# CSAB Project on Regulatory Oversight:

# Study Protocol 1

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## I. INTRODUCTION

The Center for the Study of American Business' Project on Regulatory Oversight (CSAB/PRO) is a two-year effort to monitor and evaluate the extent to which federal agencies comply with various statutory and executive requirements for disclosure, regulatory procedure, regulatory analysis, and the exercise of administrative discretion in rulemaking. In addition, CSAB/PRO is studying the effectiveness of executive and legislative regulatory systems established to oversee these requirements.

Considerable attention has been devoted in recent years to alternative proposals that would reform the way in which federal agencies perform these functions. Proponents of reform have asserted that federal regulatory agencies are "out of control," making decisions for which there is weak scientific basis, economic merit or statutory authority. Opponents of reform have countered that existing statutory and executive requirements are both extensive and sufficient to ensure proper political control and public accountability. They believe that important protections of health, safety, and the environment would be lost if these proposed reforms were enacted.

The Office of Information and Regulatory Affairs (OIRA), a statutory division of the Office of Management and Budget (OMB), has been charged since 1981 with overseeing federal regulation by executive branch agencies. This oversight has occurred under authority vested in the president by Article 2 of the Constitution of the United States.

Congress has its own oversight authority under Article 1. Moreover, Congress enacted two laws in 1996 related to the exercise of delegated legislative authority by the executive and significantly expanded its own capacity to oversee regulatory actions taken by the executive. These laws also established new obligations for regulatory agencies, particularly in the areas of intergovernmental relations and the regulation of small businesses and other entities.

No systematic or comprehensive record exists to document actual agency performance of these statutory and executive requirements. Similarly, there are no systematic studies of executive or legislative oversight. CSAB/PRO represents the first such effort.

CSAB/PRO will conduct three primary studies over the next two years:

1. An evaluation of federal regulatory agency compliance with existing statutory and executive requirements for disclosure, regulatory procedure, regulatory analysis, and the exercise of administrative discretion;

2. An evaluation of centralized executive regulatory oversight, primarily as it is conducted by OMB's Office of Information and Regulatory Affairs; and

3. An evaluation of Congressional oversight of federal regulatory agencies, primarily with regard to the Congressional Review Act of 1996.

This document, Study Protocol 1, describes in detail how the first of these three projects will be conducted. Section II identifies the hypotheses CSAB/PRO intends to test. Section III describes the methods that will be used to test these hypotheses, including descriptions of the data that will be collected; the criteria for objectively evaluating agency compliance with existing statutory and executive requirements; and the grading scale we devised to subjectively judge the adequacy of compliance. Section IV provides a more detailed discussion of the data that will be collected. Section V discusses how these data will be evaluated. Section VI provides a brief tour of the statutory and executive authorities for which compliance will be assessed.

We have provided an extensive set of appendices to document the basis for each derived evaluative criterion. In each appendix, the evaluative criterion is aligned next to the text of the statutory or executive authority that forms the basis for the criterion. Minor liberties have been taken to simplify language where the text in the underlying authority is judged to be unusually convoluted. Words critical to the precise meaning (or inherent ambiguity) of the text have been retained. Similarly, where the underlying texts can be read to imply nested provisions, the derived evaluative criteria explicitly identify this nesting sequence. Finally, while substantial portions of the relevant underlying authorities have been reproduced verbatim to ensure proper context, critical portions of these texts are underlined to help readers crosswalk the language of the text to the appropriate derived evaluative criterion.

## II. HYPOTHESES

The obvious and fundamental question to be addressed in this study is whether federal regulatory agencies do, in fact, comply with

existing generally applicable statutory and executive requirements for disclosure, regulatory procedure, regulatory analysis, and the exercise of discretion in regulatory decision making. Some of these requirements are relatively new, while others have been in place for many years. A secondary (but vitally important) question is whether compliance (or noncompliance) with these requirements enhances (or inhibits) rational decision making.

Section IV below describes in more detail how we define "compliance." In short, our approach is to use the specific requirements set forth by the various statutory and executive authorities. Requirements that "ought" to be contained in these (or other) authorities are excluded on the grounds that there is no obvious consensus supporting their inclusion. In contrast, each existing statutory and executive requirement exists because of a shared understanding of its legitimacy.

We hypothesize that federal agencies do in fact comply with each generally applicable statutory and executive requirement. For example, regulations designated as "economically significant" under Executive Order 12866 are required to be submitted to OIRA with a detailed economic analysis, the contents of which are specified in the Order itself and elaborated upon in guidance issued by OMB. Because independent agencies and commissions are exempt from Executive Order 12866, we hypothesize that no such documents are prepared in support of regulations by independent agencies and commissions. Similarly, we hypothesize that regulatory agencies required to address questions of unfunded mandates (under the Unfunded Mandates Reform Act) or the effects on small entities (under the Regulatory Flexibility Act, as amended) actually do precisely what is required of them by law.

If the hypothesis of substantial compliance is not disproved, then any shortcomings observed in regulatory decision making would be attributable to limitations in the language of the generally applicable statutory and executive requirements themselves, or to underlying statutory constraints that trump these requirements. The distinction between these interpretations is significant. Where shortcomings in regulatory decision making can be attributed to specific underlying statutory constraints that prohibit or restrict agencies from complying, then it is inappropriate to conclude that the generally applicable requirements themselves have failed. Rather, failure must be attributed to the overarching statutory constraints. However, where shortcomings are observed despite the absence of such constraints, then it is the generally applicable requirements themselves that have

failed. In the former case, the implication is that specific statutory constraints ought to be rescinded to permit generally applicable requirements to function unimpeded. In the latter case, however, the generally applicable requirements themselves would have failed to achieve their desired results and may warrant amendment, retooling or repeal.

If instead the hypothesis of compliance is disproved, then it is not clear that observed shortcomings in regulatory decision making can be attributed to any weaknesses or limitations in the requirements. Shortcomings may be attributable to independent structural problems or institutional constraints. An obvious example of such a structural problem could be the presence of statutory or judicial deadlines for agency action; such deadlines frequently disrupt normal administrative procedure and regulatory analysis. An obvious example of an institutional constraint would be the absence of credible enforcement tools such as explicit executive powers or judicial review.

## III. METHODS

CSAB/PRO will examine all "major" final rules promulgated by federal agencies between April 1, 1998, and March 31, 2000. The number of such actions is expected to be about 50 per year. For comparison, OMB reports that between April 1, 1997, and March 31, 1998, there were 33 "major" final rules promulgated by nine executive departments and agencies, and approximately 20 additional "major" final rules promulgated by independent agencies and commissions.[1]

We prefer a census approach because it avoids the possibly intractable problem of devising a statistically valid sample across such a diverse yet small population of federal agencies and regulatory actions. Further, the purpose of CSAB/PRO is to examine detailed questions in specific cases, not to estimate aggregate costs and benefits of federal regulation per se, so there is little to be gained in devising a sample from which population estimates might be derived.[2]

[1] See OMB 1998 at 44. OMB reports 41 "major" rules promulgated by independent agencies and commissions over the two-year period April 1, 1996 – March 31, 1998. Ibid. at 61.

[2] Aggregate estimates of benefits and costs would be valid and reliable only if a number of strong assumptions hold. Chief among these assumptions is that agency estimates of benefits and costs for individual major rules are themselves valid and reliable, for it is impossible for aggregate estimates to be reliable (except by chance) if individual estimates are not. The conventional wisdom based on anecdotal evidence is that agency estimates frequently fail the tests of validity and reliability. An important objective of CSAB/PRO is to rigorously ascertain to what extent the conventional wisdom is correct.

We have developed an extensive battery of questions based on the array of existing statutory and executive requirements. These questions cover four dimensions of regulatory oversight: regulatory procedure, regulatory analysis, decision making, and judicial review.[3] Procedural matters include such issues as scope and applicability; public participation; submission of required documents, statements and certifications; and public disclosure. Analytic questions primarily involve benefit-cost analysis and, when they provide important underlying inputs, quantitative risk assessments. Secondary analytic questions include matters of distributional effects and equity, the analysis of which is required under certain applicable executive orders. Questions about decision making focus primarily on stated statutory objectives where they are expressed with clarity, and secondarily on how agencies exercise administrative discretion where statutory objectives are ambiguous. For executive branch departments and agencies, we rely on published presidential guidance concerning the exercise of administrative discretion as the basis for evaluating decision making.[4]

Although there is a firm documentary basis for each evaluative question in the battery, not every question is relevant to every major regulation. Question batteries are presented in the appendices accompanied by the text of the authority under which the question may be relevant.

[3] We include judicial review provisions for completeness, as this has become a highly controversial issue and represents an important potential tool for enforcement. However, evaluating the effectiveness of judicial review provisions, to the extent that they exist (or could be enacted), lies beyond the scope of the project.

[4] Presidential guidance on the exercise of administrative discretion applies only "to the extent permitted by law." This guidance is thus inapplicable in cases where Congress has clearly articulated the decision rules agencies must (or must not) follow. It also does not apply to independent agencies and commissions. In these instances we have used presidential guidance only as a baseline for comparison, not to pass judgment as to whether executive agencies or the independents have "succeeded" or "failed" to comply with it.

## IV. DATA COLLECTION

Our data collection procedure involves examining Federal Register notices and referenced supporting documents, such as regulatory impact analyses, Regulatory Flexibility Act analyses and quantitative risk assessments, for answers to these evaluative questions in each battery. Each regulation will be examined individually using a system of triage intended to sharpen the focus on the most important issues. This triage proceeds as follows for each evaluative question:

1. Relevance. In many instances, specific evaluative questions or sets of question are irrelevant to the regulation at hand. For example, requirements to examine potential effects on children's health are irrelevant to regulations aimed at reducing mortality or morbidity among the aged. In such a case, we record that the question is not relevant for this specific regulation.

2. Screening-level assessment. Risk analysts frequently perform screening-level risk assessments to determine whether a particular substance or activity poses any significant threat even under worst-case conditions. This tool is widely recommended to discern whether more rigorous analysis is warranted to estimate *likely* risk levels. Such efforts generally are not justified when worst-case analysis demonstrates that upper-bound risk estimates are still too small to pose any material concern.

Screening-level assessment is similarly appropriate in the analogous practice of regulatory analysis. For example, if worst-case assumptions yield paperwork cost estimates that are widely regarded as trivial, then it seems quite reasonable for the agency to devote few of its limited resources to developing more precise estimates. On the benefits side, best-case assumptions can be used to obtain a bounding value for a particular category of benefits. If this value is regarded as trivial, then further refinement of the estimate generally would not be warranted. While screening-level assessments are useful for allocating scarce analytical resources, it is also generally understood that such assessments are *calculated quantities* and thus not *estimates* of any parameters or outputs of interest.

3. Detailed assessment. In each instance where an evaluative question cannot be dispensed with as either (1) irrelevant to the regulation at hand or (2) yielding trivial values even under worst- or best-case assumptions, we will systematically examine the relevant agency documents for more specific

answers. Because the evaluative question batteries derive from authoritative external sources, we believe that arguments about the merits of these questions should be directed to these authorities. Our task is simply to evaluate the extent and nature of agency compliance with these external authorities.

## V. DATA ANALYSIS AND EVALUATION

Defining "compliance," or more specifically, determining what level of compliance is adequate, poses the most difficult problem underlying this research. The injection of undisclosed subjectivity would undermine the project at the outset. Thus, we have bifurcated our definition of compliance into objective and subjective components.

### A. Objective Evaluation of Compliance

The objective component consists of the criteria set forth by the relevant statutory and executive authorities themselves. We examine whether agencies have adequately disclosed and documented the performance of each relevant task. Because we are unable to determine exactly what an agency has or has not actually done, and are limited to the public record the agency provides, we first evaluate the adequacy of an agency's *disclosure* of its performance. Thus, in the case where an agency provides no regulatory analysis in support of a major rulemaking, we conclude only that the agency has *failed to disclose* the completion of such a document rather than a failure to prepare one.

Where an agency's disclosure indicates that a relevant task has been performed, we evaluate the agency's performance of that task by the documentation it provides. Thus, where an agency is required to consider "reasonable" alternatives to its preferred regulatory approach, we examine whether the number and type of alternatives reported in the agency's analysis appear to be reasonable, based on the applicable statutory or executive requirement. Again, in the case where we judge the agency's array of alternatives to be inadequate, we conclude that the agency *failed to disclose* an analysis of reasonable alternatives, not that it failed to actually analyze them.[5]

We evaluate the quality of regulatory analysis based on the criteria set forth in applicable guidance or other directives. Again, we do not insert guidance from other sources unless such guidance is explicitly or implicitly referenced in the applicable directive. For example, OMB's guidance for economic analysis under Executive Order 12866 implicitly calls on agencies to "meet best practices in the use of this method" whenever they rely on

[5] An exception to this rule arises when an agency declares that the array of alternatives disclosed is identical to the array it considered.

contingent valuation.[6] Although OMB does not specify exactly what qualifies as "best practices" in this regard, it does identify and describe major pitfalls. In addition, the economics literature provides ample additional guidance, particularly concerning which methods and practices do *not* qualify.

We use a similar framework for evaluating compliance with decision-making requirements. For example, where a requirement exists to "select the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule,"[7] we examine whether the alternative selected by the agency satisfies any one of these criteria. Where an agency is subject to a presidential directive to "propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs,"[8] we examine whether the agency has made such a determination, the reasoning it has provided, and the logical basis and empirical support for its reasoning.

In no case does compliance require perfection, for under none of the generally applicable statutory and executive requirements is there such a mandate. The appropriate test is one of materiality – only departures that are material to regulatory procedure, analysis or decision making qualify as errors.

We define "material errors" in analogous terms. With respect to procedural requirements, a material error is one so great that a fundamental objective of the required regulatory procedure has been lost. For regulatory analysis, we define a material error as one so great that, if it were corrected, a decision maker faithfully trying to use applicable decision-making guidance could reach a different conclusion. Finally, a material error in decision making requires an agency to misinterpret the results of its own analysis or misconstrue the meaning of the applicable decision-making guidance.

Thus, we can evaluate objectively an agency's compliance with value-laden principles by simply taking these principles as given and determining whether an agency has met them. For example, we can examine whether an agency has complied with the normative principle of benefit-cost decision making because this principle can be found in certain statutory provisions as well as presidential guidance for the exercise of administrative discretion. Similarly, we can objectively evaluate

[6] See OMB 1996 at sec. III.B.4.

[7] See §205(a) of the Unfunded Mandates Control Act [2 USC 1535(a)].

[8] See §1(b)(6) of Executive Order 12866.

the extent to which an agency has complied with the normative principle of distributional equity because this principle, as well, is grounded in certain statutory and executive authorities. In both cases, our objective evaluation consists of determining whether the agency has demonstrated its obedience to the relevant principle. The fact that these principles may occasionally conflict does not undermine our analysis; rather, it raises more fundamental questions about how regulatory agencies should balance statutory and executive directives that may be internally inconsistent.

### B. Subjective Evaluation of Compliance

To some extent, evaluating "compliance" is an inherently subjective task even if it is based on ostensibly "objective" evaluative criteria. Policy analysts can (and do) interpret the same evaluative information differently, for often there is no consensus as to what constitutes a "correct" interpretation. At this level, subjectivity cannot be avoided and instead should be simply acknowledged and fully revealed.[9]

To guard against the risk that we impart undisclosed policy biases into this exercise, we reach our subjective judgments primarily by utilizing the detailed compilations of agency compliance with the "objective" criteria described above. At the same time, we propose to grade agencies' performance on an A-F scale based on specified criteria and measurements that we believe are both reasonable and replicable by other analysts. These grades will be posted on four dimensions:

1. Transparency and full disclosure;
2. Compliance with procedural requirements;
3. Compliance with analytic requirements; and
4. Compliance with decision making requirements.

Each rule receives letter grades that summarize our subjective evaluation of agency compliance based on pre-defined grading standards. Tables 1

[9] The inevitable "problem" of subjectivity undermines all attempts to devise "expert systems" that would integrate all the available information into one or more summary measures. All expert systems require the assignment of weights to each component, and there is no obvious basis for the assignment of such weights. Note that placing equal weights on all components does not solve this problem, for weighing all components equally constitutes but one of a near infinite number of possible weighting schemes. In principle, a multiattribute decision theoretic approach could be used to assign weights, but such an approach presumes that the identity of the decision maker (or the precise mix of values to be used in making complex decisions) is known.

through 4 list the performance levels which correspond to each grade level.

Table 1, which summarizes the adequacy of the agency's disclosure of relevant information, represents a cross-cutting look across the procedural, analytic and decision-making dimensions. Full disclosure is an important general principle embodied in all generally applicable statutory and executive requirements. We take this principle at face value; where we as experienced analysts have to resort to extraordinary means to obtain relevant information, we believe that a prima facie case exists that the agency in question is demonstrably non-compliant with respect to full disclosure.

We have chosen to set relatively high standards for full disclosure for three reasons. First, full disclosure is a prerequisite for effective regulatory oversight. Evaluating compliance with any of the important margins is problematic unless the agency has "shown its work" instead of just its answers. Second, full disclosure has become inexpensive with the advent of the World Wide Web. Internet-based storage, search and retrieval technologies have become such a commonplace phenomenon that it seems highly unusual that we should exempt the government from effectively utilizing them. Third, agencies have an obligation under the 1995 amendments to the Freedom of Information Act (FOIA) to make such documents electronically available. In short, FOIA provides yet another external statutory authority that requires regulatory agencies to make information available without hindrance or delay.

Tables 2 through 4 provide a symmetrical scheme for grading compliance on the procedural, analytical and decision-making margins based on the concept of "material error," which was defined and discussed above. We believe that the presence of any material error renders an agency's administrative procedure or regulatory analysis suspect for intelligently informed decision making and thus deserving of a failing grade. Likewise, a single material error in interpreting or applying a substantially correct analysis in the decision-making process deserves a grade of "F" because it undermines and trivializes the efforts of regulatory analysts. We consider an analysis worthy of a "C" if it contains multiple non-material errors that collectively tend to yield a bias in an identifiable direction. Such errors invite misinterpretation and even purposeful misuse. We reserve the grade of "A" for work that displays no evidence of material error, efforts that display the highest commitment to effective administrative procedure, competent and rigorous regulatory analysis, and faithful exercise of administrative discretion.

## VI. DISCUSSION OF GENERALLY APPLICABLE STATUTORY AND EXECUTIVE REQUIREMENTS

Apart from the Administrative Procedure Act, two relatively new statutes and several executive orders have generally applicable requirements governing how federal agencies engage in regulation. We call them "generally applicable" not because they apply universally to all federal agencies and regulatory actions, but because they apply unless the agency or action in question is specifically *exempted* or *excepted*. These terms are similar but not identical; an *exemption* means that the agency or action is excluded outright from coverage by the statutory or executive requirement, whereas an *exception* means that the agency or action need not address a specific issue because of the existence of a particular characteristic. Thus, independent agencies and commissions are *exempt* from the requirements of Executive Order 12866 because they are not subject to the oversight of the president. Certain regulations promulgated by covered executive departments and agencies are *excepted* from specific requirements because they have specific characteristics (e.g., a statutory or judicial deadline) which may make timely compliance infeasible.[10]

The two new statutes – both enacted in 1996 – are the Unfunded Mandates Control Act (UMRA) and the Small Business Regulatory Enforcement and Fairness Act (SBREFA). UMRA focuses primarily on regulatory actions that require state and local governments to perform certain tasks or duties without the benefit of federal funds to pay for them. SBREFA, an amendment to the Regulatory Flexibility Act of 1980, imposes new requirements on agencies engaged in regulatory actions that have disproportionate impacts on small businesses and other entities, including small governments.

[10] CSAB/PRO does not plan to evaluate compliance with the Administrative Procedure Act. Such an evaluation is well beyond the scope of the project. The effectiveness of selected APA provisions will be examined, however, in CSAB/PRO's examination of executive and legislative oversight.

| Table 1:<br>Transparency and Full Disclosure | |
|---|---|
| ***Grade*** | ***Performance*** |
| A | All relevant information is provided (1) in the preamble to the final rule; or (2) in documents properly referenced in the preamble that are electronically available on the agency's web site. |
| B | All relevant information is provided (1) in the preamble to the final rule; or in documents properly referenced in the preamble that are either (2a) electronically available on the agency's web site or (2b) available upon request without having to visit the agency's regulatory docket. |
| C | All relevant information is provided either (1) in the preamble to the final rule; in documents properly referenced in the preamble that are either (2a) electronically available on the agency's web site or (2b) available upon request without having to visit the agency's regulatory docket; or (3) available in the agency's docket. |
| D | All relevant information is not provided, but can be obtained by intensive inspection of both the agency's docket and the regulatory review docket of OMB's Office of Information and Regulatory Affairs. |
| F | All relevant information is not provided and it cannot be obtained without extraordinary effort; or it does not exist. |

| Table 2:<br>Compliance with Procedural Requirements | |
|---|---|
| ***Grade*** | ***Performance*** |
| A | No material errors. All relevant procedural requirements satisfied. |
| B | One or more procedural errors, none of which appears to be material. |
| C | Multiple procedural errors which collectively tend to yield a bias in an identifiable direction. |
| D | Multiple procedural errors that individually may not be material, but probably meet the materiality test when considered in combination. |
| F | One or more material procedural errors. |

| Table 3:<br>Compliance with Analytic Requirements | |
|---|---|
| ***Grade*** | ***Performance*** |
| A | State-of-the-art analysis or otherwise worthy of use as a model for other applications. Equivalent in quality to a doctoral dissertation in policy analysis or applied benefit-cost analysis. |
| B | No material errors, but significant opportunities for improvement. Equivalent in quality to a satisfactory master's thesis in policy analysis or applied benefit-cost analysis. |
| C | Multiple analytic errors which collectively tend to yield a bias in an identifiable direction. Equivalent in quality to an above-average undergraduate term paper in policy analysis or applied benefit-cost analysis. |
| D | Multiple analytic errors which individually may not be material errors, but probably meet the materiality test when considered collectively. Equivalent in quality to a below-average term paper in policy analysis or applied benefit-cost analysis. |
| F | One or more material errors. Equivalent in quality to an unacceptable term paper in policy analysis or applied benefit-cost analysis. |

| Table 4:<br>Compliance with Decision Making Requirements | |
|---|---|
| ***Grade*** | ***Performance*** |
| A | No material errors. All relevant decision-making requirements satisfied. |
| B | One or more decision-making errors, none of which appears to be material. |
| C | Multiple procedural errors which collectively tend to yield a bias in an identifiable direction. |
| D | Multiple decision-making errors that individually may not be material, but probably meet the materiality test when considered collectively. |
| F | One or more material decision-making errors. |

Executive Order 12866 is the principal generally applicable executive requirement. Issued by President Clinton in 1993, it replaced Executive Order 12291, which was put in place by President Reagan in 1981.[11] Executive Order 12866 established procedures for agencies (and OMB) to follow; regulatory analysis requirements for all "significant" (and especially "economically significant") regulations; and set forth presidential guidance concerning how agencies should exercise the administrative discretion available to them under federal law.[12]

Three additional executive orders have general applicability to regulatory actions. These orders deal with the specific topics of intergovernmental relations (Executive Order 12875); environmental justice (Executive Order 12898); and children's environmental health and safety risks (Executive Order 13045).[13]

In the remainder of this section, we summarize the generally applicable procedural, analytic, and decision-making requirements embedded in these statutory and executive authorities. Readers should consult the relevant appendix to get more details and to see the specific evaluative criteria we have derived from these authorities.

[11] These executive orders are similar in many respects but contain important differences, a matter that will be examined in detail in a subsequent CSAB/PRO study on executive oversight.

[12] The definition of a "significant" regulation is highly elastic; it is currently defined circularly as any regulation that both the regulating agency and OMB decide is not "non-significant." An "economically significant" regulation is similar but not identical to the definition of a "major rule" under Executive Order 12291. Both definitions are similar but not identical to the definitions of an "unfunded mandate" under UMRA and a "major rule" under Subtitle D of SBREFA. Subtle distinctions matter in interpreting agency compliance with specific evaluative criteria set forth in the appendices.

[13] Executive Order 12612 ("Federalism") may also qualify as a generally applicable executive requirement. This Order, which dates from 1987, was revoked in May by Executive Order 13083 (also entitled "Federalism"). This latter Order generated considerable controversy among officials and representatives of State and local governments because it established a host of principles directly contrary to Executive Order 12612, which they strongly prefer. Further, Executive Order 13083 was put in place without any of the consultation otherwise required under Executive Order 12875 ("Enhancing the Intergovernmental Partnership"), though to be fair Executive Order 13083 also revoked Executive Order 12875, rendering these consultation requirements moot. In August 1998, President Clinton suspended Executive Order 13083 because of this controversy (via Executive Order 13095). Technically, this suspension restored both Executive Orders 12612 and 12875; the action to suspend Executive Order 13083 implicitly "unrevoked" both previously-revoked orders. See EOP 1987, 1998a, and 1998c.

We have retained Executive Order 12875 within our set of generally applicable executive requirements in part because the Order is generally not inconsistent with the Unfunded Mandates Reform Act, which supercedes it. However, we do not currently include Executive Order 12612 as a generally applicable executive requirement because the Clinton administration has quite publicly indicated its disaffection for it. In response to a number of early comments, we are reconsidering the wisdom of this decision. Additional comments on this issue are welcome.

### A. The Unfunded Mandates Reform Act (UMRA)

Title II of the Unfunded Mandates Control Act (UMRA) established new requirements for regulatory agencies engaged in actions that affect state, local, and tribal governments. UMRA was modeled in part on President Clinton's Executive Order 12875, but by virtue of having been enacted into law must be regarded as a superior authority.[14] Since UMRA's enactment, Executive Order 12875 has taken on the character of guidance for UMRA implementation insofar as it is not inconsistent with UMRA.[15]

UMRA applies to all executive branch departments and agencies and exempts independent agencies, boards, and commissions. Covered agencies must perform certain procedures before they propose or promulgate any regulation that may result in an aggregate unfunded mandate of $100 million or more, adjusted each year for inflation. These procedures include, among other things, consultation with affected state and local governments and the provision of adequate opportunities for affected governments to participate in the rulemaking. Agencies must prepare a written statement documenting their compliance with these procedural requirements. Under a variety of specific conditions, agencies may be exempt from these procedures.

In general, agencies also must perform extensive analyses of the benefits, costs and other impacts of any covered regulation, as well as "a reasonable number of regulatory alternatives." As in the case of UMRA's procedural requirements, specific regulatory actions also may be exempt or excepted from these analytic requirements under certain conditions.

The centerpiece of UMRA is its decision-making directive. Agencies generally are required to "select the least costly, most cost-effective or least burdensome alternative that achieves the objective of the rule." In addition, UMRA contains certain exemptions and exceptions that restrict the applicability of this decision-making directive.

[14] As a general matter, an executive order does not have the force of law but instead is issued "only to improve the internal management of the executive branch and is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person." See, e.g., Executive Order 12875, §6. This means that no person has any legal authority to enforce its provisions.

[15] UMRA required OMB to issue implementing guidance, as well. OMB did so on September 21, 1995, via OMB Memorandum M-95-20. Where OMB's guidance is relevant to agency compliance, we utilize its language to derive evaluative criteria. We examine agency compliance with Executive Order 12875 separately, focusing on those provisions that are not duplicative.

### B. The Small Business Regulatory Enforcement and Fairness Act (SBREFA)

The Small Business Regulatory Enforcement and Fairness Act (SBREFA) amends and expands upon the Regulatory Flexibility Act of 1980. This law is intended to motivate regulatory agencies to take special account of small business concerns.[16] Unlike its 1980 predecessor, certain provisions of SBREFA may be enforced in court by adversely affected parties.

SBREFA's procedural requirements largely follow the model set forth in the Regulatory Flexibility Act of 1980. However, SBREFA expanded these procedural requirements in certain ways. For example, agencies now must prepare "compliance guides" for small businesses, and these guides must be written in plain English.[17] There are a number of exemptions and to these procedural requirements that may be triggered depending on specific characteristics of the regulation.

Agencies generally must prepare a Regulatory Flexibility Analysis (RFA), and unlike previous law, agencies now may be subject to limited legal challenges. "Significant alternatives" must be considered, and agencies must explain the reasons why they rejected such alternatives.

Like its 1980 predecessor, SBREFA contains no decision-making directives concerning how agencies should choose among regulatory (or nonregulatory) alternatives. SBREFA requires agencies to document the reasons for their decisions, but neither prescribes nor proscribes any particular class, type, or style of regulatory decision.

### C. Executive Order 12866 ("Regulatory Planning and Review")

Executive Order 12866 applies only to executive departments and agencies; independent boards, agencies and commissions are exempt because they are not formally subject to presidential direction. All executive agency actions of general applicability and effect are covered, but a large fraction of all rulemakings are exempt because they are "non-significant."[18] The Order's application to guidance

[16] SBREFA applies to "small entities," which include small businesses, other small organizations, and small governments. For ease of exposition in this section, we use the term "small business" as a placeholder for all small entities.

[17] SBREFA's "plain English" requirement is reinforced by Vice President Gore's 1998 memorandum to agency heads requiring them to write rules in "plain language." See EOP 1998b.

[18] While the distinction between a "non-significant" and a "significant" regulation is an extremely important one, the Order does not provide useful definitions. See footnote 12.

documents, policy statements, and other quasi-regulatory actions is unclear, just as ambiguities arose in similar situations under its predecessor, Executive Order 12291.

Executive Order 12866 established an array of procedural, analytic and decision making requirements that apply to all "significant" regulations, plus additional requirements that apply to "economically significant" rules. The general threshold for an "economically significant" regulation is one that "may have an annual effect on the economy of $100 million," or the presence of certain specified qualitative characteristics. The Order does not define "annual effect," creating additional ambiguities.[19]

Procedural requirements include consultation in a variety of forms; mechanisms for public participation; and the use of clear, plain English to minimize interpretative uncertainties. Agencies also must provide OMB with a complete package of rulemaking documents and disclose a variety of explanations for how the regulation satisfies specified statutory and executive objectives. Additional documentation is required for "economically significant" regulations. Finally, there is an array of disclosure requirements that apply both to the agencies and to OMB.

Executive Order 12866 contains substantial analytic requirements, both for rules that are merely significant as well as those that are "economically significant." Where more extensive analysis is required, it must include descriptions of the underlying market or institutional failure that the regulation is supposed to remedy; the extent to which existing laws or regulations may be responsible for these failures; the identification and examination of a range of alternatives; and a thorough analysis of social benefits and costs.

The Order also sets forth presidential guidance concerning how agencies should exercise discretion they have under law. This guidance contains a relatively long list of decision-making *factors* for agency heads to consider, such as incentives for innovation, consistency, and predictability; the costs of enforcement and compliance; flexibility; distributive impacts and equity; and harmonization with the regulations of other agencies and levels of government. For these decision-making factors, however, the Order offers only ambiguous guidance

[19] The term "effect" is broader than "benefit," "cost," "expenditure," and other related terms. Similarly, "annual" may mean "during one year," "during *any* one year," or "annualized across many years." The use of "may" preceding this definition creates additional interpretative elasticity.

as to how they are supposed to be interpreted and applied.[20]

Despite this persistent ambiguity, a few decision-making *factors* in Executive Order 12866 imply interpretable *criteria* for decision making. Examples include cost-effectiveness; the minimization of burdens on state and local governments; the avoidance of regulations that are inconsistent, incompatible, or duplicative; and the tailoring of regulations to impose the least burden on society. The most obvious of these is the "statement of regulatory philosophy" found at the beginning of the Order, which states that "agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach."

### D. Economic Analysis Under Executive Order 12866

Strictly speaking, this guidance document issued on January 11, 1996, belongs within the previous section on the executive order to which it applies. We have separated it because it contains a rich vein of insight concerning how agencies are supposed to comply with the analytic requirements of the Order. In addition, the document's status is somewhat ambiguous. The Clinton administration consistently refers to it as a "best practices" document, implying that it contains a wealth of good ideas that are more suggestive than prescriptive.[21] For their part, agencies seem to understand it to be authoritative "OMB Guidance."[22] Although it has been modified to take account of certain extensions in the economics literature and differences in political orientation, the *economic* contents of the document closely track OMB's "Guidance for Regulatory Impact Analysis" first published as Appendix V in the 1990 edition of the Regulatory Program of the United States Government. Thus, the principles embedded in the

[20] Perhaps the most obvious example in this regard is the reference to "distributive impacts and equity." The Order provides no indication as to what pattern of "distributional impacts" agency heads should seek to achieve (or avoid). Nor does it define any particular distribution as either meeting (or failing) a test of equity.

[21] See, e.g., Katzen 1996 at 6 (footnote 3), referring to the document as "a best practices manual." Subsequent administration reports, such as OMB 1997 and 1998, consistently use similar language. It should be noted that the term "best practices" appears only twice in the document: once in a discussion of the proper use of contingent valuation methods (in which a strong recommendation is made that only CVM studies that employ "best practices" ought to be considered), and in a freestanding introductory paragraph.

[22] For example, the Environmental Protection Agency consistently refers to it as an "OMB Guidance" document in its own draft "Guidelines for Preparing Economic Analysis," the most recent version dated November 3, 1998. The draft refers to the document as a "best practices" guide only once (at 1-1), and 23 times as "OMB Guidance."

document, however it is referred to, have been in place for about a decade.

Most of this guidance document deals with specific issues in applied benefit-cost analysis. While many of these issues have highly technical aspects, their importance for generating valid and reliable estimates of benefits and costs can be easily understated. The utility of benefit-cost analysis, both as a decision-making rule and as a framework for identifying, describing, and quantifying tradeoffs where other decision rules might be preferred, depends critically on whether it is performed correctly.

Persistent doubts have arisen about whether agencies in fact perform benefit-cost analysis correctly, and thus generate valid and reliable estimates. Both OIRA and independent analysts have frequently discovered serious flaws in specific agency analyses, but no existing study has systematically and comprehensively examined the quality of federal agency analyses, thus leaving these doubts to fester.[23] By examining the extent to which agencies comply with OMB's 1996 guidance, CSAB/PRO thus will provide the first systematic record to inform this debate.

### E. Executive Order 12875 ("Enhancing the Intergovernmental Partnership")

Executive Order 12875 was issued in late 1993 when the issue of unfunded mandates first began to gain traction. As indicated earlier, it provided the foundation for the Unfunded Mandates Reform Act of 1995. UMRA built upon the provisions in this Order, however, which was less focused on reducing unfunded mandates per se as it was on providing states with compliance flexibility, particularly with their implementation of federal health and welfare programs.[24]

Executive Order 12875 includes a number of procedural requirements but limited analytic requirements, chiefly related to the issue of waivers from existing federal rules. Decision-making requirements are limited, as well, to provisions that require federal agencies to give reasons for the denial of state waiver applications.

[23] Two recent reports to Congress by OMB did not even open the question to debate. Instead, they simply reported agency estimates and gave citations where interested readers could find details, then subtly warned readers against actually interpreting the figures as meaningful. See OMB 1997, 1998.

[24] As indicated earlier, President Clinton revoked Executive Order 12875 when he signed Executive Order 13083 May 1998. However, his subsequent suspension of this latter Order the following August implicitly restored the applicability of Executive Order 12875.

The Order also has several large exemptions and exceptions. Most notably, rules that are required by law are exempt from all of the Order's procedural, analytic, and decision-making requirements. Also, as in the case of executive orders generally, Executive Order 12875 does not provide any formal enforcement mechanism in the event that an agency fails to comply with its provisions.

### F. Executive Order 12898 ("Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations ")

Executive Order 12898 links environmental policy to civil rights. It was the product of a number of books and articles, which asserted that minority and low-income communities bore a disproportionate share of environmental risk.

This Order is generally not regarded as one with implications for regulatory actions per se, but a closer inspection of its actual language reveals some important analytic requirements. In particular, in any case where a regulation purports to address an environmental and human health risk that is disproportionately high and adverse across race, national origin or income, the agency issuing the regulation has an obligation to collect, maintain and analyze information assessing and comparing environmental and human health risks. We construe this as an implicit requirement to document claims of disproportionately high and adverse effects and to discover such cases through analysis.

In addition, the Order requires agencies to imbue their risk assessment practices with environmental justice concerns. In particular, agencies must identify and analyze high-risk subpopulations, and examine local environmental exposures where stationary sources or Toxic Release Inventory reporters are involved.

### G. Executive Order 13045 ("Protection of Children from Environmental Health Risks and Safety Risks")

Executive Order 13045 applies to "economically significant" regulations "initiated after" April 23, 1997, or proposed on or after April 23, 1998, which "concern an environmental health or safety risk that an agency has reason to believe may disproportionately affect children." The term "environmental health or safety risk" is defined as:

> ...risks to health or to safety that are attributable to products or substances that the child is likely to come in contact with or ingest (such as the air we breath [sic], the food we eat, the water we drink or use for

recreation, the soil we live on, and the products we use or are exposed to).

The number of rules to which the Order applies thus depends on how broadly this definition is interpreted and agencies' proclivity to "have reason to believe" that such risks "may disproportionately affect children."

Because the language of Executive Order 13045 admits to such divergent and highly subjective interpretations, we approach the question of regulatory compliance by interpreting the language in a manner that is analogous to the concept of revealed preference in economics. That is, we will look for evidence in each specific rulemaking that an agency has demonstrable concern about disproportionate effects on children; where we observe evidence of such concern, we will infer the threshold for applicability has been exceeded. Conversely, where we do not observe any evidence of such agency concern, we will infer that no agency believes that the threshold for applicability has been breached. In each case where we conclude that the Order applies, we will evaluate the agency's compliance with it whether or not the agency explicitly invoked its provisions.[25]

For any covered rule, Executive Order 13045 imposes additional procedural and analytic requirements beyond those contained in Executive Order 12866. In particular, agencies are required to assess these risks and ensure that their regulations address them. Also, agencies must provide new analyses to OIRA specifically relevant to these risks.

Agencies are guided in their decision making under Executive Order 13045 by statements of principles, general policy and targeted annual priorities set by the Task Force on Environmental Health Risks and Safety Risks to Children. This interagency Cabinet-level body was established by the Order and is co-chaired by the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency.

[25] The second prong of the test for applicability requires that *an* agency have reason to believe that an environmental health risk or safety risk may disproportionately affect children. It does not require the *promulgating agency* to share this belief. Thus, we will look for evidence that *any* agency displays such belief or concern and consider the second prong to be satisfied whenever such evidence exists.

### H. Future Expansions of CSAB/PRO

We have designed the project in a modular way that permits its expansion as new generally applicable statutory or executive requirements are enacted or established. For this reason, CSAB/PRO will continue to monitor various legislative and executive proposals and examine how they could be incorporated.

The reporting of CSAB/PRO results poses an additional area of residual uncertainty. Because of both the expansive nature of the project and the hierarchical character of the information it will collect, we are exploring opportunities for Web-based publication as an alternative to traditional print formats. Additional project funding would be necessary to pursue this innovative option.

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