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Risk Regulation at the Federal Level: Administrative Procedure Constraints and Opportunities

Erratum

This article was incorrectly identified in the table of contents as "Federal Regulation: Administrative Procedure Constraints and Opportunities." The correct title is "Risk Regulation at the Federal Level: Administrative Procedure Constraints and Opportunities."

Risk Regulation at the Federal Level: Administrative Procedure Constraints and Opportunities

Jeffrey S. Lubbers*

Introduction¹

Administrative agencies — the "twigs" on our fourth branch of government — are established to handle the details of administration deemed too painstaking, technically complex or even controversial for direct Congressional or Presidential involvement.

In the current government structure, sometimes called the "modern administrative state," these details of administration have taken on a paramount importance to us all. The risks to public health and safety have become so well documented and ventilated that the various "acronymic" agencies that have been created to deal with the risks (e.g., OSHA, FDA, EPA) have become highly visible "twigs" indeed. But the task of these agencies in the risk regulation area is not an easy one. It is, indeed, extremely complex, painstaking and controversial — so much so that the increasingly robust Congressional and Presidential bureaucracies have gladly delegated major risk management responsibilities to these agencies while seeking only to retain enough oversight and other controls to prevent political problems from penetrating the moat that separates the agency from the elected official.

To understand the task that awaits the federal risk regulator, one must understand the legal framework in which he or she must operate.

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¹ Except where indicated, the views expressed herein are solely those of the author.

Of course, science, engineering, medicine and philosophy (not to mention politics) play a crucial role in the substantive decision to be made, but the process requirements often affect the timing and nature of the ultimate decision.

Regulatory Statutes

Any discussion of the risk regulation process must begin with the individual regulatory statutes. Examination of those statutes that authorize regulation of cancer-causing chemicals, for example, shows different approaches to assessment of risks, burden of proof, data generation and the balancing of costs and benefits.

As was pointed out in the 1983 National Academy of Science Risk Assessment study,² several laws require the regulating agencies to balance costs and benefits before issuing rules or orders that regulate the use of carcinogenic chemicals. Other statutes involve the establishment of technology-based exposure controls, and a few mandate control techniques to reduce risks to zero whenever the hazard is identified. The best known example of a zero-tolerance statute is, of course, the Delaney Clause in the Federal Food, Drug and Cosmetic Act.³ As the Academy study pointed out:⁴

There can be little question that differing statutory standards for decision affect the weight that agencies accord risk assessments.... If risk is but one of several criteria that a regulator must consider or if data are expensive to obtain, it would not be surprising if an agency devoted less effort to risk assessment.

² NATIONAL ACADEMY OF SCIENCES, COMMITTEE ON THE INSTITUTIONAL MEANS FOR ASSESSMENT OF RISKS TO PUBLIC HEALTH, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS, 40-50 (1983).

³ The clause bars the approval of food additives shown to induce cancer in animals or humans; see 21 U.S.C. §§ 348(c)(3)(A) [food additives]; 360b(d)(1)(H) [animal drugs]; 376(b)(5)(B) [color additives].

⁴ NAS Report, *supra* note 2, at 43.

The procedure called for in risk-regulation statutes may also differ markedly between those that involve premarketing approval of substances and those that utilize post-hoc mechanisms such as emission limits. Peter Huber illustrated some of the ramifications that flow from the procedural distinction when he differentiated between what he called "screening" procedures (e.g., permission is sought from the FDA through an advance licensing procedure) and "standard setting" (e.g., as initiated by OSHA or CPSC to tell industry how to set up its work place or construct a toy).⁵ He perceived a bias in favor of screening out new risks and for simply setting standards for the production of old risks:⁶

Thus, we set standards for cars, but screen aircraft. We set standards to control the old hazards of burning coal, but screen new nuclear power plants. Under the Toxic Substances Control Act, EPA is supposed to screen all major new productions of 'new' chemicals, but is directed merely to set standards for the production and handling of old ones. EPA screens new pesticides but for the most part leaves the old ones alone.

This difference between screening and standard setting obviously affects the burden of proof. A screening agency can put the onus on the license applicant to prove that its product is safe and effective — an expensive proposition that may dampen innovation (such as orphan drugs where the potential payoff may not be great enough to overcome the cost of approval) and may drive applicants to seek economies of scale as through proposals for larger and larger nuclear plants. The screening process also places the cost of delay on the applicant and the benefit of delay on the opponent-intervenor.

The standard-setting agency, on the other hand, must develop the scientific evidence necessary to support the intended restriction — a task

⁵ Huber, *Exorcists vs. Gatekeepers in Risk Regulation*, Regulation, Nov/Dec 1983, 23-32. See also, Huber, *The Old-New Division in Risk Regulation*, 69 U. VA. L. REV. 1025 (1983).

⁶ *Id.*, at 24.

made more arduous and expensive by the typical statutory admonition to the agency, common in such statutes, to take the costs of regulation into account. It is unsurprising then that, in Huber's terms, the "exorcist" standard-setting agency usually goes after the big targets and is often accused of slothful action by the public interest groups, while the "gatekeeper" licensing agencies often are accused of regressive, over-cautious actions by the business community.

Much more could be said about the importance of the procedural scheme created by the regulatory statutes themselves. But until a consensus develops around when licensing is to be preferred over standard setting, the regulator will take the legislative cards dealt, and then consult the rules of administrative procedure to see how the game must be played. Whether these rules provide more opportunities than constraints, is the subject of this paper.

The Administrative Procedure Act

The Federal Administrative Procedure Act of 1946 (APA)⁷ basically governs the following activities of federal agencies (unless later statutes provide otherwise): (1) Rulemaking, (2) Adjudication, (3) Judicial review of agency action, (4) Access to agency information (Freedom of Information Act amendment), and (5) Open meetings (Government in the Sunshine Act amendment).

Under the APA, all agency action is either rulemaking or adjudication. Licensing is adjudication (albeit with some special treatment) and standard setting is rulemaking.

Rulemaking Under the APA

Rulemaking is the issuance of an agency statement of future effect, usually of general applicability. Most agencies are expressly authorized by Congress to make their general policies known to the regulated

⁷ 5 U.S.C. §§ 551-559, 701-706, 1305, 3105, 3344, 5372, 7521.

entities and to the public through the issuance of rules. The statutory procedure for issuing rules is simple. A notice of the proposed rule is published in a nationally available government publication known as the Federal Register. The public is given an opportunity to comment on the proposal — usually for 30 or 60 days — although this step may be skipped in certain emergency circumstances or where the rule is deemed to be of little public interest. The agency must consider the comments and publish the final rule, explaining how it responds to the comments. Such rules are subject to challenge in court — usually directly in the court of appeals.⁸

Professor Kenneth Culp Davis, author of the leading treatise on administrative law has proclaimed that notice-and-comment rulemaking is "one of the greatest inventions of modern government."⁹ The basic APA procedure is quite streamlined: proposed rule, comment period, final rule with explanation. But as the importance of, and skirmishing over, agency rulemaking increased, courts and Congress began to demand more of rulemakers. Courts began to demand expanded notices of proposed rulemaking, including information on the agency's "intent to rely" on specific information in its possession. The "rulemaking record" became the focus of judicial scrutiny and in some cases courts demanded that agencies allow oral argument or even cross-examination to air controversial issues in the proceeding.¹⁰ Congress, for its part, began to pass statutes, labeled "hybrid rulemaking" statutes which departed from the APA and required public hearings and cross-

⁸ See generally, ADMINISTRATIVE CONFERENCE OF THE U.S., A GUIDE TO FEDERAL AGENCY RULEMAKING (1983) (Revised edition forthcoming).

⁹ Administrative Law Treatise (1970 Supplement) (§ 6.15); reaffirmed in 1 Administrative Law Treatise (2nd ed. 1978) (§ 6.1).

¹⁰ See, e.g., *International Harvester Corp. v. Ruckelshaus*, 478 F.2d 615 (D.C. Cir. 1973), and other cases described in Williams, "Hybrid Rulemaking" Under the Administrative Procedure Act: A Legal and Empirical Analysis, 42 U. Chi. L. Rev. 401 (1975).

examination. Many of these statutes are key risk regulation statutes: the Occupational Safety and Health Act (1970),¹¹ the Consumer Product Safety Act (1972),¹² the Safe Drinking Water Act (1974),¹³ the Clean Water Act (1977),¹⁴ and the Clean Air Act Amendments (1977).¹⁵

This trend toward formalization of rulemaking was arrested in the late 1970s. The Supreme Court's *Vermont Yankee* decision in 1978¹⁶ barred reviewing courts from requiring agencies to use additional procedures not required by the APA (or other statutes). The Administrative Conference's studies of hybrid rulemaking statutes like the FTC's Magnuson-Moss Act also reached the conclusion that such procedures have not been effective and urged that "Congress should not ordinarily require, for agency rulemaking, procedures in addition to those specified by section 553 of the APA, although the agencies should have the discretion to utilize them."¹⁷

Impact Statements

Although it was generally recognized that procedural encrustation of rulemaking may have gone too far, the concern remained that agencies ought to give special attention to the impact of their regulations. The granddaddy of the "impact statement" approach was the 1970 National Environmental Policy Act (NEPA)¹⁸ that directs all agencies to provide

¹¹ Pub. L. No. 91-596, rulemaking provision codified at 29 U.S.C. § 655.

¹² Pub. L. No. 92-573, rulemaking provision codified at 15 U.S.C. § 2056.

¹³ Pub. L. No. 93-523, rulemaking provision codified at 42 U.S.C. § 300g-1(d).

¹⁴ Pub. L. No. 95-217, rulemaking provision codified at 33 U.S.C. § 1317(a).

¹⁵ Pub. L. No. 95-95, rulemaking provision codified at 42 U.S.C. § 7607(d).

¹⁶ *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council*, 435 U.S. 519 (1978).

¹⁷ ACUS Recommendation 80-1, 1 C.F.R. § 305.80-1. See Boyer, *Report in Support of Recommendation 80-1* in ADMINISTRATIVE CONFERENCE OF THE U.S. [hereinafter ACUS], 1980 RECOMMENDATIONS AND REPORTS 33-204.

¹⁸ Pub. L. No. 91-190, 42 U.S.C. §§ 4321-4347.

an environmental impact statement with all proposals for "major Federal actions significantly affecting the quality of the human environment." This requirement, which has been rather aggressively enforced by the courts, applies to the gamut of agency actions including rules, licenses, construction plans and procurements.

Modeled on NEPA was the Regulatory Flexibility Act of 1981,¹⁹ which only applies to rulemaking. The Act requires rulemaking agencies to produce a regulatory flexibility analysis (essentially a small business impact statement). This requirement is overseen by the Small Business Administration, but is not enforceable in court.

OMB Review

A series of Presidential Executive Orders has given the President (through the Office of Management and Budget) a crucial role in clearing and coordinating Executive branch regulations, while also making use of the impact statement approach to analyzing regulatory costs and benefits. Executive Order 12291²⁰ issued by President Reagan soon after his inauguration mandates OMB clearance of all proposed and final rules and also requires a preliminary and final "regulatory analysis" for any major rule (i.e., a rule with an annual effect on the economy exceeding \$100 million or having significant impact on costs, prices, competition, employment, investment, or innovation). A later Executive Order, 12498,²¹ required agencies to provide OMB with their regulatory plans for the upcoming year, with the general admonition that matters not in the plan could not normally be pursued by the agency.²²

¹⁹ Pub.L. No.96-354, 5 U.S.C. §§ 601-612.

²⁰ Federal Regulation, Exec. Order 12291, 3 C.F.R. 127 (1981).

²¹ Regulatory Planning Process, Exec. Order 12498, 3 C.F.R. 323 (1985).

²² For a description of how the OMB views its accomplishments, see Regulatory Program of the United States (April 1, 1988, March 31, 1987), Executive Office of the President (1989) (especially Part 1, Overview and Summary). See also Bruff,

OMB's authority in this regard was bolstered by the Paperwork Reduction Act of 1980²³ which gave it the power to clear any agency "information collection requests" including those imposed through rulemaking. This Act applies to all agencies, including independent regulatory commissions not covered by the Executive Order.

The most recent application of the impact statement approach is Executive Order 12612,²⁴ which requires Executive branch agencies to provide OMB with "Federalism Assessments" whenever proposed agency actions have the potential of affecting state laws or prerogatives.

What is a Rulemaker to Do?

Assuming a decision has been made to proceed with a proposed regulation — a decision that ought to imply a rational choice from among competing priorities, the agency rulemaker's navigational job has just begun. From the outset he or she must prepare for each stage of the process carefully and with an eye to the likely court challenge that awaits most significant rules once the agency head signs off on the final rule. The APA requirements are relatively easy to satisfy. What is more difficult and challenging is assembling the various impact statements that may be required, marshalling the information and evidence in support of the rule (including persuasive responses to all "cogent comments" received during the comment period) and persuading OMB that the benefits of the rule outweigh its costs. Obviously, this requires deft management, close coordination with agency program staff, lawyers and policymakers, negotiations with OMB desk officers, and facility in technical writing as well as in "plain English" writing. It necessitates judicious use of consultants to help prepare the sophisticated regulatory

Presidential Management of Agency Rulemaking in ACUS, 1988
RECOMMENDATIONS AND REPORTS 527.

²³ Pub. L. No. 96-511, 44 U.S.C. §§ 3501-3520.

²⁴ Federalism, Exec. Order 12612, 3 C.F.R. 252 (1987).

analyses and other impact statements. It also requires attention to the probable application of the Freedom of Information Act²⁵ (which commenters often use to seek insights into agency predilections), the Government in the Sunshine Act²⁶ (requiring open meeting of multi-member agencies), the Ethics in Government Act²⁷ (involving possible recusal issues), and rules restricting the receipt of ex parte communications.²⁸

There are few shortcuts in the process of promulgating a major rule. However, several techniques advocated by the Administrative Conference of the U.S. (ACUS) may help.

Generic Rules

It was early recognized that licensing agencies should seek to identify recurring environmental issues appropriate for resolution in a "generic" proceeding.²⁹ More recently, the ACUS study of OSHA rulemaking, performed by Professors McGarity and Shapiro, pointed out the advantages of generic regulations such as industry-wide, multiple-chemical or work-practice standards.³⁰ The short-term costs of

²⁵ Pub. L. No. 89-554 (as amended), 5 U.S.C. § 552.

²⁶ Pub. L. No. 94-409, 5 U.S.C. § 552b.

²⁷ Pub. L. No. 95-521 (as amended); 5 U.S.C. Appendix (§§ 201-210 concerning executive personnel financial disclosure requirements); 18 U.S.C. § 207 (post-employment restrictions). A recent Executive Order issued by President Bush sets forth 14 principals of ethical conduct for executive branch employees: Principles of Ethical Conduct for Government Officers and Employees, Exec. Order 12674, (1989).

²⁸ See the APA's provision concerning barring ex parte (off-the-record) contracts in adjudications, 5 U.S.C. § 557(d). With respect to informal rulemaking, the APA is silent, but some courts have imposed restrictions, see *Home Box Office, Inc. v. FCC*, 567 F.2d 9 (D.C. Cir. 1977). See A GUIDE TO FEDERAL AGENCY RULEMAKING, *supra* note 8, Ch. 7.

²⁹ See ACUS Recommendation 73-6, Procedures for Resolution of Environmental Issues in Licensing Proceedings, 1 C.F.R. § 305.73-6 (1988).

³⁰ See McGarity and Shapiro, *OSHA Regulation: Regulatory Alternatives and*

undertaking such a broadly applicable standard would, if it could be achieved, ease future rulemakings immensely. OSHA has, indeed, already followed this advice in a proposed generic rulemaking.³¹

Building Consensus

Obviously, the rulemaking's process hurdles are lowered considerably when consensus is substituted for contentiousness. Moreover, in a litigious atmosphere (80 percent of all EPA rules are challenged in court)³² attempts to achieve consensus have a high potential payoff.

Interaction with private standard-setting organizations

ACUS has recommended that agencies should draw on the knowledge of active technical committees that develop relevant voluntary consensus standards and should interact with such committees.³³ Of course, the procedures and composition of such committees must be carefully considered by the agencies in determining the weight to be given to their work product.

Advisory Committees

An agency can appoint a body of outside experts to advise it on its

Legislative Reform, 1987 ACUS Report 999, 1012-1020; Shapiro and McGarity, *Reorienting OSHA: Regulatory Alternatives and Legislative Reform*, 6 YALE J. Reg. 1, 27-31 (1989); ACUS Recommendation 87-10, Regulation by the Occupational Safety and Health Administration, 1 C.F.R. § 305.87-10 (1988).

³¹ See Generic Standard for Exposure Monitoring (OSHA advance notice of proposed rulemaking) 53 Fed. Reg. 37591 (September 27, 1988).

³² See EPA PROGRAM EVALUATION DIVISION, OFFICE OF MANAGEMENT SYSTEMS AND EVALUATION, OFFICE OF POLICY PLANNING AND EVALUATION, AN ASSESSMENT OF EPA'S NEGOTIATED RULEMAKING ACTIVITIES, 1, (December 1987) in ACUS, NEGOTIATED RULEMAKING SOURCEBOOK Ch. 1, appendix (forthcoming).

³³ ACUS Recommendation 78-4, Federal Agency Interaction With Private Standard-Setting Organizations in Health and Safety Regulation, 1 C.F.R. § 305.78-4 (1988).

rulemaking. Such committees must, however, be chartered and operated under the Federal Advisory Committee Act³⁴ (and their creation is subject to advance notice to OMB under E.O. 12498). Once established, advisory committees can assist agencies by explaining technical issues, promoting dialogue with outside experts and providing a form of peer review of the agency's decisions. The FDA has traditionally relied heavily on advisory committees whereas OSHA, which has some statutory restrictions on the composition of advisory committees, has largely eschewed their use.³⁵

Negotiated Rulemaking

Finally, in some cases true consensus can be reached prior to the proposed rule stage. This is the goal of negotiated rulemaking which has been strongly endorsed by ACUS.³⁶ Several health and safety agencies (EPA, FAA, OSHA) have used this approach — which calls for convening representatives of all interested parties into a negotiating committee under agency auspices — with some success. "Reg neg" may not be well suited for all rulemakings, but in most of the 19 instances where it has been tried (by eight different departments and agencies), areas of controversy have been eliminated or at least narrowed considerably.³⁷

Adjudication Under the APA

Regulatory programs normally involve a mix of rulemaking and adjudication. Standard-setting agencies like OSHA must also investigate

³⁴ 5 U.S.C. app.

³⁵ See McGarity and Shapiro, *supra* note 30, at 1039.

³⁶ ACUS Recommendations 82-4, 85-5, Procedures for Negotiating Proposed Regulations, 1 C.F.R. § 305.82-4, 85-5.

³⁷ See "Agency Experience with Negotiated Rulemaking," in ACUS, NEGOTIATED RULEMAKING SOURCEBOOK Ch. 10 (forthcoming).

and enforce violations of their regulations. (In OSHA's case, the civil penalty violation is adjudicated by a separate agency — the Occupational Safety and Health Review Commission.) Screening agencies like FDA or NRC principally rely on adjudications to rule on the safety and/or effectiveness of proposed new drugs or power plants. Of course, those agencies can and do issue regulations designed to resolve issues that recur in adjudications. The Supreme Court has upheld, generally, agency discretion to make policy through rulemaking or adjudication, provided appropriate procedures are followed.³⁸

Under the APA, if the statute under which the agency is conducting the program calls for an adjudication (whether it be an enforcement action, license application or benefit claim) that is "required to be determined on the record after an agency hearing," then the APA procedures apply.³⁹ These procedures, generally speaking, require use of a special type of agency employee — an administrative law judge (ALJ) — to preside over the hearing and make an initial decision in the case. (Theoretically, the head of the agency may preside, but practically, ALJs are used in nearly all APA hearings.)

Administrative Law Judges

ALJs are given special status and independence by the APA. Although they are technically agency employees, they are selected by the agencies off a special register maintained by the Office of Personnel Management (OPM). The selection process for ALJs is quite rigorous. At a minimum, an ALJ applicant must have at least seven years of experience in administrative law and/or trial experience as an attorney or a judge. OPM then rates the applicant on a 100-point scale, based on a review of the applicant's experience, a written demonstration and a

³⁸ See *NLRB v. Bell Aerospace Co.* 416 U.S. 267 (1974).

³⁹ 5 U.S.C. § 554(a). See generally, Lubbers, *Federal Agency Adjudications: Trying to See the Forest and the Trees*, 31 FED. BAR NEWS AND J. 383 (1984).

panel interview. Agencies then fill vacancies from the top of the register.⁴⁰

OPM prescribes ALJs' pay. ALJs may not be assigned duties inconsistent with their duties as ALJs, their job performance may not be formally evaluated by the agencies, they may not be advised or consulted by agency investigators or prosecutors, and they may not be fired or reprimanded unless charges are brought against them by the agency in a formal procedure.⁴¹

Other "Non-ALJ" Adjudicators

The APA permits the use of other types of adjudicators in certain types of cases. In cases that are not required by statute to be heard under the APA, the agency is free to craft its procedure and use any employee to preside so long as the due process clause is satisfied. And, Congress can always specify in other laws that a particular type of adjudicator be used (e.g., a panel of lawyers, physicists, engineers, or environmental scientists in nuclear power plant licensing cases). As a consequence, there are several major programs (immigration appeals, federal employee appeals, veterans' benefit cases) where specified non-ALJ adjudicators preside over cases that are otherwise similar to APA cases.⁴²

Agency Review

In general, once an initial decision is made by the agency presiding

⁴⁰ For a detailed description of the ALJ selection process, see Sharon and Pettibone, *Merit Selection of Federal Administrative Law Judges*, 70 JUDICATURE 216 (1987).

⁴¹ See the various protections in 5 U.S.C. §§ 554(d), 1305, 3105, 4302, 5372, 7521.

⁴² See Robie and Morse, *The Federal Executive Branch Adjudicator: Alive (and) Well Outside the Administrative Procedure Act?* 33 FED. BAR NEWS AND J. 133 (1986).

officer, the losing party (sometimes the agency staff) has an opportunity to seek review by the agency head (or his designee). If no review is sought, the agency head may call the case up "on his own motion."

The APA provides that the agency head has "all the powers which it would have in making the initial decision."⁴³ This broad power to reverse or modify the presiding officer's decision has been tempered by court decisions requiring the agency head to justify such a change, especially where the initial decision was based on witness testimony.⁴⁴ Agencies have discretion as to how they structure their appeal process. Some agency heads (usually boards or commissions) hear appeals themselves; other have created special panels or individual positions to hear such appeals.⁴⁵

Adjudication of Scientific Issues

The above description outlines the normal adjudication procedure used by the approximately 40 agencies that employ or borrow ALJs to preside over their formal hearings. It is a well-understood system, heavily dependent on the cadre of over 1,000 merit-selected, legally trained ALJs. Although the system has its critics who desire faster decision-making or more independent judges, it seems to work relatively well for the mine run of disputes over benefit claims, labor relations practices, or civil money penalties — where "adjudicative facts" are at issue. However, where the disputes concern "legislative facts" or policy issues, especially those on the frontiers of scientific

⁴³ 5 U.S.C. § 557(b).

⁴⁴ See, e.g., *Brock v. L.E. Meyers Co.*, 818 F.2d 1270, 1277 (6th Cir. 1987). (Commission must articulate reasons for its failure to credit ALJ's findings, where ALJ had "unique opportunity of observing the demeanor of the witnesses....")

⁴⁵ See *Cases, Agency Review of Administrative Law Judges' Decisions*, 66 B.U.L. REV. 1 (1986); ACUS Recommendation 83-3, *Agency Structure for Review of Decisions of Presiding Officers Under the Administrative Procedure Act*, 1 C.F.R. § 305.83-3 (1988).

knowledge, the adjudicative hearing before a legally trained decider becomes more anomalous.⁴⁶

Although APA adjudication procedures can be, and are, regularly invoked by Congress whenever dispute resolution procedures are called for, this may not always make sense. For example, it seems perfectly appropriate to allow (and due process may require allowing) a company charged with a safety violation by OSHA to put on a defense with its own witnesses and an opportunity to cross-examine opposing witnesses before an administrative law judge. However, if the FDA must decide whether a new food additive should be allowed on the market in the face of charges that it may cause cancer, it seems doubtful that a legal trial is the best procedure.

What is an Adjudicator to Do?

Unless Congress has authorized a deviation from the APA (either specifically or by not requiring a hearing "on the record"), the agency may be required to offer an ALJ hearing. But there are avenues for a risk regulator to pursue in seeking to improve dispute resolution procedures.

Flexibility within the APA

As Paul Verkuil has noted, the APA itself presents "opportunities for procedural reform that have been underutilized or even ignored since its enactment."⁴⁷ Several provisions allow significant procedural flexibility in initial licensing cases that might be important in some risk regulatory areas. For example, in initial licensing, under the APA, "an agency may, when a party will not be prejudiced thereby adopt procedures for the submission of all or part of the evidence in written

⁴⁶ See K. C. DAVIS, 1 ADMINISTRATIVE LAW TREATISE (2nd ed.) (§ 6.16).

⁴⁷ Verkuil, *The Emerging Concept of Administrative Procedure*, 78 COLUM. L. REV. 258, 313 (1978).

form."⁴⁸ Moreover, in initial licensing an agency may assign the recommended decision to a "responsible employee" who need not be an ALJ.⁴⁹ Finally, an agency need not follow the normal separation-of-functions restrictions in such cases.⁵⁰ That is, an agency decision-maker could, according to the APA, consult with staff experts without worrying whether they might have been involved in that proceeding or a factually related one. There may, of course, be some inhibition on agencies taking full advantage of these provisions (or they may be superseded by the regulatory statute), but it would behoove agency decision-makers to take another look at the APA.

Departures from the APA

Agencies can, of course, seek exceptions or modifications from the APA procedures. Congress has sometimes shown its willingness to depart from the APA. For example, in NRC nuclear plant licensing cases, Congress authorized three-member panels to hear the cases with legal and technical experts on the panels. Or the agency can try to convince Congress that alternative dispute resolution procedures should be tried. Commentators have suggested that a deficiency in the APA, notwithstanding its flexibility in some types of cases, is the absence of procedures for informal adjudication, i.e., those that do not require trial-type hearings.⁵¹ The APA contains no real procedures covering those agency adjudications.

Voluntary Alternatives

Although Congress has required FDA to offer a "formal evidentiary

⁴⁸ 5 U.S.C. § 556(d).

⁴⁹ 5 U.S.C. § 557(b).

⁵⁰ 5 U.S.C. § 554(d).

⁵¹ See Gardner, *The Procedures By Which Informal Action is Taken*, 24 ADMIN. L. REV. 155 (1972) (proposing an informal procedure statute).

hearing" in disputes over applications for food additives or for new drugs, the FDA has sought to avoid unnecessary use of adversary procedure by offering three voluntary alternatives: a hearing before the Commissioner of the FDA, a hearing before an advisory committee or a hearing before a Public Board of Inquiry (PBOI).⁵²

The PBOI is perhaps the most interesting variation, despite the fact that it has only been tried twice. As Professor Shapiro's study for the Administrative Conference shows, the PBOI is the closest analogue in government to the oft-proposed science court.⁵³ It consists of a panel of three scientists appointed by the Commissioner of FDA — two of which are selected from recommendations of the parties. The Board obtains scientific "testimony" within an informal quasi-adjudicative hearing framework in which the advocacy role of lawyers is minimized in favor of a "scientific forum" approach — although the Board's decision is an "initial decision" and has the same legal status as an initial decision of an ALJ.

The Administrative Conference concluded that:⁵⁴

Other agencies with regulatory programs that depend on scientific determinations should consider experimental use of a process similar to PBOI as a voluntary alternative to a hearing that would otherwise be held to resolve issues of scientific uncertainty.

It seems clear that greater experimentation is called for in this area. If agencies are to be charged with making the best scientific decisions, then perhaps scientific method should, in appropriate circumstances, substitute for legal method. This in turn would require a willingness on

⁵² See Shapiro, *Scientific Issues and the Function of Hearing Procedures: Evaluating the FDA's Public Board of Inquiry*, 1986 DUKE L.J. 288.

⁵³ See Kantrowitz, *Proposal for an Institution for Scientific Judgment*, 156 SCIENCE 763 (1967) and other sources cited in Shapiro, *supra*note 52 at 299-300.

⁵⁴ ACUS Statement on hearing procedures for the resolution of scientific issues, 1 C.F.R. § 310.11 (1988).

the part of Congress to depart from the APA in appropriate circumstances. It is a challenge for leaders in the risk regulation community to help develop methods for doing so while safeguarding the democratic need for public participation and due process of law.

Conclusion

Two primary types of policy-making procedure in administrative law are available to risk regulators: rulemaking and adjudication. Rulemaking under the APA may be quite informal, requiring only adequate notice and opportunity for comment. On the other hand, APA adjudication normally requires a trial presided over by a legally trained judge.

What is ironic is that as the inappropriateness of APA adjudication to disputes over scientific and technical questions is increasingly well-recognized, the simplicity of notice-and-comment rulemaking is being lost through a proliferation of legislatively and presidentially-imposed additions to the process.

Clearly there is a need for new thinking in the area of risk regulation procedures.⁵⁵ The current system, while manageable to skilled navigators, is not conducive to the merger of scientific method and legal method.

⁵⁵ A potentially fruitful approach is "risk comparison," examined by Baram, *Use of Comparative Risk Methods in Regulatory and Common Law*, 13 COLUM. J. ENVTL. L. 1 (1987).