

Todd D. Rakoff,

*The Choice Between Formal and Informal Modes of Administrative Regulation*

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Abstract by Sandra S. Lee

On February 18, 1997, the Food and Drug Administration (FDA) issued "Good Guidance Practices" to describe procedures in the use of guidance documents. Guidance documents are a new category recognized in American administrative law. This explicit recognition follows the trend of agencies' return to informal administrative procedures. Professor Rakoff begins his discussion with an overview of the American legal framework. Specifically, he discusses two viewpoints of agency management of the economy. One view is that agencies administer statutes to change the outcomes produced by the economy; the second view is that agencies are not businesspeople. The author proposes the possibility of satisfying both notions through early notification of broadly-applicable rules. He stresses the importance of a separation of powers in a state of procedural regularity.

Rakoff then summarizes a discussion of the Administrative Procedure Act (APA), which established the framework for rulemaking or adjudication. Agencies were given discretion on using the APA in announcing its views. However, over time, there were major changes in the handling of regulations and procedures. Costs became a factor, decisions were vague and inconsistent, and an emerging need for generally-applicable standards became problematic. The growing bureaucracy of APA requirements became a hindrance to getting things done. Hence, agencies returned to a less formal procedure.

The discussion continues with examples of this trend, including negotiated rulemaking, use of interpretive rules, and finally, organized "guidance." This final category combines interpretive rules and policy statements into an alternative system of regulation. Essentially, guidance documents include statements of no legal consequence, but with enormous practical consequence on agency regulation. After breaking down the types of guidance documents, the author concludes with a thorough evaluation of these developments.