

## A Proposed Framework for Evidence-Based Regulation

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### ABSTRACT

The systematic application of evidence-based approaches to improve policymaking has received serious treatment by both scholars and policymakers, but its successful implementation to improve regulatory outcomes requires a separate framework. Regulation is a distinct subset of federal policymaking that must be evaluated differently from other policy areas—particularly considering that many of the existing recommendations to improve the use of evidence are

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<sup>1</sup> This working paper reflects the views of the author, and does not represent an official position of the GW Regulatory Studies Center or the George Washington University. The Center's policy on research integrity is available at <http://regulatorystudies.columbian.gwu.edu/policy-research-integrity>.

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undesirable, or even illegal, when applied to the rulemaking process. Because evidence-based recommendations need to be tailored to the context of regulatory agencies, we propose the use of an Evidence-Based Regulation (EBR) framework. An EBR process plans for, collects, and uses evidence throughout the life a regulation to predict, evaluate, and improve outcomes.

This paper begins by detailing how the regulatory process differs from other federal policymaking and establishes our EBR framework. We proceed by discussing the main barriers that regulatory agencies face in implementing an EBR approach: 1) agency noncompliance with internal administrative requirements, 2) inadequate funding for evaluation of the outcomes of regulation, and 3) the complex nature of using data to build evidence. We also advance concrete proposals for overcoming these barriers; our policy prescriptions for implementing EBR balance stricter oversight with increased flexibility for regulatory agencies.

## **TABLE OF CONTENTS**

I.	Introduction to Evidence-Based Regulation (EBR) .....	3
A.	The Regulatory Process Differs from Other Policymaking .....	3
B.	A Framework for Evidence-Based Regulation .....	5
II.	Challenges, Barriers, and Policy Prescriptions .....	6
A.	The Challenge of Noncompliance with Internal Directives .....	7
B.	Solving Noncompliance through Independent Review, Codification, and Competition.....	9
i.	Strengthening Independent Review .....	10
ii.	Codification of Accepted Practices .....	11
iii.	Changing Incentives by Creating Competition .....	12
C.	The Problem of Inadequate Funding .....	13
D.	Three Possible Solutions to the Problem of Inadequate Funding .....	14
i.	Allowing Greater Flexibility in Agency Budgets .....	14
ii.	Setting Aside Funding for Evaluation .....	14
iii.	Tailoring Evaluation to the Context .....	15
E.	The Challenge of Using Data to Generate Evidence .....	15
i.	Data and Findings Must be separated from Policy .....	16
ii.	Muddled Fact and Policy Causes Problems .....	18
F.	Clear Separation and Broad Access Addresses This Problem.....	18
i.	Access to Evidence Organized by ‘Program Theory’ Could Benefit Regulators .....	19
III.	Institutionalizing Retrospective Review as a Cornerstone of Rulemaking .....	20
IV.	Overly Prescriptive Analytical Requirements Should be Avoided .....	23
A.	Experiment and Evaluate Different Regulatory Approaches .....	24
V.	Conclusion .....	25
VI.	Recommendations for Implementing an Evidence-Based Regulation Framework .....	26

## I. Introduction to Evidence-Based Regulation (EBR)

Regulation may have a larger impact on society than any other single federal policymaking process. Regulations protect public health, promote economic growth, and help preserve our environment. However, various estimates of regulation's costs on society vary from over \$260 billion to over \$2 trillion.<sup>5</sup> By comparison, the total cost of all federal funding for research and development, for instance, is less than \$160 billion a year.<sup>6</sup> The size and scope of this impact necessitates a careful evaluation of how regulatory resources are allocated and their ultimate effects.<sup>7</sup> We posit that the results of these evaluations can be improved given that they are: 1) informed by evidence-based approaches and 2) sensitive to the existing administrative constraints and requirements that distinguish the regulatory process from other forms of government policymaking.

### A. The Regulatory Process Differs from Other Policymaking

When considering strategies to build better evidence-based programs and policies throughout government, it is vital to understand the regulatory policymaking process already includes numerous requirements regarding the collection, use, and accessibility of data that differ from those in other policymaking processes. Scholars and practitioners have produced insightful work detailing approaches to expand the use of evidence in federal policymaking, but the promising practices they advance tend to focus on the evaluation of programs rather than regulations.<sup>8</sup> As we describe throughout this article, the federal regulatory process is a distinct policy process that requires a tailored approach for successful implementation of evidence-enhancing strategies.

This is partly a function of the unique data constraints placed on regulatory policymaking. In some situations, a recommendation that may benefit most methods of policymaking may be undesirable, or even illegal, in the rulemaking process.<sup>9</sup> For instance, certain agencies looking to

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<sup>5</sup> Maeve P. Carey, Congressional Research Service, *Methods of Estimating the Total Cost of Federal Regulations*, 2 (Jan. 21 2016). Available at <https://www.fas.org/sgp/crs/misc/R44348.pdf>

<sup>6</sup> American Association for the Advancement of Science, *Historical Trends in Federal R&D*, (June 22, 2016). Available at <https://www.aaas.org/page/historical-trends-federal-rd>

<sup>7</sup> Reeve T. Bull, Building a Framework for Governance: Retrospective Review and Rulemaking Petitions, 67 ADMIN. L. REV. 265 (2015); Sofie E. Miller & Susan E. Dudley, Regulatory Accretion: Causes and Possible Remedies, 67 ADMIN. L. REV. ACCORD 2.

<sup>8</sup> See, for instance, The Commission on Evidence-Based Policymaking, THE PROMISE OF EVIDENCE-BASED POLICYMAKING (2017),

<sup>9</sup> See, for example, the discussion of the Paperwork Reduction Act (PRA) in Miller, 2015. SOFIE E. MILLER, GEO. WASH. UNIV. REG. STUDIES CTR., LEARNING FROM EXPERIENCE: RETROSPECTIVE REVIEW OF REGULATIONS IN 2014 15 (2015), [https://regulatorystudies.columbian.gwu.edu/sites/regulatorystudies.columbian.gwu.edu/files/Retrospective%20Review%20in%202014\\_MillerS\\_11\\_3.pdf](https://regulatorystudies.columbian.gwu.edu/sites/regulatorystudies.columbian.gwu.edu/files/Retrospective%20Review%20in%202014_MillerS_11_3.pdf). The Administrative Conference of the United

bolster their use of evidence might seek out particular types of data and experts in order to help determine where federal grants may have the greatest impact. However, regulatory agencies that follow formal or adjudicatory rulemaking procedures may be subject to charges of inappropriate *ex parte* communication if they undertook the same action.<sup>10</sup> Even for informal notice-and-comment rulemaking, final actions are often subject to litigation,<sup>11</sup> which places additional constraints on the evidence in the record. In short, recommendations to improve the use of evidence-based approaches to regulation must be tailored to regulatory agencies.<sup>12</sup>

For instance, the Administrative Procedure Act of 1946<sup>13</sup> (APA) requires regulatory agencies to both disclose, as well as request from the public, data or other information pertinent to a rulemaking.<sup>14</sup> Likewise, the APA compels agencies to justify most regulatory decisions based on the data, analyses, and other information collected and made part of a publicly available record. If, for instance, a decision appears “arbitrary and capricious” compared to the evidence in the public record the resulting regulation may be vacated.<sup>15</sup>

The APA is not the only important mandate affecting the collection, dissemination, and analysis of data during regulatory policymaking. Other requirements unique to regulations include, but are not limited to:<sup>16</sup>

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States (ACUS) noted in its 2014 recommendation that “agencies should be mindful of the potential applicability of the Paperwork Reduction Act” when devising plans for retrospective review. Admin. Conference of the United States, *Admin. Conference Recommendation 2014-5: Retrospective Review of Agency Rules* (December 4, 2014). Available at [https://www.acus.gov/sites/default/files/documents/Recommendation%25202014-5%2520%2528Retrospective%2520Review%2529\\_1.pdf](https://www.acus.gov/sites/default/files/documents/Recommendation%25202014-5%2520%2528Retrospective%2520Review%2529_1.pdf)

<sup>10</sup> Unlike designing a grant program, the prohibition of *ex parte* contact during certain rulemakings recognizes that making regulations can have the character of an adjudication with a decision ‘on the record’ by an impartial decision-maker. Because such contacts may not be monitored, they create a risk that the decision-maker’s neutrality may be compromised. See Edward Rubin, *It’s Time to Make the Administrative Procedure Act Administrative*, 89 CORNELL L. REV. 95 (2003) Available at <http://scholarship.law.cornell.edu/cgi/viewcontent.cgi?article=2940&context=clr>

<sup>11</sup> See, for instance, on the prevalence of private litigation and the U.S. federal regulatory process at Sean Farhang, *The Litigation State* (2010).

<sup>12</sup> ACUS similarly recommended in 1995 that “processes for review of existing regulations should not be “one-size-fits-all,” but should be tailored to meet agencies’ individual needs” and that the scope of retrospective review should be determined by agency-specific circumstances. United States. Admin. Conference of the United States, *Admin. Conference Recommendation 95-3: Review of Existing Agency Regulations* (June 15, 1995). Available at <https://www.acus.gov/sites/default/files/documents/95-3.pdf>

<sup>13</sup> PUB.L. NO. 79–404, 60 Stat. 237.

<sup>14</sup> See, for instance, the requirements to disclose information at 5 U.S.C. § 552(a) and to request information at 5 U.S.C. § 553(c).

<sup>15</sup> 5 U.S.C. § 706(2)(A).

<sup>16</sup> This list is adapted with permission and updated from SUSAN E. DUDLEY & JERRY BRITO, *The Geo. Wash. Uni. Reg. Studies Ctr., and The Mercatus Ctr. REGULATION: A PRIMER*, 45-7 (2d ed. 2012).

- The Regulatory Flexibility Act of 1980 which requires agencies collect and assess data regarding the effect of major proposed regulations on small businesses;
- The Unfunded Mandates Reform Act of 1995 which established a requirement to collect and analyze data regarding certain regulatory burdens on state and local governments;
- The Small Business Regulatory Enforcement Fairness Act of 1996 requiring *ex ante* evaluations of the impact of certain regulations on small businesses;
- The Congressional Review Act of 1996 requiring the submission of certain regulatory data and documentation to Congress;
- The Truth in Regulating Act of 2000 allowing Congress to request the Government Accountability Office (GAO) evaluate certain proposed and final rules;
- Executive Orders 12,866, 13,563 and 13,579, as well as the Office of Management and Budget’s Circular A-4 regarding analyses that must be performed before certain rulemakings can be proposed or finalized;
- These Executive Orders and Executive Order 13,610 also encourage agencies to perform *ex post* reviews of the effectiveness of regulations; and
- Executive Orders 13,771 and 13,777, which instruct agencies to remove two rules for each new significant rule issued and create task forces to evaluate existing regulations, respectively.

In addition, there are other laws affecting data collection and use which, while not unique to the regulatory process, originated due to concerns regarding regulations. Such laws include the Paperwork Reduction Act of 1980<sup>17</sup> (affecting the government collection of information) and the Information Quality Act of 2000<sup>18</sup> (which established minimum requirements for the utility, integrity, and objectivity of information used by government).

## **B. A Framework for Evidence-Based Regulation**

Regulators should be able to demonstrate they are benefitting peoples’ lives by creating policies that address a “compelling public need,” as directed by Executive Order 12,866.<sup>19</sup> Increasing the use of evidence within the rulemaking process will make agencies smarter, improve regulatory decisions, and, ultimately, result in better outcomes for society. Recognizing this, we offer the following integrated framework describing a system that produces evidence-based regulation

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<sup>17</sup> PUB.L. NO. 96-511, 94 Stat. 2812.

<sup>18</sup> PUB.L. NO. 106-554, 114 Stat. 2763.

<sup>19</sup> EXEC. ORDER NO. 12,866, 58 Fed. Reg. 51735 (Sept. 30, 1993).

(EBR) (see box below). *An EBR process plans for, collects, and uses evidence throughout the life of a regulation to predict, evaluate, and improve outcomes.*

The framework is structured around the three main phases of regulating: design, decision-making, and retrospective review. It creates a feedback loop (through retrospective review) during implementation of the rule so that data are not only used in developing the regulation but also in periodically reassessing its value and modifying the rule as appropriate. Notably, this framework incorporates important and current requirements of the federal rulemaking process pertinent to the collection and use of data.

## **Evidence-Based Regulation Framework**

### **I. Regulatory Design**

- A. Identify the problem (state the “compelling public need”).
- B. Evaluate whether modifications to existing rules can address the problem.
- C. Identify and assess available alternatives to direct regulation.
- D. If regulating, determine that the preferred alternative addresses the problem.
- E. Set clear performance goals and metrics for outputs and outcomes.
- F. Exploit opportunities for experimentation.
- G. Plan and budget for retrospective review.

### **II. Regulatory Decision-making**

- A. Assess the expected benefits, costs, and other impacts.
- B. Clearly separate scientific evidence from policy judgments.
- C. Make relevant data, models and assumptions available to the public.

### **III. Retrospective Review**

- A. Reassess planned retrospective review and modify if necessary.
- B. Gather necessary data on regulatory outputs and outcomes.
- C. Implement retrospective review plan.
- D. Compare measured outcomes to original performance goals.
- E. Reassess the rule using new information and the factors in the regulatory design.

## **II. Challenges, Barriers, and Policy Prescriptions**

The following sections identify several types of challenges and existing barriers that agencies face in expanding their use of evidence in the regulatory process. We identify each in turn and suggest concrete proposals to improve regulation using an EBR framework. These issues

include: agency noncompliance with internal administrative requirements, inadequate funding of program evaluation, the complex nature of using data to build evidence, difficulties in conducting truly effective retrospective review, and determining appropriate research designs. In addition to the following in-depth treatment of each issue, we summarize our policy recommendations in Appendix A.

## A. The Challenge of Noncompliance with Internal Directives

One barrier to evidence-based regulation is a lack of faithful compliance with internal administrative requirements.<sup>20</sup> For instance, since 1981 presidents have required regulators who were considering a new regulation to identify and disclose the problem they intended to solve by regulating and assess different regulatory alternatives to solving that problem (these are items I.A. and I.C. under “Regulatory Design” in the EBR Framework shown above). In addition, each president since Jimmy Carter has required regulators to assess and disclose both the expected benefits and the expected costs of the regulatory alternatives<sup>21</sup> (the estimation of both benefits and costs is shown in item II.A. in the EBR Framework).

Identifying the problem to be solved is a prerequisite for designing a regulation that provides net social benefits<sup>22</sup> and for evaluating the effectiveness of a rulemaking once it is in place.<sup>23</sup> Absent a clearly identified market failure, regulation and other forms of government intervention can disrupt competition and lead to misallocation of resources.<sup>24</sup> Thus, targeting a fundamental problem rather than relying on anecdotes to support regulation is important, not only for regulatory design but for knowing what data to collect. Likewise, laying out policy alternatives<sup>25</sup> and using data to assess expected benefits and costs<sup>26</sup> is a fundamental method of informing

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<sup>20</sup> See, for instance, Colin Kirkpatrick and David Parker (eds). *Regulatory Impact Assessment: Towards Better Regulation?* (2007).

<sup>21</sup> See, for instance, EXEC. ORDER NO. 12,044, 43 Fed. Reg. 12661 (March 24, 1978).

<sup>22</sup> According to EXEC. ORDER NO. 12,866, 58 Fed. Reg. 51735 (Sept. 30, 1993) (“Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.”).

<sup>23</sup> Miller, *supra* note 9

<sup>24</sup> Office of Management and Budget, *Circular A-4: Regulatory Analysis* (Sept. 17, 2003). Available at [https://www.whitehouse.gov/omb/circulars\\_a004\\_a-4](https://www.whitehouse.gov/omb/circulars_a004_a-4)

<sup>25</sup> EXEC. ORDER NO. 12,866, 58 Fed. Reg. 51735 (Sept. 30, 1993) states, (“Each agency shall identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.”).

<sup>26</sup> EXEC. ORDER NO. 12,866, 58 Fed. Reg. 51735 (Sept. 30, 1993) states, (“Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.”).

decision-makers. Nonetheless, in 2014 GAO estimated that less than a fourth of new significant rules complied with these four basic presidential requirements.<sup>27</sup>

A more recent example of agency noncompliance with internal administrative requirements regards the retrospective review of regulations (items I.G. and III. in the EBR Framework).<sup>28</sup> Every president since Jimmy Carter has required the *ex post* evaluation of regulations (retrospective review).<sup>29</sup> Most regulatory decisions rely on predictive models and assumptions, but rarely are those hypotheses evaluated based on real world evidence.<sup>30</sup> A requirement to evaluate whether predicted effects of regulations were realized would provide a powerful incentive to improve *ex ante* regulatory impact analyses, as well as improve regulations that are already in place.<sup>31</sup>

With this in mind, in 2011 and 2012 President Barack Obama signed three Executive Orders attempting to get agencies to more aggressively adopt retrospective review of regulations: Executive Order 13,563 “Improving Regulation and Regulatory Review,”<sup>32</sup> which reinforced the requirements of Executive Order 12,866; Executive Order 13,579,<sup>33</sup> which expanded the requirements to independent regulatory agencies; and Executive Order 13,610, which emphasized that “further steps should be taken...to promote public participation in retrospective review.”<sup>34,35</sup> However, an independent review of high-impact rules issued in 2014 found that the key requirements in these directives were seldom followed.<sup>36</sup>

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<sup>27</sup> Government Accountability Office, *Federal Rulemaking: Agencies Included Key Elements of Cost Benefit Analysis, but Explanations of Regulations’ Significance Could Be More Transparent*, 18 (Sept. 2014). Available at <http://www.gao.gov/assets/670/665745.pdf>

<sup>28</sup> Bull, *supra* note 7

<sup>29</sup> JOSEPH E. ALDY, ADMIN. CONFERENCE OF THE UNITED STATES LEARNING FROM EXPERIENCE, 6, (2014). <https://www.acus.gov/sites/default/files/documents/Aldy%2520Retro%2520Review%2520Draft%252011-17-2014.pdf>.

<sup>30</sup> See, for instance, on the challenges of conducting rigorous ex-post evaluation of regulatory outcomes SUSAN E. DUDLEY, THE GEO. WASH. UNI. REG. STUDIES CTR., *Retrospective Evaluation of Chemical Regulations*, OECD Environmental Working Papers 118 (2017).

<sup>31</sup> SUSAN E. DUDLEY, THE GEO. WASH. UNI. STUDIES CTR., *A Retrospective Review of Retrospective Review*, 2 (May 2013). Available at <http://regulatorystudies.columbian.gwu.edu/files/downloads/20130507-a-retrospective-review-of-retrospective-review.pdf>

<sup>32</sup> EXEC. ORDER NO. 13,563 was followed by implementation guidance. See Memorandum from OIRA Administrator Cass Sunstein to the Heads of Executive Departments and Agencies, *Retrospective Analysis of Existing Significant Regulations*, (April 25, 2011). Available at <https://www.whitehouse.gov/sites/default/files/omb/memoranda/2011/m11-19.pdf>

<sup>33</sup> EXEC. ORDER NO. 13,579, 76 Fed. Reg. 41587 (July 14, 2011).

<sup>34</sup> It should be noted that, in addition to these Executive Orders, some laws require the retrospective review of certain regulations. For instance, section 812 of the Clean Air Act Amendments of 1990 requires the Environmental Protection Agency to periodically assess the benefits and costs of regulations promulgated under

For example, the identification of measurable metrics that could be subsequently used to evaluate the impacts of rules were only identified in one-third of the regulations and even fewer for rules issued by independent agencies. To be clear, this is not a recent problem. As a general matter, such levels of noncompliance with presidential Executive Orders and other internal Executive Branch guidance in modern times are not unusual.<sup>37</sup>

More recently, President Donald Trump signed two Executive Orders providing agencies with incentives for conducting retrospective review and instructing them to identify rules for removal based on review. Executive Order 13,771, “Reducing Regulation and Controlling Regulatory Costs,” requires agencies to identify two regulations for removal for every new significant regulation issued by Executive Branch agencies.<sup>38</sup> Executive Order 13,777 enforces this “two-for-one” policy by establishing regulatory reform task forces within executive agencies to implement EOs 13,563 and 13,771 and evaluate existing rules and make recommendations for reform.<sup>39</sup>

### C. Solving Noncompliance through Independent Review, Codification, and Competition

In examining how to improve the performance of people working in government bureaucracies, management expert William Medina has laid out three ways to change behavior.<sup>40</sup>

- compel them (forced change);
- persuade them (through education); and/or
- change their incentives.

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the Act.

<sup>35</sup> EXEC. ORDER NO. 13,610, 77 Fed. Reg. 28469 (May 10, 2012).

<sup>36</sup> SOFIE E. MILLER, THE GEO. WASH. UNI. REG. STUDIES CTR. *Learning from Experience: Retrospective Review of Regulations in 2014*, (Nov. 2015). Available at [https://regulatorystudies.columbian.gwu.edu/sites/regulatorystudies.columbian.gwu.edu/files/Retrospective%20Review%20in%202014\\_MillerS\\_11\\_3.pdf](https://regulatorystudies.columbian.gwu.edu/sites/regulatorystudies.columbian.gwu.edu/files/Retrospective%20Review%20in%202014_MillerS_11_3.pdf). As a general matter, other researchers have also concluded that there is generally a lack of compliance with retrospective review requirements. See Reeve T. Bull, *Building a Framework for Governance: Retrospective Review and Rulemaking Petitions*, 67 ADMIN. L. REV. 265 (2015).

<sup>37</sup> See, for instance, the lack of compliance with eight government-wide reforms since 1965 discussed in MARCUS C. PEACOCK, THE GEO. WASH. REG. STUDIES CTR., *Improving the Accountability of Federal Regulatory Agencies Part II: Assessing Eight Government-wide Accountability Reforms*, (June 28, 2016). Available at [https://regulatorystudies.columbian.gwu.edu/sites/regulatorystudies.columbian.gwu.edu/files/downloads/RegInsight\\_Peacock-Reforms-Improving-Accountability\\_pt2.pdf](https://regulatorystudies.columbian.gwu.edu/sites/regulatorystudies.columbian.gwu.edu/files/downloads/RegInsight_Peacock-Reforms-Improving-Accountability_pt2.pdf)

<sup>38</sup> EXEC. ORDER NO. 13,771, 82 Fed. Reg. 9339 (January 30, 2017).

<sup>39</sup> EXEC. ORDER NO. 13,777. 82 Fed. Reg. 12285 (February 24, 2017).

<sup>40</sup> William A. Medina, *Changing Bureaucracies: Understanding the Organization Before Selecting the Approach*, 118-9 (1982).

A recent review of a lack of faithful compliance of government-wide reforms aiming to improve compliance within U.S. federal agencies over a period of fifty years found three possible ways to improve behavior: create independent organizations to help execute the rules; codify administrative requirements into law; and create competition.<sup>41</sup> The first two methods force change while the third attempts to change incentives.

### ***i. Strengthening Independent Review***

There are many examples of governments tackling the problem of internal noncompliance by creating independent organizations to either monitor compliance (such as the Inspectors General) or to faithfully execute the requirements themselves. A specific example of the latter strategy is found in the European Union (EU).<sup>42</sup> Concerns regarding a lack of compliance with internal guidelines requiring the self-evaluation of the effectiveness of policies<sup>43</sup> resulted in the EU creating a separate *ex post* evaluation body. This new organization is completely independent from the member nations and reports directly to the European Parliament.<sup>44</sup>

Independent review does not necessarily entail creating a new entity. For instance, one approach could be to enlist the U.S. court system to improve compliance. Judicial review has been largely successful in achieving compliance with the public notice and evidentiary requirements codified in the APA.<sup>45</sup> Agencies know their regulations can be nullified unless they can convince a court that the standards of transparency and assessment set out in the APA have been met. Expanding the existing judicial review of regulations to include one or more elements of the EBR Framework, such as determining whether a final rule includes an adequate plan for retrospective review, would undoubtedly improve compliance with those elements. For instance, Cass

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<sup>41</sup> See MARCUS PEACOCK, THE GEO. WASH. UNI. REG. STUDIES CTR., *Improving the Accountability of Federal Regulatory Agencies Part III: What Reforms Work Best*, 22 (Sept. 12, 2016). Available at <https://regulatorystudies.columbian.gwu.edu/improving-accountability-federal-regulatory-agencies-part-iii-what-reforms-work-best>

<sup>42</sup> CÉLINE KAUFFMANN, THE GEO. WASH. UNI. REG. STUDIES CTR., *The OECD Perspective on Good Regulatory Practices and International Regulatory Cooperation*, (Dec. 19, 2014). , Available at <https://regulatorystudies.columbian.gwu.edu/oecd-perspective-good-regulatory-practices-and-international-regulatory-cooperation>

<sup>43</sup> See, in particular, Court of Auditors, Special Report No. 1/2006 on the contribution of the European Social Fund in combating early school leaving, together with the Commission's replies, C 99 O.J. 01 (2006). This audit found that agencies allocating funding for the purpose of keeping students in school generally did not utilize readily available performance data.

<sup>44</sup> This is the Ex Post Impact Assessment Unit in the European Parliamentary Research Service. See European Parliament, *Evaluation and ex-post impact assessment at EU level*, (Sept. 2016). Available at [http://www.europarl.europa.eu/RegData/etudes/BRIE/2016/581415/EPRS\\_BRI\(2016\)581415\\_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/BRIE/2016/581415/EPRS_BRI(2016)581415_EN.pdf)

<sup>45</sup> *Supra*, note 6.

Sunstein notes that whenever a statute authorizes a regulatory agency to use benefit-cost analysis to estimate whether a regulation is likely to increase social welfare and it chooses not to use this approach, courts can find that the agency acted arbitrarily (in violation of the APA).<sup>46</sup> Relying on the courts would also avoid the cost of creating a new entity within the federal government.

## *ii. Codification of Accepted Practices*

Another approach to motivating agencies to comply with internal administrative requirements is to codify such requirements in law. For instance, the last section below includes a recommendation that elements of the EBR Framework that have been adopted by consecutive presidents over a long period of time be more firmly institutionalized by putting them in law. This would be an incremental step in improving compliance, as it would increase their permanence and subject compliance to greater oversight—particularly by Congress.

For example, Senators Heidi Heitkamp (D-N.D.) and James Lankford (R-Okla.) have proposed the Smarter Regulations Act<sup>47</sup> which would require agencies to include in major rules a framework for reassessing the rule, including the timeframe for reassessment,<sup>48</sup> the metrics that should be used to gauge efficacy,<sup>49</sup> and a plan to gather relevant data to compile these metrics.<sup>50</sup> The framework established in this proposed legislation was approved by a Senate committee by voice vote in October 2015 and was reported out of committee with an amendment in June 2016 during the 114<sup>th</sup> Congress.<sup>51</sup> The bill is consistent with the EBR Framework and our recommendation below.

More recently, the House passed the Searching for and Cutting Regulations that are Unnecessarily Burdensome Act (SCRUB Act)<sup>52</sup> which would establish a Retrospective Regulatory Review Commission to review and identify existing regulations for repeal. The SCRUB Act would also require new rules to include a prospective plan for retrospective review<sup>53</sup> and would facilitate judicial review of agency compliance with these review provisions.<sup>54</sup>

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<sup>46</sup> CASS R. SUNSTEIN, COST-BENEFIT ANALYSIS AND ARBITRARINESS REVIEW. Harvard Pub L. Working Paper 16-12 (2016).

<sup>47</sup> SMARTER REGS ACT OF 2015, S. 1817, 114<sup>th</sup> Cong. (2015).

<sup>48</sup> S. 1817, § 2(f)(1)(D).

<sup>49</sup> S. 1817, § 2(f)(1)(B).

<sup>50</sup> § 2(f)(1)(C).

<sup>51</sup> For more information on S. 1817 see <https://www.congress.gov/114/crpt/srpt282/CRPT-114srpt282.pdf>

<sup>52</sup> SEARCHING FOR AND CUTTING REGULATIONS THAT ARE UNNECESSARILY BURDENSOME ACT OF 2017, H.R. 998, 115<sup>th</sup> Cong. (2017)

<sup>53</sup> H.R. 998, §301

<sup>54</sup> H.R. 998, §401

### iii. *Changing Incentives by Creating Competition*

It would be a mistake to assume that creating an independent organization or codifying best practices would completely solve the problem of unfaithful execution. For instance, presidents have relied on the Office of Information and Regulatory Affairs (OIRA) in the U.S. Office of Management and Budget (OMB), in part, to better enforce administrative benefit-cost analysis requirements on regulatory agencies. Yet compliance with these standards remains far from perfect.<sup>55</sup>

In addition to relying on independent organizations and codification to help defeat unfaithful execution, it may be effective to change the incentives of federal agencies by making them compete with each other or other entities. Competition has long been recognized as an extremely powerful motivator of federal agencies.<sup>56</sup> While it may not seem obvious, federal agencies already compete with each other. For instance, they are in constant and robust competition to maintain or increase their budgets. As proof of competition's effects, this long running competition for funding has resulted in a panoply of clever budget strategies.<sup>57</sup>

One way to create a healthy competition among federal agencies is to use comparison data. While their effects may vary, comparison data have been shown to be a strong motivator in state governments<sup>58</sup> particularly if the data are accessible and trustworthy. Indeed, federal agencies themselves are increasingly using comparison data to change the incentives of the entities they regulate including everything from colleges<sup>59</sup> to nursing homes<sup>60</sup> to chemical manufacturers.<sup>61</sup> One idea would be to look for federal programs that have very similar goals but achieve them in different ways, such as through grants, regulations, tax credits, and/or loan guarantees.<sup>62</sup> A third

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<sup>55</sup> Patrick McLaughlin et al., *Continuity, Change, and Priorities: The Quality and Use of Regulatory Analysis Across U.S. Administrations*, 7 REGUL. GOV. 2, 153-73 (Aug. 13, 2012). Available at <http://onlinelibrary.wiley.com/doi/10.1111/j.1748-5991.2012.01149.x/full>

<sup>56</sup> See, for instance, William A. Niskanen, *Competition among Government Bureaus*, IN CAROL H. WEISS & ALLEN H. BARTON (EDS.) MAKING BUREAUCRACIES WORK, 167-74 (1980).

<sup>57</sup> Aaron Wildavsky, *The Politics of the Budgetary Process*, 64-84 (4th ed. 1984).

<sup>58</sup> See E. Blaine Liner et al., The Urban Institute, *Making Results-based Government Work*, 18 (April 2001). Available at <http://www.urban.org/sites/default/files/alfresco/publication-pdfs/310069-Making-Results-Based-GovernmentWork.PDF>

<sup>59</sup> The U.S. Department of Education *College Scorecard*, Available at <https://collegescorecard.ed.gov/>

<sup>60</sup> The Medicare program's *Nursing Home Compare* Available at <https://www.medicare.gov/NursingHomeCompare/About/Ratings.html>

<sup>61</sup> Jason Scorse, Penn State University, *Do Pollution Rankings Affect Facility Emissions Reductions?: Evidence From The Toxic Release Inventory (2003)*. Dissertation available at <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.511.173&rep=rep1&type=pdf>

<sup>62</sup> Budget subfunctions may be a method for narrowing these programs down. See <https://www.whitehouse.gov/tax-receipt/functions>

party, GAO, for instance, could then collect data regarding the efficiency of each program and rank the various programs on this criterion. This may mean, for instance, estimating the reduction in greenhouse gas emissions for every dollar spent on abatement, or estimating the quantity and quality of environmentally sensitive land set-aside from agricultural production for every dollar given to farmers.

One might initially expect large differences in the results agencies achieve. For instance, both the Center for Disease Control (CDC) and the Environmental Protection Agency (EPA) have regulatory programs to reduce instances of lung cancer: CDC by discouraging smoking, and EPA by targeting the indoor pollutant radon. However, a 2017 back-of-the-envelope analysis found that CDC's regulatory programs are significantly more cost-effective than EPA's at reducing lung cancer because radon causes lung cancer primarily in individuals who already smoke.<sup>63</sup> The periodic publication of such data from a reliable source could result in agencies having strong incentives to collect, analyze, and act on evidence to improve their program and achieve a better ranking.<sup>64</sup> Evidence-based policymaking could become the method by which agencies in compete in a "race to the top."

#### **D. The Problem of Inadequate Funding**

Another barrier to evidence-based regulation is funding for *ex ante* and *ex post* analysis and evaluation. Like the barrier of noncompliance, this problem is not unique to EBR but can block the collection and evaluation of data regardless of program. It may be that some of the substantial resources currently spent on *ex ante* regulatory review could be more prudently shifted to conducting a retrospective review of federal rules. Such a reallocation could in turn strengthen *ex ante* analyses by providing direct information on the causal outcomes one would expect as the result of regulatory policy.<sup>65</sup>

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<sup>63</sup> Richard Williams found that CDC's campaign cost \$540 per case of lung cancer avoided vs. a cost of \$10.7 million per case for programs targeting radon emissions. Richard Williams, LNT AND ECONOMIC ANALYSIS, SOCIETY FOR RISK ANALYSIS CONFERENCE: M4-A BENEFITS, COSTS, AND RISKS FOR HEALTH ENVIRONMENT (2017).

<sup>64</sup> In some respects, the *Best Places to Work in the Federal Government* rankings released by the Partnership for Public Service provide a model for such a system of comparison. Available at <http://bestplacetowork.org/BPTW/>

<sup>65</sup> SUSAN E. DUDLEY, THE GEO. WASH. UNI. REG. STUDIES CTR., *Retrospective Evaluation of Chemical Regulations*, OECD Environmental Working Papers 118 (2017).

## E. Three Possible Solutions to the Problem of Inadequate Funding

### i. Allowing Greater Flexibility in Agency Budgets

One means of accomplishing this goal without significantly altering the federal budget is for Congress and OMB to more readily allow the reallocation of resources from current *ex ante* regulatory impact analyses to gathering the data and evaluation tools necessary to subsequently test *ex ante* predictions. This may simply require the appropriation of less “one-year money” and more “multi-year money” to allow agencies greater flexibility in when they use their budget authority.<sup>66</sup> Currently, the vast majority of funding for analyses is spent upfront and very little is used after rules are promulgated. It seems extremely unlikely this is an optimal balance.

### ii. Setting Aside Funding for Evaluation

Another possible solution is to allow, or require, a small percentage of funds be set aside for program evaluation or for policies based on program evaluation. This is not unprecedented. In 1978 Congress allowed the U.S. Department of Agriculture (USDA) to set aside up to 0.5 percent of the program funds allocated for its Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) to evaluate the program’s performance, including experimenting with different pilot projects.<sup>67</sup> More recently, the Senate Appropriations Bill for FY 2014 allowed five percent of mental health block grants to states be used for “evidence-based programs that address the needs of individuals with early serious mental illness, including psychotic disorders.”<sup>68</sup>

Constrained budgets tend to result in agencies “curtailing the funds needed for evaluation studies and performance monitoring systems.”<sup>69</sup> However, there is considerable evidence that the use of evaluation not only leads to improved regulatory outcomes, but also provides additional benefits for nonregulatory agencies—particularly those operating in an environment of stagnant or decreasing budgets. For example, Newcomer *et al.* detail several instances where the results of evaluation data on program performance caused agencies to shift funding and effort away from less successful programs towards better-performing initiatives. The data made available to Congress regarding success in achieving outcomes allowed agencies to maintain or even expand their programs during periods of significant cuts in federal domestic spending during the 1980s.

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<sup>66</sup> “One-year money” is budget authority that expires at the end of the fiscal year in which it was appropriated.

<sup>67</sup> Kathryn E. Newcomer, Harry P. Hatry & Joseph S. Wholey (eds). *Handbook of Practical Program Evaluation*, 807 (2015).

<sup>68</sup> S. REP. 113-71, 114 (2013).

<sup>69</sup> NEWCOMER ET AL., *supra* at 807.

These programs included the Department of Labor’s Job Corps program and the aforementioned WIC program at USDA.<sup>70</sup>

### ***iii. Tailoring Evaluation to the Context***

Finally, it is important to note that the cost of both *ex ante* and *ex post* analyses and evaluation need not be high. An important principle is that the cost of conducting a regulatory analysis should reflect the potential value of such analysis and, if necessary, can be quite inexpensive.<sup>71</sup> Joseph Wholey proposes that evaluators use “a sequential purchase of information” approach such that “resources are invested in further evaluation only when the likely usefulness of the new information outweighs the costs of acquiring it.”<sup>72</sup> EBR would benefit from such flexible standards regarding what constitutes useful analysis and evaluation.<sup>73</sup>

## **F. The Challenge of Using Data to Generate Evidence**

In regulatory processes agencies are compelled, with narrow exceptions, to make data, analysis, and other evidence used by decision-makers available to the public.<sup>74</sup> As noted above, agencies must place information they use in decision-making in a public record and justify their decisions based on the evidence in that record.<sup>75</sup>

We support the bedrock regulatory principle of openness, and this is reflected in item II.C. of the EBR Framework under Regulatory Decision-making. With regards to information that will be used to make regulatory decisions, as much information as possible should be made widely available to the public. The public has a right to know what evidence policy officials consider in making decisions that affect them.

We offer two suggestions to improve the use of data, research results, and findings from evaluation in the regulatory process. The first relates to the need for transparency in regulatory decision-making. The second regards how evidence may be best organized to promote its best use.

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<sup>70</sup> NEWCOMER ET AL., *supra* at 829.

<sup>71</sup> Christopher Carrigan & Stuart Shapiro, What’s wrong with the back of the envelope? A call for simple (and timely) benefit–cost analysis. 11 REGUL. GOV. 2. 203-12 (April 26, 2016).

<sup>72</sup> NEWCOMER ET AL., *supra* at 89. This approach is one of several suggestions contained within Wholey’s framework of Evaluability Assessment which proposes several techniques for evaluators to leverage low cost information for substantive program improvement.

<sup>73</sup> See, for example, the recommendations for tailoring review to agency needs and circumstances in ACUS, *supra* note 12

<sup>74</sup> *Supra* note 8 on 5 U.S.C. § 552(a).

<sup>75</sup> *Supra* note 7.

### *i. Data and Findings Must be separated from Policy*

Regulatory agencies are generally compelled to provide the public an opportunity to submit data and other feedback on proposed regulations and consider any “relevant matter presented” in their final rulemaking.<sup>76</sup> However, the opportunity for public comment should include access to the various data, statistics, findings and other information the agency is using to make a regulatory decision. Public review can provide agencies with valuable information and insights they may not have otherwise fully considered.<sup>77</sup>

The EBR Framework addresses important guidance on how data and other evidence should be used and communicated. In particular, in regulatory decision-making the presentation of evidence should be separated from policy decisions so that the public understands what is a fact (what *is*) and what is a policy judgment (what *ought to be*).<sup>78</sup> This has important implications for public access to the data, models and assumptions used to make regulatory decisions, particularly when it comes to scientific information.

The boundary between objective science and policymaking is inherently fuzzy.<sup>79</sup> Creating clarity regarding where this boundary is and the role of scientists at this boundary is important.<sup>80</sup> In our democracy, the public must be able to hold regulatory policymakers, typically the president and his or her appointees, accountable for their decisions. It is for this reason the regulatory process already mandates requirements for policymakers to reveal and explain how they reached a regulatory decision based on publicly available evidence.<sup>81</sup> This process assumes the public is

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<sup>76</sup> *Supra* note 8 on 5 U.S.C. § 553(c).

<sup>77</sup> Public review and input address what economist Friedrich Hayek termed the local knowledge problem, wherein relevant knowledge is distributed among many participants and not fully encompassed in a single centralized policymaking entity. Friedrich A. Hayek, *The Use of Knowledge*, XXXV AMER. ECON. REV. 4, 519-30 (1945).

<sup>78</sup> Susan E. Dudley and Marcus C. Peacock, *Improving Regulatory Science: A Case Study of the National Ambient Air Quality Standards*, SUPREME COURT REV. 24 (2018 forthcoming). *See also*, The Bipartisan Policy Center provided recommendations tailored to science and regulation in a 2009 report, noting that “policy debate would be clarified and enhanced if a systematic effort were made to distinguish between questions that can be resolved through scientific judgments and those that involve judgments about values and other matters of policy when regulatory issues comprise both. This transparency would both help force values debates into the open and could limit spurious claims about, and attacks on science.” Bipartisan Policy Center, *Improving the Use of Science in Regulatory Policy*, 15 (2009). Available at <http://www.bipartisanpolicy.org/sites/default/files/BPC%20Science%20Report%20fnl.pdf>

<sup>79</sup> *See*, for instance, the discussion in Susan E. Dudley & George M. Gray, *Improving the Use of Science to Inform Environmental Regulation*, in JASON S. JOHNSON (ED.), INSTITUTIONS AND INCENTIVES IN REGULATORY SCIENCE, 165-98 (2012). *See also* Allan Mazur, *The Dynamics of Technical Controversy* (1981).

<sup>80</sup> *See* Ann Campbell Keller, *Science in Environmental Policy: The Politics of Objective Advice* (2009).

<sup>81</sup> *Supra*, note 8.

able to separate the evidence the decision-maker considered from the judgments they made. Evidence-based policy expert Ray Pawson explains:

Evidence does not deliver decisions; its function is to deliver decision support. When evidence is called into play in policy formation, it is never a case of simply ‘following the evidence’ but rather one of ‘interpreting the evidence’ and then ‘adapting the evidence’ to local circumstances. No method of synthesis can tell the policy maker what to do.<sup>82</sup>

Given both the fuzzy boundary between evidence and policy and the need to keep scientific and policy judgments as separate as possible for reasons of accountability, the solution is for regulatory agencies to be as open as possible regarding the decisions they make. Recounting his experience as the Administrator of the EPA from 1977 to 1980, Doug Costle has explained:

People tend to think science is hard and numerical and precise. It’s not, particularly in the environmental area. But there is one way, and only one way, to deal with that, and that is just to be absolutely open and honest about the gray areas. Anyway you cut it, we’re making judgments, social policy judgment calls...<sup>83</sup>

A notable example of conflating evidence and policy is application of the precautionary principle. In short, the precautionary principle advocates for the use of preemptive regulation in the face of scientific uncertainty regarding possible threats to the health of humans or ecosystems.<sup>84</sup> The application of the precautionary principle is not a purely scientific decision. Indeed, it confuses scientific uncertainty with scientific ignorance and is squarely inconsistent with an approach built on a foundation of evidence. As Ray Pawson has pointed out:

The precautionary principle betokens a move from evidence to advocacy. It forecloses debate and stifles the search for further evidence. By definition the zero

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<sup>82</sup> Ray Pawson, *Science of Evaluation: A Realist Manifesto*, 190 (2003).

<sup>83</sup> Ronald Brand et al., TRUE GREEN: EXECUTIVE EFFECTIVENESS IN THE U.S. ENVIRONMENTAL PROTECTION AGENCY, 77 (2012). In his seminal work on the fuzzy boundary between scientific evidence and policy, *Science and Trans Science*, 10 MINERVA 2, 209-22, (1972). Alvin Weinberg put it another way, (“Though the scientist cannot provide definite answers to trans-scientific questions any more than can the lawyer, the politician or a member of the lay public, he does have one crucially important role: to make clear where science ends and trans-science begins.”).

<sup>84</sup> Marco Martuzzi & J. Ann Tickner (eds.), World Health Organization, *The precautionary principle: Protecting public health, the environment and the future of our children* (2004).

emission, zero concentration, zero tolerance standards are not empirically derived—they concede that the evidence is not yet in.<sup>85</sup>

## **ii. Muddled Fact and Policy Causes Problems**

Despite the necessity of separating what *is* from a decision regarding what *ought to be*, scientific evidence and policy decisions have become increasingly muddled.<sup>86</sup> This results in a host of significant problems including degrading the perceived integrity of evidence-based policymaking. As the Bipartisan Policy Center notes:

Policy makers often claim that particular regulatory decisions have been driven by, or even required by science; their critics, in turn, have attacked the quality or the interpretation of that science. Such conflict has left the U.S. with a system that is plagued by charges that science is being “politicized” and that regulation lacks a solid scientific basis. As a result, needed regulation may be stymied, dubious regulations may be adopted, issues can drag on without conclusion and policy debate is degraded. Moreover, the morale of scientists is weakened, and public faith in both government and science is undermined.<sup>87</sup>

The Bipartisan Policy Center concludes that “a tendency to frame regulatory issues as debates solely about science, regardless of the actual subject in dispute, is at the root of the stalemate and acrimony all too present in the regulatory system today.”<sup>88</sup>

## **G. Clear Separation and Broad Access Addresses This Problem**

The EBR Framework calls for the separation of these elements during regulatory decision-making (see item II.B.). If not clearly separated, the increased use of evidence may ironically harm, rather than improve, the integrity of the regulatory process. As the Bipartisan Policy Center concluded, “the Administration needs to devise regulatory processes that, in as many situations as possible, could help clarify for both officials and the general public which aspects of disputes are truly about scientific results and which concern policy.”<sup>89</sup> “This transparency would

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<sup>85</sup> PAWSON, *supra* at 174.

<sup>86</sup> The scientific community increasingly wrestles with fact more and more scientists are being encouraged to become engaged with the public policy process. *See*, for instance, Deborah Runkle & Mark S. Frankel (ed.), *Advocacy in Science: Summary of a Workshop convened by the American Association for the Advancement of Science*, 2-3 (May 1, 2012).

<sup>87</sup> Bipartisan Policy Center, *Improving the Use of Science in Regulatory Policy*, 10 (2009). Available at <http://www.bipartisanpolicy.org/sites/default/files/BPC%20Science%20Report%20fnl.pdf>

<sup>88</sup> Bipartisan Policy Center, *supra* note 87 at 11.

<sup>89</sup> Bipartisan Policy Center, *supra* note 87 at 4.

both help force values debates into the open and could limit spurious claims about, and attacks on science.”<sup>90</sup>

Given the need to make it clear what the data show vs. what policymakers decide, the public should have as broad an access to data, statistics, results of research, and findings from evaluation as possible so that people are better able to make their own judgments regarding the interpretation of data. President Obama’s March 2009 Scientific Integrity Memo supports this goal, stating that “[t]o the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking.”<sup>91</sup>

Access to the “results of research” should include risk assessments, models, and the assumptions that were used to synthesize data for the purpose of making regulatory decisions. The National Research Council has concluded that there should be “unrestricted access” to public-use data that pose no confidentiality problems.<sup>92</sup> This category should also include any models and other analytic tools used to assess data that, by their nature, do not pose concerns about the breach of individual, household or other confidential personal information. If such a tool was used to materially inform a regulatory decision, the public should have access to that tool. As is being shown in the case of opening up competing proprietary climate change models, scrutiny from others will very likely improve the models’ credibility and accuracy and result in the data’s “best use.”<sup>93</sup>

#### ***i. Access to Evidence Organized by ‘Program Theory’ Could Benefit Regulators***

The use of evidence may also benefit from modifying the approach to how evidence is organized. Regulatory evaluations are often categorized under their substantive program area (e.g., environment, health, or education). As a practical matter this can limit the amount of data that is consulted during regulatory design and decision-making, such as during the consideration of alternatives (see item I.C. in the EBR Framework). Evaluation data could additionally be categorized under broader criteria of program theory domains. This approach groups policy interventions by the approach used to affect outcomes (e.g., incentives, target setting, or behavior change) rather than narrowly by issue-area. Consulting the widest possible range of evaluation

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<sup>90</sup> Bipartisan Policy Center, *supra* note 87 at 5.

<sup>91</sup> *Scientific Integrity*, Memorandum for the Heads of Executive Departments and Agencies from Barack Obama, 74 Fed. Reg. 10671 (March 9, 2009). Available at <https://www.gpo.gov/fdsys/pkg/FR-2009-03-11/pdf/E9-5443.pdf>

<sup>92</sup> National Research Council Panel on Data Access for Research Purposes, *Expanding access to research data: reconciling risks and opportunities*, 3 (2005).

<sup>93</sup> Paul Voosen, *Climate scientists open up their black boxes to scrutiny*, 354 SCIENCE 6311, 401-02 (Oct. 28, 2016).

data for similar program theory domains allows regulators to survey a broader knowledge base and help discover more constraints or barriers that might, for instance, limit the expected benefits or increase the expected costs of regulations.

Theoretically, existing efforts to make evaluation data available across agencies—such as in a clearinghouse, will help create a wider distribution of evidence going forward. However, grouping evidence by program theory can tie together seemingly different interventions and help regulators identify unintended consequences or important contexts to consider during their early design of potential regulatory approaches.<sup>94</sup> For example, Ray Pawson’s organizing principles of evaluation science suggest that such a level of abstraction “provides the means of establishing a common language to draw out the similarities between different interventions...to link their evaluations” and increase learning.<sup>95</sup>

An example of this is evaluations from state/local “ban the box” legislation, which prevents employers from asking prospective applicants about their criminal record with the intention of decreasing discrimination against those with a criminal record. Evaluations of these programs indicate that in several contexts they have the unintended/perverse effect of increasing discrimination against minorities, particularly African Americans.<sup>96</sup> Rather than thinking of this, conceptually, as a “lesson learned” for officials at the Department of Labor, there is a broader finding that is applicable to other federal agencies: namely, the unintended consequence of trying to incentivize certain behavior by limiting data availability. Additionally, this framework helps shift evaluation thinking from simply inquiring whether a program “works” towards the more nuanced and effective “what works for whom in what contexts.”<sup>97</sup>

### **III. Institutionalizing Retrospective Review as a Cornerstone of Rulemaking**

*Ex post* regulatory evaluation (retrospective review) is a vital and integral element of the EBR Framework (see items I.G. and III). Retrospective review advances knowledge over the mere hope that regulations are delivering the benefits society expects. However, it must be incorporated into regulatory design in order to facilitate this evaluation. Similar to other federal

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<sup>94</sup> See also Robert Merton, *On Theoretical Sociology: Five essays old and new* (1967).

<sup>95</sup> PAWSON, *supra* at 190.

<sup>96</sup> Amanda Y. Agan & Sonja B. Starr, Princeton Uni. Dept. of Econ. & Uni. of Mich. L. *Ban the Box, Criminal Records, and Statistical Discrimination: A Field Experiment*, (June 15, 2016). See also: Jennifer Doleac, Brookings Institute, ‘*Ban the Box*’ does more harm than good, (May 2016). Available at <https://www.brookings.edu/opinions/ban-the-box-does-more-harm-than-good/>

<sup>97</sup> PAWSON, *supra* at xiii.

programs, waiting until after a regulation is implemented to plan *ex post* measurement can greatly hamper retrospective review.<sup>98</sup>

Both OMB<sup>99</sup> and the Administrative Conference of the United States (ACUS) have recommended that agencies design their rules prospectively for retrospective analysis. For instance, in his report to ACUS, Joseph Aldy concludes:

Well-designed regulations should enable retrospective analysis to identify the impacts caused by the implementation of the regulation. For a given select, economically significant rule [sic], agencies should present in the rule’s preamble a framework for reassessing the regulation at a later date. Agencies should describe the methods that they intend to employ to evaluate the efficacy of and impacts caused by the regulation, using data-driven experimental or quasi-experimental designs where appropriate.<sup>100</sup>

These recommendations echo a larger body of research. For instance, in a study for the World Bank, Paul Gertler *et al.* conclude that the appropriate methods for conducting program evaluation, or retrospective review, should be identified “at the outset of a program, through the design of prospective impact evaluations that are built into the project’s implementation.”<sup>101</sup> This allows evaluators to fit their evaluation methods to the program being reviewed, and to plan for review itself through the design and implementation of the program (or regulation).

For these reasons, we have prominently included retrospective review as a necessary element of regulatory design in the EBR Framework, and we recommend this design requirement be codified in law to emphasize its importance.<sup>102</sup>

It should be noted that the strong connection between regulatory design and retrospective review also strengthens the need to complete other elements of the regulatory process in the design

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<sup>98</sup> Other reasons to plan evaluations in advance include compliance with the Paperwork Reduction Act which requires the prior approval of the U.S. Office of Management and Budget before collecting information from 10 or more members of the public. *See* 5 C.F.R. 1320.8(b)(3)(iii) (2015).

<sup>99</sup> U.S. Office of Management and Budget. 2015 Draft Report to Congress on the Benefits and Costs of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities, 7, (2015).

<sup>100</sup> Joseph E. Aldy, *Learning from Experience: An Assessment of the Retrospective Reviews of Agency Rules and the Evidence for Improving the Design and Implementation of Regulatory Policy*, 6, (2014).

<sup>101</sup> Paul J. Gertler et al., *The World Bank, Impact Evaluation in Practice*, xiii-xiv (2011).

<sup>102</sup> See section II(B)ii of this paper for a discussion of legislation that seeks to institutionalize these and similar practices for agency retrospective review.

stage. For instance, in addition to planning for retrospective review, the EBR Framework requires regulators to:<sup>103</sup>

- Identify the problem they are trying to solve.
- Evaluate whether modifications to existing rules can address the problem.
- Identify and assess available alternatives to direct regulation.
- If regulating, determine that the rule addresses the problem.
- Set clear performance goals and metrics for outputs and outcomes.
- Exploit opportunities for experimentation.

All six of these design components directly relate to retrospective review. One purpose for incorporating these components into rules at the outset is to plan for review well before much of the crucial information necessary for an effective evaluation has been generated. Otherwise, agencies may not have identified the goal(s) of the regulation much less how to collect data on the regulation's impacts.<sup>104</sup> This information is crucial for assessing how well a rule has met its intended target and the extent to which there may be other, unintended, consequences. Independent regulatory agencies especially should make greater efforts to outline what they intend for their rules to accomplish.<sup>105</sup> This transparency allows the public to know what to expect from new regulations and what observers should strive to measure to assess the success of a rule.

Although few regulations have been designed to facilitate *ex post* review, the recent driverless cars policy guidance is an example of what may be possible. In September 2016, the National Highway Traffic Safety Administration (NHTSA) released its Federal Automated Vehicles Policy<sup>106</sup> establishing how the agency will address driverless car technology through its current regulatory structure and identifying new regulatory tools that could be used in the future.

Given the state of change in automated vehicle technology, NHTSA plans to update this policy in an iterative process so as to respond to new data and technologies as they emerge. For instance, in September 2017 NHTSA published a revised draft guidance making significant

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<sup>103</sup> These components are adapted from Miller, *supra* 10.

<sup>104</sup> See, for example, the discussion of the Paperwork Reduction Act (PRA) in MILLER and ACUS *supra* note 9.

<sup>105</sup> Independent agencies are less likely than executive branch agencies to write rules that identify the problem they are intended to solve, provide metrics for assessing whether a problem has been solved, and link the proposed rule to intended outcomes. See SOFIE E. MILLER, THE GEO. WASH. UNI. REG. STUDIES CTR., *Learning from Experience: Retrospective Review of Regulations in 2014*, 18 (Nov. 2015).

<sup>106</sup> National Highway Traffic Safety Administration & the U.S. Department of Transportation, *Federal Automated Vehicles Policy: Accelerating the Next Revolution In Roadway Safety* (Sept. 2016). Available at <https://www.transportation.gov/sites/dot.gov/files/docs/AV%20policy%20guidance%20PDF.pdf>

changes from its initial policy.<sup>107</sup> This iterative approach combined with a commitment to collect and synthesize evidence as it comes in appears to reflect a thoughtful approach to regulating a new and promising technology.<sup>108</sup>

Recent Executive Orders and Trump Administration regulatory policies build on previous presidential efforts to institutionalize retrospective review. Executive Order 13,771 institutes both an incremental regulatory cost cap and a regulatory offset system in which agencies are required to “offset” the costs of each new significant regulation by removing two existing rules.<sup>109</sup> Because review is tied to the promulgation of new rules, these policies provide agencies with stronger incentives to evaluate their existing stock of regulations and determine which ones have outlived their usefulness.

#### **IV. Overly Prescriptive Analytical Requirements Should be Avoided**

The EBR Framework does not specify what types of research designs should be used in analyzing or evaluating regulations. Rather, the rigor of the analysis should match the regulatory context and the value such analysis may offer decision-makers.<sup>110</sup>

Randomized controlled trials are well-regarded tools used by program evaluators to understand the effect of different treatments on outcomes.<sup>111</sup> However, where randomized trials are not feasible, pilot studies or approaches that allow for variation in regulatory treatments can provide valuable information for evaluating outcomes and their causal links.<sup>112</sup> According to Coglianese:

Variation in observational studies can arise in one of two ways: either over time or across jurisdictions. When regulations vary over time within a single jurisdiction, researchers can compare outcomes longitudinally, that is, before and after the adoption of the regulation. When the variation exists across jurisdictions, researchers can compare outcomes cross-sectionally, that is, comparing outcomes

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<sup>107</sup> National Highway Traffic Safety Administration & the U.S. Department of Transportation, *Automated Driving Systems 2.0: A Vision for Safety* (Sept. 2017). Available at [https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/documents/13069a-ads2.0\\_090617\\_v9a\\_tag.pdf](https://www.nhtsa.gov/sites/nhtsa.dot.gov/files/documents/13069a-ads2.0_090617_v9a_tag.pdf)

<sup>108</sup> Although NHTSA’s approach to review and iteration is well-aligned with the principles of the EBR Framework, the agency does discourage state-level competition which would be aligned with the principles explored in the section immediately below: *Keep Evaluation Options Flexible*.

<sup>109</sup> EXEC. ORDER NO. 13,771, 82 Fed. Reg. 9339 (January 30, 2017).

<sup>110</sup> See *supra* note 24.

<sup>111</sup> See Angela Ambroz & Marc Shotland, Better Evaluation, *Randomized Controlled Trial (RCT)*, Available at <http://betterevaluation.org/plan/approach/rct>

<sup>112</sup> Sofie E. Miller & Susan E. Dudley. *Regulatory Accretion: Causes and Possible Remedies*, 67 ADMIN. L. REV. 2.

in jurisdictions with the regulation being evaluated with those in jurisdictions without that regulation.<sup>113</sup>

Designing regulations from the outset in ways that identify and exploit variations in compliance could be a valuable way to understand the relationship between regulatory actions and outcomes. A pilot study or “an experiment in which certain regulations would be imposed on some factories and not on others offers the real prospect of determining whether those regulations are useful.”<sup>114</sup>

In the U.S. federalist system, the states provide a particularly valuable opportunity for experimentation. For example, Oates suggests that “the introduction in the 1970s and 1980s of a variety of emissions trading systems at the state level demonstrated the feasibility of such systems and some of their very appealing properties—as well as certain pitfalls.” He suggests that this state-level experimentation with innovative solutions to emissions problems led to the successful introduction of the national system of tradable sulfur allowances under the 1990 Clean Air Act Amendments.<sup>115</sup> Such approaches facilitate learning from experience in a way that implementing large-scale, irreversible regulatory programs do not.<sup>116</sup>

#### **A. Experiment and Evaluate Different Regulatory Approaches**

The EBR Framework calls on regulators to look for and exploit opportunities for experimentation during regulatory design. For instance, researchers have suggested how the statutorily required five-year National Ambient Air Quality Standards reviews could incorporate quasi-experimental techniques to gather and analyze epidemiology data and health outcome trends in different regions of the country and compare them against predictions.<sup>117</sup>

The EBR Framework also requires agencies to plan and budget for retrospective review as part of their regulatory design. This means agencies should lay out a program for empirical testing of assumptions and hypothesized outcomes. To incentivize more robust evaluation, they could also be required to test the validity of risk-reduction predictions before commencing new regulation that relies on models. For example, for regulations aimed at reducing health risks from environmental factors, quasi-experimental techniques should be used to gather and analyze

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<sup>113</sup> Cary Coglianese, OECD, *Evaluating the Impact of Regulation and Regulatory Policy*, (2012). Available at [https://www.oecd.org/gov/regulatory-policy/1\\_coglianese%20web.pdf](https://www.oecd.org/gov/regulatory-policy/1_coglianese%20web.pdf)

<sup>114</sup> John O. McGinnis, *Accelerating Democracy: Transforming Governance through Technology*, 112 (2013).

<sup>115</sup> Wallace E. Oates, Resources for the Future (RFF), *Environmental Federalism* (2009). Available at <http://www.rff.org/Publications/WPC/Pages/Environmental-Federalism-Wallace-E-Oates.aspx>

<sup>116</sup> Sofie E. Miller & Susan E. Dudley, *Regulatory Accretion: Causes and Possible Remedies*, 67 ADMIN. L. REV. 2.

<sup>117</sup> Francesca Dominici et al., *Particulate Matter Matters*, 344 SCIENCE 257 (2014).

epidemiology data and health outcome trends in different regions of the country and compare them against predictions.<sup>118</sup>

## V. Conclusion

Evidence-based policy continues to grow in prominence as a mechanism for improving program measurement and outcomes. However, evidence-based policy as it is currently understood is not designed to encompass the sphere of regulatory policy, which comes with its own constraints and preexisting requirements for data and analysis. Despite these limitations, federal regulation could benefit significantly from evidence-based policy practices by structuring the collection of data and improving analyses of regulatory outcomes.

By working within the existing statutory and executive constraints on agencies, an EBR framework plans for, collects, and uses evidence throughout the life of a regulation to predict, evaluate, and improve outcomes. By focusing on the design, decision-making, and retrospective review phases of regulation, an EBR framework creates a feedback loop rule so that data are not only used in developing the regulation but also in periodically reassessing its value and modifying the rule as appropriate.

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<sup>118</sup> Sofie E. Miller & Susan E. Dudley. *Regulatory Accretion: Causes and Possible Remedies*, 67 ADMIN. L. REV. 2.

## VI. Recommendations for Implementing an Evidence-Based Regulation Framework

Finding	Observation	Recommended Action
<p><b>REGULATORY POLICY</b></p> <p>Regulatory policymaking is already subject to significantly different information requirements than other policymaking processes.</p> <p>The increased use of evidence will result in better regulatory decisions.</p>	<p>Actions to improve evidence-based policymaking should be tailored to the regulatory process.</p> <p>It would be beneficial to identify a model process for creating evidence-based regulations.</p>	<p>“OMB should integrate evidence more effectively in its...regulatory decisions by tracking and evaluating the results of the policies it issues.”<sup>119</sup></p> <p>The president should consider commissioning a set of experts to describe an ideal evidence-based regulatory process and identify specific steps necessary to move to such a system.</p>
<p><b>ACCOUNTABILITY</b></p> <p>Regulatory decision-makers need to be held publicly accountable for the decisions they make.</p>	<p>The interpretive models, analyses and other tools used by regulators to make decisions should be accessible to the public.</p>	<p>The president should provide unrestricted access to all interpretive data tools used by regulators to make decisions.</p>
<p><b>COMPLIANCE</b></p> <p>Federal regulatory agencies do not always faithfully comply with presidential executive orders and other internal administrative guidance.</p>	<p>Compliance with presidential directives and administrative guidance should be improved.</p> <p>Codification of a requirement in law results in greater compliance than administrative guidance.</p>	<p>Regulatory principles accepted by the last five presidents<sup>120</sup> should be codified in law and subject to judicial review.</p> <p>Regulatory requirements in Executive Orders 13,563, 13,579 and 13,610 regarding retrospective review should be codified in law and subject to judicial review.<sup>121</sup></p>

<sup>119</sup> Recommendation of the Partnership for Public Service, *From Decisions to Results: Building a More Effective Government Through a Transformed Office of Management and Budget*, 24 (Oct. 2016). Available at <https://ourpublicservice.org/publications/viewcontentdetails.php?id=1349>

<sup>120</sup> See EXEC. ORDER NO. 12,866, 58 Fed. Reg. 51735 (Oct. 4, 1993). Available at [https://www.reginfo.gov/public/jsp/Utilities/EO\\_12866.pdf](https://www.reginfo.gov/public/jsp/Utilities/EO_12866.pdf)

<sup>121</sup> See Administrative Conference of the United States, Recommendation 2014-5, *Retrospective Review of Agency Rules*. Available at <https://www.acus.gov/recommendation/retrospective-review-agency-rules>

Finding	Observation	Recommended Action
<p><b>COMPETITION</b></p> <p>Competition can change the incentives and behavior of government organizations in positive ways.</p>	<p>The president and Congress should encourage methods of having programs with similar goals compete on the basis of program efficiency (e.g., desirable outcomes achieved per dollar spent by society).</p>	<p>The president and congress should commission experts to categorize federal programs with similar goals and identify metrics that could be used to compare their efficiency.<sup>122</sup> A limited set of comparisons should be implemented within two years.</p>
<p><b>FUNDING</b></p> <p>Federal discretionary spending is likely to be flat or decreasing in the future while entitlement program spending will continue to increase.</p> <p>Lack of funding is a barrier to collecting and using evidence.</p> <p>The cost and depth of evaluations and their value to decision-making can greatly vary.</p>	<p>The collection and use of evidence will need to be funded by shifting discretionary funding from lower priorities.</p> <p>The type of evaluation performed should reflect its potential value to improving federal policy.</p>	<p>Congress should provide greater flexibility to reallocate discretionary funding from lower priority uses to the greater collection and use of evidence.</p> <p>The president and congress should refrain from institutionalizing any particular type of evaluation method.</p>
<p><b>EVIDENCE AND POLICY</b></p> <p>Government officials sometimes muddle a description of “what is” with “what ought to be.”</p>	<p>The use of evidence needs to better separate scientific descriptions from policy judgments.</p> <p>This confusion masks policy decisions. This degrades political accountability and harms the integrity of evidence-based policymaking.</p>	<p>The president should “promulgate guidelines (through executive orders or other instruments) to ensure that when federal agencies are developing regulatory policies, they explicitly differentiate, to the extent possible, between questions that involve scientific judgments and questions that involve judgments about economics, ethics and other matters of policy.”<sup>123</sup></p>

<sup>122</sup> Such an effort could greatly benefit from the experience of the Council of State Governments’ State Comparative Performance Measurement Project. Available at <http://www.csg.org/programs/policyprograms/CPM.aspx>

<sup>123</sup> See Recommendation One at Bipartisan Policy Center, *Improving the Use of Science in Regulatory Policy*, 4 (2009).

Finding	Observation	Recommended Action
<p><b>RETROSPECTIVE REVIEW</b></p> <p>Regulatory retrospective review is best planned out when a regulation is initially designed.</p> <p>Regulatory retrospective review relies on other elements of regulatory design, such as defining the problem to be solved and identifying alternatives for comparison.</p>	<p>Regulatory design must include retrospective review and its supporting elements.</p>	<p>Regulatory requirements in Executive Orders 13,563, 13,579 and 13,610 regarding retrospective review should be codified in law and subject to judicial review.<sup>124</sup></p> <p>Regulatory principles accepted by the last five presidents that support retrospective review should be codified in law and subject to judicial review.<sup>125</sup></p>
<p><b>CATEGORIZATION OF EVIDENCE</b></p> <p>Regulators can benefit from learning lessons from programs not in their substantive expertise.</p>	<p>The best use of evidence may require it be organized by program theory (e.g., behavioral change) rather than issue area (e.g. transportation)</p>	<p>To the extent evidence of evaluations are consolidated, require “type of program theory” to be a characteristic that can be used to find evidence of federal program impacts.</p>
<p><b>EXPERIMENTATION</b></p> <p>The increased collection and use of evidence from regulatory evaluations will result in better regulatory decisions.</p>	<p>Randomized controlled trials to evaluate regulations are not always feasible.</p> <p>Pilot studies or approaches that allow for variation in regulatory treatments (“quasi-experiments” or QEs) can provide valuable information at less cost.</p>	<p>The president should encourage regulators to adopt QE techniques where more expensive evaluations may be infeasible or of less value.</p> <p>If necessary, Congress should amend regulatory authorities to allow agencies greater flexibility to design regulations to facilitate differences in implementation that allow quasi-experimentation. For instance, laws should allow limited pilot studies, or defer more to the natural experimentation possible at the state level.</p>

<sup>124</sup> This repeats a recommendation shown in the “Compliance” section above.

<sup>125</sup> This closely matches a recommendation shown in the “Compliance” section above.