Regulatory Experimentation

Committee on Rulemaking

Proposed Recommendation for Committee | November 6, 2017

Introduction:

Making sound regulatory decisions demands information and analysis. Several ACUS recommendations encourage agencies to gather data when making new rules and when reviewing existing rules.[1] This recommendation reinforces analytic requirements imposed on agencies by legislation,[2] executive order,[3] and judicial decisions.[4]

Agencies need information about the problem that the regulation will address: the cause of the problem, its severity, and so forth. But agencies also need information about potential solutions to the problem. What possible alternative rules or rule designs might help solve the problem? How effective are these alternatives in addressing the underlying problem? Are there constraints, barriers, or unanticipated consequences that arise in the use of these different

[1] *See, e.g.,* Administrative Conference of the United States, Recommendation 2014-5, Retrospective Review of Agency Rules, 79 Fed. Reg. 75114 (Dec. 17, 2014), *available at* https://www.acus.gov/sites/default/files/documents/Recommendation%25202014-5%2520%2528Retrospective%2520Review%2529_1.pdf; Recommendation 85-2, Agency Procedures for Performing Regulatory Analysis of Rules, 1 CFR § 305.85-2(7)(c) (June 13, 1985), *available at* https://www.acus.gov/recommendation/agency-procedures-performing-regulatory-analysis-rules; Recommendation 79-4, Public Disclosure Concerning the Use of Cost-Benefit and Similar Analyses in Regulation, 44 FR 38826 (June 8, 1979), *available at* https://www.acus.gov/recommendation/public-disclosure-concerning-use-cost-benefit-and-similar-analyses-regulation

[2] *See,* P.L. 114-140 at § 4(a)(3) (Mar. 30, 2016); By-Laws and Operating Procedures of the Committee on Evidence Based Policymaking, *available at* https://www.cep.gov/content/dam/cep/about/by-laws.pdf

[3] *See, e.g.*, Executive Order 12866 § 5, 58 Fed. Reg. 51735, 51739 (Oct. 4, 1993), ("…to…improve the effectiveness of existing regulations… each … agency will periodically review its existing significant regulations to determine whether any such regulations should be modified or eliminated so as to make the agency's regulatory program more effective in achieving the regulatory objectives…"); Executive Order 13563 § 6, 58 Fed. Reg. 3821, 3822 (Jan. 21, 2011) (requiring agencies to "consider how best to promote retrospective analysis of rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned"); Executive Order 13771 § 2, 82 Fed. Reg. 9339 (Feb. 3, 2017) (requiring the repeal of two existing regulations for each new regulation proposed, and leaving in place prior requirements for the repeal of rules, including analyzing the costs and benefits of each action proposed for repeal); Executive Order 13777 § 3, 82 Fed. Reg. 12285, 12286 (Mar. 1, 2017) (requiring the establishment of Regulatory Reform Tasks forces that "shall evaluate existing regulations (as defined in section 4 of Executive Order 13771) and make recommendations to the agency head regarding their repeal, replacement, or modification, consistent with applicable law.")

[4] *See* Motor Vehicle Mfr.'s Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 53 (1983) (explaining that the agency must show that its action was the result of "reasoned decisionmaking.").

alternatives? In terms of understanding possible alternatives and how well they might work in practice, agencies benefit from having information from experience with these alternatives. Learning from experience is the focus of this recommendation.

No uniform or tidy formula exists as to how agencies should generate, gather, and analyze the data necessary to facilitate the learning needed to support sound regulatory decisions. A variety of well-accepted and widely used methods exist from which agencies may choose, with the appropriate choices often varying agency by agency and even from situation to situation. Practical considerations such as resource and data availability will affect the choices agencies make about the methods of learning used to support regulatory decision making.[5] Still, it is possible to clarify some of the main choices of methods for learning from experience that are available to agencies and which they should be encouraged to consider using at different stages of the rulemaking lifecycle. These methods, which are not necessarily mutually exclusive, can be used before or after a rule is adopted--and they may potentially be considered on occasion as part of the final rule itself, which might be structured to encourage or allow for variation that can facilitate future learning by agency officials.

The discussion that follows in this preamble will proceed according to the rulemaking lifecycle, beginning with ways for agencies to learn from experience before a rule is adopted, so as to inform the agency of how the rule should be designed. Learning before a rule is adopted will be vital for agency decision-makers in all instances; however, agencies may also consider methods for learning that could be incorporated into or otherwise facilitated by the design of a final rule itself as well as that could be facilitated by actions, such as waivers, that agencies could take after a rule is issued.

At any stage of the rulemaking lifecycle, an agency learns from experience with varied solutions to regulatory problems. Variation generally arises either between time periods[6] or

[5] A general discussion of factors to consider in choosing methods and measurements in regulatory learning can be found in Cary Coglianese, *Measuring Regulatory Excellence*, in Achieving Regulatory Excellence (C. Coglianese, ed. 2017).

[6] Longitudinal analysis is a research design that involves repeated observations of the same subjects over a period, where variation in the intervention occurs over time (i.e., data before and after an intervention is introduced). *See* Cary Coglianese,

jurisdictions[7] where a regulatory obligation has been imposed with those time periods or jurisdictions without such a regulatory obligation. For example, a regulation that goes into effect in 2017 leaves the agency with two distinct time periods to analyze: the relevant years before 2017, and 2017 and beyond. A rule that applies in Jurisdictions X and Y but not in Jurisdictions A and B leaves the agency with the ability to compare X and Y with A and B. The agency then can learn whether outcomes are improved in those time periods or jurisdictions with the regulatory obligation, compared with those without the obligation. However, agencies must be careful not to assume automatically that any differences in outcomes that they observe have been caused by the intervention of the regulation. Other factors that correlate with the observed outcomes might also vary across the same time periods or jurisdictions.

The Virtues and Drawbacks of Randomized and Observational Approaches

To try to isolate the effects just of the regulatory intervention, agencies have two main analytical approaches: randomized approaches and observational approaches. True randomized approaches guarantee internal validity, but they do have drawbacks. For one, there is always a question as to whether the results of a randomized experiment are externally valid[8]: a perfectly designed randomized experiment may prove that a chemical causes cancer in rats, but there is always a question as to whether this means the same chemical causes cancer in humans. Regarding regulatory randomization, there is a further complication that implicates internal validity.[9] Because double, or even single, blindness[10] is not possible in regulatory

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Measuring Regulatory Performance: Evaluating the Impact of Regulation and Regulatory Policy, Organisation for Economic Co-Operation and Development Expert Paper No, 1 39 (August 2012).

[7] Cross-sectional analysis means analysis of data collected at a specific point in time but where variation exists across at least two groups or jurisdictions, one subject to the intervention (such as a regulation) and one that is not. *See id.*

[8] External validity refers to the extent to which a study's results are generalizable to entities or individuals other than those included in the study.

[9] Internal validity refers to the extent to which the outcomes observed in a study can be said to have been caused by the intervention rather than by potential confounders.

[10] "Blindness" in this context means lack of awareness of being in the treatment or control group. "Double blindness" means neither the subjects nor the researchers know which subjects received the treatment, and which received the placebo. *See* Michael Abramowicz, Ian Ayres, and Yair Listokin, Randomizing Law, University of Pennsylvania Law Review, 948-950 (March 2011), *available at* http://scholarship.law.upenn.edu/cgi/viewcontent.cgi?article=1096&context=penn_law_review

randomization, regulated parties may engage in strategic behavior and researchers analyzing the data may exhibit biases that skew the results.

In addition to these methodological challenges, randomization can present legal, policy, and ethical obstacles. From a legal standpoint, subjecting similar parties to different rules may be thought to raise concerns under the Constitution's equal protection clause or the APA's arbitrary and capricious standard. Of course, an agency might present a valid argument that the rational basis, or non-arbitrary reason, for its action is to generate information necessary to make an informed decision.[11] From a policy standpoint, if some are subject to regulation and others are not, the agency may have artificially distorted a market, depending on what the rule requires. From an ethical standpoint, if the rule specifically sets up an experiment with the idea that after the experiment the rule will change, parties that have invested heavily in capital-intensive equipment will have unnecessarily incurred a sunk cost. Due to these legal, policy, and ethical challenges with regulatory randomization, in addition to the methodological ones discussed in the paragraph above, it may be appropriate for an agency to use it only under a limited set of circumstances.

Observational approaches are generally less ideal than randomized ones from the standpoint of drawing causal inferences, since internal validity is always a concern and must be accounted for in the design by using various statistical methods that attempt to mimic statistically what occurs with randomization.[12] However, they may in some circumstances have stronger external validity than randomization and they generally will not raise the same legal or policy concerns as randomization. With observational studies, the agency is either exploiting natural variation that would have arisen from the rule anyway, or is allowing for state-by-state flexibility, which generally does not garner significant criticism.

[11] *See id.* at 968

[12] Examples of such statistical methods are: difference-in-differences; propensity score matching; multivariate regression; instrumental variables; and regression discontinuity. *See* Cary Coglianese, Measuring Regulatory Performance: Evaluating the Impact of Regulation and Regulatory Policy, Organisation for Economic Co-Operation and Development Expert Paper No, 1 39-42 (August 2012).

As discussed in the sections that follow, agencies can choose at each stage of the rulemaking lifecycle--pre-rule, rule, and post-rule--between either randomized or observational methods. Agencies should factor the advantages and drawbacks discussed above in their decision making.

Pre-rule

In the pre-rule stage, an agency is gathering data to help inform a regulatory action it plans to take.

Randomized Methods. In addition to analyzing peer-reviewed studies that incorporate a randomized design, agencies can use pilot programs to learn from randomized study data. For example, if trying to determine whether a certain default rule of, say, saving for retirement should be required of all employers offering 401(k) plans, an agency could seek the cooperation of some large employers and ask them to randomly assign a default rule of opting into a certain saving plan versus one that defaults everyone into the plan but then allows them to opt out. That would be voluntary by the company but random (and not voluntary) by the individual. The agency might learn which default rule is better and then adopt that in a regulation that applies to everyone.

Observational Methods. Agencies can also set up observational studies, alone or in combination with the randomization approaches discussed above. Agencies might, for example, employ a cross-sectional research design by looking at variation in existing policies at the state level or perhaps in other countries, taking to heart Justice Louis Brandeis's observation that "a state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country."[13] In fact, Congress has, on numerous

[13] *See* New State Ice Co. v. Liebmann, 285 U.S. 262, 311 (1932)

occasions, directed agencies to analyze state-by-state variation to help determine optimal policies.[14]

Written into rule

An agency can write a rule to facilitate learning or can take advantage of variation that stems naturally from the rule.

Randomized Methods. One potential approach an agency might consider when appropriate would be a randomized control trial (RCT).[15] This would entail writing a rule such that some entities or people that fall within the agency's regulatory scope are subject to one version of the rule and some are subject to another version of the rule or not subject to the rule at all. The agency's decision as to who falls within each category is made on a random basis. For example, one could imagine a test of speed limits in which the posted limits on different roads were randomly increased or decreased. The drivers on these roads could be informed of the regulatory intervention (i.e., the speed limit on that road) without necessarily knowing that they were participating in a randomized experiment.[16] Although this example falls outside the realm of federal rulemaking, federal agencies can think of ways to extrapolate from this example to design an RCT that fits within their regulatory authority.

Despite potential methodological, legal, and policy concerns discussed above, there may be circumstances in which these concerns can be adequately addressed and an RCT will be an appropriate way for an agency to generate variation that facilitates learning from experience. For example, it might be that there is such uncertainty involved with the rule that the only way the agency can resolve the uncertainty is to put in place the rule. The conditions for the appropriate

[14] *See, e.g.*, P.L. 109-58 § 139 ("...the Secretary...shall conduct a study of State and regional policies that promote cost-effective programs to reduce energy consumption (including energy efficiency programs) that are carried out by utilities that are subject to State regulation.")

[15] *See* Michael Abramowicz, Ian Ayres, and Yair Listokin, Randomizing Law, University of Pennsylvania Law Review (March 2011), available at http://scholarship.law.upenn.edu/cgi/viewcontent.cgi?article=1096&context=penn_law_review

[16] *See id.* at 951

use of an RCT in the regulatory context could be limited, but it is nonetheless one approach that agencies should consider in deciding on methods for learning as they write rules.

Observational Methods. For the reasons discussed above, agencies will generally find it more feasible to use observational approaches in their rulemaking than randomized ones. First, it should be noted that, in any rulemaking, there is variation in the sense that there was the world before the rule went into effect and the world in which the rule is in effect. Further, in the case of a rule that an agency has rescinded, there are three worlds: the world before the rule went into effect, the world in which the rule was in effect, and the world after the rule was rescinded. Such variation presents rich opportunities for observational studies. Keeping in mind this natural, temporal variation that arises with any rule, agencies can, at the outset of the rule, commit to setting up a longitudinal study. In doing so, they will need to collect data from regulated parties before the rule goes into effect, then collect data once the rule is in effect (and then a third time if the agency rescinds the rule), identify potential confounders, and then use statistical techniques such as multivariate regression to control for them.[17]

Additionally, agencies can deliberately introduce non-random variation into the rule by setting some federal minimum standard and permitting states to exceed that standard. Agencies then can commit to using the resulting state-by-state variation to set up a cross-sectional design. An example of such a cross-sectional design would be to compare firms separated by a very short distance in neighboring states that have adopted different rules. Using regression discontinuity, the agency would be able to approximate randomization (i.e. the assignment of firms to a state with one rule versus another would be effectively random).[18]

[17] *See* Administrative Conference of the United States, Recommendation 2014-5, Retrospective Review of Agency Rules, 79 Fed. Reg. 75114 (Dec. 17, 2014)

[18] *See* Jonah B. Gelbach and Jonathan Klick, University of Pennsylvania Law School, Institute for Law and Economics, Research Paper No. 14-39 (October 10, 2014), *available at* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2507324

Post-Rule

Once a rule has been put in place, the agency has further opportunity to take advantage of variation.

Randomized Methods. Once a rule has been adopted, an agency can deregulate a segment of the market on a random basis to learn from variation. In 2004, the Securities and Exchange Commission (SEC) did this with respect to its "Uptick Rule."[19] The SEC concluded that the rule did not substantially increase market efficiency and consequently rescinded the rule.[20]

Observational Methods. In addition to deregulating on a random basis, agencies can achieve variation once the rule is in place by considering conditional waivers and exemptions. For example, if a regulated entity can present some evidence to suggest that it can meet the purpose of the regulation using an alternative approach, the agency could grant a waiver to that entity with the condition that the entity uses that alternative approach.[21] After granting a certain number of waivers, the agency can then test the effectiveness of its rule by setting up a cross-sectional design in which it collects data and compares entities that have selected different approaches. Agencies may find it necessary to use statistical techniques to control for potential confounders. Over time, these kinds of studies may provide the agency with information that justifies amending an existing rule, and it may help identify rules that will benefit from retrospective review. Fairness, legal, and ethical concerns are minimized when using conditional waivers if the agency permits all regulated entities to seek a waiver based on presentation of evidence, and the agency widely publicizes its waiver availability.[22]

[19] *See* SEC Release No. 50104 (July 28, 2004), *available at* https://www.sec.gov/rules/other/34-50104.htm

[20] *See* Zack Gubler, Regulatory Experimentation 42, *available at* https://www.acus.gov/report/regulatory-experimentation-draft-report (Sep. 19, 2017)

[21] *See* Recommendation 1 of current ACUS draft recommendation on waivers and exemptions, *available at* https://www.acus.gov/recommendation/waivers-and-exemptions-recommendation-revised; *See* Aaron Nielson, Waivers, Exemptions, and Prosecutorial Discretion: An Examination of Agency Non-Enforcement Practices 30, *available at* https://www.acus.gov/sites/default/files/documents/ACUS%20Waiver%20Report%20FINAL_0.pdf

[22] *See* Recommendation 5 of current ACUS draft recommendation on waivers and exemptions, *available at* https://www.acus.gov/recommendation/waivers-and-exemptions-recommendation-revised

Common Issues

Each stage of the rulemaking lifecycle presents agencies with the opportunity to learn from variation. Agencies can learn from both randomized and observational approaches, keeping in mind the virtues and challenges of each. Whichever method an agency chooses, there are two issues that an agency will need to think about across any part of the regulatory lifecycle: data collection and public input.

Data Collection

Collecting data is essential to ensuring that correct lessons are drawn from analyzing regulations. Agencies must be mindful of the Paperwork Reduction Act when collecting data, which limits their ability to send a survey instrument to ten or more parties.[23] Agencies may find it helpful to work closely with OIRA as part of their data collection endeavors.

Public Input

Best practices call for some opportunity for the public to learn about and comment on the results of the learning the agency has undertaken. For pre-rule learning, the notice-and-comment process is the required means for engaging the public, but there are other methods of public input that might be useful, even at the pre-rule stage, for public input beyond just notice and comment.[24] If an agency is planning to revise a rule, a subsequent notice and comment rulemaking will provide that opportunity. If there were for whatever reason a sunset on the initial rule, that would again provide the public with the opportunity to offer input on a notice and comment rulemaking to keep or modify the rule. Additionally, interim final rules -- where an agency adopts a rule without notice and comment procedures, pursuant to the APA's good

[23] *See* 5 CFR § 1320.3

[24] *See, e.g.,* Administrative Conference of the United States, Recommendation 2013-5, Social Media in Rulemaking, 78 FR 76269, *available at* https://www.acus.gov/sites/default/files/documents/Social%20Media%20Rec_Final_12_9_13.pdf

cause exemption -- facilitates learning through experience by incorporating public notice and comment at some point following adoption of the rule.[25]

But even absent a new notice and comment rulemaking--even if the agency is keeping the rule "as is"--it may benefit and learn from outside input on the systematic learning effort it has undertaken, whether through peer review process, advisory committees, public hearings or meetings, or just a solicitation of comments. The decision as to which approach to use to solicit public input turns on numerous factors, including resource constraints; the scope of the issues in question and the need for expert analysis on those issues; the agency's internal expertise; the availability of, and the agency's awareness of, outside experts; the scope of the issues to be analyzed; and the extent to which the agency is aware of relevant experts in the field.[26]

[25] Administrative Conference of the United States, Recommendation 95-4, Procedures for Noncontroversial and Expedited Rulemaking, 60 Fed. Reg. 43,110 (1995).

[26] *See* Zack Gubler, Regulatory Experimentation 54, *available at* https://www.acus.gov/report/regulatory-experimentation-draft-report (Sep. 19, 2017)

Appendix

Examples of the main methods of learning discussed in the preceding sections can be summarized in Table 1:

Table 1 Summary of Methods for Regulatory Learning

	Randomized	**Observational**
Pre-rule	• Randomized voluntary pilot programs; studies that rely on randomization	• Pilot programs where intervention is not assigned randomly (such as with voluntary programs) • Analysis of regulatory approaches in different jurisdictions and countries
Written into rule	• Randomized assignment of different regulatory obligations Control Trial (RCT)	• Rules that allow for state implementation and variation (e.g., cooperative federalism) • Cooperative federalism; • Analysis of temporal differences (i.e. "before and after" comparisons); • Creation of regulatory thresholds that will facilitate later comparing observations of entities above/below a threshold • Analysis of temporal differences (i.e., before and after rule adopted)
Post rule	• Regulated entities randomly selected for different types suspension of enforcement	• Granting of waivers that allow for the adopting of conditional upon adopting alternative approaches that can be studied.

RECOMMENDATION

Learning from Flexibility

1. To improve the quality of their rules, agencies should always seek opportunities to generate information to bring to bear on regulatory decision making. One way of generating information is through variation agencies intentionally introduce or foster, such as through pilot projects, demonstrations, or flexibility among states or regulated entities. Agencies should conduct learning in such ways that responsibly give due regard for legal, practical, and fairness considerations. They can learn from experience at one or more stages of the rulemaking lifecycle, from pre-rule analysis to retrospective review.

2. When agencies analyze variation to learn more about the effectiveness of policy options, they should make every effort to collect data and conduct reliable analysis. Only where appropriate, agencies should consider creating variation through a randomized control trial.

3. Congress should ensure that the agencies have adequate resources and authority to implement these recommendations.

Structuring Sunset Provisions

4. If an agency chooses to establish and learn from a temporary rule, the sunset period provided in such a rule should afford the agency enough time for evaluation and enough time to engage in notice and comment rulemaking in the event it chooses to adopt the rule on a permanent basis.

Data Collection and the Paperwork Reduction Act

5. When gathering data, agencies should be mindful of the potential applicability of the Paperwork Reduction Act, and agencies and OMB should use flexibilities within the Act and OMB's implementing regulations (e.g., a streamlined comment period for collections associated with proposed rules) where permissible and appropriate.