The George Washington University Regulatory Studies Center (the Center) improves regulatory policy through research, education, and outreach. As part of its mission, the Center approaches regulatory problems from the perspective of the public interest and occasionally responds to government requests for input. The Center provides these comments regarding question numbers 1, 10, and 15-19 presented in the Supplementary Information section of the Commission on Evidence-Based Policymaking’s (the Commission’s) Federal Register notice issued on September 14, 2016. These comments are organized in six sections. The first section is an introduction. Each subsequent section corresponds to one or more of the Commission’s questions. An additional section at the end proposes specific findings, conclusions and recommendations for legislation or administrative action that the Commission may want to include in its final report.

1 This comment reflects the views of the authors, 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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Introduction: 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. Various estimates of regulation’s impact on society vary from over $260 billion to over $2 trillion. By comparison, the total of all federal funding for research and development, for instance, is less than $160 billion a year.

The Regulatory Process Differs from Other Policymaking

As the Commission examines strategies to better build evidence-based programs and policies throughout government, it is vital to understand the regulatory policymaking process already incorporates significant requirements regarding the collection, use and accessibility of data that differ from other policymaking processes. For instance, the Administrative Procedure Act of 1946 (the APA) requires regulatory agencies to both disclose, as well as request from the public, data or other information pertinent to a rulemaking. 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.

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:

- 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;

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6 This estimate was produced by the American Association for the Advancement of Science in 2016. See http://www.aaas.org/sites/default/files/Function%3B.jpg
8 See, for instance, the requirements to disclose information at 5 U.S. Code § 552(a) and to request information at 5 U.S. Code § 553(c).
• 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 evaluate certain proposed and final rules;
• Executive Orders 12866, 13563 and 13579, as well as OMB Circular A-4 regarding analyses that must be performed before certain rulemakings can be proposed or finalized; and
• These Executive Orders and Executive Order 13610 also encourage agencies to perform ex post reviews of the effectiveness of regulations.

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 (affecting the government collection of information) and the Information Quality Act of 2000 (which established minimum requirements for the utility, integrity, and objectivity of information used by government).

The unique data constraints placed on regulatory policymaking makes evidence-based regulation a distinct subset of evidence-based policymaking. It means that in some situations a recommendation that may benefit most methods of policymaking may be undesirable, or even illegal, in the rulemaking process. For instance, the Commission could recommend agencies seek out particular types of data and experts in order to help determine where federal grants may have the greatest impact. Regulatory agencies who follow formal, or adjudicatory rulemaking procedures, however, may be subject to charges of inappropriate ex parte communication if they undertook the same action.11 Even for informal, notice-and-comment rulemaking, final actions are often subject to litigation, which places additional constraints on the evidence in the record. The Commission may well need to make recommendations that are tailored to regulatory agencies or, at least, identify which recommendations do, or do not, apply to regulatory policymaking.

11 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. For more information see Edward Rubin, “It’s Time to Make the Administrative Procedure Act Administrative,” Cornell L. Rev. 89:95 (2003). See http://scholarship.law.cornell.edu/cgi/viewcontent.cgi?article=2940&context=clr
In order to assist the Commission in making recommendations specific to regulatory policymaking, the following comments focus solely on the regulatory process. The Center is available to assist the Commission in determining whether other recommendations it wishes to consider may or may not improve regulatory policymaking.

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 12866. Increasing the use of evidence in making regulations 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 (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. Importantly, this framework incorporates important and current requirements of the federal rulemaking process pertinent to the collection and use of data.

While it is not necessary for the Commission to endorse the EBR Framework, the Framework provides a coherent integrated system for answering a number of the Commission’s specific questions.

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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.
Questions 1 & 15 Regarding Challenges, Barriers, and Solutions

Question 1. Are there successful frameworks, policies, practices, and methods to overcome challenges related to evidence-building from state, local, and/or international governments the Commission should consider when developing findings and recommendations regarding Federal evidence-based policymaking? If so, please describe.

Question 15. What barriers currently exist for using survey and administrative data to support program management and/or evaluation activities?

Questions 1 and 15 are combined since two of the barriers we identify in response to question 15 can be overcome by policies, practices and other methods that we also identify for question 1. Specifically, agency noncompliance with internal administrative requirements and inadequate funding of program evaluation are two barriers the regulatory system currently faces in collecting and using data to improve regulations and offers potential solutions to each one.

The Challenge of Noncompliance with Internal Directives

A barrier to evidence-based regulation is a lack of faithful compliance with internal administrative requirements. 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 (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 and for evaluating the effectiveness of a rulemaking once it is in place. Absent a clearly identified market failure, regulation and other forms of government intervention can disrupt competition, and lead to misallocation of resources. 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

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13 According to E.O. 12866, “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.” (Principles of Regulation, Sec.1(b)(1))


15 E.O. 12866 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
and using data to assess expected benefits and costs\textsuperscript{16} is a fundamental method of informing decision-makers. Nonetheless, in 2014 the Government Accountability Office estimated that less than a fourth of new significant rules disclosed these four basic presidential requirements.\textsuperscript{17}

A more recent example of agency noncompliance with internal administrative requirements entails the retrospective review of regulations (items I.G. and III. in the EBR Framework). Every president since Jimmy Carter has required the \textit{ex post} evaluation of regulations (retrospective review). Most regulatory decisions rely on predictive models and assumptions, but rarely are those hypotheses evaluated based on real world evidence.\textsuperscript{18} A requirement to evaluate whether predicted effects of regulations were realized would provide a powerful incentive to improve \textit{ex ante} regulatory impact analyses, as well as improve regulations that are already in place.\textsuperscript{19}

With this in mind, in 2011 and 2012 President Barack Obama signed three Executive Orders attempting to get agencies to more aggressively adopt the retrospective review of regulations: Executive Order 13563 “Improving Regulation and Regulatory Review,”\textsuperscript{20} which reinforced the requirements of Executive Order 12866; Executive Order 13579,\textsuperscript{21} which expanded the requirements to independent regulatory agencies; and Executive Order 13610, which emphasized that “further steps should be taken…to promote public participation in retrospective review.”\textsuperscript{22,23}

\begin{itemize}
\item \textsuperscript{16} E.O. 12866 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.” (Sec.1(b)(6))
\item \textsuperscript{20} Executive Order 13563 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,” 25 April 2011 at https://www.whitehouse.gov/sites/default/files/omb/memoranda/2011/m11-19.pdf
\item \textsuperscript{21} Executive Order 13579, “Regulation and Independent Regulatory Agencies.” July 14, 2011. 76 FR 41587.
\item \textsuperscript{22} 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 the Act.
\end{itemize}
However, an independent review of high-impact rules issued in 2014 found that the key requirements in these directives were seldom followed. 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.

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:

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

A recent review of a lack of faithful compliance with government-wide reforms in 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. The first two methods force change while the third attempts to change incentives.

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**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 in the European Union (EU).\(^{28}\) Concerns regarding a lack of compliance with internal guidelines requiring the self-evaluation of the effectiveness of policies\(^ {29}\) 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.\(^ {30}\)

Independent review does not necessarily entail creating a new entity. The Commission may wish to consider, for instance, enlisting 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 (discussed above). 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. Relying on the courts would also avoid the cost of creating a new entity within the federal government.

**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.


\(^{29}\) See, in particular, Official Journal of the European Union, 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,” 2006/C 99/01. This audit found that agencies allocating funding for the purpose of keeping students in school generally did not utilize readily available performance data.

For example, Senators Heidi Heitkamp (D-N.D.) and James Lankford (R-Okla.) have proposed the Smarter Regulations Act\textsuperscript{31} which would require agencies to include in major rules a framework for reassessing the rule, including the timeframe for reassessment,\textsuperscript{32} the metrics that should be used to gauge efficacy,\textsuperscript{33} and a plan to gather relevant data to compile these metrics.\textsuperscript{34} The framework established in this proposed legislation was approved by a Senate committee by voice vote in October 2015.\textsuperscript{35} The bill is consistent with the EBR Framework and our recommendation below.

**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, the Office of Information and Regulatory Affairs (OIRA) was created 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.\textsuperscript{36}

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 is long been recognized as an extremely powerful motivator of federal agencies.\textsuperscript{37} While it may not seem obvious, federal agencies already compete with each other. For instance, they are in a 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.\textsuperscript{38}

One way to create a healthy competition among federal agencies is to use comparison data. While their effects may vary, comparison data has been shown to be a strong motivator in state governments\textsuperscript{39} particularly if the data are accessible and trustworthy. Indeed, federal agencies

\textsuperscript{32} S. 1817, § 2(f)(1)(D).
\textsuperscript{33} S. 1817, § 2(f)(1)(B).
\textsuperscript{34} S. 1817, § 2(f)(1)(C).
\textsuperscript{35} For more information on S. 1817 see https://www.congress.gov/114/crpt/srpt282/CRPT-114srpt282.pdf
\textsuperscript{39} See E. Blaine Liner, Harry P. Hatry, Elisa Vinson, Ryan Allen, Pat Dusenbury, Scott Bryant, Ron Snell, “Making
themselves are increasingly using comparison data to change the incentives of the entities they regulate including everything from colleges\textsuperscript{40} to nursing homes\textsuperscript{41} to chemical manufacturers.\textsuperscript{42} 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.\textsuperscript{43} A third party, the Government Accountability Office, 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 how many homeless families are provided long-term shelter for each dollar spent, or how many unemployed persons get and retain a job for each dollar spent.

One might initially expect large differences in the results agencies achieve. For instance, in 2003 a back of the envelope comparison of flood mitigation programs showed that for the same federal expenditure a Department of Agriculture grant program appeared to produce 40 percent more floodplain protection benefits than a Federal Emergency Management Agency grant program.\textsuperscript{44} The periodic publication of such data from a reliable source could result in agencies having strong incentives to collect, analyze, and act on evidence so as to improve their program and achieve a better ranking.\textsuperscript{45} Evidence-based policymaking could become the method by which agencies in compete in a “race to the top.”

**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.\textsuperscript{46} Such a reallocation could in turn

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\textsuperscript{40} The U.S. Department of Education’s “College Scorecard” at https://collegescorecard.ed.gov/
\textsuperscript{41} The Medicare program’s “Nursing Home Compare” ratings at https://www.medicare.gov/NursingHomeCompare/About/Ratings.html
\textsuperscript{43} Budget subfunctions may be a method for narrowing these programs down. See https://www.whitehouse.gov/tax-receipt/functions
\textsuperscript{44} U.S. Office of Management and Budget, *Addendum to the Fiscal Year 2006 Budget*. See https://www.whitehouse.gov/omb/memoranda_m02_06_addendum
\textsuperscript{45} 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. See http://bestplacetowork.org/BPTW/
strengthen *ex ante* analyses by providing direct information on the causal outcomes one would expect as the result of regulatory policy.\(^{47}\)

**Three Possible Solutions to the Problem of Inadequate Funding**

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.\(^{48}\) Right now 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.

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.\(^{49}\) 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.”\(^{50}\)

Constrained budgets tend to result in agencies “curtailing the funds needed for evaluation studies and performance monitoring systems.”\(^{51}\) 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

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\(^{48}\) “One-year money” is budget authority that expires at the end of the fiscal year in which it was appropriated.


\(^{50}\) S. 1284, Report No. 113–71, p. 114.

\(^{51}\) Newcomer et al., p. 807.
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. These programs included: the Department of Labor’s Job Corps program and the aforementioned WIC program at USDA.52

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.53 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.”54 EBR would benefit from such flexible standards regarding what constitutes useful analysis and evaluation.

Questions 10 & 16: Access and Use of Evidence

Question 10. How should the Commission define “qualified researchers and institutions?”
To what extent should administrative and survey data held by government agencies be made available to “qualified researchers and institutions?”

Question 16. How can data, statistics, results of research, and findings from evaluation, be best used to improve policies and programs?

This response addresses questions 10 and 16 regarding access and use of 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. As noted above, agencies must place information they use in decision-making in a public record and be able to justify their decisions based on the evidence in that record.

We support the bedrock regulatory principle of openness and this is reflected in item II.C. in the EBR Framework under Regulatory Decision-making. Thus, in answer to question 10, with regards to information that will be used to make regulatory decisions, as much information as

52 Ibid, p. 829.
53 Christopher Carrigan and Stuart Shapiro, “What’s wrong with the back of the envelope? A call for simple (and timely) benefit–cost analysis,” Regulation and Governance, 26 April 2016.
54 Newcomer et al., p. 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 significant program improvement.
possible should be made available and it should be made available to everyone. The public has a right to know what evidence policy officials consider in making decisions that affect them.

We offer two answers to question 16, regarding the “best use” of “data, statistics, result of research, and findings from evaluation.” The first relates to the need for transparency in regulatory decision-making. The second answer regards how evidence may be best organized to promote its best use.

**Data and Findings Must be Separated from Policy**

Regulatory agencies are generally compelled to request information and other data from the public. 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. The “best use” of information will likely occur only after it is scrubbed by public review.

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 must 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*). 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. Creating clarity regarding where this boundary is and the role of scientists at this boundary is important. 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. This process assumes the public is 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

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‘adapting the evidence’ to local circumstances. No method of synthesis can tell the policy maker what to do.\textsuperscript{57}

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…\textsuperscript{58}

An 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.\textsuperscript{59} 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 emission, zero concentration, zero tolerance standards are not empirically derived—they concede that the evidence is not yet in.\textsuperscript{60}

\textsuperscript{58} As quoted in Ronald Brand, Thomas Kelly, A. Stanley Meiburg, Robert Wayland, Susan Wayland, David Ziegele, \textit{True Green: Executive Effectiveness in the U.S. Environmental Protection Agency}, Gerald A. Emison and John C. Morris, eds., Lexington Books: Lanham, MD (2012), p. 77. In his seminal work on the fuzzy boundary between scientific evidence and policy (“Science and Trans Science,” \textit{Minerva},10(2): 209-222, 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.”
\textsuperscript{60} Pawson, p. 174.
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.\(^{61}\) 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.\(^{62}\)

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.”\(^{63}\)

Clear Separation and Broad Access Solves 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.”\(^{64}\) “This transparency would both help force values debates into the open and could limit spurious claims about, and attacks on science.”\(^{65}\)

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\(^{61}\) 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,” 1 May 2012, pp. 2-3.


\(^{63}\) Ibid., p. 11.

\(^{64}\) Ibid., p. 4.

\(^{65}\) Ibid., p. 5.
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 have the ability 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.”

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. 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.”

Access to Evidence Organized by ‘Program Theory’ Could Benefit Regulators

The “best use” of evidence can also be improved by 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). Categorizing evaluation data under the additional criteria of similar program theory domains (e.g., incentives, target setting, or behavior change) could greatly improve rulemaking. Consulting the widest possible range of evaluation 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 reduce the expected costs of regulations.

Theoretically, the efforts to make evaluation data available across agencies, such as in a clearinghouse, will help create a wider distribution of evidence going forward. However,

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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. 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.

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 they have the unintended/perverse effect of increasing discrimination against minorities, particularly African Americans. Rather than thinking of this, conceptually, as a “lesson learned” for officials at the Department of Labor, there is a broader finding that could be applicable to other federal agencies: namely, the unintended consequence of trying to incentivize certain behavior by limiting data. Additionally, this framework helps shift evaluation thinking from simply inquiring whether a program “works” to the more nuanced “what works for whom in what contexts.”

Questions 17 & 18: Address Retrospective Review in Regulatory design

Question 17. To what extent can or should program and policy evaluation be addressed in program designs?

Question 18. How can or should program evaluation be incorporated into program designs?
What specific examples demonstrate where evaluation has been successfully incorporated into program designs?

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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70 Pawson, p. 190.


72 Pawson, p. xiii.
programs, waiting until after a regulation is implemented to plan *ex post* measurement can greatly hamper retrospective review.73

Both OMB74 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, 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.75

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.”76 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.

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 stage. For instance, in addition to planning for retrospective review, the EBR Framework requires regulators to:77

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73 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. Part 1320.8(b)(3)(iii) (2015).
77 These components are adapted from Miller, p. 10.
• 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. 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. 78 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 79 establishing how the agency will address driverless car technology through its current regulatory structure and identified 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, the agency has already noted it will consider the option of implementing a sunset on federal motor vehicle safety standards so that the agency can reconsider whether the standards are still effective as driverless car technology continues to develop. This iterative approach combined with a

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78 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, “Learning from Experience: Retrospective Review of Regulations in 2014,” Working Paper, The George Washington University Regulatory Studies Center, November 2015, p. 18.

commitment to collect and synthesize evidence as it comes in appears to reflect the right approach to regulating a new and promising technology.80

**Question 19: Keep Evaluation Options Flexible**

*Question 19. To what extent should evaluations specifically with either experimental (sometimes referred to as “randomized control trials”) or quasi-experimental designs be institutionalized in programs? What specific examples demonstrate where such institutionalization has been successful and what best practices exist for doing so?*

The EBR Framework does not specify what types of experimental designs should be used in analyzing or evaluating regulations. Rather, the rigor of the analysis should match the regulatory situation and the value such analysis may offer decision-makers.81

Randomized controlled trials are well-regarded tools used by program evaluators to understand the effect of different treatments on outcomes.82 However, where randomized trials are not feasible, pilot studies or approaches that allow for variation in regulatory treatments can serve as “quasi-experiments” (QEs) that provide valuable information for evaluating outcomes and their causal links.83 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 in jurisdictions with the regulation being evaluated with those in jurisdictions without that regulation.84

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80 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.*

81 See supra note 45.

82 See Angela Ambroz and Marc Shotland, *Randomized Controlled Trial (RCT)*, Better Evaluation: Sharing information to improve evaluation at http://betterevaluation.org/plan/approach/rct


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.”

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. Such quasi-experimental approaches facilitate learning from experience in a way that implementing large-scale, irreversible regulatory programs do not.

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 QE techniques to gather and analyze epidemiology data and health outcome trends in different regions of the country and compare them against predictions. Unfortunately, the U.S. Environmental Protection Agency has not pursued this idea.

The EBR Framework also requires agencies 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, QE techniques should be used to gather and analyze epidemiology data and health outcome trends in different regions of the country and compare them against predictions.

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Suggested Recommendations for Findings, Conclusions and Legislation or Administrative Actions

We suggest the Commission consider including the following findings, conclusions and recommendation for legislation or administrative actions in its report to the President and Congress.

<table>
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<th>Suggested Finding</th>
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<tr>
<td><strong>REGULATORY POLICY</strong></td>
<td>Actions to improve evidence-based policymaking should be tailored to the regulatory process. It would be beneficial to identify a model process for creating evidence-based regulations.</td>
<td>“OMB should integrate evidence more effectively in its…regulatory decisions by tracking and evaluating the results of the policies it issues.”[^90] 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.</td>
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<td>Regulatory policymaking is already subject to significantly different information requirements compared to other policymaking processes. The increased use of evidence will result in better regulatory decisions.</td>
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<td><strong>ACCOUNTABILITY</strong></td>
<td>The interpretive models, analyses and other tools used by regulators to make decisions should be accessible to the public.</td>
<td>The president should provide unrestricted access to all interpretive data tools used by regulators to make decisions.</td>
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<td>Regulatory decision-makers need to be held publicly accountable for the decisions they make.</td>
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<td><strong>COMPLIANCE</strong></td>
<td>Compliance with presidential directives and administrative guidance should be improved. Codification of a requirement in law results in greater compliance than administrative guidance.</td>
<td>Regulatory principles accepted by the last five presidents[^91] should be codified in law and subject to judicial review. Regulatory requirements in Executive Orders 13563, 13579 and 13610 regarding retrospective review should be codified in law and subject to judicial review.[^92]</td>
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<td>Federal regulatory agencies do not always faithfully comply with presidential executive orders and other internal administrative guidance.</td>
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[^91]: These principles will be found in Section 1 of Executive Order 12866 issued by President William Clinton on October 4, 1993. Available at https://www.whitehouse.gov/sites/default/files/omb/inforeg/eo12866/eo12866_10041993.pdf
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<td><strong>COMPETITION</strong></td>
<td>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).</td>
<td>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. A limited set of comparisons should be implemented within two years.</td>
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<td>Competition can change the incentives and behavior of government organizations in positive ways.</td>
<td>The collection and use of evidence will need to be funded by shifting discretionary funding from lower priorities. The type of evaluation performed should reflect its potential value to improving federal policy.</td>
<td>Congress should provide greater flexibility to reallocate discretionary funding from lower priority uses to the greater collection and use of evidence. The president and congress should refrain from institutionalizing any particular type of evaluation method.</td>
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<td><strong>FUNDING</strong></td>
<td>The use of evidence needs to better separate scientific descriptions from policy judgments. This confusion masks policy decisions. This degrades political accountability and harms the integrity of evidence-based policymaking.</td>
<td>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.”</td>
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<td>Federal discretionary spending is likely to be flat or decreasing in the future while entitlement program spending will continue to increase. Lack of funding is a barrier to collecting and using evidence. The cost and depth of evaluations and their value to decision-making can greatly vary.</td>
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<td><strong>EVIDENCE AND POLICY</strong></td>
<td>Government officials sometimes muddle a description of “what is” with “what ought to be.”</td>
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<td>The use of evidence needs to better separate scientific descriptions from policy judgments. This confusion masks policy decisions. This degrades political accountability and harms the integrity of evidence-based policymaking.</td>
<td>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.”</td>
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93 Such an effort could greatly benefit from the experience of the Council of State Governments’ State Comparative Performance Measurement Project. See http://www.csg.org/programs/policyprograms/CPM.aspx

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<td><strong>RETROSPECTIVE REVIEW</strong></td>
<td>Regulatory design must include retrospective review and its supporting elements.</td>
<td>Regulatory requirements in Executive Orders 13563, 13579 and 13610 regarding retrospective review should be codified in law and subject to judicial review. (^{95}) Regulatory principles accepted by the last five presidents that support retrospective review should be codified in law and subject to judicial review. (^{96})</td>
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<td>Regulatory retrospective review is best planned out when a regulation is initially designed. Regulatory retrospective review relies on other elements of regulatory design, such as defining the problem to be solved and identifying alternatives for comparison.</td>
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| **CATEGORIZATION OF EVIDENCE** | The best use of evidence may require it be organized by program theory (e.g., behavioral change) rather than issue area (e.g., transportation) | 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. |
| Regulators can benefit from learning lessons from programs not in their substantive expertise. | | |

| **EXPERIMENTATION** | Randomized controlled trials to evaluate regulations are not always feasible. Pilot studies or approaches that allow for variation in regulatory treatments (“quasi-experiments” or QEs) can provide valuable information at less cost. | The president should encourage regulators to adopt QE techniques where more expensive evaluations may be infeasible or of less value. 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. |
| The increased collection and use of evidence from regulatory evaluations will result in better regulatory decisions. | | |

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\(^{95}\) This repeats a recommendation shown in the “Compliance” section above.  
\(^{96}\) This closely matches a recommendation shown in the “Compliance” section above.