, 48,314 n.97 (Aug. 8, 2011).

<sup>&</sup>lt;sup>34</sup> See Viscusi & Aldy, supra note 30 (citing regulations promulgated in the 1990s that used VSLs ranging from \$1.7 million to \$6.3 million).

<sup>&</sup>lt;sup>35</sup> Some academics have calculated the implicit VSL of different rules based on the ratio between expected costs and lives saved and found a much wider range in values. *See* Tammy O. Tengs et al., *Five Hundred Life-Saving Interventions and their Cost-Effectiveness*, 15 RISK ANALYSIS 369 (1995); John F. Morall III, *Saving Lives: A Review of the Record*, 27 J. RISK & UNCERTAINTY 221 (2003). However, others have contested the meaningfulness of these calculations. *See*, e.g., Lisa Heinzerling, *Five-Hundred Life Saving Interventions and Their Misuse in the Debate Over Regulatory Reform*, 15 RISK: HEALTH SAFETY & THE ENV'T 151 (2002).

<sup>&</sup>lt;sup>36</sup> While it may be argued that having different VSLs by agency is justified as reasonable individuation due to the different types of risk under their statutory charge, this is highly unlikely. There is no consensus on how to account for heterogeneity in the willingness to pay for risk reduction in the VSL, so there is no reason to assume that agencies are employing a consistent set of assumptions. Furthermore, each agency that has approached the issue has established a single VSL across all of their rules, *see* Cass R. Sunstein, *Valuing Life: A Plea for Disaggregation*, 54 DUKE L.J. 385, 388–89 (2004), even though one agency may deal with multiple populations with different willingness to pay to reduce risk of death, or multiple types of risk which people value differently.

<sup>&</sup>lt;sup>37</sup> Lewis Kornhauser, *The Value of Life*, 38 CLEV. St. L. Rev. 209, 220 (1990) (pointing out that coordinated life values would enable Congress to evaluate agency performance and set budgets accordingly).

<sup>&</sup>lt;sup>38</sup> See Morall III, supra note 35.

<sup>&</sup>lt;sup>39</sup> Michael Greenstone, *Toward a Culture of Persistent Regulatory Experimentation and Evaluation, in New Perspectives* on Regulation 111, 114 (David Moss & John Cisternin eds., 2009).

<sup>&</sup>lt;sup>40</sup> Sunstein, *supra* note 36, at 388-89 (2004).

<sup>&</sup>lt;sup>41</sup> See, e.g., Richard L. Revesz, Environmental Regulation, Cost-Benefit Analysis, and the Discounting of Human Lives, 99 COLUM. L. Rev. 941, 968–74 (1999) (arguing for VSL differences based on voluntariness of the risk and the "dread nature of the harm"); Cass R. Sunstein, Valuing Life: A Plea for Disaggregation, 54 DUKE L.J. 385, 390–95 (2004)

One frequently cited risk variable that could justify different VSLs is the degree of voluntariness involved in the risk.<sup>43</sup> Some people express greater willingness to pay for greater safety when the background risk seems to be particularly out of their control. For example, as discussed above, people may be willing to pay more to reduce the risk of environmental harm because they did not decide to take on the risk ("involuntary risk"), as opposed to automotive crashes, where people implicitly accept a degree of risk by choosing to drive ("voluntary risk") and therefore are less willing to pay to reduce the risk of a crash.

If voluntariness is to be used as an individuation rationale, it is critical that agencies are mindful of potential cognitive biases. For example, it is well established that an oversized percentage of people believe themselves to be safer than average drivers. People may, therefore, undervalue the background risk of a car crash as applied to themselves. Furthermore, if the working group establishes a VSL adjustment based on voluntariness, agencies must be careful to consider whether an activity is appropriately characterized as "voluntary." For example, risk of workplace injuries is often seen as more voluntarily assumed because of the implicit option to work somewhere else. However, if the local labor market is monopolistic, workers may not have a practical choice other than to work for the local employer that dominates the market. For example, the Mine Safety and Health Administration (MSHA) recently expressed reservations about calculating willingness to pay based on the risks taken on by coal miners because they may work in areas with limited alternatives. 45

Another risk variable could be the amount of pain and dread involved in the death risk.<sup>46</sup> It makes intuitive sense that people are willing to pay more to reduce the risk of a particularly drawn out and unpleasant death, and it would not be difficult to establish a standard higher VSL for such risks. This could be as simple as creating a higher VSL for all cancer mortality risk reductions, or the working group could, for example, establish a set of percentage add-ons for a range of mortality risks that people fear above others.<sup>47</sup> The working group would need to determine how to calculate this variable if it finds that individuation is appropriate.

In contrast to these and other reasonably probable risk variables, some academics have proposed the use of "life years" (a constant value for each year of life saved) as a way to assign value to lives based on age.<sup>48</sup> This approach can lead to substantial errors if misused.<sup>49</sup> Empirical research has shown that individual willingness to pay to avoid risk stays relatively constant throughout one's adult life rather than decreasing steadily with age as proponents of

(arguing for multiple VSLs closely tailored to individual willingness to pay); U.S. Environmental Protection Agency, National Center for Environmental Economics, Valuing Mortality Risk Reductions for Environmental Policy: A Working Paper (Dec. 10, 2010), *available at* yosemite.epa.gov/ee/epa/eerm.nsf.

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<sup>&</sup>lt;sup>42</sup> U.S. Office of Mgmt. & Budget, Exec *supra* note 27, at 29.

<sup>&</sup>lt;sup>43</sup> See, e.g., Revesz, supra note 41, at 968–74; Sunstein, supra note 36, at 390–95.

<sup>&</sup>lt;sup>44</sup> Iain A McCormick, Frank H. Walkey & Dianne E. Green, *Comparative Perceptions of Driver Ability—A Confirmation and Expansion*, 18 Accident Analysis & Prevention 3, 205–208 (1986).

<sup>&</sup>lt;sup>45</sup> MSHA, Proximity Detection Systems for Continuous Mining Machines, 76 Fed. Reg. 54,163, 54175 (Aug. 31, 2011).

<sup>&</sup>lt;sup>46</sup> Revesz, supra note 41, at 972–74.

<sup>&</sup>lt;sup>47</sup> See U.S. Environmental Protection Agency, National Center for Environmental Economics, Valuing Mortality Risk Reductions for Environmental Policy: A Working Paper 20-26 (Dec. 10, 2010), available at yosemite.epa.gov/ee/epa/eerm.nsf/vwFUM/da9832e5cfdb5f56852577f90052f4bf!OpenDocument&ExpandSection= 1 (discussing ways to account for a "cancer differential" and the supporting literature).

<sup>&</sup>lt;sup>48</sup> Michael J. Moore & W. Kip Viscusi, The Quantity-Adjusted Value of Life, 26 Econ. Inquiry 269 (1988).

<sup>&</sup>lt;sup>49</sup> Revesz & Livermore, *supra* note 29, at 77-84.

the life-years theory postulate.<sup>50</sup> If the working group finds it desirable to individuate based on age, it should do so with reference to empirically proven divergences in the willingness to pay.

Ultimately, the working group will need to determine which, if any, variables to account for based on not only social desirability but also on the availability of adequate empirical data. Therefore, any document produced by the working group will be necessarily limited and will need to be periodically updated to reflect improvements in data availability and changes in risk avoidance preferences.

#### Requiring and Establishing Best Practices for Distributional Analysis

Regulations that maximize social welfare may impose disproportionate costs on a particular subpopulation, resulting in both equity and efficiency problems. Recognizing this, Executive Order 12,866 permits agencies to consider "distributive impacts" and "equity" in promulgating rules,<sup>51</sup> and Executive Order 13,563 reiterated this point.<sup>52</sup> OIRA also has emphasized the importance of considering distributional effects in several guidance documents, including Circular A-4,<sup>53</sup> "Updated Principles on Risk Analysis,"<sup>54</sup> and most recently with "Cumulative Effects of Regulations."<sup>55</sup>

Academics have identified several uses of distributional analysis. For example, distributional concerns could act as "tiebreakers" between regulatory alternatives with the same aggregate net benefits<sup>56</sup> or could be used to inform tax policy.<sup>57</sup> Distributional analysis also produces important information on the effects of the regulation. The information generated by distributional analysis is especially useful when aggregated because it can show the total effects of the regulatory system on different populations.<sup>58</sup> Even if each individual rule creates an efficient balance of costs and benefits, certain groups may bear a disproportionate share of the costs of the regulatory system on the whole due to systematic biases.<sup>59</sup> Some scholars even argue that distributional asymmetries could signal a failure in the regulatory process resulting in

<sup>&</sup>lt;sup>50</sup> *Id.* at 81-82 (reviewing the body of empirical work on the effect of age on willingness to pay to avoid risk, and concluding that it "clearly disproves the life-years hypothesis").

<sup>&</sup>lt;sup>51</sup> Exec. Order No. 12,866 § 1(a), (b)(5), 58 Fed. Reg. 51,735 (1993).

<sup>&</sup>lt;sup>52</sup> Exec. Order No. 13,563 § 1(c), 76 Fed. Reg. 3821 (2011).

<sup>&</sup>lt;sup>53</sup> U.S. Office of Mgmt. & Budget, *supra* note 27, at 14 (instructing agencies to "provide a separate description of distributional effects").

<sup>&</sup>lt;sup>54</sup> See Memorandum from Office of Information and Regulatory Affairs Administrator Susan Dudley for the Heads of Executive Departments and Agencies on Updated Principles for Risk Analysis 10 (Sept. 19, 2007) (stating that agencies should consider both "the magnitude and the distribution of benefits and costs" when considering risk management alternatives).

<sup>&</sup>lt;sup>55</sup> MEMORANDUM FROM OFFICE OF INFORMATION AND REGULATORY AFFAIRS ADMINISTRATOR CASS SUNSTEIN FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES ON CUMULATIVE EFFECTS OF REGULATIONS (March 20, 2012) (although this memorandum does not state that distributional effects are a rationale for considering cumulative regulatory effects, the concern that certain entities may face disproportionate burdens may be understood as a distributional concern).

<sup>&</sup>lt;sup>56</sup> See Cass Sunstein, The Arithmetic of Arsenic, 90 GEO. L.J. 2255, 2260 (2002).

<sup>&</sup>lt;sup>57</sup> See Nicholas Bagley & Richard L. Revesz, Centralized Oversight of the Regulatory State, 106 COLUM. L. REV. 1260, 1325–28 (2006); see also id. at 1313 (noting the widespread belief that "tax-and-transfer policy can minimize any distributional problems in light of the cumulative impact of regulatory policy" (emphasis added)).

<sup>&</sup>lt;sup>58</sup> See Michael A. Livermore & Jennifer S. Rosenberg, *The Shape of Distributional Analysis: Toward Efficient and Equitable Redistribution in the Developing World, in* Cost-Benefit Analysis and Environmental Decisionmaking in Developing and Emerging Countries (Richard L. Revesz and Michael A. Livermore, eds.) (Oxford 2012) (forthcoming).

<sup>&</sup>lt;sup>59</sup> See, e.g. David Schlosberg, Defining Environmental Justice: Theories, Movements, and Nature (2007) (arguing that environmental policies ignore the disproportionate pollution exposure of urban, minority, and poor communities).

cost-benefit inefficiencies.<sup>60</sup> While there may be disagreement on the most important uses of this information, there is wide agreement that having the information would be valuable.

However, as OIRA recently recognized,<sup>61</sup> agencies rarely incorporate distributional considerations into their regulatory impact analyses. Simply asserting the importance of distributional analysis has not spurred widespread use. Where appropriate, OIRA should require that agencies conduct distributional analyses in a common format determined by an interagency working group. It should then aggregate that information in its annual report to Congress.

Agencies have not been undertaking thorough distributional analyses for a number of reasons. They have limited resources, and additional analysis is costly and time consuming. Therefore, any new analytical requirement should seek to limit the additional burdens placed on agencies. Furthermore, agencies have not been instructed to seek distributional goals nor been required to conduct comprehensive distributional analysis, so they may see little reason to do so. In other words, for an agency seeking to promulgate a particular rule, distributional analysis may seem both burdensome and unnecessary.

Agencies might be further incentivized to perform distributional analysis if they had a greater appreciation for the broader importance of distributional analysis, and it was less costly to do so. Convening an interagency group to develop a set of best practices for distributional analysis would accomplish both goals.

Once a set of best practices are established, it will become less costly for an agency to do a distributional analysis in each rulemaking because the agency can refer back to established practice rather than developing a new methodology each time. The interagency group should carefully consider the existing requirements for distributional analysis and seek to establish a single methodology that would satisfy all of them. For example, the new distributional analysis should encompass the Regulatory Flexibility Act's requirement to consider distributional effects on small businesses.<sup>62</sup> It should also consider the congressional information requests that agencies must respond to and seek to create a methodology that will satisfy such inquiries.

Furthermore, participation in the interagency group will promote a shared understanding that distributional analysis is important for broader policy reasons, even if it does not change the outcome of individual rules. If agencies believe in the value of the aggregate information provided by OIRA, they should be more willing to spend time to enable that information.

Compiling useful information about which groups face disproportionate burdens requires a coordinated approach. Therefore, OIRA should create a common methodology for agencies' distributional analyses, including a common set of subgroups on which to focus. Subgroups could be broken down by standardized deciles of the population based on income, wealth, race,

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<sup>60</sup> See Livermore & Rosenberg, supra note 58.

<sup>61</sup> OFFICE OF INFORMATION AND REGULATORY AFFAIRS, 2011 REPORT TO CONGRESS ON THE BENEFITS AND COSTS OF FEDERAL REGULATIONS AND UNFUNDED MANDATES ON STATE, LOCAL, AND TRIBAL ENTITIES, *supra* note 3, at 11 ("[S]o far as we are aware, there is only limited analysis of the distributional effects of regulation in general or in significant domains; such analysis could prove illuminating . . . ."), *see also* Robert W. Hahn and Patrick M. Dudley, *How Well Does the Government Do Cost-Benefit Analysis?*" 1 Rev. Envr'L Econ. & Pol'y 192 (2007); Sunstein, *supra* note 56, at 2260 (calling for a stronger requirement that agencies conduct distributional analysis).

<sup>&</sup>lt;sup>62</sup> Regulatory Flexibility Act, 5 U.S.C. §§ 601–612. For a discussion on how the Regulatory Flexibility Act process could be refined, *see* Letter from the Institute for Policy Integrity to the U.S. Small Business Association on Suggested Improvements to the Implementation of the Regulatory Flexibility Act (Feb. 24, 2012), *available at* http://policyintegrity.org/documents/Policy\_Integrity\_Letter\_to\_SBA\_on\_RFA.pdf.

or age.<sup>63</sup> Using a common methodology will make the distributional analyses interoperable, so that OIRA will be able to aggregate that information in its annual report to Congress.

Once the interagency group makes its report, OIRA should incorporate it into the regulatory review process by accepting it as standard practice and insisting that agencies follow its recommendations unless they have a particularized reason not to. After agencies begin employing more regular distributional analysis of their rules, it will become possible for OIRA to aggregate those analyses for inclusion in its annual report to Congress.

# **Establishing Best Practices for Labeling Rules**

OIRA's recent support for "behaviorally informed approaches to regulation" is a welcome improvement. In particular, the guidance document "Disclosure and Simplification as Regulatory Tools" 65 does a good job of laying out the important substantive considerations for an agency intent on promulgating a labeling rule (also known as "summary disclosure"). However, many agencies have been requiring product labels for decades and as a result have built up institutional knowledge about the best procedures for these rules. OIRA should harness and standardize this information by convening an interagency working group to establish best practices for developing labeling rules.

Labeling requirements can be a highly effective way to achieve regulatory objectives while imposing limited costs. By enabling informed decisionmaking, labels improve market dynamics by allowing people to act based on their true preferences. Without labels, consumers may be unaware of information that is important to them, or that information may be insufficiently salient at the time of purchase.

However, to be effective, labels must be designed based on careful consideration of the way people process information.<sup>66</sup> The label must be understandable to the intended user; it must present the most important and meaningful information and do so at a time when the consumer will actually be able to utilize that information.<sup>67</sup>

Methodologies for determining the best label design vary by agency. For example, last year, EPA and DOT underwent an extensive study before publishing the new motor vehicle fuel economy label rule.<sup>68</sup> They consulted a market research program, public hearings, public comments, and a state agency (the California Air Resources Board).<sup>69</sup> The market research program included a literature review, multiple sets of focus groups, an expert panel, and an internet survey.<sup>70</sup> In contrast, around the same time DOE revised its Energy Guide Labels but only consulted public

<sup>63</sup> See Bagley & Revesz, supra note 57, at 1328.

<sup>64</sup> Office of Information and Regulatory Affairs, 2009 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities *supra* note 3, at 35.

<sup>65</sup> MEMORANDUM FROM OFFICE OF INFORMATION AND REGULATORY AFFAIRS ADMINISTRATOR CASS SUNSTEIN FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES ON DISCLOSURE AND SIMPLIFICATION AS REGULATORY TOOLS (June 18, 2010).

<sup>&</sup>lt;sup>66</sup> Office of Information and Regulatory Affairs, 2009 Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities *supra* note 3, at 37 ("If disclosure requirements are to be helpful, they must be designed to be sensitive to how people process information").

<sup>&</sup>lt;sup>67</sup> *Id.* ("To be effective, disclosure should be clear, meaningful, timely, and salient").

<sup>&</sup>lt;sup>68</sup> U.S. Environmental Protection Agency & Department of Transportation, Revisions and Additions to the Motor Vehicle Fuel Economy Label, 76 Fed. Reg. 39,478 (July 6, 2011).

<sup>69</sup> Id. at 39,479.

<sup>&</sup>lt;sup>70</sup> *Id.* at 39,482.

comments.<sup>71</sup> DOE might have undergone more extensive study if it had clear information on what approach would yield the best information.

A set of best practices would reduce the cost to agencies in determining the best course of study. The interagency working group should develop best practices that draw upon the experience of agencies' established methodologies and improve them. While the actual labels will differ widely by subject matter and relevant population, the procedures necessary to determine what is the best label for a given goal should be similar. Is it better to consult an expert panel before drawing up alternatives to show a focus group? Do public hearings actually produce information that written comments do not? A set of default answers to these kinds of procedural questions would make regulatory decisionmaking more efficient and effective.

## **Standardizing Cancer Risk Assessment**

For at least three decades, experts have recognized the need for cancer risk assessment standardization.<sup>72</sup> OIRA does have far-reaching power to influence data collection through the Information Quality Act.<sup>73</sup> However, cancer risk assessment requires not only policy judgments and standardization but also scientific expertise. The necessary judgments are combined "science-policy judgments."<sup>74</sup> One way to approach these technical and scientific issues would be for OIRA to convene a working group in conjunction with the Office of Science and Technology Policy (OSTP), an office recognized for its scientific expertise, to harmonize agency cancer risk assessment.

Standardization Will Help Equalize Levels of Regulatory Stringency and Reduce the Marginal Costs of Regulations

As with the discussion of VSL above, if agencies make differing assumptions about how carcinogenic substances may be, the resulting rules will prevent cancer at different levels of cost effectiveness. As a result, one agency could be regulating at a level of stringency that achieves a marginal benefit that could be achieved more cheaply by another agency. Furthermore, differences in agency assumptions make it harder for policymakers to use agencies' conclusions comparatively.<sup>75</sup>

In fact, agencies' cancer policies do use different assumptions<sup>76</sup> and methods.<sup>77</sup> Moreover, their default rules are not always decided on nor written down.<sup>78</sup> Agencies also have different methods of translating animal studies into risks for people, although they have started to

<sup>77</sup> See Id. at 41 tbl1. (highlighting different methods).

<sup>&</sup>lt;sup>71</sup> U.S. Department of Energy, Full Fuel Cycle Analysis, 76 Fed. Reg. 51,281 (Aug. 18, 2011).

 $<sup>^{72}</sup>$  See Bagley & Revesz, supra note 57, at 1317–20 (describing attempts to and calls for cancer risk assessment standardization since the Carter Administration).

 $<sup>^{73}</sup>$  *Id.* at 1314–16 (describing attempts to and calls for cancer risk assessment standardization since the Carter Administration).

<sup>&</sup>lt;sup>74</sup> See Bagley & Revesz, supra note 57, at 1316 ("[R]egulators must invariably make a number of strong assumptions (also known as 'science-policy judgments...."); Sidney A. Shapiro, OMB and the Politicization of Risk Assessment, 37 ENVTL. L. 1083, 1089 (2007) ("Default assumptions are not purely scientific, because they also reflect public policy.").

<sup>&</sup>lt;sup>75</sup> See GAO, SELECTED FEDERAL AGENCIES' PROCEDURES, ASSUMPTIONS, AND POLICIES 47 (2001) ("Nevertheless, our report highlights the value of policymakers and other interested parties becoming aware of the underlying risk assessment context, procedures, assumptions, and policies when using risk assessment data for risk management and other public policy decisions.").

<sup>&</sup>lt;sup>76</sup> *Id.* at 30–31.

 $<sup>^{78}</sup>$  *Id.* at 26 (2001) ("[N]either FDA nor OSHA had written internal guidance specifically on conducting risk assessments at the time of our review.").

converge on that issue.<sup>79</sup> Still, the overall differences are significant. For this reason, OIRA has previously recommended that "[j]udgments used in developing a risk assessment, such as assumptions, defaults, and uncertainties, should be stated explicitly."<sup>80</sup>

## OSTP's Scientific Expertise

OIRA is positioned to coordinate agency regulation across the federal government and has power to regulate information quality under the Information Quality Act. However, agencies have been resistant to OIRA's efforts to improve scientific methodology.<sup>81</sup> For instance, EPA has been resistant to efforts by OIRA to involve itself in the Integrated Risk Information System (IRIS)—EPA's internal system for determining the health risks of particular substances—because of the concern that OIRA was politicizing science and delaying implementation of scientific results.<sup>82</sup> Academic experts also argue that OIRA does not have sufficient expertise to be the final arbiter on science-policy judgments.<sup>83</sup>

Recognizing the wariness with which some agencies may view OIRA involvement in scientific issues, OIRA may want to convene an interagency working group to handle the issue. To add objective scientific legitimacy to the project, such a group should be convened in conjunction with OSTP. OIRA has previously worked with OSTP to consider scientific-policy judgments surrounding risk.<sup>84</sup> OSTP is statutorily authorized to develop science-policy judgments on behalf of the President.<sup>85</sup>

Agencies have shown that they are interested in coordinating assessment of chemical risks. For example, several agencies have joined forces to research cancer risk in the Tox21 automatic testing and modeling program.<sup>86</sup> Therefore, they should be receptive to a harmonization effort as long as OIRA makes clear that its interest is in coordination and not in a particular view of the science.

In the alternative, OIRA could also promote risk assessment policy harmonization in a more disengaged manner.<sup>87</sup> OIRA could ask agencies that perform risk assessment to write down and

<sup>&</sup>lt;sup>79</sup> *Id.* at 36-37, 42 (2001).

<sup>&</sup>lt;sup>80</sup> Susan E. Dudley & Sharon L. Hays, Office of Information and Regulatory Affairs & Office of Science and Technology Policy, M-07-24: MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES 8 (2007), http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory\_matters\_pdf/m07-24.pdf.

<sup>81</sup> See, e.g., Bressman & Vanderburgh, supra note 6, at 97 (discussing EPA objections to OIRA input into science).

<sup>&</sup>lt;sup>82</sup> See GAO, CHEMICAL ASSESSMENTS: CHALLENGES REMAIN WITH EPA'S INTEGRATED RISK INFORMATION 10 (2011) (noting that EPA and not OMB now runs the interagency reviews that are part of the IRIS process); OMBWATCH, OMB INTERFERES IN IRIS ASSESSMENTS OF TOXIC CHEMICALS: QUESTIONS AND ANSWERS (2008),

http://www.ombwatch.org/files/regs/PDFs/IRISfactsheet.pdf (accusing OMB of interfering in IRIS risk assessment process); *see also* Shapiro, *supra* note 74, at 1105 "[O]ur experience to date with OMB supervision of science suggests that it should have a limited role in the creation of common default rules.").

<sup>&</sup>lt;sup>83</sup> See, e.g., Daniel A. Farber, Rethinking the Role of Cost-Benefit Analysis, 76 U. CHI. L. REV. 1397 (2009) (book review) ("OIRA is utterly unsuited to perform some of these roles, such as harmonizing scientific procedures, . . . Its expertise is in economics, not the sciences, so scientific coordination is a poor assignment."); David M. Driesen, Distributing the Costs of Environmental, Health, and Safety Protection: The Feasibility Principle, Cost-Benefit Analysis, and Regulatory Reform, 32 B.C. Envil. Aff. L. Rev. 1, 93 (2005) (referring to "scientifically ignorant OMB economists")

<sup>84</sup> Dudley & Hayes, supra note 84.

<sup>85</sup> See 42 U.S.C. § 6613-6614.

<sup>&</sup>lt;sup>86</sup> U.S. Environmental Protection Agency, Tox21, http://epa.gov/ncct/Tox21/ (coordinated effort by EPA, National Institutes of Environmental Health Sciences/National Toxicology Program, National Institutes of Health/National Human Genome Research Institute, NIH Chemical Genomics Center (NCGC), and the Food and Drug Administration) (last visited Mar. 2, 2012).

<sup>87</sup> See Shapiro, supra note 74, at 1105–06 (2007) (describing a hand-off way to coordinate).

distribute their risk analysis policies, similar to how GAO surveyed risk policies. If each agency has its own policy written down and disseminated, the agencies can collectively and informally work toward establishing best practices.

#### **CONCLUSION**

OIRA holds a unique position at the hub of the regulatory state that enables it to improve regulatory decisionmaking. There are countless ways that OIRA could use its influence to press for better federal rulemaking, and this letter lays out just a few. Addressing claims of regulatory conflict and incoherence in the annual report would create important benefits in raising public and Congressional confidence in the regulatory system and in OIRA itself. Standardizing various aspects of regulatory analysis creates a more logical regulatory system with rules that can be more easily compared across agencies. In particular, OIRA should consider convening interagency working groups to address the disparate Values of a Statistical Life, the importance of distributional analysis, the best practices for labeling rules, and the need for standard cancer risk assessment protocols.

Respectfully submitted,

Michael A. Livermore Alex Kondo Brian Levy Jennifer S. Rosenberg

INSTITUTE FOR POLICY INTEGRITY
NEW YORK UNIVERSITY SCHOOL OF LAW