

Agency Rulemaking, Political Influences, Regulation, and Industry Compliance

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This article empirically examines the impact of congressional oversight and agency rulemaking on firm compliance behavior in FDA-regulated industries. Congressional oversight hearings provide signals to firms about future changes in regulatory enforcement strategies. Agency rulemaking influences firms' incentives to comply with regulation because firms must invest significant resources to keep up with changing agency policy. This analysis uses three-stage least squares to simultaneously estimate both the numbers of FDA inspections and industry violators between 1972 and 1994. Results show that congressional oversight deters industry noncompliance. The effect of agency rulemaking on noncompliance differs between industries. For instance, an increasing stock of human drug rules has raised compliance among drug firms because newer more, cost-effective rules have replaced older, more costly rules. In contrast, the increasing stock of medical device rules has reduced industry compliance among device firms because these rules have increased the complexity and the scope of regulation.

1. Introduction

The number of FDA inspections of regulated firms has declined dramatically since the late 1970s and early 1980s. In 1980, the FDA conducted 47,009 inspections of regulated firms while in 1990, the FDA conducted only 17,282 inspections. Data suggests that the number of inspected firms found to be in violation with regulatory law has increased dramatically, particularly since the early 1980s. In 1980, 2229 inspected firms were found in violation while in 1990, 8085 inspected firms were found in violation of regulatory law. This represents almost a fourfold increase in violative firms. In percentage terms, the rate of noncompliance among the inspected firms has increased from 4.7% in

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1980 to 46.8% in 1990. What explains the changing trends in firm compliance in the industries regulated by the FDA?

Previous research has examined the relationship between noncompliance and the level of enforcement for OSHA regulation (Viscusi, 1979, 1986; Bartel and Thomas, 1985) and for EPA water pollution regulation (Magat and Viscusi, 1990). Results suggest that a reduction in inspection activity reduces firms' incentives to comply with existing regulations and hence leads to increased noncompliance among firms.¹ Other research (Wood, 1988; Wood and Waterman, 1991, 1993; Wood and Anderson, 1993; Olson, 1996) has examined how changes in the political environment affect an agency's enforcement or inspection strategies. These studies show that changes in the agency's budget, in presidential administrations, or in regulatory oversight impact the strategies employed by regulators. However, few studies have examined the direct impact of such political forces on firms' compliance behavior.² Changes in the political or regulatory environment may provide signals to firms about future changes in regulatory enforcement strategies and hence may directly affect firms' compliance decisions.

In addition to political influences, little attention has been devoted to the study of the impact of agency rulemaking on firm compliance behavior. New rules promulgated by regulatory agencies represent the current guidelines and standards applied to regulated firms and products. In effect new rules may increase the complexity of existing regulatory policy and increase the transaction costs to firms of complying with current policy guidelines. Firms must devote significant resources to keep up with changing agency policy and a growing stock of regulations. For these reasons, agency rulemaking is expected to influence firms' incentives to comply with regulation.

Little attention has focused on FDA enforcement and industry compliance with FDA law. The data in this study suggest that the change in compliance behavior among FDA-regulated firms is substantial. This analysis compares the impact of congressional oversight and agency rules to other possible determinants of industry compliance behavior, including regulatory inspection activity and industry-specific effects. The question of interest is the degree to which political signals and regulatory rules influence industry compliance trends. This analysis simultaneously treats both FDA inspection decisions and the number of industry violators as endogenous and explains variations in industry violators over time as a function of political, economic, and bureaucratic factors.

Results indicate that both congressional oversight hearings and FDA inspection activity produce a deterrence effect among regulated industries. Oversight deters noncompliance because firms view oversight as a signal of congressional preferences to increase agency enforcement. These results suggest that the reduction in oversight and FDA inspection activity in the early 1980s did lead to

1. This research has also explored how industry or firm-specific characteristics influence noncompliance in regulated industries.

2. Scholz (1991) examines the impact of such political influences on both the level of enforcement and the effectiveness of enforcement (related to noncompliance) in the case of OSHA.

an increase in the level of noncompliance with FDA law. However, as oversight increased in the late 1980s and early 1990s, it led to improved compliance among firms.

Results also show that the stock and flow of agency rulemaking affects industry compliance trends, but their effects differ across industries. For instance, in the human drug industry, the flow of new rules reduces industry compliance, perhaps because some firms may be unaware of the new rules and hence are found to be noncompliant in the short run. However, as learning occurs, increases in the stock of human drug industry rules has raised compliance among drug firms in the long run because newer, more cost-effective rules have replaced older, more costly rules. In contrast, an increasing stock of medical device rules has reduced industry compliance among device firms because these rules have predominantly increased the complexity and the scope of regulation.

This article is organized as follows. Section 2 provides a framework for understanding firm compliance behavior and industry compliance trends. Section 3 examines FDA inspection and industry noncompliance trends. Section 4 describes the methodology and data used in this study. Section 5 presents the results. Concluding remarks are offered in the last section.

2. Modeling Firm Compliance Strategies

A useful place to begin to understand industry noncompliance is at the level of the firm. Compliance decisions by firms are a function of two general factors: the deterrence level and the cost of complying. The deterrence level is influenced by several agency-specific strategies. Both the number of inspections and the efficiency of inspections influence the level of deterrence among firms. More inspections increases each firm's expectation that a violation will be uncovered and hence increases each firm's incentives to comply with regulatory guidelines. The agency may also develop ways to increase the efficiency of its inspections policy. For example, Bardach and Kagan (1982) and Scholz (1994) suggest that a regulatory agency can increase the efficiency of its inspections policy by targeting problematic firms for inspection. Holding all else equal, increasing the efficiency of inspections will increase the level of deterrence. Increased penalties for detected noncompliance may also increase deterrence among regulated firms, although the strength of this relationship depends on the magnitude of the penalties.³

In addition to these agency-specific factors, the political environment also contributes to the level of deterrence. The reason is that firms may lack information about agency enforcement efforts and hence may be uncertain about the true level of deterrence. Enforcement outcomes for individual firms are typically difficult to observe in this industry unless the press identifies a public scandal.⁴ Given that firms may not readily observe agency enforcement

3. Gray and Scholz (1991) find that higher penalties for OSHA violations did not result in a reduction in general or specific deterrence.

4. Because information about the violations of any given firm is not readily available from the FDA and because violation information may have stock market ramifications, most firms won't

actions taken against their competitors, firms may use clear political changes such as changing presidential administrations or congressional oversight hearings as signals of anticipated changes in agency enforcement.⁵ For instance congressional oversight hearings directed at a particular industry may signal congressional pressure on regulators to target noncompliance in an industry. Expecting increased agency enforcement, firms may choose to increase compliance investments to reduce the likelihood of regulators detecting violations and to avoid becoming a target of agency scrutiny.⁶

Different presidential administrations may also signal changing political preferences for regulatory enforcement. As administrations change, firms may anticipate shifts in political preferences for regulatory enforcement and may alter their compliance decisions accordingly. For instance, the Reagan administration signalled a preference for reducing the size and scope of the federal government and for reducing regulator discretion by taking steps to limit several agencies enforcement capabilities. Recognizing this, firms' incentives to make compliance investments may have diminished.

Firms' costs and anticipated benefits of complying with regulatory law are influenced by several factors. First, the stringency of regulation impacts firms' compliance costs in that more stringent regulation generally entails greater compliance costs. Since the stringency of regulation differs among the industries regulated by the FDA, the cost of complying with FDA regulation may also be expected to vary among industries. Regulatory stringency is determined in part by the original regulatory legislation. However, regulatory stringency is also affected by the rules developed by the agency to define the details of these regulatory arrangements. Agencies promulgate rules to define the specific standards, evidence, or procedures that firms must use to satisfy regulatory requirements.⁷ For instance, pharmaceutical legislation introduced in 1962 set the new standard, proof of efficacy and safety, for new drug approval. However, the FDA used rulemaking to develop a very elaborate set of premarket drug approval procedures and to define the specific evidentiary requirements needed to gain approval. The rules promulgated and adopted by regulatory agencies together with the original regulatory legislation represents

be aware of the compliance status of their rivals unless the information is released in the popular press. The difficulty of observing enforcement outcomes contributes to firm uncertainty about the level of agency enforcement.

5. Support for this idea is found in the trade publications subscribed to by firms. For instance, the trade publication *Pharmaceutical Technology* contains a regular feature called the "Washington Report" which highlights current legislative and oversight activities focusing on the FDA and discusses the potential impact of these activities on firms and on the FDA.

6. Regulated firms also want to avoid being the target of congressional investigations because the adverse public attention directed at the firm may hurt firm profitability (and industry profits if there are spillover effects). This occurred for some generic drug firms following the generic drug scandal in 1988.

7. Some general categories of rules adopted by the FDA include quality standards for products and production methods, performance standards, purity and identity standards, and labeling requirements.

the current guidelines and standards enforced by the agency. This suggests that agency rulemaking is a second factor that will directly impact firms' compliance costs.

Rulemaking can impact firms' compliance costs or firms' compliance behavior in different ways. While there are always transaction costs to keeping abreast of regulatory changes, some rules may complicate regulatory compliance while other rules may simplify the compliance process. The overall impact of agency rulemaking on firms' compliance costs will depend on which of these effects dominate. In any year, more new rules mean that a firm must spend more resources to keep informed of regulatory changes. The transaction costs of keeping up with changing agency rules may prevent some firms from complying with current regulatory law. For example, small firms may not have the resources available to hire regulatory experts or consultants and as a consequence may be less informed about current regulatory changes (Shover et al. 1984). If firms are unwilling to invest the resources needed to keep up with changing agency policy, then increasing numbers of new rules may lead to more violative firms and reduced compliance.

Alternatively, new rules may simplify regulations or provide information which reduces firm uncertainty about ambiguous or unclear regulations. For instance, a new rule can define a specific safety standard tailored for a new class of products or a new rule can clarify existing regulatory procedures for an industry. In these cases, new rules may improve compliance because they provide firms with better information about how to comply with existing regulations. As long as the firm's expected benefits exceed the transaction costs of keeping informed, new rules such as these may lead to a reduction in the number of violative firms. In some cases rules which ultimately improve compliance are actually designed with input from the regulated industry.⁸ This observation further suggests that the impact of rulemaking may differ among industries depending on the degree to which regulators work with and depend upon the information from regulated firms.

In addition to the flow of new rules, the stock of existing rules may also influence firms' compliance investments. A greater stock of regulatory rules may imply that the complexity and scope of regulation has increased. If true, then increasing the stock of regulatory rules should correspond to increased compliance costs and hence an increased likelihood of noncompliance among firms. However, an increase in the stock of rules may also reflect the tendency of newer, more cost-effective rules to replace or improve upon older, more costly rules. If true, then as the stock of regulatory rules grows, compliance costs may fall for firms and hence lead to a higher level of compliance among firms. Once again, these possibilities suggest that the impact of agency rulemaking on compliance may vary among industries because different industries have

8. For example, the practice of gang-labeling for dissimilar drug products can result in labeling mix-ups and the subsequent recall of pharmaceuticals. To reduce these problems, regulators worked with drug industry representatives to amend the existing rule to one that helped firms restructure their labeling operations to prevent mislabeling. This new rule was designed to improve compliance.

different relationships, histories, and experiences with regulators which may be reflected in the stock of industry-specific rules.

In addition to regulatory stringency and agency rules, industry-specific characteristics are another factor that may influence firms' compliance costs. Certainly, the scale and scope of a firm's operations will influence its compliance costs. The competitive conditions within an industry may influence firm incentives to make compliance investments. These factors along with the complexity of the technologies and the production processes used to create products in different industries will directly impact the cost of complying with different regulations.

The benefits of increased compliance investments include a reduction in the probability that violations are detected and a reduction in the expected penalties imposed on the firm for noncompliance. In addition, there are reputational benefits for firms that invest in compliance. Since FDA regulation increases consumer confidence in the industries where consumers have difficulty knowing the health and safety aspects of the products they consume, then having a reputation as a compliant firm or a firm that produces safe or effective products can generate financial benefits for firms. These benefits include increased demand in the marketplace if the increase in compliance investments leads to a reduction in product-related risk for consumers. Because some of the benefits of increased compliance may depend on the demand conditions in a particular market, the state of the economy may also potentially affect firms' incentives to invest in incremental compliance investments. When the economy is weak, firms may expect fewer benefits from increased compliance than when economy is strong. Of course, such reputational benefits will disappear and turn into losses if consumers are informed about noncompliance by firms.⁹

Firms choose their compliance investments to balance the incremental cost of additional compliance investments with the incremental benefits of increased compliance. Unfortunately, firms' compliance investments are unobservable. The true number of firms in violation of regulatory law is also unobservable. However, it is possible to observe regulatory outcomes such as the number of detected noncompliant firms.¹⁰ Such regulatory outcomes are jointly determined as functions of both firm and regulator behavior. This creates a problem for interpreting changes in the number of detected violative firms as a proxy for changing industry noncompliance.

The expected number of violators $E(v_{i,t})$ detected by regulators in industry i at time t equals the number of inspections $I_{i,t}$ for industry i at time t multiplied by the probability that a firm is noncompliant $P_{i,t}(D, C)$, where D represents

9. Reputations for noncompliance are often highlighted by the media. For instance, during the generic drug scandal the media reported the accusations against and activities of the violative firms. However, even in the absence of public scandals, media reports about FDA-initiated product seizures or recalls involving a specific firm have a negative impact on the value of the firm's stock (Dranove and Olsen, 1994).

10. As indicated in Feinstein (1990) and Brehm and Hamilton (1996), the actual number of noncompliant firms may exceed these numbers because of imperfect regulation.

the level of deterrence and C represents the cost of complying:

$$E(v_{i,t}) = I_{i,t}P_{i,t}(D, C).$$

The problem is that the proxy (aggregate detected violators) is a function of the level of agency inspection activity $I_{i,t}$. For instance, increases in the number of violative firms may result from increased probability of noncompliance among firms; however, more violative firms may also result from increased regulatory scrutiny or agency inspection activity.¹¹ To address this problem, a measure of current FDA inspection activity must be included as a determinant for the number of detected noncompliant firms. Including a contemporaneous inspections variable in the noncompliance expression provides a way for the econometrician to control for the portion of the change in detected noncompliant firms that is due to changing FDA inspection activity. The other explanatory variables in the noncompliance expression represent the factors that influence the probability of noncompliance, namely factors affecting either the level of deterrence or the costs (and benefits) of complying.

The case that the number of detected violative firms reflects changing compliance behavior in the industry would be strengthened by two results. First, regulators should respond accordingly to changes in the number of detected violators over time. If the number of violative firms increases and if this represents an increase in industry noncompliance, then regulators should respond by increasing the number of inspections. Hence, the results should demonstrate that the number of lagged violators is positively related to the current level of inspection activity. Second, increases in the level of inspection activity should produce a deterrence effect among regulated firms in the industry and subsequently lower the probability of noncompliance. A deterrence effect would imply that the current level of inspections should be inversely related to the current number of violative firms so that increased inspections should lead to fewer noncompliant firms.¹² Together these two results strengthen the support for the interpretation of the number of detected violative firms as a proxy for industry noncompliance.

The framework developed in this section suggests that expectations about aggregate industry noncompliance can be understood as a function of (i) the factors influencing the probability of noncompliance; and (ii) the overall level of FDA inspection activity. The discussion highlights the theoretical reasons why variables such as congressional oversight or agency rules may impact the number of violative firms in an industry. It also explains why it is important to control for the level of FDA inspection activity when looking at industry

11. Increased scrutiny by regulators is also likely to lead to a higher number of violations detected inside the firm and a higher number of aggregate violations. However, this type of bias is lessened by focusing on the number of detected violative firms instead of the aggregate number of violations. Aggregate violations are likely to fluctuate more with changing FDA activities than the number of noncompliant firms.

12. A positive relationship between current inspections and current violative firms supports the alternative view that increased FDA inspection activities results in increased violative firms.

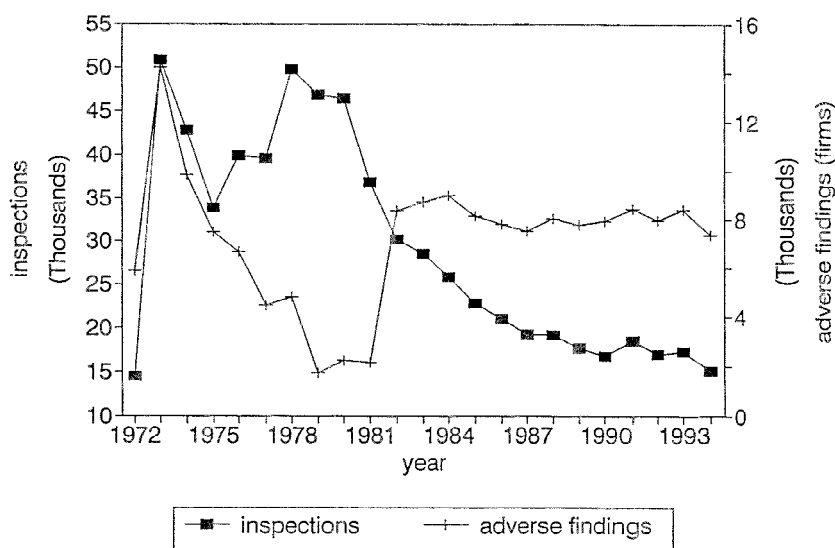


Figure 1. FDA inspections and adverse findings.

violators. This framework provides the basis for the empirical specification used to model industry noncompliance in my analysis.

3. Inspection and Noncompliance Trends

Figure 1 shows aggregate FDA inspections and the number of firms in violation of regulatory law between 1972 and 1994. The initial surges in both inspections and violative firms in the early 1970s occur as the agency hired hundreds of new FDA inspectors as a response to several food-related scandals. From 1975, industry violators begin to decrease as FDA inspections increase in the mid to late 1970s. From 1981 to 1982, there is an almost threefold increase in the number of violative firms. This occurred as the number of inspections fell approximately 20%. Following 1982, the aggregate number of violative firms remains high while inspections continue to decrease throughout the 1980s. What is noticeable is that as inspections continue to decrease in the 1980s, the aggregate number of violative firms does not increase. This article suggests that other features, besides the level of inspection activity, within the political and regulatory environment may have contributed to firms' compliance behavior.

An examination of industry-specific violators reveals some interesting similarities and differences. One similarity is that all industries experienced increases in detected violators between 1981 and 1982. Following 1982, however, violators in some industries, human drugs and medical devices, continued to increase while violators in other industries, food and cosmetics and animal drugs, fall. These divergent trends occurred as inspections in all regulated industries

declined during most of the 1980s.¹³ This data suggests that noncompliance is greater for the human drug and medical device industries relative to the food and animal drug industries throughout the 1980s and 1990s.¹⁴ These differences in industry noncompliance are not depicted in Figure 1, but further suggest that factors other than the level of FDA inspection activity may have affected firms' compliance behavior.

The political environment was a source of important changes that influenced the FDA's enforcement strategies. Congress began reducing the FDA's budget (in real terms) and its staff beginning in 1979 (Olson, 1995). The 1982 fiscal year was the first year in which a newly elected Republican president, Ronald Reagan, and a Republican-controlled Senate could potentially impact agency budget appropriations. Between 1981 and 1982 the FDA's (and other social regulatory agencies) budget was sharply reduced. The reduction in the agency's budget directly limited the FDA's ability to maintain its previous inspection levels (Olson, 1996). Carpenter (1996) and others (Bendor and Moe, 1985; Wood, 1988; Wood and Anderson, 1993; Wood and Waterman, 1993) suggest that these actions also signaled to the agency that its political environment had changed.

At the same time, demand for product approvals from regulated industries was increasing due to the growth of regulated industries and the new legislation expanding the generic drug market. Public concern about drug safety was raised in 1982 by reports of several deaths in Chicago of individuals who had taken cyanide-laced Tylenol gelscaps. Fraud among generic drug manufacturers and reports of defective heart valves renewed consumer concerns about safety in the drug and medical device industries in the late 1980s and early 1990s. The FDA needed to figure out how it would adapt to the new political environment, the budget and staff reductions, and the increasing demand for product approval from regulated industries.

These pressures led regulators to search for ways to maintain current FDA enforcement levels with fewer resources. Regulators needed to find ways to increase the efficiency of the agency's enforcement operations. One bureaucratic response was increased use of targeting by the FDA regulators (Bardach and Kagan, 1982; Scholz, 1994). Targeting means that past violators will have a greater likelihood of being inspected by regulators than nonviolators.¹⁵ Targeting can increase the efficiency of the agency's inspection policy because it enables regulators to achieve a given level of deterrence with fewer inspections.

Evidence that the FDA may have encouraged targeting during this time is found in the FDA's *Inspection Operations Manual* (1982, reprinted in 1987)

13. Human drug inspections begin to increase in 1987 while medical device inspections begin to increase in 1989.

14. This observation is consistent with media reports focusing attention on scandals in the human drug (generic drugs) and device industries (faulty heart valves and silicone breast implants) in the late 1980s and early 1990s.

15. Targeting could also imply that the length and the intensity of the inspection is greater for past violators than nonviolators.

which is given to its inspectors. The manual provides specific directives for inspectors to review prior to the inspection, information which could be used to target a firm including past inspection reports, district profiles, new drug applications, sample results, and consumer complaints. It instructs inspectors to ensure that past violations have been corrected and to investigate any current complaints against the firm. Inspectors are further instructed on the inspectional approach. The manual states that “in-depth inspection of all manufacturing and control operations is usually not feasible” and advises inspectors to adopt an audit approach which encourages inspectors to focus on the most complex or difficult to manufacture drugs or products (*Inspection Operations Manual*, 1987:541.2). This represents another form of targeting within the inspection process. Targeting strategies enable the agency to achieve a particular deterrence effect with fewer inspections. This implies that the reduction in FDA inspections observed in the 1980s need not result in increased noncompliance among firms.

However, the differences in industry-specific violator trends in the late 1980s suggest that targeting may have differed in its effectiveness among industries. Targeting that is effective deters future noncompliance. Targeting that is ineffective does not alter the deterrence level so that as inspections fall, the level of deterrence will also fall, resulting in greater noncompliance.¹⁶ Targeting may be ineffective if regulators fail to detect the “bad apples,” perhaps because of the uncertainty surrounding whether firms are in violation of FDA regulations. For industries where violations may be harder to detect because of technological complexity and regulator uncertainty, as in the human drug and medical device industries, targeting may be less effective as a deterrent than in industries where violations are easier to detect, as in the food industry. The differences in the effectiveness of targeting may explain the divergent trends in noncompliance among regulated industries in the late 1980s.

The political environment in the 1980s is also characterized by trends in FDA rulemaking and congressional oversight. President Reagan implemented procedural changes in the agency rulemaking process which made it more difficult or costly for agencies to promulgate new rules. This is reflected in a decline in the number of new rules adopted by the FDA in the 1980s. Congressional oversight hearings also decreased between the late 1970s and early 1980s. However, unlike the trend in rulemaking, oversight hearings increased in the later 1980s and early 1990s.¹⁷ These trends in both rulemaking and oversight may have directly influenced compliance behavior as firms responded to the signals from the political environment.

The next section analyzes the impact of these bureaucratic and political factors on noncompliance trends in FDA-regulated industries. Because the production processes for some products, such as human pharmaceuticals and medical

16. Helland (1998) finds empirical evidence that the EPA's targeting of violative firms leads to an increase in self-reported violations from firms, but not a reduction in overall noncompliance.

17. See Aberbach (1990) for a discussion of trends in congressional oversight in the 1970s and 1980s.

Table 1. Summary Statistics for Annual Panel Data, 1972–1994

Symbol	Definition	<i>N</i>	Mean	SD
<i>VIOL</i>	Noncompliant firms	92	1743	1352
<i>INSP</i>	Firm inspections	92	7176	7483
<i>RULE</i>	Annual rules adopted	92	76	65
<i>CRULE</i>	Cumulative rules adopted	92	878	574
<i>OVER</i>	FDA oversight hearings	92	29	6
<i>GDP</i>	Real GDP (1990 \$)	92	\$4600 billion	\$764 billion
<i>SIZE</i>	Industry employment	92	481,279	591,781
<i>UNEMP</i>	U.S. unemployment rate	92	6.53	1.34
<i>BUD</i>	FDA budget (1990 \$)	92	\$520 million	\$109 million
<i>APPL</i>	Approval applications	92	5327	3785

devices, are more complex than the production processes for other products, such as food and cosmetics, it is important to control for the differences in noncompliance that may be due to the greater complexity of these products by including industry-specific effects.

4. Methodology and Data

The empirical equation models industry violators as a function of FDA inspection activity and factors affecting the probability of noncompliance, namely the deterrence level and costs (and benefits) of complying. These factors include the level of regulatory enforcement, congressional oversight, agency rulemaking, the state of the economy, and industry-specific characteristics. An alternative specification of Equation (1) includes presidential administration dummy variables. A log-linear specification is used and the coefficients are interpreted as elasticities.

$$\begin{aligned} \ln(VIOL_{i,t}) = & \alpha_0 + \beta_1 \ln(INSP_{i,t}) + \beta_2 \ln(VIOL_{i,t-1}) + \beta_3 \ln(RULE_{i,t-1}) \\ & + \beta_4 \ln(CRULE_{i,t-1}) + \beta_5 \ln(OVER_t) + \beta_6 \ln(SIZE_{i,t}) \\ & + \beta_7 \ln(GDP_t) + \beta_8 \ln(UNEMP_t) + \delta_i + \epsilon_{i,t} \end{aligned} \quad (1)$$

The analysis utilizes panel data from the FDA from four distinct regulated product areas between 1972 and 1994: (i) food and cosmetics, (ii) medical devices, (iii) human pharmaceuticals, and (iv) animal pharmaceuticals. The descriptions of the variables are provided below and summary statistics are presented in Table 1.

4.1 The Variables

The dependent variable $VIOL_{i,t}$ is the aggregate number of firms in industry i found in violation of regulatory law in year t . The variable $INSP_{i,t}$ is the number of establishments in industry i inspected by the FDA in year t . This variable is included in Equation (1) as a control for changing FDA inspection activity. The number of annual inspections proxy for the level of enforcement adopted by the agency. For instance, vigorous enforcement is characterized by a frequent

inspections policy. Frequent inspections increase the likelihood that violations will be uncovered by regulators, and hence such a policy acts as a deterrent to firms.¹⁸ The predicted sign of the coefficient for *INSP* in Equation (1) is negative because more inspections should increase a firm's incentive to make compliance investments and so should deter violations.

The impact of agency rulemaking on the number of violative firms is represented by two variables. The first variable, $RULE_{i,t-1}$, is the number of new rules affecting industry *i* in year $t - 1$. The second variable, $CRULE_{i,t-1}$, is a measure of the cumulative rules affecting industry *i* in year $t - 1$. It is constructed as follows: $CRULE_t = \sum_{i=0}^T RULE_t$. Lagged values of both of these variables are used because it may take regulators time to enforce new rules. The predicted signs for these two coefficients are ambiguous. If firms are unwilling to invest the resources needed to keep up with changing agency rules and a growing stock of regulation, then more rules may lead to more violative firms and reduced compliance. This corresponds to predicted positive coefficients for these variables. However, if the information contained in the rule reduces a firm's uncertainty about how to comply with existing regulations or if newer rules replace older rules, then increases in the stock and flow of rules may actually lead to fewer violative firms and increased compliance. This corresponds to predicted negative coefficients for these variables.

The variable $OVER_t$ represents the number of congressional oversight hearings focusing on the FDA in year t . An alternative specification includes the variable $OVER_{i,t}$, which represents the number of oversight hearings targeted at a particular industry *i* in year t . Congressional oversight hearings are a source of political pressure for regulators and may influence regulatory behavior (McCubbins and Schwartz, 1984). However, such oversight may also provide a signal to firms of future congressional efforts to increase regulatory enforcement. Since firms may have difficulty observing FDA enforcement actions taken against their competitors, such congressional action provides a more visible signal of anticipated changes in agency enforcement behavior. If true, then congressional oversight may have a direct impact on firm compliance behavior as well as an indirect impact through the regulator.

An interesting question is the degree to which firms respond to oversight directed at all industries $OVER_t$ or oversight specifically targeted at an industry $OVER_{i,t}$. Firms in industry *A* will respond to oversight directed at another industry *B* if the firms in industry *A* believe that agency enforcement efforts are correlated across industries. This suggests that there are spillover effects of oversight across industries and corresponds to the significance of the coefficient for $OVER_t$. If there are no spillover effects of oversight and firms only respond to the oversight directed at their respective industry, then the coefficient for targeted oversight $OVER_{i,t}$ will be significant. In both cases, the coefficients

18. Over most of the period, the FDA couldn't levy civil fines against most regulated firms for inspection violations and instead relied on the threat of adverse media attention, injunction, seizure, or criminal prosecution to gain compliance. Hence, data on FDA fines are not available and so are not included in the analysis.

for these variables are predicted to be negative because increased oversight acts as a deterrent to firms and may consequently result in fewer violations over time.

Two variables, GDP_t and $UNEMP_t$, are included as indicators for current economic conditions. The variable GDP_t is a measure of real gross domestic product in year t and $UNEMP_t$ is the rate of unemployment. The state of the economy influences both the expected benefits from investing in additional compliance and it influences the economic pressures facing firms. Firms may be more likely to comply with regulations when the economic conditions facing firms are good. In contrast, a poor economic climate may indicate that firms are facing more economic pressures or fewer market rewards from their compliance investments and hence they are less willing to invest in compliance. This corresponds to a predicted negative coefficient for the GDP variable. Since a high rate of unemployment reflects a poor economic climate, we should observe more violators when unemployment is high. This corresponds to a predicted positive coefficient for $UNEMP$.

To control for industry-specific characteristics such as differences in the stringency of regulation, technological differences, and differences in cost of complying due to industry-specific factors, separate constant terms δ_i are included for the different industries. In addition, the variable $SIZE_{i,t}$, representing the total number of employees in a particular industry, is included as a proxy for the size of the regulated industry. The sign of its coefficient is expected to be positive, indicating that increasing industry size leads to increasing numbers of violations.

To test whether slope coefficients were similar across different industries, Equation (1) was estimated using separate slope coefficients for each industry and then an F -test was used to test the equality of slope coefficients for each variable across the different industries. Results indicate that the null hypotheses of equal slope coefficients across industries could not be rejected at the 5% level for most variables except GDP , $RULE$, and $CRULE$. For this reason, separate slope coefficients for each industry for GDP , $RULE$, and $CRULE$ are included in Equation (1). These variables are $GDPd$, $GDPm$, $GDPf$, and $GDPa$ for gross domestic product; $RULEd$, $RULEm$, $RULEf$, and $RULEa$ for new rules; and $CRULEd$, $CRULEm$, $CRULEf$, and $CRULEa$ for the cumulative rules in the human drug (d), medical device (m), food (f), and animal drug (a) industries, respectively.

A one-period lagged violations variable is included in Equation (1) as an explanatory variable to reduce autocorrelation.¹⁹ The coefficient for $VIOL_{i,t-1}$ is predicted to be positive. A positive coefficient indicates the extent to which unmeasured factors influencing the number of past violators in a particular industry also influence the number of current violators. While the magnitude and significance of the coefficient for this variable provides little new insight

19. Johnson (1984) provides a nice discussion of the inclusion of lagged dependent and independent variables in regression equations.

about the underlying sources of noncompliance, its inclusion in Equation (1) can be expected to increase the explanatory power of the model as measured by R^2 .

Another empirical issue to address is the possible endogeneity of some of the regressors in Equation (1). Although current violations may create incentives for congressional oversight, I treat the number of current oversight hearings as exogenous because it takes Congress time (often a year or more) to respond to violations and initiate oversight hearings. Because FDA inspections are endogenous, it is necessary to simultaneously estimate the level of inspections along with the level of current violators. Failure to account for the endogeneity of current inspections in Equation (1) leads to misleading conclusions about the deterrence effect of current inspection policy. In fact, when ordinary least squares is used to estimate Equation (1), assuming current inspections are exogenous, the resulting coefficient for $INSP$ ($-.02$) is not significantly different from zero (standard error of $.16$). For this reason, inspections are treated as endogenous.

The specification for the inspections equation is taken from Olson (1996), who models FDA inspections as a function of the following variables: the FDA's budget, the number of approval applications received from regulated industries, lagged inspections, lagged violations, congressional oversight, industry-specific effects, and presidential administration effects. This specification relies on a framework in which regulators are assumed to respond to the external signals from different groups.²⁰ The variable $SIZE_{i,t}$ is also included in Equation (2) to control for changes in industry size over time.

$$\begin{aligned} \ln(INSP_{i,t}) = & \alpha_0 + \gamma_1 \ln(INSP_{i,t-1}) + \gamma_2 \ln(BUD_{i,t}) + \gamma_3 \ln(OVER_{t-1}) \\ & + \gamma_4 \ln(APPL_{i,t}) + \gamma_5 \ln(VIOL_{t-1}) + \gamma_6 \ln(SIZE_{i,t}) \\ & + President_j + \delta_i + \epsilon_{2i,t} \end{aligned} \quad (2)$$

The equation for $INSP_{i,t}$ given in Equation (2) is estimated simultaneously with the equation for $VIOL_{i,t}$ in Equation (1) using three-stage least squares (3SLS).²¹ This procedure allows for the errors $\epsilon_{1i,t}$ in Equation (1) and $\epsilon_{2i,t}$ in Equation (2) to be contemporaneously correlated. Such correlation represents the effect of unmeasured factors, such as the courts, on inspection and violator activity.

Congressional signals include the agency's budget BUD_t in year t and the number of congressional oversight hearings $OVER_{t-1}$ focusing on the FDA in year $t-1$.²² Since larger budgets enable the agency to perform more inspections,

20. The external signals model was introduced by Joskow (1974) and Noll (1985) and has been applied by Magat, Krupnick, and Harrington (1986) to the case of environmental regulation and by Olson (1995) to the case of FDA approval decisions.

21. For more details about this procedure, see Greene (1997).

22. Weingast and Moran (1983) argue that the agency's budget and congressional oversight can be used by Congress to control agency discretion. Bendor and Moe (1985), Wood (1988), Wood and Anderson (1993), and Wood and Waterman (1993) have also shown the importance of the agency's budget in bureaucratic decisions.

the predicted sign for the coefficient for BUD is positive. Oversight hearings represent adverse feedback from Congress. Such feedback may lead the FDA to increase its enforcement efforts by increasing the number of inspections. Because it may take regulators time to respond to congressional oversight and because of bureaucratic inertia, a one-period lagged value of $OVER$ is used in Equation (2). The predicted sign for the coefficient for $OVER_{t-1}$ in Equation (2) is positive.

In addition to feedback from Congress, the agency also responds to feedback from the regulated industries. One indicator of industry feedback is the regulated industry's demand for product approval services from the FDA. The variable $APPL$ is the number of applications for product approval submitted by brand-name drug firms, generic drug firms, and medical device firms. Increasing demand for product approval by industries increases the workload for regulators and may lead the agency to divert resources away from enforcement activities and into approval activities. Hence, the predicted sign for the coefficient of $APPL$ is negative. Another industry signal, $VIOL_{i,t-1}$, is the number of firms in industry i from year $t - 1$ found to be in violation with regulatory law. This serves as an indicator of noncompliance to regulators. Regulators are expected to respond to past noncompliance by increasing the number of inspections. For this reason the predicted coefficient for the $VIOL_{i,t-1}$ is positive. The predicted sign for the coefficient for $SIZE_{i,t}$ is also positive since increased industry size should lead regulators to perform more inspections.

Presidential dummy variables, $President_j = nixon, ford, carter, reagan, bush,$ and $clinton$, are included to control for the impact of different presidential administrations on FDA inspections.²³ Because certain administrations are correlated with both trends in the FDA's budget and trends in social regulatory spending over time, these dummy variables are adjusted to control for changes in the FDA's budget relative to the changes in budgets for all other social regulatory agencies (see Olson, 1996).²⁴ Changes in the agency's relative budget represents an indicator of the political attention directed at this agency over time. The coefficient for this variable measures the impact of different presidents on FDA inspections independent of changes in the agency's relative budget. An alternative specification of Equation (1) includes these presidential dummy variables to determine if they impact industry compliance.

In addition, separate intercept terms δ_i are included in Equation (2) for the different regulated industries to control for differences in regulation between these industries. As in the $VIOL$ expression, when separate slope coefficients are estimated for each variable by industry, an F -test could not reject at the 5% level the equality of respective slope coefficients across the different industries in the $INSP$ expression. This suggests that different slope coefficients can be restricted to be the same across industries.

23. Moe (1985) argues that presidents may have significant influence over agency operations.

24. The dummy variable is constructed as follows: presidential dummy $\times \frac{\delta BUD}{\delta SOC BUD}$, where δBUD is the annual change in the FDA's budget, and $\delta SOC BUD$ is the annual change in spending in other social regulatory agencies.

As in the estimation of Equation (1), both potential endogeneity of some of the regressors and autocorrelation must be addressed in the estimation of Equation (2). Although current FDA enforcement may influence a firm's incentive to submit approval applications, I treat the industry applications variable as exogenous because it takes a firm a substantial amount of time (often several years) to compile the evidence needed to submit a completed application to the FDA. The agency's budget *BUD* may also be endogenous. However, when the budget variable is simultaneously estimated in this system using 3SLS, as in Olson (1995), the signs and significance of the resulting coefficients in Equation (2) are similar to the estimation in which the budget variable is treated as exogenous. For this reason, I ignore the endogeneity of the budget variable in the estimation of Equations (1) and (2). Finally a lagged inspections variable is included as an explanatory variable in Equation (2) to reduce autocorrelation. As in Equation (1) the inclusion of the lagged dependent variable is expected to increase the R^2 for the model without contributing much in the way of new information about the underlying sources of changing inspection levels.

4.2 Data

For each of the four industry groupings, I have collected the aggregate numbers of establishment inspections *INSP* and the aggregate numbers of violative firms *VIOL* between 1972 and 1994. This data, along with the annual number of product approval applications *APPL* submitted to the FDA from brand-name drugs, generic drugs, and medical devices, are from *FDA Quarterly Activities Reports* from 1972 to 1994.

The annual number of congressional oversight hearings *OVER* conducted in both the House and the Senate focusing on FDA activities is from the *Congressional Information Service Index* for various years. The aggregate number of new rules *RULE* affecting a particular FDA regulated industry was taken from the *Annual Federal Register Index* from 1975 to 1994. Prior to 1975, the *Annual Federal Register Index* does not distinguish between adopted rules, proposed rules, and notices in its listing for the different industries. This makes it extremely difficult to determine which of the listings are rules that were adopted between 1972 and 1974.²⁵ For this reason, only *RULE* and *CRULE* values between 1975 and 1994 are used in the analysis. Hence, the coefficients for these variables measure the impact of new rules between 1975 and 1994 on industry compliance trends. The values for these variables in prior years (1972–1974) are set to zero.²⁶

25. The only way to determine which listings are adopted rules is to look up each individual listing (of which there are more than a thousand) in the *Federal Register*.

26. The substantive results are unaltered when the 1972–1974 rule variables are treated as missing. Since lag values of rule variables are used, the estimation must exclude 4 years of data for each of the four industries, a total of 16 fewer observations. The signs and significance of most of the coefficients including the flow of human drug rules are similar to those reported in Table 2, although the coefficients for the stock of human drug and devices rules are not quite significant at the .1 level. Also in this estimation, the coefficient for the stock of animal drug rules remains positive, but becomes significantly different from zero.

The 1990 constant dollar values for U.S. gross domestic product (GDP) was taken from the *International Financial Statistics Yearbook* published by the IMF. Unemployment rates *UNEMP* were taken from DRI BASIC Economics (formerly Citibase). Data for industry employment *SIZE* is taken from the Census of Manufacturers and the Annual Survey of Manufacturers, Bureau of Census, Commerce Department for various years. The FDA's budget *BUD* (expressed in 1990 dollars) is from *Congressional Quarterly Almanacs*. The 1990 constant dollar values for the budget are constructed using the GDP deflator.

5. Results

The three-stage least squares regression results from the simultaneous estimation of Equations (1) and (2) are presented in Table 2. The first column of the table lists the estimated coefficients from the violations equation while the second column lists the estimated coefficients from the inspections equation.²⁷ The cross-model correlation between the violation and inspection equations was relatively high (.60), indicating that three-stage least squares offers improved estimates over two-stage least squares. Also, tests for autocorrelation were performed on each expression. Since each expression contains a lagged dependent variable as a regressor, Durbin's *m*-test, which is equivalent to a modified LM test, is the appropriate test to use.²⁸ In each equation, Durbin's *m*-test rejects the presence of autocorrelation.

The coefficient for the inspections variable in Equation (1) is negative as predicted and significant at the .01 level. In particular, a 10% increase in aggregate inspections produces a 7.9% reduction in the number of firms found to be in violation of FDA guidelines. This result suggests that the frequency of FDA inspections acts as a deterrent to noncompliance among regulated firms. In addition to the frequency of inspections, the coefficient for lagged violators in Equation (1) is positive as predicted and significant at the .01 level. The coefficient indicates that a 10% increase in lagged violations results in a 5.0% increase in current violations. This result indicates that unmeasured factors that determine past violators are an important influence on the current level of industry violators.

Together the subset of agency rulemaking variables in Equation (1) is jointly significant at the .01 level.²⁹ However, the effect of regulatory rules varies across the regulated industries. In the medical device industry, only the coefficient for the stock of rules *CRULEm* is significant at the .1 level. Its coefficient, which is positive, suggests that the growing stock of medical device rules increases

27. The inclusion of the lagged dependent variables in both Equations (1) and (2) certainly contribute to the high values for the system-weighted R^2 .

28. In this test the residual $\epsilon_{i,t}$ from each expression is regressed on the lagged residual $\epsilon_{i,t-1}$ and all other explanatory variables in the expression. If the coefficient for the lagged residual is not significantly different from zero at the .05 level, Durbin's *m*-test rejects the presence of autocorrelation.

29. A test of the joint significance of the subset of eight variables measuring the stock and flow of agency rules in Equation (1) produced $F = 3.29$, which exceeded the critical $F(8,147) = 2.62$ needed to reject the null hypothesis at the .01 level.

Table 2. Determinants of FDA Inspection and Noncompliance Trends: 3SLS Estimation Using Annual Panel Data, 1972–1994

Variable	VIOL	INSP	VIOL	INSP
<i>INSP</i>	-.79*** (.22)	—	-.63** (.22)	—
<i>VIOL</i> (<i>t</i> - 1)	.50*** (.10)	.15*** (.05)	.47*** (.11)	.14*** (.05)
<i>RULEd</i>	.44++ (.21)	—	.59+++ (.21)	—
<i>RULEm</i>	-.13 (.09)	—	-.10 (.09)	—
<i>RULEf</i>	.13 (.18)	—	.24 (.19)	—
<i>RULEa</i>	-.15 (.21)	—	-.03 (.20)	—
<i>CRULEd</i>	-.56+++ (.20)	—	-.71+++ (.22)	—
<i>CRULEm</i>	.18+ (.10)	—	.05 (.11)	—
<i>CRULEf</i>	-.19 (.18)	—	-.32+ (.19)	—
<i>CRULEa</i>	.26 (.21)	—	.11 (.20)	—
<i>OVER</i>	-.58*** (.17)	—	-.47*** (.20)	—
<i>OVER</i> (<i>t</i> - 1)	—	.20** (.11)	—	.17* (.11)
<i>SIZE</i>	.47 (1.06)	.50** (.23)	1.12 (1.05)	.53** (.24)
<i>UNEMP</i>	.64*** (.22)	—	1.17*** (.29)	—
<i>GDPd</i>	4.15*** (1.67)	—	6.69*** (1.94)	—
<i>GDPm</i>	.61 (1.78)	—	2.08 (1.91)	—
<i>GDPf</i>	-.01 (1.78)	—	2.75 (2.05)	—
<i>GDPa</i>	-3.83** (1.98)	—	-1.07 (2.10)	—
<i>INSP</i> (<i>t</i> - 1)	—	.60*** (.08)	—	.60** (.09)
<i>BUD</i>	—	.54*** (.22)	—	.74*** (.23)
<i>APPL</i>	—	-.17*** (.04)	—	-.16*** (.04)
<i>Nixon</i>	—	2.96++ (1.49)	6.99++ (3.10)	4.42+++ (1.64)
<i>Ford</i>	—	-.77 (.91)	-1.46 (2.61)	-.73 (1.01)
<i>Carter</i>	—	-.44 (.61)	1.31 (1.27)	-.26 (.72)

Continued

Table 2. *Continued*

Variable	VIOL	INSP	VIOL	INSP
<i>Reagan</i>	—	-.59 (.40)	.16 (.88)	-.52 (.49)
<i>Bush</i>	—	-1.57+++ (.49)	-2.04++ (1.01)	-2.15+++ (.57)
<i>Clinton</i>	—	-1.05+++ (.30)	-1.45++ (.65)	-1.39+++ (.34)
Industry dummies		Significant	Significant	
R^2	.95	.95	.95	.95
n	92	92	92	92

Standard errors are given in parentheses.

* $p < .1$, ** $p < .05$, *** $p < .01$ (1-tailed test).

+ $p < .1$, ++ $p < .05$, +++ $p < .01$ (2-tailed test).

noncompliance among medical device firms. The coefficient implies that a 10% increase in the stock of medical device rules produces an almost 2% increase in noncompliance. This result supports the theory that an increase in the stock of medical device rules has increased industry noncompliance because these rules have predominantly increased the complexity and the scope of regulation in the medical device industry.

In the human drug industry, the coefficient for the flow of new drug rules *RULEd* is also positive and significant at the .05 level, which suggests that an increase in new human drug rules raises noncompliance among drug firms. In particular, a 10% increase in human drug rules produces a 4.4% increase in the number of noncompliant drug firms. The coefficient for the stock of human drug rules *CRULEd* is also significantly different than zero at the .01 level. However, its coefficient is negative, which suggests that increases in the stock of human drug rules has led to a reduction in the number of noncompliant drug firms over time. Specifically, a 10% increase in the stock of human drug rules produces a 5.6% reduction in the number of noncompliant drug firms. These two results are not inconsistent, but suggest that the short- and long-term effects of rulemaking differ in this industry. In the short run, firms may be ignorant about new rules and hence may be found to be noncompliant. However, learning may occur in the long run and hence lower noncompliance. The second result suggests that increases in the stock of human drug rules corresponds to reduced noncompliance among human drug manufacturers, perhaps because newer, more cost-effective or informative rules have replaced older, more costly or ambiguous rules.

In addition to the agency variables, political influences also impact industry compliance behavior. Current congressional oversight has a direct impact on the number of noncompliant firms detected over time. The coefficient for aggregate congressional oversight hearings *OVER*, in Equation (1) is negative as predicted and significant at the .01 level, which suggests that congressional oversight provides an informative signal to which firms respond. Specifically, oversight

acts as a deterrent to firm noncompliance. A 10% increase in FDA oversight hearings produces a 5.8% reduction in the number of noncompliant firms. The result also suggests that there are spillover effects of congressional oversight of the FDA across different regulated industries, which is not surprising given the agency's enforcement efforts are correlated across these industries.

To examine the impact of oversight targeted at a particular industry, an alternative estimation was performed which substituted oversight $OVER_{i,t}$ targeted at industry i for aggregate oversight $OVER_t$. The coefficient for targeted oversight, when included in Equation (1), is also negative, which suggests that firms in an industry also respond to oversight targeted at their specific industry.³⁰

The economic climate impacts firms' compliance behavior. The coefficient for the rate of unemployment $UNEMP$ is significant at the .01 level and positive as predicted, which suggests that increased unemployment leads to more noncompliant firms. The reason is that high unemployment signals lower market rewards from firms' compliance investments and hence firms have fewer incentives to make compliance investments. Although the four variables GDP_i are jointly significant at the .05 level, the effect of GDP varies across the regulated industries.³¹ Only in the animal drug industry is the coefficient for GDP_a negative as predicted and significant at the .05 level, which suggests that animal drug firms comply less with existing regulations when GDP low. A 1% decrease in GDP produces a 3.8% increase in the number of noncompliant animal drug firms. In contrast, in the human drug industry the coefficient for GDP_d is positive and significant at the .01 level. This result suggests that GDP may not be a good indicator for demand conditions facing human drug firms, but instead may reflect other unmeasured characteristics of the industry.

Finally, the significance of the industry dummy variables indicate that it is important to control for industry-specific characteristics and differences in regulation between the regulated industries. These variables are jointly significant at the .01 level.³² However, the coefficient for $SIZE$ is not significantly different from zero. This suggests, after controlling for FDA inspection activity, that industry size does not appear to have an independent effect on the number of noncompliant firms.

The second column of Table 2 shows that congressional influences also impact FDA inspection level. The coefficient for the agency's budget appropriation from Congress is positive as predicted and significant at the .01 level. This suggests that reductions in the agency's budget have led to a reduction in inspections over time. Specifically, a 10% reduction in the agency's budget produces a 5.4% reduction in the number of inspections. The coefficient for the

30. The coefficient for $OVER_{i,t}$ is $-.13$ with a standard error of $.09$, which is significant at the .1 level using a one-tailed t -test. The signs and significance of the other variables are unaffected by the inclusion of this variable and hence are not reported.

31. A test of the joint significance of GDP_d , GDP_m , GDP_f , and GDP_a produced $F = 3.65$, which exceeded the critical $F(4,147) = 3.44$ needed to reject the null hypothesis at the .01 level.

32. The test of joint significance produced an $F = 4.70$ which exceeded the critical $F(3,147) = 3.91$ needed to reject the null hypothesis at the .01 level.

number of congressional oversight hearings $OVER_{t-1}$ is positive as predicted and significant at the .05 level, which suggests that increased oversight leads regulators to increase the level of agency enforcement by increasing the number of inspections. A 10% increase in oversight hearings leads to a 2.0% increase in inspections. In an alternative estimation of Equation (2) the variable for targeted oversight $OVER_{i,t-1}$ is substituted for aggregate oversight $OVER_{t-1}$. Results indicate that regulators also respond to industry-targeted oversight by increasing inspections.³³

Inspection levels are also responsive to the regulated industry demands for product approval. The coefficient for product approval applications is negative and significant at the .01 level, which suggests that increased industry demand for product approval leads to a reduction in inspections. A 10% increase in the number of approval applications from industry produces a 1.7% reduction in the number of inspections. In addition, the coefficient for industry employment is positive and significant at the .05 level, which suggests that as the size of the industry increases, regulators increase inspections. Although not reported, the industry dummy variables in Equation (2) are jointly significant at the .01 level, which suggests that FDA inspection levels are influenced by differences in regulation and technology between the different industries.³⁴

Certain presidential administrations influenced FDA inspection policy. Specifically, the coefficients for *nixon*, *bush*, and *clinton* are all significantly different than zero. Controlling for changes in the agency's relative budget, the Nixon administration had a large positive effect on FDA inspections. This is because the Nixon administration was instrumental in the hiring of several hundred new FDA inspectors to police the processed food industry. Even though the food industry was the focus of Nixon's political attention, there were spillovers to other regulated industries as inspections increased for all industries. Both the Bush and Clinton administrations are associated with a significant reduction in FDA inspections controlling for changes in the agency's budget.

Finally, the coefficients for both lagged inspections and lagged violations are positive and significant at the .01 level. The coefficient for the lagged violations variable in Equation (2) indicates that past violators are positively related to current inspections. In particular, a 10% increase in lagged violations leads to a 1.5% increase in inspections. This result is consistent with the theory that the FDA targets past violators for inspection.

The last two columns of Table 2 contain the results from the estimation of Equations (1) and (2) including the presidential dummy variables in both expressions. As expected the results from the inspection equation given in the fourth column are unaffected by the inclusion of the presidential variables in the violation equation. The resulting coefficients from the estimation of

33. The coefficient for $OVER_{i,t-1}$ is .09 with a standard error of .05, which is significant at the .05 level using a one-tailed t -test. The signs and significance of all the other variables are unaffected by the inclusion of this variable and hence are not reported.

34. The test of joint significance produced $F = 4.72$, which exceeded the critical $F(3,147) = 3.91$ needed to reject the null hypothesis at the .01 level.

Equation (1) with the presidential dummy variables are presented in the third column of Table 2.

The results show that most of the coefficients in the violators equation are robust to the inclusion of the presidential dummy variables. Of the presidential dummy variables that influence FDA inspection levels, *nixon*, *bush*, and *clinton* also directly impact industry compliance behavior. Controlling for the changes in the agency's relative budget, the coefficients imply that the Nixon administration led to an increase in industry violators, while the Bush and Clinton administrations led to a decline in industry violators. The signs of the coefficients, however, suggest that these administration variables are not clear signals to firms of changing FDA enforcement actions. If they were, then presidential administrations, such as Nixon's, which led to increased FDA inspection activity should deter noncompliance and hence lead to fewer violators.

5.1 Estimation Using Quarterly Inspection and Violator Data

This section presents the results of the simultaneous estimation of Equations (1) and (2) using quarterly time-series data for each industry between 1972 and 1994. The data consist of 92 quarterly observations for each of the four regulated industries: human drugs, medical devices, food, and animal drugs. Because there are very distinct quarterly patterns of variation in each data series, quarterly dummy variables are included in Equations (1) and (2).³⁵ Also, in the *VIOL* equation, one-, two-, three-, and four-quarter lags of the dependent variable are needed to provide temporal control and to reduce autocorrelation. In the inspection equation, only one-quarter lag of the dependent variable is needed to reduce autocorrelation. In addition, one-, two-, three-, and four-quarter lags of the violators variable $VIOL_t$ are included in the inspections equation because it may take the FDA one or more quarters to respond to increased noncompliance. For explanatory variables where quarterly values are not readily available, such as the agency's budget and the presidential dummy variables, the annual values are used in each quarter.³⁶

The results from these estimations are presented in Tables 3 and 4. The four columns in Table 3 list the estimated coefficients from the human drug, medical device, food, and animal drug industry violation equations. The four columns in Table 4 list the estimated coefficients from the human drug, medical device, food, and animal drug industry inspection equations. As in the previous section, Durbin's *m*-test for autocorrelation was performed on each expression since they contain lagged dependent variables.³⁷ In each equation, Durbin's

35. Inspections and violators in each industry generally increase (by discrete jumps) by quarter over the course of a year.

36. Annual values of agency rules and oversight hearings are also used in this analysis because of the difficulty in obtaining quarterly values for these variables.

37. When more than one lagged dependent variable is included in an expression, the residual $\epsilon_{i,t}$ from the corresponding expression must be regressed on the corresponding number of lagged residuals $\epsilon_{1,t-1}$, $\epsilon_{1,t-2}$, $\epsilon_{1,t-3}$, etc., and all other explanatory variables in the expression. If the coefficients for the lagged residuals are not significantly different from zero at the .05 level, Durbin's *m*-test rejects the presence of autocorrelation.

Table 3. Determinants of Noncompliance Levels By Industry: 3SLS Results Using Quarterly Time-Series Data, 1972–1994

Variable	Human drug	Medical device	Food	Animal drug
<i>INSP</i>	-.45** (.23)	.17 (.12)	-.19* (.15)	.32** (.16)
<i>VIOL</i> (<i>t</i> - 1)	.14 (.13)	.09 (.09)	.41*** (.11)	.25*** (.09)
<i>VIOL</i> (<i>t</i> - 2)	.12 (.12)	.12* (.09)	.11 (.12)	.25*** (.10)
<i>VIOL</i> (<i>t</i> - 3)	.22** (.12)	.03 (.09)	.08 (.12)	.02 (.09)
<i>VIOL</i> (<i>t</i> - 4)	.13 (.12)	.13* (.09)	-.04 (.11)	.15** (.09)
<i>RULE</i>	.34+++ (.10)	-.25++ (.05)	.11 (.12)	-.03 (.08)
<i>CRULE</i>	-.41+++ (.11)	.15++ (.06)	-.24+ (.12)	-.03 (.08)
<i>OVER</i> (<i>t</i>)	-.41*** (.14)	-.22* (.16)	-.37** (.19)	-.18 (.16)
<i>SIZE</i>	-1.15* (1.08)	-.89 (1.02)	-4.91*** (2.32)	-.16 (1.03)
<i>UNEMP</i>	.34** (.21)	.60** (.33)	.49** (.25)	.38** (.20)
<i>GDP</i>	3.75*** (1.01)	2.47 (1.81)	1.34 (1.08)	.81 (.86)
Quarterly dummies	Significant		Significant	
<i>R</i> ²	.92	.89	.92	.80
<i>N</i>	92	92	92	92

Standard errors are given in parentheses.

* $p < .1$, ** $p < .05$, *** $p < .01$ (1-tailed test).

+ $p < .05$, ++ $p < .01$ (2-tailed test).

m-test rejects the presence of autocorrelation at the .05 level for all lags of the dependent variables.

Although many of the signs of the coefficients in Tables 3 and 4 are similar to those reported in Table 2, the significance of these variables does vary by industry. Beginning with Table 3, evidence for the deterrence hypothesis is supported by the significantly negative coefficient *INSP* in the human drug and food industries. The results suggest that current inspection activity in these two industries leads to a reduction in the number of noncompliant firms. However in the animal drug industry the coefficient for *INSP* is positive and significant. The result suggests that declining inspection activities directed at animal drug firms result in fewer violators being detected. Hence, inspections of animal drug firms do not have the same deterrence effect as in the human drug and food industries.

The estimation with quarterly data provides further support for the differential impact of the stock and flow of rulemaking on different industries. Like

Table 4. Determinants of FDA Inspection Levels by Industry: 3SLS Results Using Quarterly Time-Series Data, 1972–1994

Variable	Human drug	Medical device	Food	Animal drug
<i>INSP</i> (<i>t</i> – 1)	.46*** (.10)	.51*** (.12)	.60*** (.08)	.60*** (.13)
<i>VIOL</i> (<i>t</i> – 1)	–.23*** (.06)	–.31*** (.09)	–.18*** (.07)	–.27*** (.11)
<i>VIOL</i> (<i>t</i> – 2)	.13*** (.06)	.07 (.09)	.13** (.07)	.22*** (.08)
<i>VIOL</i> (<i>t</i> – 3)	.10** (.05)	.01 (.09)	–03 (.07)	.16** (.08)
<i>VIOL</i> (<i>t</i> – 4)	.05 (.05)	.06 (.11)	.16*** (.06)	.04 (.08)
<i>APPL</i>	–.13*** (.04)	.10 (.17)	–.51*** (.10)	–.12** (.05)
<i>BUD</i>	.17 (.14)	.69** (.33)	.85*** (.25)	.37* (.25)
<i>OVER</i> (<i>t</i> – 1)	.09 (.07)	.05 (.14)	.02 (.11)	.14 (.13)
<i>EMP</i>	.27 (.42)	.83** (.40)	–9.39*** (2.27)	.68 (.73)
<i>Nixon</i>	–.47 (.93)	–2.30 (3.63)	7.74+++ (1.79)	–1.71 (1.75)
<i>Ford</i>	–1.18+ (.66)	.47 (1.39)	–2.82++ (1.19)	–.28 (1.08)
<i>Carter</i>	.21 (.42)	–.54 (.80)	–1.05 (.65)	–1.11 (.74)
<i>Reagan</i>	–.08 (.29)	.07 (.53)	–.58 (.45)	–.57 (.49)
<i>Bush</i>	–.40 (.34)	–.74 (.60)	–.88+ (.53)	–2.11+++ (.67)
<i>Clinton</i>	–.23 (.21)	–1.94+++ (.45)	–.27 (.35)	–.96+++ (.38)
Quarterly dummies	Significant		Significant	
<i>R</i> ²	.92	.89	.92	.80
<i>N</i>	92	92	92	92

Standard errors are given in parentheses.

p* < .1, *p* < .05, ****p* < .01 (1-tailed test).

+*p* < .05, ++*p* < .05, +++*p* < .01 (2-tailed test).

Table 2, the first column of Table 3 shows that the flow of new human drug rules significantly increases the number of noncompliant firms, perhaps because firms in the industry may not be familiar with the new rules. However, as learning occurs, increases in the stock of human drug rules leads to a reduction in the number of noncompliant firms. Unlike Table 2, the coefficient for the stock of food rules is also negative and significant at the .05 level, which suggests

that increases in the stock of food rules, much like drug rules, has led to greater compliance in the food industry over time.

Both the variables for the stock and flow of medical device rules are significantly different from zero in Table 3. In the second column of Table 3, increases in the flow of new medical device rules (*RULE*) significantly reduce the number of noncompliant medical device firms. This suggests that new rules may clarify existing ambiguous regulations in the medical device industry and hence improve compliance. This effect differs from the stock of medical device rules *CRULE* which significantly increases the number of noncompliant medical device firms over time. This result further suggests that the growing stock of medical device rules has increased the complexity and the scope of regulation in this industry.³⁸

The estimations with quarterly data also show that congressional oversight reduces noncompliance among FDA-regulated industries. All of the coefficients for *OVER*, in Table 3 are negative as predicted, and in three cases—the human drug, medical device, and food industries—the coefficients are significantly different from zero. These results suggest that the reduction in oversight observed in the early 1980s led to increased noncompliance in these industries. However, as oversight increased in the late 1980s and early 1990s, it led to improved compliance among firms.

Lagged violation variables representing one-, two-, three-, and four-quarter lags of *VIOL* are positive as predicted and 7 of the 16 coefficients are significant. In contrast to Table 2, the coefficients for *SIZE* are negative and significant at the .1 and .01 levels in the human drug and food industries, respectively. This suggests that increased employment in the human drug and food industries has led to a reduction in the number of noncompliant firms. Among the variables which may proxy for the economic climate facing firms, only the coefficients for the rate of unemployment *UNEMP* are positive as predicted and significantly different from zero for all industries. The results support the hypothesis that firms in any industry comply less with existing regulations when the economic climate reflected by the rate of unemployment is poor. Like Table 2, the coefficient estimates for quarterly GDP in Table 3 suggest that GDP is not a good proxy for demand or competitive conditions facing these industries. Finally, the quarterly dummy variables in all expressions, although not reported, are highly significant.

In Table 4, coefficients for lagged quarterly inspections are all positive as predicted and significant at the .01 level. Lagged violators also influence current quarterly inspections; however, the signs of the coefficients indicate that it may take regulators at least two quarters to increase inspections in response to an increase in detected noncompliance. Most coefficients for two-, three-, and four-quarter lags of *VIOL* are positive as predicted and 6 of the 12 coefficients are significant, indicating that more detected violators in lagged quarters leads

38. This result is consistent with the characterization of medical device regulations provided by Higgs (1995).

to an increase in current inspections. The negative coefficients for the one-quarter lag of *VIOL* suggests that an increase in violators last quarter causes fewer inspections this quarter. The result suggests that violations from the immediate quarter may place a drain on the agency's inspection resources in the current quarter.

Like Table 2, the coefficients for industry approval applications *APPL* in Table 4 are negative as predicted and significant for the human drug, food, and animal drug industries, indicating that increased demand by regulated industries for approval services led the FDA to reduce quarterly inspections in these industries. Industry size is a significant determinant of FDA inspections in the medical device and food industries. However, the coefficients suggest that while increased employment in the medical device industry has led to increased inspections, increased employment in the food industry has led to a significant reduction in FDA inspections.

The agency's budget is an important determinant of the number of medical device, food, and animal drug industry inspections conducted in a quarter. The coefficient for *BUD* is positive as predicted and significant in the second, third, and fourth columns, indicating that budget reductions for this agency led to reduced quarterly inspections in these industries. The coefficients for oversight hearings *OVER* are positive as predicted but not significantly different from zero in Table 4.

Quarterly dummy variables, although not reported, are all significant. As in Table 2, the Nixon, Bush, and Clinton administrations had a significant impact on FDA quarterly inspections; in Table 4 it is possible to see which industries were predominantly affected by a specific administration. Also, Ford's administration is shown to have had a significant impact on human drug and food industry quarterly inspections in Table 4.³⁹

6. Conclusions

The analysis in this article shows that political influences such as congressional oversight not only impact agency enforcement, but also influence firms' compliance behavior in FDA-regulated industries. The reason is that such oversight provides firms with information and signals changes in agency enforcement strategies. Results indicate that congressional oversight hearings (i) lead to increased FDA inspection activity and (ii) produce a deterrence effect among FDA-regulated firms because firms view oversight hearings as a signal of congressional preferences to increase agency enforcement. The results further imply that the reduction in FDA oversight in the early 1980s contributed to the increase in industry noncompliance. However, as oversight increased in the late 1980s and early 1990s, it led to improved compliance among firms.

39. When presidential administration dummy variables are included in the quarterly data estimation of Equation (1), results indicate that the Reagan and Clinton administrations led to a decline in human drug industry violators, the Nixon and Carter administrations led to an increase in food industry violators, and the Nixon administration led to an increase in animal drug industry violators. None of the presidential variables impacted medical device industry violators.

Will congressional oversight play a similar role in other regulated industries? The answer to this question will depend on the degree of uncertainty facing the regulated firms about the true level of deterrence and the degree to which politicians influence the agency's enforcement strategies. When firms cannot easily observe regulatory enforcement actions, oversight hearings may signal information to firms about changing enforcement strategies. However, when enforcement actions are more easily observable or when politicians fail to influence regulatory agencies, the signalling role of oversight will be diminished.

In addition, this analysis shows that agency rulemaking also impacts industry noncompliance. This result is not too surprising given that agency rules influence regulatory stringency and hence firms' compliance costs. However, what is surprising is that the effect of rulemaking differs across FDA-regulated industries. For instance, it is the flow of new rules that has diminished compliance among human drug firms because some firms may be unfamiliar with the new rules and hence are found to be noncompliant in the short run. However, as learning occurs, increases in the stock of human drug rules has raised compliance among drug firms because newer, more cost-effective rules have replaced older, more costly rules over time. In contrast, an increasing stock of medical device rules has reduced industry compliance among device firms because these rules have predominantly increased the complexity and the scope of regulation in this industry. These results raise new questions about the impact of rulemaking in other regulated industries. Have other agencies been successful in designing rules which improve compliance or have these agencies sought to increase the scope and complexity of regulation through the rulemaking process? These results further imply that rulemaking provides a source of discretionary behavior for the agency in its relationship with regulated industries.

This research and its results contribute, more generally, to the debate about the relationship between enforcement and compliance. This analysis argues that it is important to consider the endogeneity of agency enforcement actions when examining firm compliance behavior. Failure to recognize the endogeneity of agency inspection or enforcement activity may result in a failure to correctly characterize a deterrence relationship between the level of enforcement and the degree of noncompliance among regulated firms. In this study, both FDA inspections and the number of industry violators were estimated simultaneously, with violators expressed as a function of the current level of FDA inspection activity. The results show that FDA inspection activity deters industry noncompliance. This finding implies that the reduction in inspection activity that occurred in the 1980s contributed to increased industry noncompliance.

However, regulators may have tried to offset the adverse effects of the reduced inspections by increasing the use of targeting during the 1980s. If targeting is effective, it allows regulators to increase inspection efficiency and provides an alternative way for regulators to increase the level of deterrence. Hence, with successful targeting regulators could reduce inspections over time without necessarily reducing the level of deterrence. However, noncompliance trends suggest that targeting may have differed in its effectiveness among industries,

and hence differed in its impact on the level of deterrence facing firms in those industries. Because technological complexity and regulatory uncertainty may have been greater for human drug and medical device industries, targeting may have been less effective as a deterrent than in industries, such as food processing, where violations are easier to detect. A true test of the targeting hypothesis would require inspection and violation data at the firm level instead of the industry level.

In conclusion, the analysis highlights how political and regulatory instruments may shape industry compliance behavior. While previous studies have shown that politicians influence regulatory agency behavior, this analysis shows that political influences also directly impact industry compliance behavior. This suggests that signals from the political environment may be an effective way to influence industry behavior because these actions have both a direct and an indirect impact on firm compliance behavior and because they are more visible than agency enforcement actions.

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