

Does the amount of participation matter? Public comments, agency responses and the time to finalize a regulation

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**Does the Amount of Participation Matter? Public Comments, Agency
Responses and the Time to Finalize a Regulation**

Abstract*

The notice and comment rulemaking process is a fundamental part of how agencies write regulations. While this process is starting to receive more empirical attention, the question of how the number of comments that an agency receives affects its decisionmaking process has received little examination. This paper uses Boolean analysis to examine nine rules from two agencies at the Department of Health and Human Services and evaluates the impact of a high volume of comments on agency changes to proposed rules and the time an agency takes to finalize a proposed rule. These nine cases suggest that agencies are most likely to change their proposals when they receive a high volume of comments on highly complex rules that are not very politically salient. Highly complex rules are also likely to take a long time to finalize when there are many public comments however it is often other factors that cause a long delay between proposed and final rules.

I Introduction

The notice-and-comment process for administrative rulemaking has been in place for nearly six decades. Despite its central function in policymaking, its purpose is still debated. Understanding the notice and comment process has become even more crucial because of the large governmental effort being made to implement electronic rulemaking ("e-rulemaking")

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primarily to facilitate increased participation in rulemaking.¹ These initiatives which will allow commenters to submit electronic comments on all agency proposals promise a revolution in participation in the regulatory process (Johnson 1998). However, scholars still have an uneven understanding of how notice-and-comment works in the non-electronic setting. If there is to be a revolution, it would behoove us to understand the regime being overthrown.

In particular, the impact of the number of comments on agency decisionmaking has been virtually ignored in the literature. While there are theories about the interaction between participation and deliberation and concerns about bureaucrats merely tallying comments as votes, few empirical studies exist using the volume of comments as an independent variable. Do more numerous public comments, by increasing information available to agencies, make agencies more likely to make changes requested by commenters (Zavestoski and Shulman 2002)? Or do agencies pay more attention when they have fewer comments on which to focus (Rossi 1997)? Further, do additional comments mean that agencies take more time to finalize proposed rules, because they have to respond to the comments (even if only to reject them)? An affirmative answer to this last question would mean that a greater volume of comments could lead to further ossification of the rulemaking process (McGarity 1992).

The multiple-case study discussed in this article examines nine rules from the Department of Health and Human Services (HHS), each rule with a different number of comments. My aim is to relate volume of comments to (1) the likelihood that agencies will change proposed regulations in response to public comments and (2) the length of time it takes to finalize a proposed rule. Using Boolean analysis (as described by Ragin (1987)), I relate two dependent

variables (the extent of change between proposed and final rules, and the length of time to finalize a rule) to the volume of comments and other potentially relevant independent variables (e.g., a rule's complexity and salience).

Boolean analysis is a method for analyzing data from a small number of observations. It is particularly useful in the multiple case study format. This article is the first use of Boolean analysis in this subject area. The product of a Boolean analysis is an equation describing combinations of independent variables that are correlated with the dependent variable. While Boolean analysis does not produce error estimates like statistical analysis, it allows the researcher to better understand the relationship between variables in a multiple case study. By using truth tables and Boolean equations, relationships that are not apparent from merely an analysis of the cases become clear.

This article proceeds as follows. Section II reviews our current understanding of the impact of the public comment process. Section III describes the nine rules studied and presents basic data on each. Section IV describes Boolean analysis and applies it to the correlation between the independent variables and my first dependent variable: the extent to which HHS changed each rule from its original form. Section V applies Boolean analysis to the relationship between independent variables and my second dependent variable: the time it takes to finalize a rule. Finally, Section VI draws conclusions about the impact of an increased volume of public comments and considers the relevance of that conclusion to the movement to electronic rulemaking.

II The Public Comment Process

While agencies have solicited input in developing their regulations for most of the history of the regulatory process (Kerwin 2003), the modern notice and comment process came about with the enactment of the Administrative Procedure Act (APA) in 1946. When promulgating regulations, agencies are required to publish a notice of that regulation, solicit public comments, and then consider those comments before finalizing the regulation.²

Understanding the impact of notice and comment rulemaking can help us understand both how regulatory policy is made and shed light on broader questions about the role of participation in governance. A central question in regulatory policy is whether elected officials influence the decisions of unelected bureaucrats. McCubbins, Noll, and Weingast (1999) argue that notice and comment, like other procedures in the regulatory process, facilitate political control of the bureaucracy by forcing bureaucrats to be responsive to the same collection of interests that politicians respond to.

Empirical examination of the notice and comment process can help us understand whether agencies are indeed responsive to the interests that comment on agency proposals. It can also shed light on the cost of increasing participation in policymaking. Responding to comments takes time for regulatory agencies. While there is nearly universal agreement that some participation in rulemaking is beneficial, there is also concern that the regulatory process has become so burdened by procedural requirements that it is no longer a good policy making option for agencies (McGarity 1992).

Several studies have evaluated the effect of the public comment process. Golden (1998), West (2004) and Yackee (2006) had the largest sample sizes. Golden (1998) reviewed eleven rules from three agencies and found that in these cases, public comments were unlikely to lead to significant changes. She also considered whether the identity³ of the commenters affected whether agencies made changes in their regulations and found that it did not. She did note that although changes were unlikely, they did seem to occur when there was a consensus among a large number of commenters that a particular change was needed.

West (2004) looked at forty-two rules and found that the role that comments played most successfully was to provide information to political overseers about constituents' views. He noted that because the comment period comes so late in the regulatory process, it is of limited usefulness. Perhaps for that reason, the agencies he studied made few changes in response to public comments. Of the forty-two rules that West examined, only sixteen had "significant" (but not "fundamental") changes, and it was not clear that even these were the result of comments. Yackee (2006) examined 40 rules from four agencies that received between 2 and 200 comments and found that comments made a difference on low salience rules (Yackee defines all rules with fewer than 200 comments as having a low salience.), particularly when commenters were in agreement on a change. It is clear that salience, defined as the amount of public attention that a rule receives, may affect how responsive agencies are to public comments.

In a broader study, Kerwin and Furlong (1992) examined a variety of factors that affect the time it takes to promulgate a rule. The number of comments is one of a series of independent variables in a regression with time as the dependent variable. They find only a statistically

insignificant negative effect of the number of comments on the time between proposal and final rule and on the time between the start of a rulemaking (identified by survey respondents) and its conclusion.

There have also been numerous smaller studies of the public comment process. Shapiro (2007) found that in one salient rulemaking, comments did affect agency decisionmaking on the final rule. Cuellar (2005) reviewed three rulemakings with high comment volumes and found that (1) agencies were more likely to listen to sophisticated commenters and (2) individual commenters raised different issues than interest groups. Balla (1998), considering a single Health Care Financing Administration rulemaking, found that the public comment process had limited influence. Furlong (1997) found little relationship between the type of interest group and the influence of the group's comments. None of these studies examined the relationship between the comments received and the time it takes to finalize a proposed rule.

Numerous works have speculated about participation in the regulatory process in the context of e-rulemaking. Johnson (1998) predicted that use of the internet will improve the rulemaking process. He extolled the broader participation that electronic rulemaking will allow, emphasizing that with more participants involved, it will be harder for small groups to hijack agencies, and it will be easier to hold agencies accountable for their decisions. Zavestoski and Shulman (2002) argued that the increased participation yielded by e-rulemaking initiatives will be beneficial if, as in the case of the USDA organics rule,⁴ additional public comment translates into more deliberation. Balla and Daniels (2007) examined rulemakings at the Department of Transportation before and after e-rulemaking was implemented and are skeptical whether more

participation will occur on any but the most prominent rules, while Stanley and Weare (2004) argue that the Internet has the potential to bring new participants into government decisionmaking but remain skeptical about the extent to which government officials will incorporate the ideas of new participants. Finally, Emery and Emery (2005) argued that as currently constructed, e-rulemaking will increase the quantity of comments without affecting their quality.

There are other prominent skeptics who have questioned the beneficial effects of widespread participation on the regulatory process outside of the discussion on electronic rulemaking. Rossi (1997) saw an inherent tension between participation and deliberation. While participation promotes a breadth of involvement, deliberation promotes depth. Participation and deliberation may be complementary at low levels of participation, but as participation increases, deliberation decreases. Excessive participation can also crowd out thoughtful analysis by agency decisionmakers and political accountability and lead to strategic obfuscation and poor decisionmaking. Herz (2004) voiced a similar concern: bureaucrats may tally large numbers of comments as if they were votes rather than engaging the substantive objections raised by commenters.

Many of these skeptics are making arguments similar to those made by McGarity (1992) back before anyone knew what the internet was. McGarity (and others) bemoaned the increased proceduralization of the rulemaking process. These procedures, notice and comment included, had made it so hard to promulgate a regulation that agencies were turning away from rulemaking as a policymaking option. Hard-look judicial review is seen by some as a significant reason for

delay in finalization of complex rules. The literature on ossification discusses the impact of hard-look judicial review extensively. An agency worried about judicial review may take longer to deal with rules with many comments than rules where there are few comments because more comments may signal a greater likelihood of judicial challenge.

There have only been very limited studies of the impact of the volume of comments on the rulemaking process. Will increased participation increase the substantive impact of notice and comment? Or will it lead to a longer regulatory process and a retreat from rulemaking?

III The Nine Rules

As a means to answer the question how the number of comments affects regulatory decisionmaking, I decided to examine the impact of varying numbers of comments on rulemakings. I selected two agencies that, over roughly the same time period, had a number of rulemakings that varied substantially in the number of comments received. I chose two agencies within the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA) and the Administration for Children and Families (ACF). Both agencies give the researcher the advantage of including considerable detail about comments received and the agency responses in the preamble to their final rules. Both agencies also promulgate rules frequently and receive varying numbers of comments on their proposed rules.

Also, while they are both within HHS, the two agencies promulgate different types of rules: FDA is a traditional regulatory agency, and most of its rules impose restrictions or costs

upon a regulated industry. By contrast, ACF's main purpose is to confer benefits -- most of its rules set restrictions either on what can be done with these benefits by beneficiaries or on ACF's partners in state governments. This allows me to examine comment response in two different regulatory contexts. We must be aware however that these two agencies, despite their differences, are only two of a myriad of agencies that promulgate regulations. Agencies outside cabinet departments or that have different relationships with their commenters may behave differently than FDA and ACF.

Within each of the two agencies, I selected rules that were proposed and finalized during the Clinton Administration in order to eliminate the possible confounding variable of administration change.⁵ All rules were rules promulgated under section 553 of the Administrative Procedures Act. In order to eliminate the confounding variable of executive-office review, I chose only rules that were "significant"⁶ and therefore reviewed by OMB. Within these constraints, I examined five rules from ACF and four rules from FDA. To choose the rules, I went through the list of final rules reviewed by OMB starting at the end of the Clinton Administration. I selected the first rule I found with a small number of comments (<10), a large number of comments (for ACF this meant more than 100 comments, for FDA, I was able to find a rule with more than 235,000 comments)⁷, and then chose two rules with intermediate numbers of comments for each agency.⁸ For each rule, the number of comments was listed in the preamble to the final rule. Table I lists the rules and the number of comments on each rule.

As one can see from the table, there is considerable variation in the number of comments received within each agency.⁹ The five ACF rules received between 19 and 300 comments and

the four FDA rules received between 9 and over 235,000 comments. The Meat and Poultry, State Assessment and Child Support rules all received a small number of comments while the Dietary Supplement,¹⁰ Juice and Head Start rules all received many comments. The commenters for the ACF rules were primarily state governments (or in the case of Tribal TANF, tribal governments) and advocacy groups. The Juice and Dietary Supplement rules received many comments from both industry and consumer groups while industry representatives and product customers were the main commenters for the Aqueous Drug Products and Meat and Poultry rules.¹¹

In the preambles to their final rules, FDA and ACF articulate in great detail their responses to comments -- one reason that I selected these two agencies for this study.¹² Certainly, relying upon an agency's own account of its response to a comment is not a perfect way to evaluate that agency's response. Other means -- e.g., review of the rule's development by an expert in its subject matter or detailed interviews with all of the commenters -- would give a more objective picture. Unfortunately, for a researcher attempting to draw conclusions about rules covering a wide spectrum of specialized subject matters and together generating thousands if not millions of comments, these means are impracticably costly. Therefore, I have relied on the agency's explanation of the change between proposed and final rules as the best-available approximation of the extent of that change.¹³ In order to understand aspects of the rulemaking process not described in the rule (such as the internal agency process for dealing with comments), I conducted interviews with at least one official involved in the regulatory process for each rule.

I categorize an agency's response to an issue raised by commenters in one of three ways:

- The agency may have dismissed the issue and made no change to the proposed rule.
- The agency may have made minor or clarifying changes in response to the issue raised by the commenter(s).
- Finally, the agency may have made a significant change to the provision commented on.

The difference between the last two categories may appear to be subjective and could be colored by the agency's description of its response. Often however the agency specifically uses the word "clarify" to describe its change so I have confidence in many of the distinctions made between these two categories.

Table II sets out, for each of the nine rules, the number of issues raised and the categories of agency response. It also shows the time between proposal and final rule for each of the nine rules studied. Once again there is considerable variation overall and within each agency in both the time to complete a rule and the extent to which changes were made. On the Meat and Poultry and Child Support rules, no major changes were made but on the Head Start rule, nearly 17% of the issues raised resulted in major changes. If one looks at total changes, the percentages vary from 12% (Child Support) to 66% (Head Start). As for time to completion, five rules were completed in 20 months or fewer with the High Performance Bonus rule taking less than a year and four rules took 31 months or more with the Meat and Poultry and Head Start rules taking more than four and a half years between proposal and promulgation.

In order to draw conclusions about the impact of the volume of comments on the extent of changes to rules, and on the time to completion, one needs to control for other independent

variables. Two particularly important independent variables are the complexity of the rule and how much political attention the rule receives.

Some rules are more complicated than others. Matland (1995) describes complexity as one of the key parameters in describing a policy issue. Quite plausibly, an increase in complexity increases the extent of change between proposed and final rule, because commenters on complex rules may have more information to offer bureaucrats than commenters on simpler rules. Also plausibly, a more complex rule takes longer to finalize than a simpler one.

Measuring the complexity of a rule is not straightforward. Agency perceptions of complexity are likely to be biased because bureaucrats working on one issue have no way of comparing the complexity of their work to work on very different issues. One objective measure of complexity might be the length of the regulatory text. Often, a text is longer when a rulemaking deals with a greater number of issues. However, even short rules can deal with complicated issues particularly if a complex rule is being revised. Therefore another measure is needed.

One possibility is categorizing rules dealing with scientific issues as complex. However, anyone who has dealt with non-scientific regulatory issues would recognize the problems with this (consider rules by the Internal Revenue Service for example). Another variable that could be correlated with complexity is the length of the comment period for the proposed rule. One could argue that complex rules require longer comment periods. Unfortunately there is little variation

in comment periods and they seem to be more dependent on agency policy than the subject matter of the rules (all of the ACF rules had 60 day comment periods).

Another objective measure of complexity might be the length of the preamble to the proposed rule.¹⁴ The purpose of the preamble is to explain the regulatory changes being proposed. Inferably, the more complex those changes, the longer the required explanation. In this study I have chosen the number of words in the preamble to the proposed rule as my measure of complexity.¹⁵ Because, as described in the next section, variables will have to assume binary values, I have arbitrarily selected 10,000 as the number of words in a preamble above which a rule is "complex."¹⁶ By that measure, five of the rules are "complex" (High Performance Bonus, Tribal TANF, Child Support, Head Start, and Juice). I note below all conclusions that are specifically dependent on this categorization of complexity compared to using a cutoff point of 20,000 words.

It is not obvious how the amount of public attention will impact the likelihood of change in a proposed rule. While all rules are "salient" to someone, some rules generate far more attention than others and agencies may react differently to these rules. West (2004) found that the primary role of public comment was to alert political overseers to concerns about proposed rules. This would argue that highly salient rules are more likely to be changed. On the other hand, Yackee (2006) found that low salience rules are more likely to be changed. As for time to complete a proposed rule, agencies may be more likely to take less time on politically salient rules because of political pressure to complete the rulemaking (Kagan 2001). To measure

saliency, I asked agency officials whether the rules in question had received media attention; the only two that had were the FDA's Juice and Dietary Supplement rules.¹⁷

While this subjective measure is admittedly imperfect, finding a measure of saliency that is independent of the number of public comments received is difficult, because more salient rules will necessarily also generate more comments.¹⁸ Therefore we are unlikely to find any rules that are high saliency and have received few comments. In statistical terms we would expect considerable co-linearity between comment volume and saliency. Indeed, in this study, the two rules receiving media attention were also the rules that garnered the most comments. Because of this correlation between saliency and volume, conclusions based on combinations of these independent variables will have to be very limited in scope.

Another independent variable that may affect the degree to and manner in which agencies respond to public comments (and the time it takes to respond to comments) is whether agencies have engaged in extensive consultation with the public prior to issuing a proposed rule (West 2004, Balla and Daniels 2007). If an agency has pre-proposal meetings with affected interests, it may learn nothing new in the public comment period. Interviews with agency officials indicated that when crafting four of the rules studied -- High Performance Bonus, Tribal TANF, Aqueous Drug Products, and Dietary Supplements -- the agency made extensive efforts prior to proposing the rule to solicit the views of affected parties.

One final independent variable likely to affect agency responsiveness to comments is the degree to which comments were dominated by a single category of stakeholder or the degree to

which commenters agree on necessary changes.¹⁹ Golden (1998) and Yackee (2006) cite this as a possible source of agency responsiveness. Wilson (1991) discusses agency capture, an agency being beholden to a particular interest group, as a source of agency decisionmaking. For the nine rules examined, I calculated the percentage of comments that were from the type of commenter submitting the greatest number of comments. (In the case of ACF rules, this was usually state or tribal government; for the FDA rules, it was industry). In the case of four rules -- State Self Assessment, Child Support, Tribal TANF, and Meat and Poultry -- over 50% of the comments came from one type of commenter.

IV Analysis: When Does the Amount of Participation Matter?

A sample size of nine cases is obviously not large enough to use statistical techniques to analyze the relationship between dependent and independent variables. To maximize the usefulness of the nine observations, I instead use the "comparative method" described by Charles Ragin (1987). Ragin's comparative method is a form of Boolean analysis. As mentioned above, the product of a Boolean analysis is an equation describing combinations of independent variables that are correlated with the dependent variable.

Boolean analysis involves the use of truth tables. A dependent variable (in this case, either the extent of change between a proposed and final rule or the time it takes to finalize a rule) and several independent variables (i.e., volume of comments, complexity, and salience) are assigned values of zero if absent and one if present.²⁰ The rows of the truth table represent every possible combination of values for the independent variables. For example, there would be four

rows for two variables, eight rows for three variables, sixteen rows for four variables and so forth. The data from the case studies is then used to fill in the appropriate value (0 or 1) for the dependent variable for each combination of independent variables observed. For example, in the first row of Table 3, there are three cases that had low comment volume and low complexity. Two of these three cases did not have many major changes so the dependent variable gets a "0" for this row.

Ragin (1987) advocates use of the Boolean method as a valuable middle ground between case studies and statistical methods. It allows the researcher both to "digest many cases and assess causal complexity." It is particularly valuable in interpreting limited amounts of data. Studies of rulemaking provide potentially fertile ground for Boolean analysis. Because large datasets are hard to assemble (and will be even as electronic rulemaking becomes a reality)²¹ researchers have used the multiple case study approach. In this study, the first study of rulemaking to utilize Boolean analysis, the technique allows me to evaluate the nature of the interaction of volume of public comments with other independent variables and determine under what circumstances more comments meant more responsiveness or more delay in the rulemaking process. Boolean analysis has the potential to significantly help our understanding of rulemaking.

In this study, I am limited to considering three independent variables at a time. If any more than three variables are used, then the majority of possible combinations will not be present in the cases.²² Even with this restriction, not all combinations of the independent variables will be present in the nine case studies.²³ As long as most of the combinations are present, analysis is

possible and some inferences can be drawn. In addition, it may be possible to make assumptions about combinations of variables that are not observed based on those combinations that were. The combinations that lead to a positive outcome (significant change between proposal and final rule or a lot of time between proposal and final rule) in the dependent variable are then placed in a Boolean expression.

As shown in Table II, there are two potential measures of the extent of change between a proposed and final rule. One could use the percentage of issues raised that resulted in *any* change or the percentage of issues raised that resulted in *major* changes. Under a "total change" metric, the agencies promulgating the State Self Assessment, Head Start and Aqueous Product rules made changes in response to 40% of issues raised by commenters. For the remainder of the rules, fewer than 30% of issues generated changes. Under a "major change" metric, the agencies promulgating the High Performance Bonus, Head Start, and Aqueous Products rule made major changes in response to 8% of the issues raised, while the remainder of the rules had major changes in response to fewer than 4%. The two metrics therefore give similar results. The following analysis relies upon the "major change" metric because so many of the minor changes do little but change language without changing meaning. However, I note when the results under the total change metric are different than the major change metric.

Constructing a truth table for volume of comments and complexity gives us four possibilities shown in Table III. The first two columns give the four possible combinations of comment volume and complexity (low volume/low complexity, high volume/low complexity, high volume/low complexity, high volume/high complexity) while the third column uses data

from the cases to categorize the dependent variable (changes to the proposed rule). This leads to the following Boolean expressions:

Large volume and Complex rule = changes

Small volume or Simple rule = few/no changes

In a full sentence: agencies are likely to make changes to proposed rules only when there is a high volume of comments and the rule is complex. This can be explained as the situation when the agency is most likely to receive information from the public that will help it better understand the area in which it is regulating. The rule is complicated and the agency receives a significant amount of information from the public. Some of this information helps the agency resolve complicated issues.²⁴

On the other hand, when either of these conditions is not met, change is less likely. In these scenarios, agencies behave as described by West and Golden. If they do not receive many comments, then they are receiving little information that would convince them to change their proposal. If a rule is not complex, the agency is more likely to thoroughly understand the rule prior to proposing it and therefore be less likely to be swayed by comments received.

What happens when we look at the volume of comments in conjunction with the salience of a rulemaking? Once again there are four possibilities shown in Table IV. Not surprisingly, there was no example of a high-profile rulemaking with few comments. As noted earlier in the article, isolating the effect of a large volume of comments from the effect of political salience is particularly challenging. The very salience of a particular rulemaking is probably one factor that helps generate comments. The data from the table again give us two equations:

Low volume and Low salience or High volume and High salience = no change

High volume and Low salience = change.

If we assume that the unlikely case of a high-profile rule with few comments would exhibit little change, then the first equation simplifies to:

Low volume or High salience = No Change

As with volume and complexity, this is a plausible relationship. Agencies are more likely to change rules when they get a high volume of comments on a rule to which political overseers are less likely to be paying attention.²⁵ The comments in such a case may give agencies additional information that is valuable, and the low-profile nature of the rule means that agency officials may not have as great a stake in sticking to their proposal. However, if either of these conditions is not met, then change is unlikely: A low volume of comments means agencies are unlikely to get much helpful information, and even if an agency does get many comments on a high-profile rule, changing a proposal that has already likely been vetted politically and likely defended in public by political officials is difficult.

What happens when we combine all three variables in one analysis? Not surprisingly, the nine rules studied do not include each of the eight possible combinations of complexity, salience, and comment volume. With that said, the table for the three variables is Table V. If we assume that the low volume-plus-high salience combination (shown in the first two shaded rows) either will never exist or will lead to few changes, then only one combination is missing: high volume, low complexity, and low salience (the third shaded row).

The missing combination could, of course, lead to either of the two outcomes. What would happen if we assume it leads to many changes and derive a Boolean expression? If we assume that this combination leads to *many* changes in agency proposals, then the conditions for change are high volume and low salience regardless of complexity.²⁶

We could also assume that high volume of comments, low complexity and low salience leads to few changes. If we assume that this missing case leads to *few* changes, then the only combination that reliably leads to change is a high volume of comments on a complex but low profile rule.

Unfortunately, given what happened in these particular nine cases, one cannot draw interesting conclusions by looking at the combination of comment volume with either early consultation or the presence of a dominant commenter (industry and state). With both variables, there are too many split outcomes (in which there were two cases, one with a significant number of changes and the other without) or outcomes that are not present.

In conclusion, we were able to identify limited circumstances in which additional comments may lead to additional changes. When coupled with low salience and high complexity, the presence of a large number of public comments led to significant changes from the proposed rule in these cases. On high salience or low complexity rules, high comment volume did not lead to changes from the proposed rule. In addition, *regardless of salience or complexity*, low comment volume made changes unlikely.

V. Do Additional Comments Mean More Time Between Proposed And Final Rule?

As shown in Table II, the rules I examined varied considerably in the amount of time it took to finalize them. The High Performance Bonus regulation was finalized nine months after it was proposed, while the Head Start rule took over five years to finalize. In order to divide the rules into two categories (a necessary simplification for Boolean analysis), I labeled the four rules that took more than two years to finalize as having taken a "long" time and the five rules that took fewer than two years to complete as having been completed "quickly" (where conclusions would be different with a cutoff of 18 months rather than two years, I note below).

Table VI illustrates the correlation between the possible combinations of comment volume and complexity to the resulting time to complete the rule. This leads to the odd finding that the rules that took the longest were those that were either simple, with few comments, or complicated, with many. The latter finding is not surprising, as sorting out complicated issues addressed by many parties is intuitively likely to take a long time.²⁷

The former finding -- that simpler rules with fewer comments take a long time -- is harder to explain. The most persuasive explanation I heard was from one of my interview subjects, who described the two rules in this category (both from FDA)²⁸ as those that the agency had put on the "back burner" in favor of other projects. Both rules were also of low salience, meaning that although simple, they were ones that no one was putting pressure on the agency to finalize (as evidenced by both the low salience and few comments).

This leads to the question of whether different agencies take longer to complete rules. We can look at that question by adding identity of agency as an independent variable to the above analysis. This is done in Table VII. The above table supports a few observations. FDA takes a long time to complete complex rulemakings with a lot of comments or simple rulemakings without many comments (the same conclusions we drew about rulemakings generally, above).²⁹ ACF, by contrast, completes rulemakings with few comments quickly, regardless of the level of complexity. FDA deals with simple issues with many comments quickly.

Looking at salience and comment volume together does little to add to our understanding of the time it takes to finalize a rule. As discussed above, there are no cases with few comments but high salience. Cases with many comments and high level of salience were split between those that were completed quickly and those that were completed slowly. The same was true for cases with a large number of comments and a low level of salience.

Discussions with the interview subjects cast further light on why some rulemakings take longer to complete than others. ACF bureaucrats discussing the Head Start rule mentioned the fact that coordination with the Department of Transportation (required because the rule dealt with vehicle safety standards) slowed down that rule's completion. Similarly, FDA bureaucrats cited difficulty in reaching agreement with the Department of Agriculture as a factor delaying work on the Meat and Poultry rule.

It is therefore clear that analysis of the time it takes to complete a rule can depend on a number of variables that may be invisible to the researcher who looks mainly at the qualities of the rule. That said, some of the visible qualities appeared to make a difference in these cases and this may have implications for the movement to electronic rulemaking. Specifically, complex rules with many comments appear to take longer to complete than most other rules. If the volume of comments increases, as electronic rulemaking becomes the norm, we may expect those rules that deal with complex issues to become harder for agencies to finalize.

VI Conclusion

The role of participation in the rulemaking process has been a central question since the passage of the Administrative Procedure Act in 1946 (Kerwin 2003). To date there has been little examination of the impact of varying levels of participation on agency regulatory decisionmaking. This examination of nine rulemakings has evaluated potential impacts of greater participation in the rulemaking process.

The notice and comment process has always held out the promise of public influence on policy decisions (Davis 1969). The public comment process, however, has also long been derided as a sham (Elliott 1992), and several empirical studies (Golden 1998; West 2004) have argued that comments have a limited impact on agency decisionmaking. In this study, the cases where comments led to changes to agency proposals were a limited subset of all rules; those rules which are complex but not politically salient. This may be because in promulgating these rules, agency bureaucrats both (1) feel safe making changes from their proposals and (2) have the

most to learn from information provided by outside parties. This may hearten advocates of participation who hail the information-providing benefits of the comment process. It may discourage advocates of political control of the bureaucracy however because those rules most likely to be of concern to political actors are those which are least likely to be changed as the result of comments.

At the same time a large number of comments can add delay on complex rules, crystallizing the cost of added participation. I also discovered, however, that it is often other factors that caused a long delay between proposed and final rules.

What do these cases mean for the movement to electronic rulemaking (or any effort that would increase the volume of public comments)? First, we should keep in mind that this study reviewed only nine cases from two agencies: therefore, generalizability may be limited. With this limitation in mind, the study generated several interesting findings. When there is greater participation in the public comment process, then on some highly complex, low salience rulemakings, a considerable benefit may occur. For the body of complex rules as a whole, the rulemaking process may take longer than it already does. This tradeoff should be part of the calculation in the decision to move toward electronic rulemaking.

This article also introduces Boolean analysis to the study of rulemaking. In doing so, strengths and weaknesses of the methodology are apparent. As Ragin (1987) describes the Boolean analysis allows us to better understand causal complexity with small sample sizes. This is particularly apparent in the finding that comments are most useful for low salience high

complexity rulemakings. On the other hand, the limited number of variables that one can examine (particularly when cases overlap on dependent variable combinations) and the need to transform all variables into binary variables are important limitations. However, given that the multiple case study approach is so common in studies of rulemaking (Golden 1998, West 2004), I think the Boolean approach has much to offer in helping researchers draw insights about the regulatory process.

Tables

Table I: Rules and Comments Received

Rule	Abbreviated title used in this article	Agency	Number of public comments
Sterility Requirements for Aqueous Based Drug Products for Oral Inhalation	Aqueous Drug Products	FDA	61
Substances Approved for Use in the Preparation of Meat and Poultry Final Products	Meat and Poultry	FDA	9
Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice	Juice	FDA	800
Regulation on Statements Made for Dietary	Dietary Supplements	FDA	> 235,000

Rule	Abbreviated title used in this article	Agency	Number of public comments
Supplements Concerning the Effect of the Product on the Structure or Function of the Body			
Tribal Temporary Assistance to Needy Families	Tribal TANF	ACF	46
Bonus to Reward States for High Performance Under the TANF Block Grant	High Performance Bonus	ACF	130
Incentive Payments, Audit Penalties, Child Support Enforcement Program	Child Support	ACF	28
State Self Assessment Review and Report	State Assessment	ACF	19
Standards for Safe Transportation	Head Start	ACF	300

Table II: Changes to Proposed Rules and Time to Finalize Proposed Rule

Rule	Number of issues raised	Number of issues in response to which agency made no change	Number of issues in response to which agency made minor change	Number of issues in response to which agency made significant change	Time Between Proposed and Final Rule
Aqueous Drug Products	12	7	4	1	32 months
Meat and Poultry	5	4	1	0	56 months
Juice	157	128	26	3	31 months
Dietary Supplements	112	95	15	2	20 months
Tribal TANF	123	87	32	4	19 months
High	66	50	8	8	9 months

Rule	Number of issues raised	Number of issues in response to which agency made no change	Number of issues in response to which agency made minor change	Number of issues in response to which agency made significant change	Time Between Proposed and Final Rule
Performance Bonus					
Child Support	90	79	11	0	14 months
State Assessment	36	20	15	1	14 months
Head Start	71	24	35	12	67 months

Table III: Truth Table Relating Volume and Complexity to Major Changes

Comment Volume (1= many, 0 =few)	Complexity (1=complex, 0 =simple)	Major changes³⁰
0	0	0 (2 out of 3 cases)
0	1	0 (2 out of 2 cases)
1	0	0 (1 case)
1	1	1 (2 out of 3 cases)

Table IV: Truth Table Relating Volume and Salience to Major Changes

Comment Volume (1= many, 0 =few)	Salience (1=high profile, 0 =low profile)	Major changes
0	0	0 (4 out of 5 cases)
0	1	no cases
1	0	1 (2 out of 2 cases) ³¹
1	1	0 (2 out of 2 cases)

Table V: Truth Table Relating Volume, Complexity, and Salience to Major Changes

Comment Volume	Complexity	Salience	Major Changes
0	0	0	0 (2 out of 3 cases)
0	0	1	no cases
0	1	0	0 (2 out of 2 cases)
0	1	1	no cases
1	0	0	no cases
1	0	1	0 (1 case)
1	1	0	1 (2 cases)

1	1	1	0 (1 case)
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Table VI: Truth Table Relating Volume and Complexity to Delay

Comment Volume (1= many, 0 =few)	Complexity (1=complex, 0 =simple)	Delay (1 = delay, 0 = no delay)
0	0	1 (2 out of 3 cases)
0	1	0 (2 out of 2 cases)
1	0	0 (1 out of 1 case)
1	1	1 (2 out of 2 cases)

Table VII: Truth Table Relating Volume, Complexity and Agency to Delay

Comment Volume (1= many, 0 =few)	Complexity (1=complex, 0= simple)	Agency (0=ACF, 1=FDA)	Delay (1 = delay, 0 = no delay)
0	0	0	0 (1 case)
0	0	1	0 (2 out of 2 cases)
0	1	0	1 (2 out of 2 cases)
0	1	1	no cases
1	0	0	no cases
1	0	1	split
1	1	0	0 (1 case)
1	1	1	1 (1 case)

¹ In the Office of Management and Budget's "E-Government Strategy: Implementing the President's Management Strategy for E-Government," issued on February 27, 2002, claims that due to electronic rulemaking, "Public participation is estimated to increase by 600 percent." See <http://www.whitehouse.gov/omb/inforeg/egovstrategy.pdf> Last viewed August 22, 2007.

² There are exceptions in the APA to this procedure and agencies have indeed made wide use of these exceptions (Shapiro 2005).

³ By identity Golden was referring to whether or not commenters were affiliated with business, pro-regulation interest groups, state or local governments, or other categories of those interested in regulation.

⁴ Federal Register December 21, 2000 65 FR 80547.

⁵ Golden (1998) uses this criteria in her study as well.

⁶ Significant is defined in Executive Order 12866.

⁷ This is admittedly two very different scales for what defines a "large number of comments." In speaking with agency officials, it was clear that the high volume rules (Head Start and Dietary Supplements) constituted the

maximum that the agency was typically prepared to deal with when responding to comments. Also, while there were more than 235,000 comments on the dietary supplement rule, the number of issues raised was much lower.

⁸ I added one rule for ACF because after doing a more thorough analysis on the Tribal TANF rule, I realized that I misread the number of comments initially and needed another rule with a large number of comments. Since the data had already been collected for the Tribal TANF rule, I left it in the sample.

⁹ The agency accepted comments electronically on only two of the nine rules in the sample and virtually none of the comments on these rules were submitted electronically.

¹⁰ Many of the public comments were form letters, but over 22,000 were individualized comments from the dietary-supplement industry, trade groups, health professionals, and consumers.

¹¹ Of the sixty-one public comments received on the Aqueous Drug Product rule, fifty were from consumers of one particular inhalant, "Breatheasy."

¹² There is no formal metric for measuring the extent to which agencies respond to comments but ACF and FDA are among the few agencies that both frequently issue regulations and carefully catalog all of the issues raised by commenters and their responses.

¹³ Various researchers have tackled the problem of measuring policy changes in different ways. West (2004) used interview responses from agency officials. Yackee (2006) did a content analysis of the regulations. Golden (1998) is not clear on her methodology but appears to have used the agency descriptions in the final rule preambles.

¹⁴ The preamble to a final rule cannot be used because it consists mainly of responses to comments, its length will be correlated with comment volume, rather than rule-complexity.

¹⁵ The correlation coefficient between words in the preamble to the proposed rule and words in the final regulatory text for these nine rules is 0.61.

¹⁶ Within the nine rules there is a considerable gap between the four rules that I consider "not complex" and the five rules considered complex. Of the complex rules, the smallest number of words in the preamble to the proposed rule is 16,000 and of the other rules the largest one has 9,000 words. The average such gap is approximately 4000 words and the median gap, approximately 2700 words.

¹⁷ Another possible measure of salience in a broader study is whether or not Office of Management and Budget (OMB) reviewed the rule. All nine rules in this study were reviewed by OMB.

¹⁸ Another possible measure of salience is whether the rule is "economically significant as defined by Executive Order 12866. Two of the rules (ACF's High Performance Bonus rule and FDA's Juice rule) meet this criteria. If this definition of salience is used, no conclusions regarding comment volume and salience are possible because too few of the possible combinations of volume and salience produce clear results using the Boolean analysis.

¹⁹ I do not expect either dominance of the comments by a single party nor early consultation to affect the time it takes to finalize a proposed rule.

²⁰ In the case of volume, zero is assigned if there are few comments and one is assigned if there are many comments. I classify the four rules that received more than 100 comments (or the two rules in each agency with the most comments) as receiving "many" comments and the remainder as receiving "few" comments.

²¹ The primary difficulty comes from assessing the extent of change between a proposed rule and a final rule. The researcher (or her assistant) must understand each issue raised by commenters and categorize the response by the agency.

²² Since there are nine cases, if I use 4 independent variables there will be sixteen combinations ($2^4 = 16$) of independent variables and at least seven of the combinations (and probably more) will be missing.

²³ If we have three variables with two possible values, then there are eight potential combinations of those values. If more than one combination was observed in more than two cases (State Self Assessment, Aqueous Products and Meat and Poultry all have low complexity, low salience, and low #'s of comments), then there will be at least one combination without any observations.

²⁴ This conclusion is dependent on characterizing rules with more than 10,000 words as complex. If the cutoff point is moved up to 20,000 words, then the only meaningful conclusion is that rules with few comments do not get changed between proposal and promulgation.

²⁵ The two rules that fall in this category are High Performance Bonus and Head Start.

²⁶ This is indeed what happens if we call only those rules with more than 20,000 words in the preamble "complex."

²⁷ As with changes to rules, this conclusion is dependent upon the categorization of complexity. Changing the cutoff or complexity to 20,000 words or more leads to an analysis with no meaningful conclusions.

²⁸ The Aqueous Products rule and the Meat and Poultry rule.

²⁹ If delay is defined as 18 months or more to complete a proposed rule, this conclusion is true of both agencies.

³⁰ The rules for which a one is assigned for major changes are those for which the agency adopted more than 8% of the majors changes suggested. For all other rules, fewer than 4% of the major changes suggested were adopted.

³¹ If we use total changes rather than major changes as the dependent variable, then this box yields an indeterminate result: one case with and one case without many total changes.

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