

# REPORT ON THE EXPERIENCE OF VARIOUS AGENCIES WITH STATUTORY TIME LIMITS APPLICABLE TO LICENSING OR CLEARANCE FUNCTIONS AND TO RULEMAKING

*Edward A. Tomlinson*

## PART I — INTRODUCTION

### A. *Summary of Findings*

Undue delay in administrative proceedings has proved to be a recurrent problem. Congress addressed the problem in general terms when it enacted the Administrative Procedure Act in 1946. Section 6(a) of the original Act<sup>1</sup> required each agency to conclude any matter presented to it “with reasonable dispatch.”<sup>2</sup> Section 10(e)(A) of the Act<sup>3</sup> authorized a reviewing court to enforce this command by compelling agency action “unlawfully withheld or unreasonably delayed.” While these two sections (now codified as section 555(b) and section 706(1) of Title 5) contain a judicially enforceable prohibition against unlawful or unreasonable delay,<sup>4</sup> they have contributed little to the reduction of delay. Courts have not developed workable rules for determining what constitutes an unlawful or unreasonable delay and have granted relief from the effects of delay only on a haphazard basis and in egregious cases.<sup>5</sup> The vagueness of the statutory terms is only partially responsible for this situation. Courts have also held

---

1. 5 U.S.C. §1005(b) (1958).

2. When Congress reenacted Title 5 in 1966, the original section 6(b) was rewritten to read: “With due regard for the convenience and necessity of the parties or their representatives and *within a reasonable time*, each agency shall proceed to conclude a matter presented to it.” 5 U.S.C. §555(b) (1970) (emphasis added).

3. 5 U.S.C. §1009 (e)(A) (1958), now codified at 5 U.S.C. §706(1) (1970).

4. See, e.g., *Deering Milliken, Inc. v. Johnston*, 295 F.2d 856 (4th Cir. 1961).

5. See the case law discussed in Part I (C) of this *Report* (adjudicatory proceedings) and in Part I(D) of the *Report* (rulemaking proceedings).

In *White v. Mathews*, 559 F.2d 852 (2d Cir. 1977), the court held that administrative delays in adjudicating disability claims violated section 205(b) of the Social Security Act, 42 U.S.C. §405(b) (1970), which required the Secretary of Health, Education and Welfare to afford a claimant aggrieved by a decision “reasonable notice and opportunity for a hearing with respect to such decision.” The court found that the time lapse between a claimant’s request for

that these statutory provisions do not affect the broad discretion enjoyed by most agencies to allocate their limited resources among the competing demands for their attention.<sup>6</sup>

Frustration over the inability of agencies and courts to eliminate undue delay has on occasion led Congress to adopt a more particular approach to the problem of administrative delay. In recent years Congress has with increasing frequency enacted statutory provisions applicable to particular agencies that require the agency to act within a prescribed period of time. The time limits in these statutes are stated in terms of a specific number of days or months; the statute also specifies the categories of agency proceedings that are subject to the time limit. Congress evidently expects that if it establishes a firm deadline for agency action the agency will comply with the deadline, or will at least make a prompter decision than would otherwise be the case.

Congressional reliance on the establishment of a firm, specific deadline as a device for reducing delay appears to be well founded. Serious problems may arise, however, when Congress itself acts to establish a deadline by statute. Even if Congress has before it sufficient information to enable it to select an appropriate time period, which is unlikely to be the case for new programs, the rigidity of a statutory time limit is not consistent with the proper use of a deadline as a monitoring or control device.

The literature of public administration supports the use of deadlines as a managerial tool to monitor the performance by subordinate employees of routine tasks.<sup>7</sup> For more complex but recurrent tasks, managers are advised to develop more elaborate flow charts with deadlines for each step in the process. A missed deadline alerts a middle or upper level manager to a potential problem that has arisen and enables him to take prompt corrective

---

a hearing and the holding of the hearing averaged 211.8 days in Connecticut and 195.2 days nationwide. The court held that these delays violated the Social Security Act and affirmed the District Court's order which required the agency to reduce the maximum delays between request for hearing and final decision by the hearing officer to 180 days by July, 1977, 150 days by December 31, 1977, and 120 days by July 1, 1978. Claimants who were required to wait longer were to receive benefits automatically from the expiration of the allotted time until a decision was rendered. The Court of Appeals declined to rule whether the delays that had occurred also violated the Administrative Procedure Act. *Id.* at 861 n.12.

6. *Id.*

7. See H. Simon, *Administrative Behavior: A Study of Decision-Making Processes in Administration Organization* 228-247 (2d ed. 1957); P. Blau, *The Dynamics of Bureaucracy: A Study of Interpersonal Relations in Two Government Agencies* 36-56 (2d ed. 1963); M. Alexis and C. Wilson, *Organizational Decision-Making* 77ff (1967); L. Gawthrop, *Bureaucratic Behavior in the Executive Branch* 86-89 (1969); A. Downs, *Inside Bureaucracy* 183-184 (1967).

It must be acknowledged that this literature does not view delay as a significant problem in administrative decisionmaking and even treats time constraints as an impediment to rational decisionmaking. See Gawthrop at 86. Blau depicts the adverse consequences that may flow from the close monitoring of subordinates' performance. Formalistic compliance with case-processing requirements may reduce the overall level of performance. Blau at pp. 55-56.

action. The establishment of a deadline provides a goal for operating employees to strive to meet and a yardstick for management to evaluate the performance of each component within the overall operation. To serve these functions a deadline must be a tight one. While it should also be a realistic one, the person setting the deadline should not expect the deadline to be met in all cases. If it is met in all or most instances, the deadline is not tight enough to serve its function as a monitoring device.

Many government administrators presently use flow charts and deadlines to monitor the performance of routine or recurrent administrative tasks. In its recent study on *Delay in the Regulatory Process*, the Senate Committee on Governmental Affairs<sup>8</sup> reported favorably on the use of these techniques by the Civil Aeronautics Board, Federal Communications Commission, Nuclear Regulatory Commission, Federal Trade Commission, National Labor Relations Board, Interstate Commerce Commission, Environmental Protection Agency, and Consumer Product Safety Commission. All of the agency initiatives described in the Committee's *Report* were of comparatively recent vintage and were adopted by the agencies without any statutory compulsion. The agencies had adopted them primarily to alleviate delay and to avoid situations where decisions were never made and proceedings never terminated. The Committee found that "[m]anagement systems to schedule agency work, monitor compliance with the schedules, and alert managers to any delays or persistent bottlenecks do in fact work to help reduce delay."<sup>9</sup> In addition, "[e]stablishing deadlines and keeping responsible personnel aware that they will be called to explain delays provides a powerful incentive to complete work promptly."<sup>10</sup>

The statutory time limits studied in this *Report* indicate that statutory deadlines may have a similar effect. While the time limits have therefore had some impact in reducing delay, their effectiveness has often been quite limited. The pressure exerted by a statutory deadline is simply one of many pressures that an agency must live with in implementing its mandate. There has been a substantial incidence of agency non-compliance with statutory time limits and very few efforts to enforce them through the courts. Statutory time limits have also had little impact on the decisional process within the agencies involved. Agencies have done little to change the process of decision to accommodate a statutory time limit and have uniformly preferred to miss a statutory deadline rather than to make a decision that the agency is not yet ready to make. On the other hand, statutory time limits have provided agencies with a measuring rod for evaluating their own performance. In this fashion they have operated to spur better performance. The case studies disclose that this "spurring" effect is likely to occur in the

---

8. Senate Committee on Governmental Affairs, 95th Cong. 1st Sess., IV *Study on Federal Regulation - Delay in the Regulatory Process* (1977) (hereinafter cited as *Delay in the Regulatory Process*).

9. *Id.* at 150.

10. *Id.*

licensing or clearance context if other pressures (e.g., the obvious need of the private party for a prompt agency decision) also operate to reduce delay. It is likely to occur in the rulemaking context only if outside interest groups are sufficiently concerned about the effects of delay to monitor the agency's performance and to bring the agency to court if necessary.

While statutory deadlines do have some beneficial effects, they also have some undesirable features that are not shared by deadlines which are established administratively. A statutory deadline is normally understood to mean that an agency is legally obligated to act within the deadline. This feature of a statutory deadline is not consistent with the use of deadlines as a monitoring device. A statutory deadline is unduly rigid in a number of other ways. While Congress may at the time it enacts a statute acquire sufficient information to establish a tight but realistic deadline, conditions necessarily change with time. It is unlikely that Congress will have the time or interest periodically to review the deadline it originally imposed. Administrative proceedings also differ widely in their complexity and in the degree of party or public participation. A deadline that is tight but realistic for one proceeding may either be too loose or completely unattainable for another proceeding conducted by the same agency under the same statute. This is particularly likely to occur in rulemaking where major controversial proposals that attract broad public participation necessarily require far longer to promulgate than do routine or technical amendments to existing rules. Deadlines therefore need to be tailored to accommodate the requirements of particular proceedings. Statutory deadlines accompanying a general delegation of rulemaking power do not permit this flexibility.

These disadvantages associated with statutory deadlines should discourage their use by the Congress. The advantages offered by deadlines in reducing delay are obtainable through either of two alternative mechanisms. First, Congress could by statute require agencies to establish their own deadlines for agency decisionmaking. These administrative deadlines would not legally obligate the agency to act within the prescribed period of time but would allow the agency (and also the oversight committees in the Congress) to monitor and review the agency's performance. Second, Congress could assign a similar role to a statutory time limit by providing that the time limit was not a matter of legal obligation but only established the normal time period during which Congress expected the agency to act. Responsibility for supervising agency compliance with the time limit would rest primarily with the Congress, although the courts might also consider a variation from the norm in determining whether to compel under section 706(1) of the Administrative Procedure Act agency action unlawfully withheld or unreasonably delayed.

Neither of these two alternatives has yet been tested; and they do present some disadvantages. These disadvantages are particularly apparent from the perspective of private parties or public groups who are aggrieved by delay in agency decisionmaking. These types of deadlines do not have the aura and force of law. The availability of judicial relief is accordingly

lessened, and the litigant seeking relief must base his case solely on the provisions of the Administrative Procedure Act.

The Senate Committee on Governmental Affairs in its recent report on *Delay in the Regulatory Process*<sup>11</sup> reached similar conclusions on the advantages of deadlines in general and the disadvantages of statutory deadlines. The Committee's Report recognizes that deadlines are "a fundamental tool for agency managers to get regulatory work done promptly and in accordance with articulated priorities"<sup>12</sup> but rejects statutory deadlines on account of their rigidity and their interference with agency planning and management.<sup>13</sup> The Committee recommends in place of statutory deadlines that the "Administrative Procedure Act should be amended to require agencies to establish deadlines, whenever possible, for general classes of proceedings and for the various stages of proceedings within each class." An agency's failure to meet its own deadline should then be considered by the courts in determining whether agency action has been unreasonably delayed under section 706(1) of the Administrative Procedure Act.

The Senate Committee on Governmental Affairs did not study the operation of particular statutory time limits. The case studies in this report provide that documentation for nine agencies whose proceedings are in large part subject to statutory time limits. While the case studies document the limited effectiveness of statutory time limits in reducing delay, they also disclose that the undesirable features of statutory time limits outlined above have not played a prominent role. The agencies have in practice treated statutory time limits as establishing a goal for agency action and not as imposing a legal obligation to act prior to a fixed deadline. Agencies have thus avoided the premature making of decisions. Comparatively few suits have been brought to enforce statutory deadlines. Those suits that are brought are almost necessarily initiated after the agency has missed the statutory deadline. The court cannot order compliance with a statutory command that the agency has already violated. The "enforcing" court becomes an equity court with broad but flexible powers to order appropriate relief.<sup>14</sup> The presence of a statutory time limit nevertheless does affect the initial availability of judicial relief, since a court will ordinarily intervene in some fashion at the behest of an aggrieved person if an agency has missed a statutory deadline.<sup>15</sup> It is this feature which primarily distinguishes a statutory deadline for agency action from other types of deadlines.

### B. Description of Project

This study reports on the experience of nine agencies whose actions are subject to statutory time limits. On the basis of these studies it attempts to

---

11. *Delay in the Regulatory Process*, supra n.8.

12. *Id.* at 151.

13. *Id.*

14. See the case law discussed in Parts I(C) and (D) of this Report.

15. *Id.*

formulate some generalizations about the effectiveness and desirability of statutory time limits. The agencies studied in detail are the Office of Trade Adjustment Assistance in the Department of Labor, the Food and Drug Administration in the Department of Health, Education and Welfare, the Office of Export Administration in the Department of Commerce, the Special Imports Program Division in the Domestic and International Business Administration in the Department of Commerce, the Consumer Product Safety Commission, the Occupational Safety and Health Administration in the Department of Labor, the National Highway Traffic Safety Administration in the Department of Transportation, the Environmental Protection Agency, and the Office of Education in the Department of Health, Education and Welfare. The specific case studies for these agencies are presented in the body of the report. This Introduction categorizes the various types of statutory time limits covered in this study and summarizes what lessons may be drawn from the experience of the nine agencies with them.

Four of the case studies focus on statutory time limits applicable to adjudicatory proceedings. Each study involves a single agency but the study of the Food and Drug Administration covers three different categories of proceedings conducted by that agency. The seven types of proceedings included in the study are determinations on the eligibility of workers for trade adjustment assistance (Office of Trade Adjustment Assistance), new drug applications (Food and Drug Administration), new animal drug applications (Food and Drug Administration), food additive petitions (Food and Drug Administration), applications for export licenses (Office of Export Administration) and applications for duty-free importation of articles of scientific value (Domestic and International Business Administration).

These proceedings all involve the licensing or clearance by the agency of proposed private activity.<sup>16</sup> The four agencies involved utilize informal procedures for adjudicating individual cases. In the case of the Food and Drug Administration, the agency is required by statute to afford the aggrieved party an opportunity for a formal adjudicatory hearing in the event of an adverse agency decision made informally.<sup>17</sup> Despite the informality of the proceedings, the licensing or clearance functions performed by these agencies are complex and difficult. These proceedings do not involve the processing of large numbers of applications which are routinely approved

---

16. The proposed private activity cleared by OTAA is an unemployed worker's obtaining of additional relocation and rehabilitation benefits from his state unemployment office. These benefits are intended to assist the worker to obtain new employment in an industry or plant that is import-competitive. While this example may strain somewhat the phrase "proposed private activity," its usage is still appropriate since the workers will not obtain what they want without clearance from OTAA.

17. See 21 U.S.C. §355(c) (1970) (new drug application); 21 U.S.C. §360b(d) (1970) (new animal drug applications); 21 U.S.C. §348(f) (1970) (food additive petitions). The FDA must within the statutory time limit either approve the application or petition or afford the applicant or petitioner an opportunity for a hearing on its proposed denial.

once they are examined for facial adequacy and completeness. On the contrary, the applications for clearance (or at least a significant percentage of them) raise difficult factual and legal issues and are subject to intensive agency scrutiny through a multistep review process. A significant number are rejected by the agency.

There are a number of reasons for selecting these proceedings for inclusion in a study on the effectiveness and desirability of statutory time limits. First, Congress has often acted to impose statutory time limits on agency action that licenses or clears proposed private activity while it has generally avoided subjecting most other forms of agency adjudication to statutory time limits. The impetus behind these time limits is normally Congressional apprehension that legitimate or desirable private activity will be unduly delayed or frustrated entirely unless private parties are assured that they will receive approval or clearance (or a denial which they may challenge at a formal administrative hearing or in court) within a prescribed period of time. The only other context where Congress has regularly subjected agency adjudication to statutory time limits is that of summary enforcement action. There are a large number of statutory provisions which require an agency to afford a private party a hearing within a prescribed period of time if the agency without prior notice or hearing takes some action that adversely affects the interests of the private party.<sup>18</sup> These time limits are primarily intended to insure that the private party receives procedural due process. Any study of their operation and effect properly belongs in a broader study of the procedures that must accompany summary agency action.<sup>19</sup>

A second reason for selecting the proceedings included in this study is the opportunity they offer for studying the effect of statutory time limits on agency decisionmaking. Time limits applicable to proceedings that do not require intensive review of party submissions and difficult exercises of judgment are unlikely to shed much enlightenment on that issue. For example, the Secretary of the Treasury is required by statute<sup>20</sup> to act within forty-five days on applications to engage in the firearms or ammunition business or to obtain a collector's license. Approximately one hundred fifty thousand applications are filed annually; the Department approves substantially all of them within the prescribed forty-five day period. In order to comply with

---

18. See, e.g., section 402 of the Federal Meat Inspection Act, 21 U.S.C. §672 (1970) (administrative detention by Department of Agriculture of adulterated or misbranded meat). If the Department of Agriculture or other agency does not institute a judicial seizure action within twenty days of the detention, the detention terminates and there is no longer any restraint on the movement of the detained animals or meat products.

19. The only other statutory time limits of any significance applicable to adjudicatory proceedings are those found in the 1974 amendments to the Freedom of Information Act which require timely agency responses to requests for agency records. See Introduction at n.42 for text of these provisions. The effect of those time limits may well deserve a separate study but is beyond the scope of this study which focuses on *regulatory* decision-making (i.e., the agency's application of a substantive statutory provision in an adjudicatory or rulemaking proceeding).

20. 18 U.S.C. §1923(a) and (b) (1970).

the statutory time limit, the Department must simply assign sufficient clerical personnel to perform the routine task of issuing licenses.

The remaining five case studies focus on statutory time limits applicable to rulemaking proceedings. Each study again covers a single agency, but a single study may include rulemaking proceedings under a number of different statutes. The agencies selected for study are the Consumer Product Safety Commission, the Occupational Safety and Health Administration, the National Highway Traffic Safety Administration, the Environmental Protection Agency, and the Office of Education.

The statutory time limits to which these agencies are subject apply to rulemaking proceedings that involve on-going standard development under a broad statutory mandate. The agencies selected are the principal agencies subject to this type of time limit. Congress intends the time limit to perform a decision-forcing function. Rulemaking proceedings are hard to contain; additional information is always available, and further evaluation of the information already in the record may well produce a better decision. At some point an agency official must make a decision on the basis of the information and evaluation then available to him. A statutory time limit determines the last date for making that decision. While time limits applicable to adjudicatory proceedings are also decision-forcing, their primary function is to protect private rights.

Congress has in addition frequently required agencies to implement new statutory provisions or programs by promulgating specific categories of regulations within a prescribed period of time. This type of time limit has generally been excluded from the coverage of this study. Many of these statutory provisions establish deadlines for procedural or program regulations rather than for regulatory decisionmaking. A well known example is the 180-day statutory time limit for agency promulgation of regulations to implement the Government in the Sunshine Act.<sup>21</sup> Even where the required regulations are more substantive in nature, the issues of how much rulemaking Congress should expect an agency to accomplish within an initial time period and of when Congress should enforce its expectations through the device of a time limit for initial agency action are significantly different than the issues raised by time limits for making decisions in an ongoing regulatory process.<sup>22</sup> The first type of time limit requires the agency to do

---

21. Pub. L. 94-409, §3(g), 90 Stat. 1241, to be codified at 5 U.S.C. §552b(g).

22. The Commission on Federal Paperwork in its *Rulemaking Study* will recommend that Congress amend the Administrative Procedure Act to authorize the President to extend for a period not to exceed one year a statutory deadline for the promulgation of agency rules under new laws in order to provide sufficient time to properly develop the regulations. The Commission believes that Congress has often required agencies to do too much too soon to implement new programs. It cites as a prime example the Employee Retirement Income Security Act of 1974 (ERISA), which required the Secretary of Labor to promulgate implementing regulations within 120 days. The sweeping changes contained in this new pension reform law precluded the completion of the task within 120 days. While the Department of Labor did rush to produce a document prior to the deadline, its initial report (EBS-1) was so ill-conceived that it created more difficulties and uncertainties than it resolved.



something to implement a new statutory requirement or program within a prescribed period of time,<sup>23</sup> while the latter type of time limit forces the agency to make timely decisions on the course its regulation will take. Of course, this distinction tends to break down, and the effects of time constraints on rulemaking proceedings may be similar in both instances. The case study on rulemaking at the Office of Education really involves both types of time limits since rulemaking at the Office ordinarily occurs in response to statutory changes and involves the implementation of new or modified programs. It nevertheless seems appropriate to focus on statutory provisions which require agencies with on-going regulatory responsibilities to make decisions within set time periods on what rules or standards to develop, propose or promulgate.

Rulemaking proceedings normally have a number of distinct phases, and this study attempts to analyze the effect of statutory time limits applicable to the different stages of rulemaking. While the following

---

23. In one instance the consultant did study intensively the effect of a statutory time limit applicable to the promulgation of initial program regulations. Section 520(g)(2)(A) of the Food, Drug and Cosmetic Act, added by the medical Devices Amendments of 1976 (Pub. L. 94-295), to be codified at 21 U.S.C. §360j(g)(2)(A), required the FDA to promulgate regulations on exempt investigational uses of medical devices within 120 days of the date of enactment (May 28, 1976). The 1976 amendments also required a minimum period of sixty days for public comment on proposed rules. From the start the FDA believed this time limit to be completely unrealistic. It had taken the agency nearly ten years to develop similar regulations on the investigational use of new drugs. There was strong evidence that Congress did not really expect the FDA to do the same thing for medical devices in 120 days. The Congressional committees that drafted the Medical Devices Amendments were only concerned about intraocular devices, which the FDA had recently classified as an investigational new drug but which the agency could only regulate as a medical device after the passage of the amendments. The committees wanted to insure the continued regulation of intraocular devices by requiring the prompt promulgation of regulations to restrict their investigational use. However, the language adopted in section 520(g)(2)(A) was not limited to intraocular devices and required the promulgation of regulations on the investigational use of medical devices generally.

The FDA nevertheless made a herculean effort to show its good faith in attempting to comply with the statutory deadline in section 520(g)(2)(A). It issued proposed regulations on August 17, 1976 (published in 41 FR 35283 on August 20, 1976) and allowed the minimum sixty days for comment. The agency received 189 comments, most of them lengthy and thoughtful. The comments convinced the FDA that it was unwise abruptly to promulgate regulations that would affect as previously unregulated area. More time was needed for educational and consultative activities and to refine the proposals. Promulgation of the final regulations was therefore held up. The committee chairmen (Senator Kennedy and Representative Rogers) were notified and did not object. The FDA now (late spring 1977) anticipates promulgating soon final regulations on intraocular devices and either reproposing or promulgating interim final regulations for other medical devices.

The FDA's decision to allow a second round of public comment is understandable in light of the hostile reaction to its initial proposal. Where the FDA was unable to resolve policy issues within the time constraints for publishing the proposal (the FDA had sought to publish a proposed rule within sixty days of the statute's enactment), it tended to adopt the more restrictive approach. In other words, the time constraints did not operate to produce a proposal that was less comprehensive or less tough than would otherwise be the case but to produce a proposal that was perhaps more restrictive than necessary. The agency resolved its doubts in favor of public health and safety and against the broader investigational use of medical devices.

breakdown of rulemaking into three distinct phases is an oversimplification, it does indicate the various types of statutory time limits which Congress has imposed. The first phase ends with the agency's decision to commence rulemaking. This normally involves a determination by the agency that a rule appears to be necessary or desirable and that the agency should commit its resources to promulgate one. Congress may require an agency to make this determination within a prescribed period of time by requiring it to respond to rulemaking petitions within a statutory time limit. The next phase involves the development of a proposed rule and normally ends with the publication of a notice of proposed rulemaking in the Federal Register. Congress may require that an agency develop a proposal or terminate the rulemaking proceeding within so many days or months of a triggering event (e.g., the agency's "decision" to commence rulemaking). Finally, there is the promulgation of the final rule. This phase normally includes an opportunity for interested persons to participate through the submission of comments and, in many instances, through oral presentations at a public hearing. Congress may require that an agency promulgate a final rule or terminate the proceeding within so many days or months after publishing a proposed rule or after the close of public participation in the rulemaking proceeding.

### *C. General Discussion of Statutory Time Limits Applicable to Licensing or Clearance Functions*

#### *1. Two Types of Time Limits*

Statutory time limits applicable to licensing or clearance functions generally take one of two forms. The first type provides for the automatic approval or clearance of proposed private activity if the agency does not act affirmatively to block the activity within a prescribed period of time. An example of this type time limit may be found in section 8(a) of the Securities Act of 1933<sup>24</sup>, which provides that the effective date of a registration statement for the issuance of securities "shall be the twentieth day after the filing thereof." While the Securities and Exchange Commission does not formally approve registration statements, a statement becomes automatically effective on the twentieth day if the Commission does not act to block it; and the issuer may then commence to market the securities.

The second type of time limit provides that the agency "shall" approve or disapprove an application within a prescribed period of time after it is filed. The agency does not ordinarily have authority to extend the statutory deadline. These time limits are action-forcing but they do not supply a decision by operation of law if the agency fails to act. An example of this type of time limit may be found in section 505(c) of the Food, Drug and Cosmetic Act of 1938, as amended by the New Drug Amendments of 1962,<sup>25</sup>

---

24. 15 U.S.C. §77h(a) (1970).

25. 21 U.S.C. §355(c) (1970).

which requires manufacturers of new drugs to obtain premarket approval from the Food and Drug Administration. While that section requires the agency to approve an application or to afford the applicant an opportunity for a hearing within 180 days of an application's filing, affirmative action by the agency is required before the manufacturer may market the new drug. The expiration of the 180-day period does not entitle the manufacturer to proceed without agency approval. A seldom-found variant of this type of time limit allows the agency to extend for good cause the statutory period during which it is required to approve or disapprove an application. Section 4(g) of the Export Administration Act,<sup>26</sup> for example, permits the Office of Export Administration to notify an applicant for an export license that it requires additional time to make a decision.

Both types of statutory time limits may operate to expedite agency action and reduce undue delay. The statutory deadline provides a target for the agency to meet and spurs the agency to obtain sufficient personnel and to develop an adequate processing system. The case studies of the Food and Drug Administration, the Office of Trade Adjustment Assistance, and the Office of Export Administration disclose that statutory time limits have had these beneficial effects at those agencies.

Statutory time limits applicable to licensing or clearance functions may nevertheless create serious problems which limit their effectiveness. An agency responsible for processing a large number of applications simply cannot meet the statutory deadline in all cases. The inevitability of non-compliance does not result from the failure of Congress to establish a realistic time limit. With the exception of the twenty-day time limit applicable to the clearance by the Securities and Exchange Commission of registration statements for the issuance of new securities, the statutory time limits discussed in this report are realistic in the sense that if everything goes smoothly the agency can complete the task subject to the time limit in the assigned 60, 90, or 180 days. The problem is that in the real world everything does not go smoothly. This is particularly likely to be true if the agency processes a substantial number of applications (several hundred or more annually) that require more than routine approval upon a determination of facial completeness.

A number of factors contribute to this inevitability of non-compliance. The agency normally has no control over the filing of applications, and an unanticipated increase in applications may cause a backlog to develop. Once a backlog develops it may prove difficult to clear. This has occurred, for example, at the Office of Trade Adjustment Assistance. An anticipated increase may have the same effect since the hiring of sufficient competent personnel often proves to be difficult and time consuming if not impossible. Morale problems at the Food and Drug Administration, for example, have

---

26. 50 U.S.C. §2403(g) (Supp. V 1975). This section was subsequently amended by the Export Administration Amendments of 1977. See Case Study #3 on the Office of Export Administration.

long made it difficult to recruit competent medical officers to review new drug applications.

Problems may also arise in processing applications that raise significant factual or policy issues. While a statutory time limit may be realistic for processing the great majority of routine applications, it may not be realistic for the minority of "tough" applications. This has occurred at the Office of Export Administration. High-level reviewers at the end of the review process may raise issues which require returning the application to the initial reviewers for further work. If the pipeline is full and if all agency reviewers are fully occupied, a referral back for additional work will almost inevitably result in a missed statutory deadline. While statutory time limits may expedite agency action, they have not normally operated to force an agency to act before it has made up its mind. In fact, the combined problems of backlog and decisional delay have resulted in a substantial degree of non-compliance with all the statutory time limits surveyed in this study. The uniform approach adopted by the agencies in this situation is to take the time necessary to make a proper decision and not just to make a decision within the statutory time limit.

## 2. *Disapproval of Time Limits of the Automatic Approval Type*

The inevitability of a significant incidence of non-compliance with a statutory time limit makes it unwise in most instances for Congress to adopt a time limit of the first type which provides for automatic approval of proposed private activity at the end of the prescribed period of time. Such a time limit forces the agency to choose between the undesirable alternatives of clearing proposed private activity that may be harmful to the public or of denying clearance out of an abundance of caution even though the denial may prove to be unnecessary.

Congress has in fact deleted automatic approval provisions in two recent instances. Prior to the New Drug Amendments of 1962, a manufacturer of a new drug could market its product if the Food and Drug Administration did not affirmatively block that action within 180 days of the manufacturer's filing of a new drug application. The nation's close escape from a thalidomide tragedy similar to that caused by the marketing of that drug in Europe convinced Congress to require affirmative approval of a new drug by the Food and Drug Administration before it could be marketed.<sup>27</sup> Similarly, prior to the Securities Acts Amendments of 1975, applications for registration as a broker or dealer or as an investment adviser became automatically effective thirty days after receipt by the Securities and Exchange Commission if the Commission did not act to block the registration within the period. The 1975 amendments increased the protection available to the public by requiring affirmative Commission approval of

---

27. For further discussion of this change and for citation of authority, see Case Study #2 on the Food and Drug Administration.

registration applications.<sup>28</sup> In the one remaining area where the Securities Acts have an automatic approval provision—the clearance of registration statements for the issuance of new securities under section 8(a) of the Securities Act of 1933—the Commission enjoys sufficient leverage to prevent issuers from invoking the unrealistic twenty-day time limit. Issuers cannot as a practical matter market new securities until the Commission has cleared them; and they therefore file delaying amendments which afford the Commission the time it needs to complete its review.

The only other significant example of a statutory time limit with an automatic approval provision may be found in section 5 of the Voting Rights Act.<sup>29</sup> That section forbids states subject to the Act from implementing any changes in their voting laws without first obtaining a declaratory judgment from the District Court for the District of Columbia that the proposed change “does not have the purpose and will not have the effect of denying or abridging the right to vote on account of race or color.” Alternatively, the state may implement the proposed change after submitting it to the Attorney General of the United States and receiving no objection within sixty days. The Attorney General has utilized the State’s burden of proof under section 5 to limit the impact of this automatic approval provision. Thus, under the Justice Department’s regulations,<sup>30</sup> which have been upheld by the Supreme Court,<sup>31</sup> the Attorney General will object to a submission if he cannot within the sixty-day time period satisfy himself that the proposed change is without a discriminatory purpose or effect. A “forced” decision will therefore necessarily be adverse to the applicant. The well-grounded fear that a “forced” decision will likely be adverse to the private interest at stake convinced Congress to soften an automatic approval provision in the Export Administration Amendments of 1977.<sup>32</sup>

### 3. *Interpretation of Time Limits of the Action-Forcing Type*

Time limits of the automatic approval type generally do not pose problems of interpretation. They usually provide that the application or proposed private activity shall be “deemed” approved or cleared unless the agency acts affirmatively to block it within the prescribed period of time. On the other hand, statutory time limits of the type which require that the agency “shall approve or disapprove” an application within so many days

---

28. Pub. L. 94-29, §16, 89 Stat. 146 (1975), codified at 15 U.S.C. 788 (Supp. V 1975).

29. 42 U.S.C. §1973c (1970).

30. 28 CFR 51.19 (1976).

31. *Georgia v. United States*, 411 U.S. 526 (1973).

32. Under the provision ultimately enacted, applications for export licenses become automatically effective 90 days after filing, but the Secretary of Commerce may block this automatic approval simply by finding that additional time is required to act on the application and by notifying the applicant in writing of the reasons for the delay and the expected date of the decision. See Case Study #3 on the Office of Export Administration for further discussion and for citation of authority.

agency acts affirmatively to block it within the prescribed period of time. On the other hand, statutory time limits of the type which require that the agency "shall approve or disapprove" an application within so many days raise significant interpretative difficulties. The primary issue is usually stated in terms of whether Congress intended the time limit to be mandatory or directory, but that formulation subsumes two separate issues. First, what relief is available to private parties if the agency does not act within the statutory time limit? Second, may the agency validly act after the expiration of the statutory time limit? There is also the subsidiary issue whether agency officials act unlawfully when they do not act within the statutory deadline. Our government is based on the rule of law, and government officials are legitimately concerned with obeying the law. Are they lawbreakers when they miss a statutory deadline? What reasons justify their doing so? The case law does not provide a clear answer to most of these questions. Of course, the answers may differ for different statutory time limits since each statutory time limit has its own wording and legislative history. Congress may itself resolve these questions in drafting statutory time limits but it normally has not done so. Congress simply provides that the agency "shall" act within so many days.

Courts have uniformly interpreted statutory time limits of the action-forcing type to permit agency action after the expiration of the statutory time period.<sup>33</sup> This body of case law originated with *Maryland Casualty Co. v. Cardillo*,<sup>34</sup> where the statute provided that the deputy commissioner of customs "shall" make a decision on a compensation claim within twenty days after the closing of the hearing. The court upheld the validity of an award made after the expiration of the twenty-day period. The court categorized the statutory time limit as directory and noted that the complaining insurance carrier had not asked the deputy commissioner to make a prompt or timely decision.

Subsequent decisions have emphasized the failure of Congress to provide a penalty or specify any consequences for non-compliance with a statutory time limit. In *Diamond Match Co. v. United States*,<sup>35</sup> the court

---

33. See, e.g., *Ralphy v. Bell*, 569 F.2d, 40 Ad. Law 2d 896, petitions for rehearing and rehearing en banc denied with opinions, 41 Ad. Law 2d 681 (D.C. Cir. 1977); *Usery v. Whitten Machine Works, Inc.*, 554 F.2d 490 (1st Cir. 1977); *United States v. Morris*, 252 F.2d 648 (5th Cir. 1958). In *Ralphy*, the Micronesian Claims Act of 1971 required that the Micronesian Claims Commission "shall wind up its affairs . . . not later than three years after the expiration of the time for filing claims." The court held that the wind-up provision did not bar a judicial remand to the Commission to redetermine an improperly determined claim even though the three year period had expired. The court did not find in the statute or its legislative history "the slightest indication that justice was to be sacrificed on the altar of speed" and doubted that the will of Congress would be served by allowing the expiration of the statutory time period to prevent official fairness. *Id.* at 922-923. On *Whitten*, see Case Study #1 on the Office of Trade Adjustment Assistance.

34. 99 F.2d 432 (D.C. Cir. 1938).

35. 181 F. Supp. 952, 958-959 (Customs Ct. 1960).

stated: "Statutes fixing the time for performance of acts will ordinarily be held directory where there are no negative words restraining the doing of the act after the time specified and no penalty is imposed." While a statutory time limit providing for the automatic approval of an application or filing does bar agency action after the expiration of the time period, a statutory time limit which does not specify any consequences for the agency's failure to comply with it does not invalidate agency action taken after the expiration of the prescribed period. The Fifth Circuit recently adopted this approach in *Fort Worth Nat. Corp. v. Federal Savings and Loan Ins. Corp.*,<sup>36</sup> where it interpreted a statutory time limit which provided that the Federal Home Loan Bank Board "shall render its decision" on an application within ninety days after the receipt of the record. The court held that the Board had authority to render a valid decision after the expiration of ninety days; and the proper remedy for a party aggrieved by the delay was to apply for a court order compelling the agency to act.

Statutory time limits of the action-forcing type are therefore generally directory to the extent that they permit the agency to act after the expiration of the statutory period. A contrary interpretation would have the draconian effect of penalizing innocent private parties, who still need to obtain clearance from the agency for their proposed private activity, for the defaults of the agency. None of the legislative materials indicate that Congress intended that harsh consequence to occur.

The *Cardillo* line of precedents interpreting statutory time limits to be directory may also support the proposition that any agency official does not act unlawfully if he fails to comply with a statutory time, at least if he has some valid reason for his default. The absence of any penalty provision supports that interpretation. There is nevertheless no clear authority on this issue. Agency officials who miss statutory deadlines do not consider themselves lawbreakers but still may complain that Congress has by law imposed requirements on them which simply cannot be met in all cases.

The mandatory vs. directory issue is hardest to resolve when it arises in the context of the relief available to private parties injured by an agency's non-compliance with a statutory time limit. In other contexts where Congress has imposed statutory requirements on government officials, courts have recognized that the word "shall" may be given a merely directory meaning if the law's purpose is the protection of the government by giving guidance to its officials. On the other hand, a mandatory meaning is apparent if Congress intended to protect private rights.<sup>37</sup> Since Congress generally enacts statutory time limits to protect private persons from the adverse effects of administrative delay, it would seem that compliance with these provisions is mandatory. If an agency does not act within a statutory

---

36. 469 F.2d 47 (5th Cir. 1972).

37. *French v. Edwards*, 80 U.S. (13 Wall) 506, 511 (1972); *Triangle Candy Co. v. United States*, 144 F.2d 195, 198 (9th Cir. 1944).

time limit, a reviewing court under section 706(1) of the Administrative Procedure Act may compel agency action on the grounds that it has been "unlawfully withheld." A district court may also exercise its mandamus jurisdiction to compel the agency to perform its legal duty.<sup>38</sup>

While these principles appear correct in the abstract, there is very little if any case law to support them in the context of statutory time limits applicable to licensing or clearance functions.<sup>39</sup> Despite substantial non-compliance with the statutory time limits surveyed in this study, private parties have rarely sought judicial relief.<sup>40</sup> They have not sought it because they apparently do not believe it is the best way to achieve their objective of obtaining a favorable decision from the agency. Applicants may remind the agency about a statutory time limit and may bring outside pressure to bear on the agency to obtain a timely decision but they are unlikely to sue the agency if it misses a statutory deadline. They want the agency to devote its resources to reviewing applications and not to defending lawsuits.

The statutory time limits applicable to agency responses to Freedom of Information Act requests provide an exception to these generalizations. The presence of these time limits has prompted a significant number of lawsuits to compel agency responses.<sup>41</sup> Section 552(a)(6)(A) of Title 5 of the United States Code, as added to the Administrative Procedure Act by the Freedom of Information Act Amendments of 1974,<sup>42</sup> requires that each agency, upon any request for records, "shall determine within ten working days . . . whether to comply with such request." The agency "shall make a determination with respect to an appeal within twenty working days . . . after the receipt of such appeal." Section 552(a)(6)(B) allows the agency to extend these administrative deadlines for an additional ten working days if there are "unusual circumstances." Thereafter, an applicant who has not received either the records requested or a denial of his request may bring suit in the appropriate District Court pursuant to section

---

38. 28 U.S.C. §1361 (1970).

39. *NRDC v. Train*, 510 F.2d 692 (D.C. Cir. 1973), a case involving statutory time limits applicable to rulemaking at EPA, provides the strongest authority for the proposition that agency action has been unlawfully withheld if an agency does not act within the time prescribed by a mandatory statutory time limit. That case, however, does not expressly cite section 706(1) of the Administrative Procedure Act.

40. The four case studies on statutory time limits applicable to adjudicatory proceedings uncovered only one instance where an applicant obtained judicial relief from the effects of a missed deadline. In *Scott v. Kennedy*, Civil No. 77—(M. D. Ky.), the court ordered the FDA to publish a food additive petition in the Federal Register. Section 409(b)(5) of the Food, Drug and Cosmetic Act, 21 U.S.C. §348(b)(5) (1970), required the FDA to give public notice of the petition within thirty days of filing. The FDA has published the petition, 41 FR 33474 (Aug. 10, 1977), but the deadline for agency action on the petition has not yet passed.

41. *Open America v. Watergate Special Prosecution Force*, 547 F.2d 605 (D.C. Cir. 1976); *Exner v. FBI*, 542 F.2d 1121 (9th Cir. 1976); *Hayden v. U.S. Dep't of Justice*, 413 F. Supp. 1285 (D. D.C. 1976); *Cleaver v. Kelley*, 415 F. Supp. 174 (D. D.C. 1976).

42. Pub. L. 93-502, §1(c), 88 Stat. 1561 (1974).



552(a)(4)(B). That court has jurisdiction to enjoin the agency from withholding records and to order the production of any agency records improperly withheld. Section 552(a)(6)(C) provides that if "the Government can show exceptional circumstances exist and that the agency is exercising due diligence in responding to the request, the court may retain jurisdiction and allow the agency additional time to complete its review of the records."

The legislative history of the Freedom of Information Act Amendments of 1974 clearly indicates that section 552(a)(6)(C), which allows a court to extend a statutory deadline, was intended to serve as a safety valve if the tight time limits for agency action proved to be unworkable.<sup>43</sup> In *Open America v. Watergate Special Prosecution Force*,<sup>44</sup> the Court of Appeals for the District of Columbia Circuit held that "exceptional circumstances" exist when an agency is deluged with a huge volume of unanticipated requests that it lacks adequate resources to process within the statutory time limits. The majority in *Open America* also held that the agency had exercised due diligence in responding to requests when it assigned all requests on a first-in, first-out basis, except those requests where exceptional need or urgency was shown.<sup>45</sup> Under these circumstances the court held that the time limits in section 552(a)(6)(A) "become not mandatory but directory" and that the District Court was required to grant the agency an extension of time.<sup>46</sup>

The great majority of statutory time limits, including all of those selected for this study, do not contain an analogous safety valve requiring courts to relieve the agency of the obligation to comply with an unrealistic deadline. The relief available to a private party aggrieved by an agency's non-compliance with a statutory deadline may nevertheless be very limited. At the time the private party seeks judicial relief the agency will have already missed the statutory deadline for agency action. What does the court do if the agency answers that it is processing applications on a first-in, first-out basis but a backlog of applications prevents it from complying with the statutory time limit or that difficult factual or policy issues raised by a particular application require further evaluation or consultation? In *NRDC v. Train*,<sup>47</sup> Judge Leventhal indicated in a rulemaking context that manpower or methodological constraints may justify non-compliance with a statutory time limit. He went on to hold that a court must apply equitable

---

43. Joint Committee Print, Freedom of Information Act Amendments of 1974, 94th Cong., 1st Sess. 178, 382, 407, 438-39, 471 (1976).

44. 547 F.2d 605 (D.C. Cir. 1976). *Open America* was followed in the subsequently decided *Exner v. FBI*, 542 F.2d 1121 (9th Cir. 1976).

45. *Id.* at 616. In a concurring opinion, Judge Leventhal disagreed with the majority's holding on due diligence which he considered to be broadened than necessary. He would simply have held that the unexpected crush of requests provided an exceptional circumstance which justified the court's affording the agency some additional time.

46. *Id.*

47. 510 F.2d 692 (D.C. Cir. 1973).

principles when asked to compel agency action or to enjoin the withholding thereof, even though the agency has failed to comply with a statutory time limit. Furthermore, the court may even "forebear the issuance of an order in those cases where it is convinced by the official involved that he has in good faith employed the utmost diligence in discharging his statutory responsibilities."<sup>48</sup> Even if the court does order the agency to act promptly on the complaining party's application, it does not have authority to utilize the contempt power to enforce an order that requires an agency official "to do an impossibility."<sup>49</sup>

The application of equitable principles normally dictates that the court fashion in its order some schedule or time table for agency action once it determines that the agency has missed a statutory deadline. This form of judicial supervision may result in a court-imposed deadline that is enforceable through the contempt power, but there is no assurance that the court-imposed deadline will be much earlier than the agency would have acted on the application in any case. A court is properly reluctant to order an agency to afford priority treatment to an applicant who has sought judicial relief, because the court's order might hurt other equally deserving applicants.<sup>50</sup> The courts' refusal so far to adopt a first-into court, first-out of agency approach limits the effectiveness of the relief available to individual<sup>51</sup> private parties. While a court may review the agency's overall efforts to comply with the statutory time limit to make sure that the agency is not engaged in foot-dragging and may impose its own deadlines to insure a high-level of future agency performance, these forms of judicial intervention are of limited benefit to applicants who are being treated no differently than other similarly situated applicants.

#### 4. *Effect of Statutory Time Limits on the Availability of Judicial Relief from Undue Delay*

Despite the limited role of the courts in enforcing statutory time limits, the presence of a time limit does appear to have an effect on the availability of judicial relief. The time limit establishes the outer limit within which Congress expects the agency to act and provides the courts with a norm for evaluating agency performance. If the agency has deviated from the norm,

---

48. *Id.* at 713.

49. *Id.*

50. "If everyone could go to court when his request had not been processed within thirty days, and by filing a court action automatically go to the head of the line at the agency, we would soon have a listing based on priority in filing lawsuits, i.e., first into court, first out of the agency." *Open America v. Watergate Special Prosecution Force*, 547 F.2d 605, 615 (D.C. Cir. 1976). Either everyone would file suit, or there would be an invidious discrimination against applicants who do not have the know-how or resources to sue. *Id.*

51. Judge Leventhal argued in favor of this approach in his concurring opinion in *Open America*: "Diligence in seeking court relief is not a fool proof way of assigning priority, but it is material and by no means unprecedented . . . . The merely curious may well be motivated enough to write a letter, but not to file a lawsuit." *Id.* at 620.

the court should at a minimum impose on the agency the burden of explaining the reasons for the delay.

In the absence of a statutory time limit, section 555(b) of the Administrative Procedure Act requires an agency to conclude any matter presented to it "within a reasonable time." Courts have recognized<sup>52</sup> that they have an obligation to enforce this requirement, since section 706(1) of the Act requires a reviewing court "to compel agency action unlawfully withheld or unreasonably delayed." Although courts have experienced little difficulty in resolving jurisdictional challenges to their authority to hear claims of unlawful and unreasonable delay,<sup>53</sup> they have not succeeded in developing standards on what constitutes a reasonable or lawful delay. While relief has been granted where the delay was egregious<sup>54</sup> or purposefully oppressive,<sup>55</sup> it has normally not been granted in other cases.<sup>56</sup> Although courts have recognized that relief is also available where the agency takes more time than is found necessary to dispose of similar proceedings, they have required the aggrieved private party to establish what constitutes the normal time.<sup>57</sup>

Courts have rarely granted relief from the effects of delay to applicants seeking a license or clearance for proposed private activity. In *Harvey Radio Laboratories, Inc. v. United States*,<sup>58</sup> for example, the court categorized the Federal Communications Commission's ten year delay in acting on Harvey Radio's application as "long and unfortunate." The Commission had held up the application in order to resolve various issues raised by it in rulemaking proceedings. The court nevertheless refused to order any relief because it believed that the policy and procedure followed by the

52. *Deering Milliken, Inc. v. Johnston*, 295 F.2d 856 (4th Cir. 1961); *Nader v. FCC*, 520 F.2d 182 (D.C. Cir. 1975).

53. "The claim of unlawful or unreasonable delay establishes court jurisdiction even though there has been no final agency order, and the relief sought is e.g., an order requiring the agency to hold a hearing." *International Ass'n of Mach. and A. Wkrs. v. National Med. Bd.*, 425 F.2d 527.535 n.3 (D.C. Cir. 1970). See also *Templeton v. Dixie Color Printing Co.*, 313 F. Supp. 105 (N.D. Ala. 1970) (jurisdiction and reviewability); *Environmental Defense Fund, Inc. v. Hardin*, 428 F.2d 1093 (D.C. Cir. 1970) (ripeness).

54. *Silverman v. NLRB*, 543 F.2d 428 (2nd Cir. 1976) (no excuse for five year delay in determining back pay—an "Orwellian nightmare"); *Texaco, Inc. v. FTC*, 336 F.2d 754 (D.C. Cir. 1964) (twelve year delay in completing unfair trade practice proceeding), vacated and remanded, *FTC v. Texaco, Inc.*, 381 U.S. 739 (1965) (dismissal of charges not an appropriate remedy for undue delay).

55. *Atlantic & Gulf Stevedores, Inc. v. Donovan*, 274 F.2d 794 (5th Cir. 1960) (refusal to adjudicate employee's claim prejudiced employer); *North American Van Lines v. United States*, 412 F. Supp. 782 (N.D. Ind. 1976) (three-judge court) (see text at n.63 below).

56. See the cases cited in nn.57-62 below.

57. *Kent v. Hardin*, 425 F.2d 1346, 1350 (5th Cir. 1970) (no unreasonable delay when hearing examiner required four months to write opinion); *FTC v. J. Weingarten, Inc.*, 336 F.2d 687 (5th Cir. 1964) (no unreasonable delay when proceeding before examiner consumed two and one-half years).

58. 289 F.2d 458 (D.C. Cir. 1961).

Commission was "not without a reasonable basis, notwithstanding the time frame involved."<sup>59</sup> In *Buckeye Cable Television Inc. v. United States*,<sup>60</sup> the court likewise found not to be unreasonable an "unfortunate" two and one half year delay by the Federal Communications Commission in acting on an expansion petition filed by the operator of a CATV system. The court cited the complexity of the problems resulting from the rapid growth of CATV and the need for the Commission to develop a uniform regulatory approach and to avoid prompt but piecemeal decisions. In *Kessler v. FCC*<sup>61</sup> the court upheld a freeze on AM radio applications while the Commission engaged in rulemaking but indicated that "there may be circumstances where the length of delay is so excessive or the reasons for the delay so arbitrary, that a hearing must be ordered to prevent substantial injustice." That point was evidently reached in *Booth American Company v. FCC*.<sup>62</sup> Booth's application for an emergency license had been pending at the Federal Communications Commission for seventeen months. In an unexplicated, unreported order the court directed the Commission to act within twenty days or explain to the court why it had not done so. The only reported instance where a court has actually ordered an agency to act on an application within a prescribed period of time is *North American Van Lines v. United States*<sup>63</sup> where the court held that the Interstate Commerce Commission had unlawfully "flagged" North American Van's applications for new operating authority while it completed a separate investigation to determine North American Van's fitness. The court ordered the Commission to grant or deny the illegally flagged applications within sixty days. Some of the applications had been stayed for up to three years while, in the court's opinion, the Commission "harrassed" North American Van without resolving the fitness issue.

These licensing cases indicate the reluctance of reviewing courts to find that administrative delay was "unlawful" or "unreasonable". Delays attributable to an agency's inefficiency, lack of resources and internal ordering<sup>64</sup> are matters for the agency to resolve unless Congress has spoken otherwise.<sup>65</sup> Only when the delay is grossly excessive or for an improper reason have courts been likely to intervene.<sup>66</sup>

The situation necessarily changes if agency action is subject to a statutory deadline. The time limit reflects a Congressional determination of

---

59. *Id.* at 460.

60. 438 F.2d 948 (6th Cir. 1971).

61. 376 F.2d 673 (D.C. Cir. 1963).

62. No. 23, 862 (D.C. Cir. 1970), noted in *Environmental Defense Fund, Inc. v. Hardin*, 428 F.2d 1093, 1100 n.32 (D.C. Cir. 1970).

63. 412 F. Supp. 782 (N.D. Ind. 1976) (three-judge court).

64. *FCC v. WJR, The Goodwill Station, Inc.*, 337 U.S. 265, 271-272 (1949) (agency may determine order in which it conducts its proceedings).

65. See generally Goldman, Administrative Delay and Judicial Relief, 66 *Mich. L. Rev.* 1423 (1968).

66. See cases cited at nn.54 and 55.

priorities on how the agency should operate. The court should therefore scrutinize more closely an agency's internal ordering of its affairs. The burden shifts to the agency to explain why it has not fulfilled Congressional expectations. While courts have not treated a statutory deadline as a matter of legal obligation when it comes to formulating an appropriate remedy, the presence of a statutory time limit insures more effective judicial review of the agency's performance. The statutory time limit provides the courts with a norm for testing what the agency has done.

The initial availability of a greater degree of judicial scrutiny where delay has resulted in missing a statutory deadline does not necessarily mean that the courts will be able to provide effective relief. The case studies in this Report of four agencies whose licensing or clearance functions are subject to statutory time limits demonstrate that those agencies have taken seriously the statutory deadlines for agency action. Delays beyond those allowed by statute are occasioned primarily by lack of manpower and by difficulty in making decisions in individual cases. Courts can do little to remedy these causes of delays and have even treated them as justifications for deviations from the statutory norm.<sup>67</sup> While it is true that court orders enforcing statutory time limits or imposing the court's own schedule on a dilatory agency "should serve like adrenalin, to heighten the response and to stimulate the fullest use of resources,"<sup>68</sup> this judicial role appears to be more effective in forcing the conclusion of complex rulemaking proceedings (the context in which it was formulated) than in expediting the processing of individual licensing applications.

#### D. *General Discussion of Statutory Time Limits Applicable to Rulemaking*

Modern rulemaking constitutes a major undertaking by an agency even if the agency utilizes the informal notice and comment procedures in section 553 of the Administrative Procedure Act. The notice of proposed rulemaking must contain a concrete proposal with an adequate evidentiary basis;<sup>69</sup> and it is now generally recognized to be improper for an agency to utilize a notice of proposed rulemaking to float an idea that it has not yet fully developed. The agency must then compile a rulemaking record for submission to a reviewing court if its rule is to survive a subsequent challenge by an aggrieved person.<sup>70</sup> In the preamble to its final rule the agency must also respond to the comments received on the proposal and supply a reasoned justification for the rule.<sup>71</sup> Statutes and court decisions have also required

---

67. See *NRDC v. Train*, 510 F.2d 692, 712-713 (D.C. Cir. 1973) Leventhal, J.

68. *Id.* at 712.

69. *National Welfare Rights Organization v. Mathews*, 533 F.2d 637 (D.C. Cir. 1976).

70. *National Welfare Rights Organization v. Mathews*, *supra*, n. 69; *Portland Cement Ass'n v. Ruckelshaus*, 486 F.2d 375 (D.C. Cir. 1973).

71. *Rodway v. United States Dep't of Agriculture*, 514 F.2d 809 (D.C. Cir. 1975); *Amoco Oil Co. v. EPA*, 501 F.2d 722 (D.C. Cir. 1974). See generally, Verkuil, *Judicial Review of Informal Rulemaking*, 60 *Va. L. Rev.* 185 (1975).

agencies to hold public hearings and to allow various forms of public participation in rulemaking proceedings in addition to the opportunity to submit written comments.<sup>72</sup>

Rulemaking therefore requires a major commitment of agency resources. This is particularly true if a rule substantially affects private interests and raises controversial issues that are likely to prompt a challenge in the courts. Agency heads throughout the federal government emphasize the importance of controlling their agency's rulemaking efforts. An agency can only engage in so much rulemaking at one time and should not embark on a major rulemaking effort without first reviewing its priorities and available resources. Rulemaking activity within a large agency must be coordinated to insure that different branches know what other branches are doing. These problems produce the constant refrain of agency heads that they must "get a handle" on their agency's rulemaking.

What contribution do statutory time limits make to this situation? The five case studies of statutory time limits applicable to rulemaking proceedings do not provide much evidence of a positive contribution. The experience of the Occupational Safety and Health Administration indicates that time limits applicable only to some stages of rulemaking may not expedite the overall process but may only shift the delays to stages that are not covered by time limits. The experience of the Consumer Product Safety Commission demonstrates that statutory time limits which are extendable by the agency for cause may have little or no impact since any time pressure or difficulty will prompt the agency to grant itself an extension. The experience of the Environmental Protection Agency, on the other hand, establishes that statutory time limits applicable to all stages of rulemaking may expedite proceedings if interested outsiders monitor the agency's compliance with the time limits. An unmonitored time limit, however, may have little or no effect and become a dead letter. Finally, the experience of the Office of Education indicates that time constraints in rulemaking may have some undesirable effects on the agency's decisional process. Its experience and that of the Environmental Protection Agency also reveal the tension created by the conflict between the evidentiary and procedural requirements for modern rulemaking enforced by the courts and the decision-forcing approach of statutory time limits.

The case studies are nevertheless indecisive on the desirability of statutory time limits for rulemaking proceedings. One's ultimate position may well depend on one's view on how much discretion Congress should allow agencies to exercise. Should an agency head be able to defer further rulemaking in area A where the agency has encountered opposition and concentrate the agency's resources in area B where new problems (or perhaps an emergency situation) has arisen? Or should the outside monitors be

---

72. *Mobil Oil Corp. v. FPC*, 483 F.2d 1238 (D.C. Cir. 1973); *NRDC v. NRC*, 547 F.2d 633 (D.C. Cir. 1976). See generally, Williams, "Hybrid Rulemaking" under the Administrative Procedure Act: A Legal and Empirical Analysis, 42 *U. Chi. L. Rev.* 401 (1975).

able to insist that Congress has required the agency to complete rulemaking in area A by a specific date regardless of the preference of the agency head first to overcome the opposition through additional consultation or negotiation or to devote the agency's rulemaking resources to area B? There is no simple or uniform answer to these questions.

In the absence of any statutory time limit or other congressional directive, an agency has broad discretion to order its own proceedings. It may first complete one rulemaking proceeding while deferring the initiation or completion of another rulemaking proceeding.<sup>73</sup> While a deferral may at some point constitute agency action unreasonably delayed, there are few reported instances where a court has intervened to compel agency action. In *Nader v. FCC*,<sup>74</sup> the court did find that the Commission had unreasonably delayed rulemaking proceedings for the resolution of two major issues on AT&T's rate structure. The court held that it could find "no justification for a delay of ten years" that had occurred in resolving the issues.<sup>75</sup> It ordered the Commission to submit within thirty days a proposed time table for the completion of the proceedings. After a period of public comment the court would either approve or reject the Commission's schedule. The Commission was then to adhere to the schedule approved by the court for the completion of the proceedings. In *Home Box Office, Inc. v. FCC*,<sup>76</sup> the court likewise found that the Commission had unreasonably delayed the completion of its "program exclusivity"<sup>77</sup> rulemaking proceeding. In that proceeding only eighteen months had elapsed since the publication of the notice of proposed rulemaking and twelve months since the close of the comment period, although the Commission had been studying the problem for nearly six years. Without further explication the court ordered the Commission to "terminate" its program exclusivity proceeding within 180 days.<sup>78</sup>

This body of case law does not provide much guidance on what constitutes an "unreasonable delay". It reflects primarily the growing impatience of the Court of Appeals for the District of Columbia Circuit with the dilatoriness of the Federal Communications Commission. The court first warned the Commission to speed up its proceedings<sup>79</sup> and finally ordered it

---

73. *Associated Press v. FCC*, 448 F.2d 1095 (D.C. Cir. 1971); *FCC v. WJR, The Goodwill Station, Inc.*, 337 U.S. 265 (1947).

74. 520 F.2d 182 (D.C. Cir. 1975).

75. *Id.* at 206.

76. 567 F.2d 9, 40 Ad. Law 2d 1007 (D.C. Cir. 1977).

77. "Program exclusivity" refers to the alleged broadcast network practice of obtaining exclusive exhibition rights against cable casters. *Id.* at 1009 n.4. The court's discussion of the unreasonable delay issue was limited to footnote 4 of its opinion.

78. *Id.* at 1034.

78. *Id.* at 1034.

79. "We presume the Commission will proceed expeditiously so that this proceeding may reach a final conclusion before it enters its second decade." *Lebanon Valley Radio, Inc. v. FCC*, 503 F.2d 196, 201 (D.C. Cir. 1974).

to do so.<sup>80</sup> No principles of general applicability have emerged from the fray.

Statutory time limits change this situation by informing the courts when they may intervene to compel agency action. If an agency misses a statutory deadline, the court has authority to intervene at that point.<sup>81</sup> The case study of the Environmental Protection Agency, and to a lesser extent, the case studies of the Office of Education and the Occupational Safety and Health Administration indicate that judicial intervention to enforce statutory time limits or the threat of judicial intervention may result in the prompter promulgation of final rules than would otherwise be the case.

The effect of this change is often quite limited. Its significance depends on the presence of interested persons outside the agency who monitor the agency's performance and who are willing to file a lawsuit if the agency does not live up to their expectations. A court enforcing a statutory time limit must also apply equitable principles, and it cannot blindly order the agency to do within the statutory time limit what Congress expected it to do. Regardless of a statutory deadline, the court may do no more than review the sincerity of the agency's effort to comply with the deadline and order the agency to accomplish what may be expected from a fair, honest effort at compliance.<sup>82</sup> This limitation on the power of the court is particularly significant in the rulemaking context where a missed deadline at an early stage of a rulemaking proceeding may prompt a lawsuit to enforce compliance with deadlines in subsequent stages. Prospective relief is also subject to equitable principles, and an agency cannot be ordered to comply with an unrealistic time limit.<sup>83</sup>

The applicability of equitable principles normally dictates that the court fashion in its order a schedule or time table for agency action that takes into account any staff shortages or methodological difficulties confronting the agency. *NRDC v. Train*,<sup>84</sup> the effluent guidelines case, indicates that this form of judicial supervision may well stimulate the fullest use of agency resources and produce final rules sooner than they would otherwise appear. In those proceedings the impact of the statutory time limit as enforced by the court was substantial. It did produce results.

Once again the cost is a loss of agency discretion to order its own house, since the court in effect instructs the agency on how to utilize its resources. Deputy EPA Administrator John Quarles complained after he

---

80. See cases cited at nn. 74 and 76.

81. *NRDC v. Train*, 510 F.2d 692 (D.C. Cir. 1973).

82. *Id.* See the discussion of *NRDC v. Train* in section C(3) of the Introduction and in case study #8 on the Environmental Protection Agency at pp. 185-191.

83. *National Congress of Hispanic American Citizens (El Congreso) v. Usery*, 554 F.2d 1196 (D.C. Cir. 1977). See the text at p. 153 of case study #6 on the Occupational Safety and Health Administration for further discussion of *National Congress*.

84. 510 F.2d 692 (D.C. Cir. 1973). See the discussion of this litigation in Case Study #8 on the Environmental Protection Agency.



left office that citizen suits to enforce specific statutory requirements severely restricted the agency's ability to direct and control its own programs and shifted many crucial policy decisions from the political to the legal arena.<sup>85</sup> Quarles cited the effluent guidelines litigation as an example of a citizen suit that not only forced the agency's management to give top priority to the promulgation of effluent guidelines but forced it to continue doing so "long after the time when we felt that it was a useful exercise from the viewpoint of trying to clean up the water. Rather than making decision based on a judgment of what we thought would be best for pollution control, our decisions have been dictated by the law and the court order."<sup>86</sup>

One might ask what is wrong with decisions made in accordance with law and a court order. The Environmental Protection Agency was only required to do what Congress intended it to do. But there is necessarily a time gap between the enactment of a law and its implementation by the agency. In 1972, when Congress passed the Federal Water Pollution Control Amendments,<sup>87</sup> it seemed quite sensible to assign top priority to the promulgation of effluent standards for all categories of point sources. The Amendments adopted the new approach of regulating discharges and rejected as ineffective the earlier approach of regulating water quality. By 1975, when the Environmental Protection Agency was struggling to promulgate effluent guidelines for the remaining categories of point sources, the situation had changed, as had the agency's perspective on the problem of water pollution. Run-off from agricultural, mining and other non-point sources and discharges of toxic substances from a limited number of point and non-point sources provided increased cause for concern. Whether the completion of the effluent guidelines proceedings still deserved top priority, or whether priority should be given to these other problem areas, was a highly debatable issue. Ideally, this type of dilemma required a reference back to the legislature for resolution, but the system does not always (or usually) work in that fashion. Congress can only direct its attention to a limited number of major legislative proposals during a given session. This phenomenon, while aggravating the problem, leaves unresolved the basic question of how much agency discretion is desirable. A statutory deadline may be rigid but it at least provides some assurance that the agency will do what Congress wanted done when it enacted the statute.

Statutory time limits do operate to favor the promulgation of a rule over a no-rule situation. They provide a handle for interested private persons to force the issuance of a rule. While an agency usually may comply with a statutory time limit by terminating a rulemaking proceeding within the prescribed period without the promulgation of a rule, there is no known instance where this has occurred and the thrust of such provisions plainly

---

85. Proceedings of the Administrative Law Section's 1976 Bicentennial Institute—Oversight and Review of Agency Decisionmaking, 29 *Ad. L. Rev.* 569, 727 (1976).

86. *Id.* at 732.

87. Pub. L. 92-500, 86 Stat. 843 (1972).

favors the production of rules. This experience indicates that statutory time limits applicable to rulemaking are most likely to be appropriate when Congress specifies in detail what it expects the agency to do and does not leave the scope of regulation largely to agency discretion. In recent environmental legislation, for example, Congress has specified in considerable detail what it wants the Environmental Protection Agency to do and has not, as in the case of the Federal Trade Commission or Consumer Product Safety Commission, broadly delegated authority to prohibit unfair or unsafe environmental practices. The case study of the Environmental Protection Agency indicates that in the former situation a statutory time limit may have the intended effect on the timeliness and quantity of the agency's output. The case study of the Consumer Product Safety Commission indicates that a statutory time limit may be less effective in reducing delay when the agency has broad discretion over what it regulates. While the reason for this distinction is not readily apparent, it may relate more to the agency's sense of mission than to the presence of a statutory time limit. An agency such as the Consumer Product Safety Commission does not really know what it is expected to accomplish. The statutes it administers tell it little more than to protect the consuming public from unreasonably hazardous products; and it has not yet developed its own expectations on what it should do to fulfill that assignment. In this situation there is no drive to act within a prescribed period of time since there is no predetermined goal.

#### *Statutory Time Limits Applicable to the Granting or Denying of Rule-making Petitions*

Unless Congress provides otherwise, an agency's decision to decide an issue (i.e., to commence a rulemaking or adjudicatory proceeding to resolve the issue) is a discretionary one. Whether the decision is committed entirely to the agency's discretion and therefore not reviewable in the courts,<sup>88</sup> or whether the agency's decision is subject to review for abuse of discretion,<sup>89</sup> is a matter of some controversy; but the latter view appears to be the prevailing one at present. Congress may of course specifically require an agency to promulgate a rule without imposing a time limit for the completion of the task. In 1966, for example, Congress enacted an amendment to the Health Insurance for the Aged (Medicare) Act<sup>90</sup> which instructed the Secretary of Health, Education and Welfare to issue regulations to provide for the retroactive corrective adjustment of payments to providers of medical services. In 1973, the court in *Kingsbrook Jewish Medical Center v.*

---

88. *Ness Investment Corp. v. United States*, 512 F.2d 706 (9th Cir. 1973) (dictum).

89. *Oljato Chapter of Navajo Tribe v. Train*, 515 F.2d 634 (D.C. Cir. 1975) (rulemaking); *Environmental Defense Fund, Inc. v. Hardin*, 428 F.2d 1093 (D.C. Cir. 1970). In *Oljato*, the court stated: "We have no doubt that it would be an abuse of discretion for the Administrator to fail to revise a standard of performance when the evidence supporting revision becomes sufficiently compelling. Such abuses are not without judicial remedy." *Id.* at 662.

90. Pub. L. 89-713, §7, (1966), codified at 42 U.S.C. §1395v(1) (1970).

Richardson<sup>91</sup> “[s]earched in vain for such regulations” and ordered the Secretary to promulgate them. Neither the statute nor the court’s order contained any time limit. Courts have also interpreted statutes delegating rulemaking authority over a subject matter to require agency promulgation of rules. In *Rockbridge v. Lincoln*,<sup>92</sup> for example, the court ordered the Bureau of Indian Affairs to promulgate regulations governing traders on Indian reservations. Congress had enacted statutes authorizing the Bureau to do so in 1876 and 1903 but no regulations had ever been promulgated. The court held that Congress had passed the statutes with a specific set of legislative objectives in mind and that the lawfulness of the Bureau’s exercise of discretion to regulate or not to regulate must be determined by reference to those objectives. Since Congress had intended that the traders on Indian reservations be subject to regulation, the agency’s decision not to regulate was unlawful.

Statutory provisions requiring an agency to grant or deny rulemaking petitions within a prescribed period of time do not necessarily affect an agency’s discretion to decide what it shall decide. The agency is only required to make that decision within the prescribed period; a disappointed petitioner may then seek whatever judicial review is available. The statutory time limit does little more than require the agency to answer its mail and to explain to the petitioner its reason for accepting or rejecting his idea. It is hard to fault such a provision which makes more meaningful the existing right of private persons under section 553(e) of the Administrative Procedure Act to petition an agency for the issuance, amendment or revocation of a rule and the existing responsibility of an agency under section 555(b) to decide all matters presented to it within a reasonable period of time.

An agency may nevertheless hesitate to grant a rulemaking petition if most or all of the subsequent stages of the rulemaking proceeding are subject to statutory time limits. Granting the petition may inexorably commit the agency to devote its resources to complete the rulemaking proceeding within the prescribed time limits regardless of other more urgent proceedings that are presently pending or may arise in the future. This loss of discretion over the internal ordering of its own proceedings has discouraged the Consumer Product Safety Commission from granting meritorious rulemaking petitions within the statutory time period. The National Highway Traffic Safety Administration, which is likewise subject to a statutory time limit applicable to rulemaking petitions, does not experience a similar compunction because it realizes that once it grants a petition the timing of the rulemaking proceeding is left largely to its discretion since there are not statutory time limits for the completion of the proceeding. As a result petitions are granted which may never emerge in the form of proposed rules.

---

91. 486 F.2d 663, 669 (2d Cir. 1973).

92. 449 F.2d 367 (9th Cir. 1971).

The broad discretion which most agencies enjoy to decide what to decide provides an answer to this dilemma. Absent a more specific statutory directive, an agency should grant a rulemaking petition only if it is ready and able to engage in rulemaking; it should deny a petition if it does not have the resources to conduct the rulemaking proceeding under a rational allocation of its resources. Congress denied the Consumer Product Safety Commission that discretion when it broadened the judicial relief available to disappointed petitioners.<sup>93</sup> Case Study #5 on the Consumer Product Safety Commission demonstrates the undesirability of combining a statutory time limit for agency action on rulemaking petitions with a reduction of the agency's discretion to grant or deny petitions.<sup>94</sup>

#### CASE STUDY NO. 1

##### *Office of Trade Adjustment Assistance (OTAA) in the Department of Labor Determinations of Workers' Eligibility for Trade Adjustment Assistance*

In the Trade Act of 1974,<sup>95</sup> Congress greatly expanded the availability of trade adjustment assistance for workers and firms injured by increased imports. Congress delegated to the Secretary of Labor the authority to determine the eligibility of workers for trade adjustment assistance; and the Secretary in turn delegated this responsibility within the Department. The Office of Trade Adjustment Assistance in the Bureau of International

93. Congress in the Consumer Product Safety Act of 1972 and the Toxic Substances Control Act of 1976 combined a statutory time limit applicable to rulemaking petitions with a broadened scope of judicial review of agency denials. Section 10(e) of the Consumer Product Safety Act, 15 U.S.C. §2059(e) (Supp. V1975) provides that the court shall order the Consumer Product Safety Commission to initiate rulemaking proceedings if the petitioner demonstrates by a "preponderance of the evidence in a *de novo* proceeding" that the consumer product which is the subject of the petition presents an unreasonable risk of injury and that the failure of the Commission to initiate rulemaking unreasonably exposes the petitioner or other consumers to a risk of injury presented by the product. As a result of this provision rulemaking activity at the Commission has been more reactive than planned and the agency has been unable to control the ordering of its own proceedings. See case study #5.

It is unlikely that the 90-day time limit for acting on rulemaking petitions under the Toxic Substances Control Act will have a similar effect at the Environmental Protection Agency. Section 21 of the Act, 15 U.S.C. §2620 (Supp. VI 1976), while mandating a similar *de novo* judicial determination on whether a rule is necessary, also authorizes the court to permit the Administrator to defer initiating rulemaking if the court finds that "the extent of the risk to health or the environment alleged by the petitioner is less than the extent of risks to health or the environment with respect to which the Administrator is taking action under this Act and there are insufficient resources available to the Administrator to take the action requested by the petitioner."

94. This combination is particularly undesirable when Congress has not legislated in detail but has, as in the case of the Consumer Product Safety Commission, largely delegated to the agency the authority to chart its own course. It also appears undesirable where the Congress has provided more specific instructions to the agency since the agency should retain some discretion over the timing or phasing in of regulation. See the discussion of *Association of American Railroads v. Costle*, 562 F.2d 1310 (D.C. Cir. 1977), *infra* n.374.

95. Pub. L. 93-618, 88 Stat. 2011, codified at 19 U.S.C. §§2251(f) (Supp. V. 1975).

Office of Trade Adjustment Assistance in the Bureau of International Labor Affairs presently administers the program. The Domestic and International Business Administration in the Department of Commerce administers a similar program of adjustment assistance for firms. That program is smaller in scope and will be mentioned only in passing.

Under section 221(a) of the Act,<sup>96</sup> groups of workers may petition the Secretary of Labor for a certification of eligibility to apply for trade adjustment assistance. While individual workers may not petition, the petitioning group may be as small as three. A certification is effective for two years and covers all affected workers at a firm or appropriate subdivision thereof. Section 223(a)<sup>97</sup> requires that the Secretary "shall determine" eligibility "[a]s soon as possible after the date on which a petition is filed . . . but in any event not later than 60 days after that date . . ." Section 222<sup>98</sup> provides that the Secretary shall certify a group of workers as eligible to apply for trade adjustment assistance if he determines:

(1) that a significant number or proportion of the workers in such workers' firm or an appropriate subdivision of the firm have become totally or partially separated, or are threatened to become totally or partially separated,

(2) that sales or production, or both, of such firm or subdivision have decreased absolutely, and

(3) that increases of imports of articles like or directly competitive with articles produced by such workers' firm or an appropriate subdivision thereof contributed importantly to such total or partial separation, or threat thereof, and to such decline in sales or production.

For purposes of paragraph (3), the term "contributed importantly" means a cause which is important but not necessarily more important than any other cause.

Certification is the government's stamp of approval that increased imports have been an important cause of the petitioning workers' actual or threatened unemployment. Workers covered by a certification are entitled to increased unemployment benefits and to training and relocation allowances to assist them in the transition to import-competitive jobs. State unemployment agencies process individual applications for benefits and distribute the benefits to eligible unemployed workers. The federal role is thus limited to the initial eligibility determination and to the financing of the entire program. Prompt certification of eligible workers is important because unemployed workers who are the helpless victims of a liberal trade policy cannot obtain rehabilitative and relocative assistance until they are covered by an effective certification.

---

96. 19 U.S.C. §2271(a) (Supp. V 1975).

97. 19 U.S.C. §2273(a) (Supp. V 1975).

98. 19 U.S.C. §2272 (Supp. V 1975).

The concept of trade adjustment assistance first appeared in the Trade Expansion Act of 1962.<sup>99</sup> Section 301(c) of that Act authorized as an alternative to industry-wide import relief (i.e. import quotas or higher rates of duty) the awarding of adjustment assistance to workers or firms adversely affected by increased imports. The United States Tariff Commission was delegated the authority to determine whether groups of workers or firms were eligible to apply for adjustment assistance. Section 301(f)(3) directed the Commission to determine the eligibility of petitioning workers or firms "at the earliest practicable time, but not later than 60 days after the date on which the petition is filed."

Despite this statutory time limit, the administration of the adjustment assistance program was beset by delay. The Tariff Commission adopted a cumbersome and time consuming petitioning process which normally did not produce eligibility determinations within the requisite 60 days. Even greater delays occurred at the state level in the distribution of benefits to those workers determined to be eligible and at the Department of Commerce in the distribution of benefits to eligible firms.<sup>100</sup> Even more disturbing to the proponents of trade adjustment assistance was the restrictive approach adopted by the Tariff Commission in determining eligibility. The Commission did not grant a single petition by a group of workers or a firm from the passage of the Act in 1962 until November, 1969. The Commission subsequently granted only a small number of workers' petitions covering an estimated forty-seven thousand workers in twenty-nine states.<sup>101</sup>

Congressional dissatisfaction with the adjustment assistance program under the Trade Expansion Act of 1962 led to the enactment in the Trade Act of 1974 of several major changes in the program. First, the responsibility for making eligibility determinations was transferred from the Tariff Commission (now renamed the International Trade Commission) to the Department of Labor (workers' petitions)<sup>102</sup> and the Department of Commerce (firms' petitions).<sup>103</sup> The 60-day statutory time limit for determining the eligibility of petitioning workers and firms was explicitly retained. The

---

99. Pub. L. 87-794, 76 Stat. 872 (1976).

100. On delays in administering the program prior to the 1974 Act, see S. Rep. No. 93-1298, 93rd Cong., 2nd Sess. (1974), reprinted in (1974) U.S. Code Cong. & Ad. News 7186, 7273-74; Commission on International Trade and Investment Policy, *United States International Economic Policy in a Changing World* 53-57 (1971) (The Williams Report); Fulda, Adjustment to Hardship Caused by Imports: The New Decisions of the Tariff Commission and the Need for Legislative Clarification, 70 *Mich. L. Rev.* 791 (1972).

101. Fulda, *supra*, n. 100 at 797; Note, Title II of the Trade Act of 1974: What Changes Hath Congress Wrought to Relief from Injury Caused by Import Competition, 10 *J. Int'l L. & Econ.* 197, 212 (1975); S. Rep. No. 93-1298, *supra* n. 100 at 7273.

102. Section 221(a) of the Act, 19 U.S.C. §2271(a) (Supp. V 1975).

103. Section 251(a) of the Act, 19 U.S.C. §2341(a) (Supp. V 1975). Section 271(a) of the Act, 19 U.S.C. §2371(a) (Supp. V 1975), established a new program of adjustment assistance to communities. The Department of Commerce has not implemented that program because similar benefits are available to communities under other legislation.

Secretary of Labor was specifically instructed by the Senate Finance Committee which drafted the legislation to streamline the petitioning process to insure "that workers displaced by increased imports receive all the benefits to which they are entitled in an expeditious manner."<sup>104</sup> Congress also loosened the requisite causal connection between an increase in imports and domestic unemployment. Section 222(3) of the 1974 Act<sup>105</sup> required only that the increase in imports "contribute importantly" to the workers' actual or threatened unemployment. Section 301(c) of the Trade Expansion Act of 1962 had previously required dual findings that an increase in imports was a "major factor" in causing unemployment and that the increase in imports had resulted in "major part" from concessions granted under trade agreements. Congress apparently believed that these two causation requirements were the primary bases for the restrictive approach adopted by the Tariff Commission in determining workers' eligibility. The loosening of the causal requirement reflected the overall Congressional intent to liberalize and expand the adjustment assistance program.

The Office of Trade Adjustment Assistance (OTAA) in the Department of Labor started receiving petitions from groups of workers in April, 1975. The Office adopted a simple one-page petition<sup>106</sup> which must be signed by at least three workers in the affected firm or subdivision thereof or by their authorized union representative. The form elicits basic information on the name of the employer firm, the identity of an official of the firm who is knowledgeable about the firm's production, sales and employment, the date of any job separations, the article or product involved, and the petitioners' reasons for believing that an increase in imports contributed importantly to the actual or threatened loss of employment. This simplified approach is consistent with the legislative intent that the Department of Labor "establish minimal filing requirements so that in the normal case a petition will be considered filed upon receipt by the Secretary."<sup>107</sup> As a result, the Office of Trade Adjustment Assistance does not "recycle" deficient petitions by requiring them to be refiled, but treats the initial filing as sufficient to trigger the running of the 60-day statutory time limit even if the petition contains insufficient information on which to base an eligibility determination. (The situation at the Department of Commerce is quite different. Petitioning firms are expected to complete a complex form which the agency refuses to accept for filing if incomplete.)

The Office of Trade Adjustment Assistance must therefore conduct its own investigation to gather the necessary factual data to make an eligibility determination. The Office's investigation is divided into two phases: an analysis of the industry and an analysis of the particular firm. The former

---

104. S. Rep. No. 93-1298, *supra* n.100, at 7273.

105. 19 U.S.C. §2272(3) (Supp. V 1975).

106. A copy of the petition form may be found as an Appendix to this case study.

107. S. Rep. No. 93-1298, *supra* n.100, at 7274.

need only be done once and need not be repeated for subsequent petitions involving different firms in the same industry. Industry analyses have not been completed (normally in conjunction with an investigation by the International Trade Commission on industry-wide import relief) for most industries that are the subject of petitions. The latter phase of the investigation requires one to three work days in the field by agency investigators who visit the firm involved and gather business information (much of it confidential and received by the Office in confidence) on the firm's production, sales and employment. In most cases the investigators also conduct a survey of the firm's customers to determine if they have increased their purchases of imported goods.

The investigators, who are generally college-trained economists, record the data they have gathered on standardized forms and write a brief investigative report (normally two or three single-spaced pages) which is reviewed by the Division Chief for Investigations and Reports and then forwarded to the Director of the Office of Trade Adjustment Assistance. On the basis of this report the Director submits to the certifying officer (a higher echelon official in the Department of Labor) his recommendation whether or not to issue to the petitioning workers a certification of eligibility to apply for adjustment assistance. An average firm analysis requires fifteen to twenty staff days to prepare from the start of the investigation through the Director's recommendation. Under the Labor Department's regulations, the Director shall submit his recommendation within forty-five days after the filing of the petition and the certifying office shall make his determination within fifteen days after receipt of the director's recommendation.<sup>108</sup>

The processing of workers' petitions does not appear to be sufficiently onerous to preclude the performance of the task within the 60-day statutory time limit in the normal case. In that time span it is possible for the staff to prepare an investigative file and report, for the Director to submit his recommendation, and for the certifying officer to make his decision. During the first five months of the program (April through August, 1975), when the volume of petitions was low (significantly less than fifty per month), the Department of Labor processed seventy-seven percent of the petitions filed within the statutory time frame. However, during the succeeding seven months (August, 1975 through March, 1976), only fifteen percent of the petitions filed were processed within 60 days.<sup>109</sup> Of the 223 petitions disposed of during the months of February, March and April 1977, only ten percent had been pending less than 60 days.<sup>110</sup>

---

108. 29 CFR 90.15 and 90.16 (1976).

109. For statistics on the program's first year of operation, see Comptroller General of the United States, *Certifying Workers for Adjustment Assistance - The First Year Under the Trade Act 37-41* (May 31, 1977) (hereinafter cited as Comptroller General's Report).

110. Statistics for periods after the first year have been supplied to the author by the Office of Trade Adjustment Assistance.



Backlog caused by a heavy caseload is the primary reason for this increasingly poor track record. The Office of Trade Adjustment Assistance estimated that it would receive fifty petitions per month during the program's first year of operation. In the final seven months of that period new filings averaged ninety-four per month. During the first four months of 1977, there were an average of 124 petitions filed per month. By the end of April 1977, the Office had received over two thousand workers' petitions. This experience contrasts sharply with that of the Department of Commerce, which over the same time span accepted for filing roughly one hundred petitions by firms.

Growing awareness of the adjustment assistance program among workers (especially union workers) provides the primary explanation for the Office's increasingly heavy caseload. Union leaders in particular quickly became aware that the Department of Labor was more generous in determining eligibility under the new Act than was the Tariff Commission under the old one. The result was a flood of petitions by union workers, not all of them meritorious. A backlog quickly developed and petitions, which were generally processed in the order filed,<sup>111</sup> had to wait in line until an investigator was free to prepare the firm analysis. Despite the liberality of the new Act, the denial rate soon exceeded fifty percent. The Department is required to prepare an adequate record to justify each denial in case a disappointed petitioner seeks judicial review.<sup>112</sup>

The hiring of additional personnel to clear the backlog has not proved to be easy. The problem is not primarily a budgetary one. The Office of Trade Adjustment Assistance has not been able to fill its budgeted positions for full-time permanent investigators but has utilized inadequately trained temporary personnel who have not always performed satisfactorily. The Office's experience in this regard is not unusual. When there is a sudden increase in workload, competent people do not magically appear to do the extra work. Recruitment and hiring take time and there is bound to be some lag between an increase in the caseload and the addition of new personnel to handle it.

---

111. Section 202(b) of the 1974 Act, 19 U.S.C. §2252(b) (Supp. V 1975), authorized the President to order the Secretary of Labor to expedite the consideration of petitions from an industry that the International Trade Commission had found suffered serious injury from increased imports. This priority provision has had little impact since the great majority of petitions received by the Office (seventy percent or more, including the more difficult ones) involve industries where the Trade Commission has found serious injury and the President has ordered expedited consideration.

112. Section 250 of the Act, 19 U.S.C. §2322 (Supp. V 1975), provides that persons aggrieved by a final determination of the Secretary may obtain judicial review in the Court of Appeals for the District of Columbia. The findings of the Secretary shall be upheld only if supported by substantial evidence. Roughly twelve petitioners have sought judicial review of denials. There are no reported decisions but a major case involving GM and Ford employees was pending in the summer of 1977.

Even if there were no backlog, the 60-day statutory time limit is not realistic in a significant minority of cases. A petition can be processed in 60 days only if everything flows smoothly. The process adopted by the Department of Labor is an informal one that relies on the cooperation of all interested persons. If an employer refuses to cooperate by supplying the necessary employment, production and sales records, the Department must resort to the issuance of subpoenas. There is no way that it can meet the statutory deadline if an employer resists disclosure. While most firms are anxious to help their workers by cooperating, a significant minority resist disclosure either because they fear that confidential business information will not be held in confidence or because they fear that they will be subject to additional contributions to state unemployment funds. Even though these fears are largely unjustified, they do cause some firms to resist disclosure, particularly if the firm believes that the petition is unmeritorious or frivolous. A firm's customers may also refuse to cooperate or be slow in cooperating when asked to supply data on their purchases of imported goods. Section 221(b) of the 1974 Act<sup>113</sup> also grants the petitioner or any other person with a "substantial interest" in the proceeding the right to request a public hearing "to produce evidence." The Department's regulations interpret this provision to require a formal adjudicatory hearing.<sup>114</sup> It is hard to imagine how petitions could be processed in the requisite 60 days if petitioners or other interested persons insisted with any regularity on their right to a public hearing. Requests for hearings are rare, and normally the petitioner who makes such a request is only interested in making a brief presentation to obtain some publicity.

Difficulties may also arise in the review process which disrupt the smooth flow of paperwork. The Division Chief of the Office of Investigations within the Office of Trade Adjustment Assistance reviews the case file and investigative report prepared by the investigators and forwards both documents to the Director of the Office who in turn submits his recommendation to the certifying officer; the recommendation must also be reviewed for legality by the Office of the Solicitor. If any one of these officials raises an issue that requires a referral of the petition back to the original investigator or to a new investigator, the time schedule is so tight that it is unrealistic to expect the 60-day deadline to be met. Such referrals back do occur where the investigators have not done a competent job and in hard cases where the reviewer raises an issue which requires additional data or analysis.

Another factor which often makes the 60-day time limit unrealistic is the inability of the Office of Trade Adjustment Assistance to control the flow of filings. For example, on December 18, 1975, the United Auto Workers filed on behalf of its members a petition covering over one hundred thousand workers at 148 different facilities of General Motors and

---

113. 19 U.S.C. §2271(b) (Supp. V 1975).

114. 29 CFR 90.13 (1976).

Ford. The Office broke down this mammoth filing into 107 separate petitions in order to allow it to assess the effect of imports on particular subdivisions of General Motors and Ford and with respect to particular automotive products. The sudden injection of one big case (or of 107 ordinary cases) into a pipeline that is already full increases the unlikelihood of processing pending petitions within 60 days. In this instance the union made it quite plain that it did not expect the Department to do so, and the Department of Labor made its eligibility determination on most of the petitions on June 4, 1976, nearly six months after the filing date. A similar incident occurred in March 1976, when unions simultaneously filed on successive days nearly one hundred petitions from the apparel industry.

The overall effect of the statutory time limit at the Office of Trade Adjustment Assistance is hard to assess. No doubt it does provide a spur and a measuring stick to expedite the decisional process. Agency officials are conscious of the number of petitions over the time limit and how long a determination is overdue. However, other pressures also operate to expedite the process. Everyone realizes the plight of unemployed workers who need a certification to obtain adjustment assistance.

There is also some tension and concern created within the Department by a statutory command that the agency "shall" make an eligibility determination within 60 days when backlog or other compelling reasons prevent the Department from doing so in most cases. Does the Department's delinquency make it a lawbreaker? Does the Department have authority to make an eligibility determination after the 60 days has expired? The latter question has now been answered in the affirmative by the First Circuit in *Usery v. Whitin Machine Works, Inc.*,<sup>115</sup> where an employer unsuccessfully contested a subpoena on the grounds that the Department had lost jurisdiction over a workers' petition when the 60 days expired. There is still something unseemly about a rigid statutory time limit that even in the best of worlds simply cannot be met in some cases.

It is also hard to assess the effect of the statutory time limit on the agency's decisional process. The Department generally does not rush to make some decision within 60 days but takes the time necessary to reach a sound decision. However, time pressures do result in a trimming of the process in at least one area—customer surveys. Investigators only contact some of a firm's customers (e.g. the ten largest) and may not wait for responses from all of them before preparing an investigative report. The GAO found that the Office of Trade Adjustment Assistance lacked a systematic approach to customer surveys,<sup>116</sup> but it is hard to imagine how the Office can do much in this regard within the tight statutory time frame. The Department has proposed regulations that permit it to reconsider eligibility determinations on the basis of subsequently acquired information,<sup>117</sup> but there have been

---

115. 554 F. 2d 498 (1st Cir. 1977).

116. Comptroller General's Report, *supra* n. 109, at 28-29.

117. 42 FR 2981 (Jan. 14, 1977)

objections that petitions for reconsideration may be used by the agency as a device for circumventing the statutory time limit.

Another possible effect of the statutory time limit is the Department's failure to develop guidelines or rules of general applicability. The statutory standards for eligibility raise difficult problems of interpretation.<sup>118</sup> For instance, how do you define the article or product that is "like or directly competitive" with the article manufactured by the petitioning workers? Is the appropriate article or product automobiles in general or compact automobiles? The answer to this question determines whether imports of the product have increased. Also, what is an increase in imports? Do you use value or volume as a measuring stick, and how much of an increase is required? Finally, how do you define "contribute importantly"? What if one of a firm's customers that is responsible for five percent of the firm's business shifts to imported goods, but the firm's closing was primarily due to bad management? The Comptroller General has faulted the Department of Labor for failing to develop guidelines or rules resolving these interpretative issues and for making eligibility determinations on a subjective, case-by-case basis which often leads to inconsistent decisions.<sup>119</sup> The Comptroller General's Report does not consider whether the tight statutory time limit has contributed to this deficiency. No doubt the Department has concentrated on problems of case flow and on deciding particular cases and has not articulated many rules of general applicability. The Department's published rules in the Code of Federal Regulations are entirely procedural except for some definitions that largely parallel the statutory text and the committee reports and do not resolve the major interpretative issues. The sheer difficulty of these issues and the newness of the program no doubt discourage Department personnel from resolving them in advance through rulemaking. The pressure of deciding cases also discourages a small operation like the Office of Trade Adjustment Assistance, which has less than 110 employees, from initiating a major rulemaking effort. Of course, the pressure to decide individual cases derives not only from the statutory time limit but also from the recognized need to make prompt eligibility determinations.

## CASE STUDY NO. 2

### *Food and Drug Administration (FDA) in the Department of Health, Education and Welfare*<sup>120</sup>

Congress has required that manufacturers of new drugs for human use, new animal drugs, and food and color additives for use in food, drugs

---

118. See text at n. 98.

119. Comptroller General's Report, *supra* n. 109.

120. Congress has not delegated any authority directly to the FDA. The Secretary of Health, Education and Welfare (previously the Secretary of Agriculture) has delegated to the Commissioner of Food and Drugs the authority given to him by the Food, Drug and Cosmetic Act and related legislation. 21 CFR 5.1 (1977). The Commissioner has in turn delegated authority within the FDA. For purposes of simplicity this case study uses throughout the term "FDA." That term covers all exercises of authority by the Commissioner and his subordinates. The FDA enjoys almost complete autonomy within the Department of Health, Education and Welfare.

or cosmetics obtain premarket approval for their products from the FDA. Congress has imposed statutory time limits on the FDA's performance of these clearance functions to insure the prompt marketing of new products.

### *New Drug Applications*

After the drug elixir sulfanilamide tragically claimed almost one hundred lives in 1938, Congress enacted the Food, Drug and Cosmetic Act of 1938<sup>121</sup> which required for the first time the premarket clearance of new drugs as to safety. Although the Act placed on the drug's manufacturer or sponsor the burden of establishing safety, section 505(c) provided that a new drug application (NDA) automatically become effective 60 days after filing unless prior to that date the FDA issued an order refusing to permit the application to become effective. Under section 505(c), an application became effective on the 60th day after filing, but the FDA could postpone that date until not more than 180 days after filing to enable it further to study and investigate the application. In order to keep a new drug from the market, the FDA was required to give notice, afford an opportunity for a hearing, complete the hearing, and issue its final order within the 180-day period.

These provisions for the automatic approval of a new drug application if the FDA did not deny it within a tight statutory time frame became a focal point of Congressional concern at the hearings and debates that led to the enactment of the Drug Amendments of 1962.<sup>122</sup> On September 12, 1960, the FDA had received a new drug application for thalidomide. Despite tremendous pressure from the manufacturer, the FDA simply refused to accept the application for filing. Dr. Frances Kelsey and others at the FDA had begun to hear reports from Europe that researchers suspected that thalidomide might cause birth defects when taken by pregnant women. It was widely recognized in Congress at the time of the passage of the Drug Amendments that the FDA could not possibly have completed administrative proceedings on thalidomide within 180 days and that the FDA had managed to avoid another drug tragedy in this country only by the delaying tactic of refusing to accept the application for filing. Congress responded by amending section 505(c) of the 1938 Act to eliminate the automatic approval feature and to lengthen the statutory time limits. Under the amended section,<sup>123</sup> the FDA was required within 180 days after the filing of a new drug application either to approve the application or to give the applicant notice of an opportunity for a hearing on whether the application was approvable. The 180-day time period was also made extendable by agreement between the FDA and the applicant. If the FDA notified the applicant of an opportunity for a hearing, the applicant was required to elect a hearing

---

121. Pub. L. 52 Stat. 1040 (1938).

122. Pub. L. 87-781, 76 Stat. 780 (1962).

123. Section 505(c), 21 U.S.C. §355 (c) (1970).

within 30 days and the hearing was to commence within 120 days of the notice unless the FDA and the applicant agreed to an extension. The FDA was required to conduct the hearing on an expedited basis and to issue a final order within 90 days of the date fixed for filing final briefs.

The majority in both Houses of Congress believed that this new clearance procedure which the Drug Amendments extended to cover a new drug's efficacy as well as its safety, adequately balanced the government's interest in having adequate time to evaluate new drugs and the industry's interest in promptly marketing its new products.<sup>124</sup> A strong minority in the Senate favored the elimination of all statutory time limits for the clearance process to insure that the FDA had adequate time to determine the safety of a new drug. If a drug company believed that the delay in processing its application was arbitrary or capricious, it could seek relief in the courts.<sup>125</sup>

The intensity of the FDA's review of new drugs for safety and efficacy has dramatically increased since Congress first enacted these statutory time limits in 1938 and 1962. The review process is much more complex and thorough now than it was twenty or even ten years ago. Advances in scientific knowledge, increased consumer consciousness, greater scientific and community awareness of hidden dangers that only become apparent years hence, and the difficulty of determining drug efficacy have all contributed to this phenomenon. In the 1950's a typical new drug application comprised two volumes of two hundred plus pages each. At the time of the enactment of the Drug Amendments of 1962, a major application might contain 10,000 pages.<sup>126</sup> In 1964 Commissioner Larrick complained to Congress that a typical new drug application contained over nine volumes and 4,000 pages of data and required 195 days for the FDA to review.<sup>127</sup> By 1968, a new drug application for a new anesthetic agent reached 72,300 pages in 167 volumes, while a 1972 application for a skeletal muscle relaxant consisted of 456 volumes, all two inches thick and weighing (one set) a total of 1,920 pounds.<sup>128</sup> These illustrations demonstrate that changes with the passage of time may strain an agency's capacity to meet a statutory time limit that was a realistic one at the time of enactment.

---

124. S. Rep. No. 1744, 87th Cong., 2nd Sess. (1962), reprinted in (1962) U.S. Code Cong. and Ad. News 2884, 2890-91.

125. *Id.* at 2905-08 (separate views of Senators Kefauver, Carroll, Dodd, Hart and Long).

126. Hearings on the Medical Device Amendments of 1975 before the Subcommittee on Health and Environment of the House Committee on Interstate and Foreign Commerce, 94th Cong., 1st Sess. 243 (1975) (testimony of Dr. Cooper, Assistant Secretary of Health, Education and Welfare).

127. C.C.H. *Food, Drug and Cosmetic Law Reports* ¶80,061 (reprinted in Christopher, *Cases and Materials on Food and Drug Law* 452 (1966)).

128. Hearings on the Medical Devices Amendments, n.126, at 242-44.

The FDA presently receives between one hundred and one hundred and fifty initial new drug applications annually.<sup>129</sup> The number is fairly constant although it tended to be somewhat higher in the 1960's and early 1970's. Roughly one hundred and fifty active applications are likely to be under review at one time. The number of applications approved annually ranges from thirty-nine to ninety-eight, normally falling into the upper part of that range. These figures do not include the two to three thousand supplemental applications filed annually. Supplementals seek to amend previously approved new drug applications. The amendments are usually minor or technical in nature and do not require extensive analysis. On occasion, a supplemental application covers a major new use for a previously approved drug or the over-the-counter marketing of an approved prescription drug. In these instances the processing of a supplemental application may require almost as much work as the processing of an initial application. Although supplementals are subject to the same statutory time limits as are initial applications, they normally receive low priority within the FDA since they do not involve the marketing of new drugs.

The Office of New Drug Evaluation in the Bureau of Drugs reviews and approves new drug applications. A review team for an application is normally headed by a medical officer (M.D.) and also includes a chemist and a pharmacologist. On April 1, 1977, the Office employed seventy-six medical officers, fifty-six chemists and forty-one pharmacologists. A consumer safety officer handles correspondence and other administrative matters for the review team. Despite the complexity and voluminousness needs of most new drug applications, it appears realistic to require the review process be completed within the 180-day statutory time limit. In other words, the job can be done within the time limit if adequate resources are made available to do it.

The mean or average time between the initial submission of an application and its ultimate approval has nevertheless consistently exceeded one year and in the late 1960's and early 1970's normally exceeded two years. It reached an all-time high of 37.3 months in 1971 but was reduced to 20.0 months in 1976. It should be noted that these figures include not only FDA review time but time spent by the applicant in correcting deficiencies. In most years only a handful of applications (three out of seventy-two in 1976) were approved within six months of filing. These statistics, however, do not accurately disclose the number of pending applications that are over the statutory time limit. That number is actually quite low. At the end of fiscal 1976, for example, only twenty-one out of almost two hundred pending applications were over the statutory time limit.

The reason for this apparent discrepancy is that the applicant and the

---

129. The statistical data on new drug applications in this and succeeding paragraphs derive from the Commissioner's Briefing on the New Drug Evaluation Project (May 5, 1977). A copy of the public portions of this document is on file with the author and the Administrative Conference of the United States.

FDA have agreed to an extension of the 180-day time limit or, as is more likely to be the case, the original application has been "recycled." Recycling occurs when the FDA notifies the applicant that its application is incomplete or inadequate and therefore not acceptable for filing. The applicant may (and usually does) resubmit the application after attempting to correct the deficiencies. The great majority of new drug applications are recycled at least once. For timely review of the application, the FDA begins a 180-day count-down from the day of receipt of the application and tries to take action either to approve it or notify the applicant of deficiencies within that time period. However, under the FDA's regulations<sup>130</sup> the agency's receipt of an application constitutes a "filing" that triggers the statutory time limit only if the application is subsequently found to be acceptable for filing. If a resubmitted application is accepted for filing, the 180-day time period runs from the date the FDA receives the resubmission. Although FDA handles an initial submission or a recycled submission within 180 days to the extent it can, it takes the position that the 180-day statutory time limit only applies to applications that are complete and adequate on their face and therefore acceptable for filing. However, an applicant may challenge the FDA's determination that its application is incomplete or inadequate by making a written request to file it over protest. Under its regulations the FDA must then within 60 days reevaluate the application and either approve it or give the applicant written notice of an opportunity for a hearing on the question whether the application is approvable.<sup>131</sup> Although used only infrequently in the past, this procedure has been invoked more often in the last year or two. In one recent instance when an applicant chose to file its supplemental application over protest in the fall of 1976, it resulted in a formal adjudicatory hearing on the application.<sup>132</sup>

The FDA's interpretation that the 180-day statutory time limit only applies to applications that are acceptable for filing appears to be a proper one in light of the applicant's right to file over protest. The time limit for a review process is a realistic one only if the FDA receives an application that is complete and in proper form. If it is not, the FDA can do no more than afford the applicant additional time and guidance to resubmit it or initiate formal adjudicatory hearings to deny it.

---

130. 21 CFR 314.110(c) (1977).

131. 21 CFR 314.110(d) (1977).

132. On September 17, 1976, Parke Davis & Co. filed over protest its supplemental application for over-the-counter use of Benylin Expectorant, a previously approved prescription drug. The Bureau of Drugs thereupon notified Parke Davis of the opportunity for a hearing on the agency's proposed denial of the application. 41 FR 52537 (Nov. 30, 1976). Parke Davis subsequently requested a hearing. The limited experience with this hearing and with the contemporaneous hearing on the new animal drug application for Proban (see 41 FR 51077 (Nov. 19, 1976)) indicates that the scheduling of adjudicatory hearings on new drug applications is likely to be determined by agreement between the parties which extend the unrealistically tight statutory time constraints otherwise applicable under section 505(c)(2), 21 U.S.C. §355(c)(2) (1970).



The statutory and regulatory framework outlined above does not fully describe what actually happens at the FDA. The pre-market review of new drugs under section 505 is a closed process until the data are presented to an FDA Advisory Committee. All major new drug applications are so presented; many of the minor ones are not. Most advisory committee meetings are open to the public, although until recently that was not the case. At the advisory committee meetings the public is allowed to participate by commenting and by listening to the discussion and recommendations of the committee members. There have been only two formal hearings since 1962. "Either the parties — the FDA and the manufacturer — eventually reach agreement on conditions for the release of a drug, or the applicant acquiesces in the agency's refusal to approve marketing."<sup>133</sup> The FDA enjoys considerable leverage since most drug manufacturers cannot afford the delay or the publicity associated with a formal hearing and prefer to retest or improve their drug rather than to risk a public confrontation with the agency.<sup>134</sup> Also, the drug industry generally believes it unlikely that an administrative law judge at an adjudicatory hearing or the courts on judicial review will second guess the professionals at the Bureau of Drugs who maintain that the safety and efficacy of a new drug have not been demonstrated. These factors provide applicants with strong disincentives against challenging the agency's scientific judgment or its non-compliance with statutory time limits. The applicant either resolves disagreements informally with the agency and obtains approval for its application or withdraws its application without prejudice as permitted by regulation.<sup>135</sup>

The 180-day statutory time limit for processing new drug applications has nevertheless had a profound effect at the FDA. New drug applications have received priority attention, although "crash" efforts to eliminate the backlog have proved to be somewhat cyclical. Dr. Goddard, who was Commissioner from 1965 to 1968, eliminated completely the backlog of applications pending over 180 days,<sup>136</sup> but the backlog promptly reappeared in 1969 during the stormy tenure of Dr. Ley when the agency was wracked by personnel problems and deeply involved in reviewing the efficacy of drugs already on the market.<sup>137</sup> The situation probably reached its nadir by 1971 or 1972 when the average time lapse between the initial receipt of an application and its approval exceeded thirty months, although it must be remembered that much of the thirty months was due to corrections, by the sponsors, of multiple deficiencies in the application.

---

133. J. Mashaw and R. Merrill, *The American Public Law System* 469 (1975).

134. Ames and McCracken, Framing Regulatory Standards to Avoid Formal Adjudication: The FDA as a Case Study, 64 *Calif. L. Rev.* 14, 15-17 (1976).

135. 21 CFR 314.7 (1977).

136. H. Dowling, *Medicines for Man* 204 (1970).

137. Review Panel on New Drug Regulation, *Investigation of Allegations Relating to the Bureau of Drugs, Food and Drug Administration* 63 (April 1977).

Starting in 1974 there followed another of the periodic efforts to clear the logjam. This effort focused in improved managerial techniques.<sup>138</sup> The Bureau of Drugs improved and decentralized its filing system, developed flow charts and a tracking system for monitoring pending applications, and prepared guidelines which instructed reviewers what to do at each step of the process. These changes resulted in increased productivity. The FDA also expedited the decisional process by delegating the approval of new drug applications from the Commissioner to the Director of the Bureau of Drugs and then to the Associate Director for New Drug Evaluation. By 1976, without any increase in manpower or decrease in caseload, the FDA had reduced to twenty months the average elapsed time between the receipt of the initial application and the approval of a new drug. Much of this improvement was due not only to new managerial techniques in FDA but also to improvement in the quality of applications submitted so that less recycling was required.

FDA officials deny that the statutory time limit motivated this most recent effort to expedite the review process. The primary motivation was simply a desire to clear up the backlog. Confirmation for this view may be found in the project's focus on the elapsed time between the initial receipt of an application and its ultimate approval or withdrawal. In other words, recycling, which is not counted by the FDA as part of the 180-day statutory period, was considered the heart of the delay problem.

The drug review process actually starts when a drug sponsor submits to the FDA a Notice of Claimed Investigational Exemption for a New Drug (IND). While the Food, Drug and Cosmetic Act does not mention INDs, it does authorize the FDA to promulgate regulations under which experimental (i.e. unapproved) new drugs may be used for investigational purposes by qualified experts.<sup>139</sup> The IND allows the drug's sponsor to conduct clinical tests using human subjects. FDA regulations permit drug sponsors to initiate clinical tests 30 days after the FDA receives the initial IND submission, unless the agency expressly forbids them to do so.<sup>140</sup> During the 30-day period a review team (ordinarily composed of a medical officer, chemist and pharmacologist) analyzes the sponsor's data on toxicology and on prior animal studies for which no advance clearance is required and the proposed initial clinical trials. This 30-day safety review receives the highest priority within the Office of New Drug Evaluation. Although nearly one thousand INDs are submitted annually, the FDA completes the safety review within the 30-day time limit in all cases except for a few in which the data are too voluminous. Internal agency policy also requires the preparation by the review team of a comprehensive, written review of the initial

---

138. Interview with Jerome A. Halperin, Deputy Associate Director for New Drug Evaluation, FDA (May 31, 1977).

139. Section 505 (i), 21 U.S.C. §355(i) (1970).

140. 21 CFR 312.1(a)(2) (1977).

IND submission within 60 days of filing. The Office of New Drug Evaluation also meets this self-imposed time limit in the great majority of cases.

After the completion of these two initial steps, the investigational stage of the new drug process may continue for years until a new drug application is submitted or an IND discontinued. The Review Panel on New Drug Regulation has criticized the FDA for the unstructuredness of the investigational stage. The agency does not adequately advise drug sponsors what tests to conduct; and sponsors do not perform the necessary testing, either because they do not know what is expected of them or because they do not want to bother unless they are expressly required to do so. As a result drug sponsors file incomplete or inadequate new drug applications that require recycling for additional testing or for the submission of additional information. The Review Panel identified disorganized submissions, misdirected research, and poorly designed studies as major sources of inefficiency and delay in the new drug approval process and recommended greater FDA review of new drug research during the investigational stage to expedite the whole process.<sup>141</sup> While the Review Panel presents a convincing case, the implementation of its recommendations may not prove easy in light of the available manpower. For each medical officer in the Office of New Drug Evaluation there were on April 1, 1977, only 1.96 active new drug applications under review. The number of active INDs per reviewer was 62.68.

Present efforts at the FDA to expedite the new drug approval process focus on the investigational stage and not on the review of new drug applications found to be acceptable for filing. The FDA has issued fifteen clinical guidelines for the testing of experimental drugs on humans and will issue the remainder in 1978. Also, the Office of New Drug Evaluation now classifies new drugs according to their therapeutic potential. In 1976, only six of the seventy-two new drugs approved by the FDA represented an important therapeutic gain, while fifty of the new drugs (almost seventy percent) represented little or no therapeutic gain over drugs presently on the market. The Office now identifies at the investigational stage new drugs that may involve important therapeutic gains and seeks to expedite their approval by providing additional guidance and assistance to the sponsors of the drugs. The review team will hold mandatory conferences with the sponsors to develop test protocols that should speed up the necessary research and result in new drug applications that are approvable promptly and without recycling.

The FDA initiated this new program at the end of 1976. While it shows great promise in expediting the marketing of beneficial new drugs, it also highlights a potential cost of the present statutory time limit. The time limit requires the FDA to prioritize the processing of all applications for approved new drug status, including applications for drugs that represent little or no therapeutic advance. It can be argued that this "cost" was taken into account by Congress in 1938 and in 1962 when it left new drug development

---

141. Review Panel on New Drug Regulation, *Final Report 70-71* (May 1977).

drugs proposed by industry. The existence of the statutory time nevertheless severely limits any effort by the FDA to reduce this cost. There has not been any Congressional review since 1962 of the time limits applicable to the new drug approval process. Certainly the enactment of a statutory time limit gives greater permanence to past balancings of costs and benefits than does the competing system of leaving questions of priority largely to agency discretion.

The FDA's experience also indicates that a statutory time limit applicable only to one segment of a clearance process may not prove effective in expediting the overall process but may in fact distort it. While any conclusions on this matter can only be impressionistic, it does seem that the FDA has in the past concentrated on the all or nothing decision to approve or deny new drug applications to the neglect of reviewing new drug research or monitoring the post-approval experience with marketed drugs, another area where the Review Panel (and also Congressman Moss's Subcommittee on Oversight and Investigations)<sup>142</sup> found the FDA to be deficient.

### *New Animal Drug Applications*

Prior to the Animal Drug Amendments of 1968<sup>143</sup> to the Food, Drug and Cosmetic Act of 1938, animal drugs were subject to the same provisions and regulations as were human drugs. The amendments consolidated provisions of the Act with respect to the regulation of animal drugs in section 512 of the Act.<sup>144</sup> Section 512(c) of the amended Act adopted for the processing of new animal drug applications the time limits previously made applicable to human and animal drugs by the Drug Amendments of 1962. Within 180 days after the filing of an application the FDA was required either to approve the new animal drug or give the applicant notice of an opportunity for a hearing on the agency's proposed denial of the application.

The Office of Scientific Evaluation in the Bureau of Veterinary Medicine presently reviews new animal drugs for safety and efficacy. The experience of that Office is strikingly similar to that of the Office of New Drug Evaluation in the Bureau of Drugs. Recycling of applications is the primary cause of delay. In the nine-year history under the amended Act only two or three original applications have been approved as initially submitted. The softness of the testing guidelines and the sloppiness of the industry in preparing applications combine to require the recycling of almost all applications.

FDA regulations require that the Bureau determine whether an application is acceptable for filing within thirty days of its receipt.<sup>145</sup> If the Bureau

---

142. Sub-committee on Oversight and Investigations of the House Committee on Interstate and Foreign Commerce, Report on *Federal Regulation and Regulatory Reform*, 94th Cong., 2nd Sess. 288 (1976) (case study involved nitrofurans, approved new animal drugs). This Report is hereafter cited as the Moss Report.

143. Pub. L. 90-399, 82 Stat. 843 (1968).

144. 21 U.S.C. §360b (1970).

145. 21 CFR 514.110(c) (1977).

finds that an application is not acceptable for filing, the applicant may dispute that finding or may attempt to correct the deficiencies. An applicant disputes the finding by requesting that the application be filed over protest. In that case the application is deemed filed on the date of its receipt.<sup>146</sup> The Bureau must then prepare a notice of opportunity for a hearing and serve it on the applicant within 180 days of that date. If the applicant attempts to correct the deficiencies by amending or resubmitting the application, the original application is deemed to have been withdrawn and the 180-day time period starts running anew from the date of the amendment or resubmission.<sup>147</sup> The running of the 180-day period is also tolled if prior to its expiration the Bureau requests additional samples or test results. It only resumes when the applicant supplies the requested material.<sup>148</sup>

Over fifteen hundred new animal drug applications are filed annually with the Bureau of Veterinary Medicine. This figure includes supplemental applications which amend presently approved applications. While many supplementals involve only minor changes in drug containers, manufacturing controls, etc., a few involve major new uses or labelling for an approved drug. Until the spring of 1977, the filing of a supplemental application prompted a complete review of the underlying application and the approval of a supplemental required in effect a reaffirmation of the prior approval of the underlying application. The workload for processing initial and supplemental applications therefore did not vary significantly and the Bureau did not maintain separate statistics for the two varieties of applications.

The Bureau of Veterinary Medicine is subject to considerable pressure from Congress, the drug industry, and agricultural interests to meet the 180-day time limit.<sup>149</sup> It has been reasonably successful in doing so. The Office of Scientific Evaluation within the Bureau processes approximately ninety per cent of all new drug applications within the statutory time limit. Of course, the great majority of these dispositions occur a year or two after the initial filing because the Office takes advantage of the refiling and tolling provisions in the regulations. The average total processing time is therefore almost five hundred days.

The Bureau's normal disposition of an application is either to approve it or to determine that it is not acceptable for filing. Only one applicant has even challenged a nonacceptability determination by filing an application over protest and requesting a formal hearing on the Bureau's proposed denial of the application.<sup>150</sup> Approval of an application takes the form of a

---

146. 21 CFR 514.110(d) (1977).

147. 21 CFR 514.6 and 514.100(g) (1977).

148. 21 CFR 514.100(c) (1977).

149. In early 1975, Smith Kline and the Animal Health Institute complained directly to the Commissioner about delays in processing new animal drug applications. Former Congressman Whitten also made known at that time his concern about delays.

150. See Notice of Opportunity for a Hearing on Proposal to Deny Approval of Supplemental New Drug Application for Proban, 41 FR 51077 (Nov. 19, 1976).

regulation that is signed by the Director of the Bureau of Veterinary Medicine and published in the Federal Register. While other manufacturers may in some instances rely on the regulation to market an identical product, the application process remains basically an adjudicatory one. Individual drug manufacturers apply for premarket approval of particular products.

The number of professional reviewers in the Office of Scientific Evaluation has slowly increased over the years to the present total of sixty to seventy. The review process itself involves at least twenty-seven different steps, many of which involve agency personnel from outside the Bureau of Veterinary Medicine (e.g., from the General Counsel's Office or, in the case of drugs for food-producing animals, from the Bureau of Foods). Recent efforts to expedite the review process have focused on improved administration and record keeping. The Bureau has developed flow charts, tracing systems and other methods to smooth the paper flow. A second review of applications by the Bureau of Foods was recently eliminated. The Bureau now evaluates as to human safety a new animal drug for food producing animals but receives only a reference copy of the draft regulation. The Bureau of Food's previous review of the draft regulation had produced little new input and had proved time-consuming because of the geographic separation of the two Bureaus. The Bureau of Veterinary Medicine and the Bureau of Foods have also adopted a new policy to reduce and in some instances to eliminate the review of an underlying approved application upon the filing of a supplemental application.

While there is no doubt that the existence of the statutory time limit has prompted these administrative improvements, the improvements have not resulted in a fool-proof system. Objections to an application may arise at one of the latter steps in the review process (e.g., the General Counsel has a legal objection to the text of the draft regulation) which requires a referral back to earlier steps of the process and the rethinking of an issue. If this occurs, the Bureau cannot complete its review within 180 days. While that period appears realistic to process the normal application, the schedule is a tight one and the pipeline is full. If some difficulty arises at a later stage in the process, it is not realistic to expect the agency to resolve it within the time remaining. If the agency is forced to provide an answer within the statutory time limit, it will have no choice but to deny the application. The experience of the Bureau of Veterinary Medicine thus demonstrates that it is unrealistic to expect an agency with a heavy caseload to process all (and not just ninety to ninety-five percent) of the applications filed with it within a tight time frame.

The Bureau has nevertheless struggled mightily to expedite the processing of new animal drug applications. In the eyes of its critics, however, the Bureau has not acted speedily enough in removing from the market unsafe or ineffective animal drugs.<sup>151</sup> There is no hard evidence that the priority

---

151. See Moss Report, *supra* n.142, at 288-296. FDA General Counsel Richard Merrill testified on the withdrawal of nitrogurans: "I don't think there is any excuse for the length of time we have taken." *Id.* at 295.

assigned by the statutory time limit to processing applications contributes to any sluggishness in the enforcement effort. While there may be a relationship, it is not something that is subject to demonstration. A more likely explanation for any variation in Bureau performance is the Bureau's assumption of a promotional role towards agricultural interests. Licensing new animal drugs is consistent with that role while enforcement proceedings are not. Withdrawal proceedings also require a tremendous commitment of resources which could be devoted to processing applications.<sup>152</sup> Agency officials naturally find it more satisfying to utilize a fixed amount of resources to approve one hundred new animal drugs than to conduct a contested proceeding to remove one approved drug from the market.

### *Food Additive Petitions*

The Food Additive Amendments of 1958<sup>153</sup> to the Food, Drug and Cosmetic Act of 1938 required for the first time FDA premarket approval of food additives. While the Act provided for the regulation of food additives through the promulgation of rules of general applicability, the safety review of manufacturers' petitions conducted by the FDA more closely resembles a clearance or licensing function. Under the amended Act a food is adulterated and subject to seizure if it contains a food additive unless the use of the food additive is in conformity with a regulation issued under section 409 of the Act.<sup>154</sup> The term "food additive" does not include substances generally recognized as safe (GRAS), but the manufacturer of a new food ingredient or of a new use for an existing ingredient cannot as a practical matter rely on its own independent determination that its product is GRAS and therefore not within the legal definition of a food additive. Cautious food processors normally insist that the manufacturer obtain a food additive regulation prescribing the use of the additive before they will add it to food.<sup>155</sup>

Section 409(b)(1) of the amended Act<sup>156</sup> permits any person with respect to any intended use of a food additive, to file with the FDA a petition proposing the issuance of a regulation prescribing the conditions under which the additive may safely be used. Section 409(b)(5) requires that the FDA publish in the Federal Register a notice of the proposed regulation within thirty days after filing. Within 90 days after the date a petition is filed, the FDA shall either promulgate a regulation or deny the petition. The FDA, however, may extend that period for up to an additional 90 days to

---

152. The withdrawal hearings on diethylstilbestrol (DES), where the agency was unsuccessful in obtaining summary judgment, *Hess & Clark Division of Rhodia, Inc. v. FDA*, 495 F.2d 975 (D.C. Cir. 1974), provides an example.

153. Pub. L. 85-929, 72 Stat. 1784 (1958).

154. 21 U.S.C. §348 (1970).

155. Sunshine, *Regulatory Aspects of Food Additives*, 31 *Food, Drug, and Cosmetic L.J.* 264, 269 (1976).

156. 21 U.S.C. §348(b)(2) (1970).

enable it to further study and investigate the petition. The denial of a petition is not final agency action because section 409(f) provides for a formal, on-the-record hearing for any person adversely affected by the order.<sup>157</sup> The statutory time limits also apply to petitions to amend or repeal a food additive regulation.<sup>158</sup> Under section 409(d),<sup>159</sup> the FDA may itself propose to issue, amend or repeal a food additive regulation, but no statutory time limits apply to agency-initiated proceedings.

Manufacturers and food processors file approximately one hundred food additive petitions annually. The Division of Food and Color Additives in the Bureau of Foods supervises the safety review of these petitions. The Petitions Control Branch within the Division initially receives the petitions and directs them to the appropriate office within the Bureau of Foods. The Branch's role is primarily a monitoring one. Under FDA regulations the Branch has fifteen days to determine a petition's acceptability for filing.<sup>160</sup> Roughly fifty percent of the initial filings received by the Branch are found unacceptable. In the past, the Branch conducted only a cursory preliminary review of the petition in order to comply with the fifteen day time limit for determining whether the petition should be accepted for filing; but its recent policy of reviewing more thoroughly the acceptability of petitions for filing has resulted in missing that deadline in most cases. Petitioners are evidently not unhappy with this delay, because the pre-filing safety review alerts them to major problems with a petition before a notice of the petition appears in the Federal Register. Once there is a public notice of a petition, there is some embarrassment to the petitioner if he subsequently withdraws it to avoid a formal denial. As a result, nearly ninety percent of the food additive petitions accepted for filing ultimately obtain a regulation.

The statutory time limit of 90 days (extendable to 180) for processing a food additive petition is a realistic one only in the sense that the task could normally be completed on time if trained personnel are made available specifically to do petition review. The task is much less difficult and time consuming than the review of new drug applications. There is of course the exceptional case; and it is very doubtful that the Bureau of Foods could process a controversial petition for a new artificial sweetener within the statutory time limit. But in the normal case the review process is straightforward and the end product is several lines of regulation accompanied by

---

157. 21 U.S.C. §348(f) (1970).

158. The Health Research Group recently petitioned the FDA to repeal six color additive regulations. *CCH Food, Drug and Cosmetic Reports* ¶41,874 (Jan. 11, 1977). The petition did not invoke the identical time limits applicable to color additive petitions in amended section 706(d) of the Act, 21 U.S.C. §376(d) (1970), but did invoke the FDA's new rule on citizen petitions. Under that rule the FDA has obligated itself to make some response to citizen petitions (though not necessarily a formal grant or denial) within 180 days of filing. 21 CFR 10.30(e)(2) (1977). The filing requirements for citizen petitions are less onerous than those for food and color additive petitions.

159. 21 U.S.C. §348(d) (1970).

160. 21 CFR 171.1(i)(1) (1977).



several pages of preamble. The work required is far less substantial than when the FDA itself proposes a regulation.

The Petitions Control Branch has nevertheless had a difficult time complying with the statutory time limit on account of the large number of major "brushfires" that have erupted in the last several years and distracted the personnel of the Bureau of Foods from the task of reviewing food additive petitions. The Branch has been heavily involved in the FDA's recent actions on cyclamates, chloroform, red dye #2, red dye #4, acrylonitrile, and saccharin. Outside events (e.g., the Canadian studies on the health hazards of saccharin) have often thrust these matters on the FDA, and the agency has had no choice but to assign them top priority. This approach to the "brushfires" does produce results. The FDA, for example, published its proposal to revoke the food additive regulation on saccharin thirty-eight days after it announced its intention to do so.<sup>161</sup> That time period is an exceptionally short one to develop a major proposal that is highly controversial and requires the marshalling of extensive factual support. While the task can be done in thirty days or so, it cannot be done very often or in two or more proceedings at once. The Petitions Control Branch had to defer other matters to supervise the collection of the data to support the saccharin proposal; and top level agency officials, who only have so many hours available to them in the day, became personally involved in drafting the proposal. They were also required personally to acquaint themselves with the data so that they could publicly defend the agency's action. Following the publication of the saccharin proposal, the FDA received about 70,000 comments and held many days of public hearings. FDA officials also had to prepare for lengthy appearances before Congress and the press. While the Branch's input on the saccharin proposal was going on, it also had to defer other matters to prepare for the court-ordered hearing on the FDA's proposal to ban the use of acrylonitrile as a component of soft drink bottles.<sup>162</sup>

The workload of the Petitions Control Branch reflects the disruptive effect of these brushfires. During the first six months of fiscal 1977 (October 1976 through March 1977), the Branch expended 355 staff days assembling and collating material for agency hearings and proposals. It also expended 279 staff days responding to 222 requests under the Freedom of Information Act. At the end of the period there were nevertheless 56 pending requests that had not been answered within the statutory time limits in the Freedom of Information Act. The more difficult requests processed by the Branch naturally involved the same controversial issues that were the subject of agency hearings and proposals. The Branch expended only 326 staff days on the processing of food and color additive petitions. During the period the Branch had received forty-five new petitions, but had only been able to finalize and publish regulations on thirteen petitions. Some professional staff rightly complain that they were hired to conduct safety reviews

---

161. 42 FR 25339 (May 17, 1977).

162. *Monsanto Co. v. Gardner*, D.C. Cir. No. 77-1245, March 18, 1977.

of food additive petitions but spend most of their time assembling documents for hearings and for requests under the Freedom of Information Act. As these figures indicate, the Petitions Control Branch is quite small—it has only seventeen or eighteen professionals; but the Branch exercises a coordinating function and its breakdown of staff hours reflects the likely breakdown with the larger Bureau of Foods.

Despite these difficulties, the Petitions Control Branch has had a reasonably good record in meeting the statutory deadline for acting on food additive petitions. In past years the agency acted in a timely fashion on seventy to eighty percent of the petitions, but its record is no longer that good. The Branch does of course take advantage of the provision in its regulations that a substantive amendment to a petition, including the submission of additional information and data by the petitioner at the agency's request, constitutes a new filing that starts the time period running anew.<sup>163</sup> It also routinely extends the initial 90-day period to 180 days, but the 90-day letter sent to the petitioning manufacturer at the end of the first 90-day period states when the 180-day period expires. The fixing of that date is a managerial tool that does serve to expedite the review process. Reviewers realize that a decision is expected by that date. While the deadline is not always met, it is likely that if there were no deadline the crush of more pressing business would result in still further delays. The Branch and the entire Bureau of Foods plainly give priority to extinguishing the brushfires and not to processing petitions. If it were not for the deadline applicable to petitions, action on them would be still further deferred. Agency personnel simply feel pressure develop when the 180-day deadline approaches and try to squeeze in the time to handle the matter.

### CASE STUDY NO. 3

#### *Office of Export Administration (OEA) in the Department of Commerce — Export License Applications*

The Export Administration Act of 1969<sup>164</sup> adopted a significant new approach to export policy. Under the earlier Export Control Acts, the basic policy had been to restrict trade with this country's potential enemies. The 1969 Act adopted a more liberal trade policy which basically limited restrictions to the "export of goods and technology which would make a significant contribution to the military potential of any other nation or nations which would prove detrimental to the national security of the United States."<sup>165</sup> Congress implemented this policy through a licensing system,

---

163. 21 CFR 171.6 (1977).

164. Pub. L. 91-184, 83 Stat. 841, codified at 50 U.S.C. App. §2401-2413 (1970).

165. Section 3(1)(B) of the Export Administration Act, 50 U.S.C. App. §2402(1)(B) (1970). The 1969 Act also authorized export controls to protect the domestic economy from the drain of commodities in short supply and to foster United States foreign policy. Section 3(2)(A) and (B), 50 U.S.C. App. §2402(2)(A) and (B) (1970). Short supply and foreign policy controls have played a less significant role than have national security controls.

primarily administered by the Office of Export Administration in the Department of Commerce.

All goods and technical data, with few exceptions, require for export either a general or a validated license. Exports of most product categories to most destinations are made under general licenses which require neither a specific application nor the issuance of a licensing document for a particular shipment. Licensed exporters simply present an export declaration to the customs office at the port of exit. A validated license, on the other hand, is a formal document issued by the Department of Commerce upon application of the exporter which authorizes the export to a particular destination of the commodities or technical data covered by the document. Validated licenses are required for many exports to Communist-bloc countries and for Free World exports if the product and destination are specified on the Commodity Control List. The number of applications for validated licenses has normally exceeded fifty-five thousand per year, although that figure has gradually decreased as the level of control has been reduced.

In the early 1970's exporters complained that the licensing procedures adopted by the Department of Commerce were unduly slow and burdensome and that the Department had not sufficiently responded to the liberalizing spirit of the Export Administration Act of 1969.<sup>166</sup> Delays in granting licenses had resulted in lost sales and tied-up goods and had impeded United States export potential.<sup>167</sup> Businessmen also complained that it took two months or more for the Department to approve an application.<sup>168</sup> Congress initially responded to these complaints by enacting the Equal Export Opportunity Act of 1972,<sup>169</sup> which established a number of mechanisms (e.g., technical advisory committees) for the participation of private industry in decisions about export controls. In the Export Administration Amendments of 1974,<sup>170</sup> Congress responded to continuing complaints of delay by adding a new subsection 4(g) to the 1969 Act<sup>171</sup> which required the Department to approve or disapprove all applications for validated licenses not later than 90 days after submission. If the Secretary of Commerce needed additional time, he was required to "inform the applicant of the circumstances requiring such additional time and give an estimate when his decision will be made." Under this latter provision, the Department of Commerce may extend indefinitely the 90-day statutory

---

166. Legislative Developments, *The Export Administration Amendments of 1974*, 7 *Law & Pol. Int'l. Bus.* 925, 930-932 (1975).

167. S. Rep. 93-1024, 93rd Cong., 2nd Sess. 6 (report on 1974 Amendments).

168. Hearings on S. 1890 and S. 3282 before the Subcommittee on International Finance of the Senate Committee on Banking, Housing and Urban Affairs, 93rd Cong., 2nd Sess. 401 (1974) (statement of Thomas Christiansen, manager of international trade relations for Hewlett-Packard Co.).

169. Pub. L. 92-412, 86 Stat. 644 (1972).

170. Pub. L. 93-500, 88 Stat. 1552 (1974).

171. 50 U.S.C. App. §2403(g) (Supp. V 1975).

time if it gives reasons for doing so; and it appears unlikely that an aggrieved applicant could successfully challenge on judicial review the reasons given for the extension.<sup>172</sup>

The 90-day statutory time limit poses no significant difficulty in the great majority of cases. In two sample periods in the fall of 1975 and the fall of 1976, the Office of Export Administration processed ninety percent of the free world applications and at least eighty-five percent of all applications within *twenty* days. In the fall of 1976, the Office processed ninety-seven percent of the free world applications and ninety-four percent of all applications within the requisite 90 days.<sup>173</sup> These applications were in most cases processed internally within one of the three Licensing Divisions in the Office of Export Administration and were not subject to any interagency or high-level review. Almost all of them were approved. Whether or not the statutory time limit in section 4(g) is responsible for this favorable record is unclear. One of the effects of the time limit was that the Office for the first time maintained records on the time it took to process applications. The evidence available,<sup>174</sup> however, does indicate that the Office of Export Administration expedited its processing of routine applications after Congress amended the Export Administration Act in 1972.

The 90-day statutory time limit has proved difficult to meet in a substantial minority of cases. In 1975, 1,105 applications representing roughly \$200,000,000 of exports were delayed over 90 days.<sup>175</sup> These applications largely involve high technology goods (computers, electronic equipment, etc.) and machine tools for export to Communist-bloc countries. The average processing time from receipt through disposition was approximately 184 days.<sup>176</sup> A significant number of these applications are ultimately disapproved.<sup>177</sup> While these "tough" applications represent only

---

172. The 90-day statutory time limit in section 4(g) applies to applications for validated licenses for exports subject to national security controls. It does not apply to applications for exports subject to short supply and foreign policy controls. See n.165, *supra*. Short supply applications generally are processed quickly because they involve only the imposition of a fee or quota and need not be scrutinized for national security considerations.

Foreign policy controls restrict the export of explosives, crime control and detection apparatus, and certain commodities relating to nuclear weapons. These controls prompt a comparatively low number of applications. These applications do not appear to be assigned a lower priority than applications for exports subject to national security controls.

173. The statistics for 1975 may be found in S. Rep. 95-104, 95th Cong., 1st Sess. 14 (1977). The statistics for 1976 have been supplied to the author by the Office of Export Administration. Similar statistics may be found in the so far unpublished *Report of the President's Task Force to Improve Export Administration Licensing Procedures* (1976) (hereinafter referred to as the MacAvoy Report).

174. See n.168 *supra*.

175. MacAvoy Report, *supra* n. 173, at 26.

176. The MacAvoy Report, *supra* n.173, at 28, supplies this figure for a random sample of cases studied by it.

177. 341 applications were disapproved in fiscal 1976.

a small percentage (less than five percent) of the total applications, they do represent a far larger proportion of the dollar value of the goods to be exported and roughly twenty-two percent of the Communist-bloc applications. The complexity of the technical issues raised by these applications and the layers of interagency and international review required by existing law and practice make it difficult if not impossible to squeeze the processing for many of them into the requisite 90 days.

Section 5(a) of the Export Administration Act of 1969<sup>178</sup> required the Department of Commerce to consult with other agencies on the imposition of export controls. The Executive Branch has implemented this section by establishing a complex system for interagency review of licensing applications which involves the Departments of State, Defense, Treasury, Energy, and the Central Intelligence Agency. Under policy determinations (PDs) drafted by the Office of Export Administration and approved by all the agencies involved, ninety percent or more of the applications received by the Office are processed internally without any interagency review. These applications are almost always processed within 90 days. The remaining applications are subject to either bilateral reviews by individual agencies or more formal interagency review by one or more of the interagency bodies that rise to the level of the Cabinet itself. The Department of Defense plays a special role in this review process because the Export Administration Amendments of 1974 added a new subsection 4(h) to the Act<sup>179</sup> which specifically authorized the Secretary of Defense to determine, in consultation with the Department of Commerce, which categories of exports to Communist-bloc countries should be subject to national security review by the Defense Department. When the Office of Export Administration refers an application to the Defense Department under this provision, the Secretary of Defense may within 30 days recommend to the President that he personally disapprove the licensing application because it significantly increases the military capability of the receiving country.<sup>180</sup>

In addition to this process of interagency clearance, international clearance is also required for exports to Communist-bloc countries of commodities and technologies that have strategic value. The United States participates in a voluntary arrangement with fourteen other countries (NATO countries, other than Ireland, and Japan) jointly to control exports to Communist countries. If a commodity or technology is on the international control list, the Office of Export Administration must in many cases obtain a waiver from the informal International Coordinating Committee (COCOM) headquartered in Paris before licensing the export.

Applications subject to interagency and international review must be processed through the appropriate Licensing Division of the Office of Export Administration within at least 30 days if they are to stand any chance

---

178. 50 U.S.C. App. §2404(a) (1970).

179. 50 U.S.C. App. §2403(h) (Supp. V 1975).

180. 50 U.S.C. App. §2403(h)(2)(A) (Supp. V 1975).

of approval or disapproval within 90 days. Interagency review and COCOM approval each take at least 30 days.<sup>181</sup> The initial 30-day deadline is a difficult one to meet. There is often a backlog of cases and a shortage of competent staff to analyze the complex technical issues. After the technical issues are resolved, the licensing officer must write up his analysis in language that is intelligible to the lay generalists who will subsequently review it. Putting difficult concepts into plain English is a talent that is not shared equally by everybody. The preparation of the often lengthy document that accompanies the application on interagency and international review (referred to as the Operating Committee or OC document) often cannot be completed within the 30-day time limit if it is to be written and rewritten until it is intelligible to non-scientists.

Interagency review also necessarily consumes more than 30 days in difficult cases. The present policy emphasizes the need to obtain a consensus. If there is an objection to an application by the representative of an agency, the practice is to escalate the interagency review to the next higher level until a consensus is achieved or the matter reaches the President's desk. In controversial cases, such as the application to sell a computer system of potential military significance to the Russian weather bureau which was recently disapproved, there is no way to accomplish this task within 30 days. COCOM approval, on the other hand, is more routine and normally can be obtained within 30 days. While the time for COCOM review has averaged 40 days or more in the past, the Office of Export Administration has reduced that time slightly through logistical improvements in the transmission and translation of documents. It is unlikely, however, that the time can be reduced much further given COCOM's location in Paris and use of French as its operative language.

There is little question that the 90-day statutory time has had a significant impact in expediting the processing of applications for export licenses. The Office of Export Administration employs it as a measuring stick to evaluate its own performance. The Office has also utilized it as a device to obtain additional personnel. Interestingly, the Office's request to Congress for funds for twenty-two additional positions was rejected and the Office only obtained additional technical personnel through an internal transfer of funds within the Commerce Department.<sup>182</sup> The Office has also pro-

---

181. This breakdown of the 90 days into three 30-day periods derives from the MacAvoy Report, *supra* n.173. The Office of Export Administration has itself established the goal of processing internally all applications within thirty days.

182. The Commerce Department's 1977 budget submission included almost \$600,000 for the twenty-two new positions to be offset by closing two Trade Centers overseas. The House committee on Appropriations specifically rejected the request and insisted that the Department do better with existing resources. House Report 94-1226, 94th Cong., 2nd Sess. 24-25 (1976). See also Hearings on Departments of State, Justice, Commerce, the Judiciary, and Related Agencies Appropriations for 1977 (Part 2) 94th Cong., 2nd Sess. 631-641 (1976). The Senate added the funds but the House prevailed in conference. Conference Report 94-1309, 94th Cong., 2nd Sess. 8 (1976).

mulgated additional policy determinations reducing the number of applications subject to the delays of the interagency review process. These policy determinations do not reduce the level of national security controls but simply allow the agencies involved to resolve policy issues generically rather than on a case-by-case basis when reviewing individual applications. Of course, the obvious need to process licensing applications expeditiously could have produced many of the effects that have occurred even in the absence of any specific statutory time limit.

Time pressures for processing applications have also diverted licensing officers from providing advisory services to exporters. While the Office does consider it important to assist exporters by advising them when and how to apply for a license, the level of services is less than would be afforded if more time and staff were available. Diverting licensing officers from the other tasks performed by them is not so easy since those tasks are either directly related to the case flow problem (e.g., the review of the Department's or COCOM's commodity control list or the preparation of policy directives) or plainly mandated by law (e.g., the preparation of the quarterly report to Congress on export controls mandated by section 10 of the Export Administration Act).<sup>183</sup>

The statutory time limit has had a lesser effect on the workings of the interagency review process. The McAvoy Report focuses on the interagency review process as the prime cause of delay and makes numerous recommendations which have not yet been implemented for simplifying or eliminating reviews that are unnecessary or rarely produce objections. Change so far has come glacially because the reviewing agencies are jealous of their prerogatives. While only the Department of Defense has an explicit statutory right to participate in the review process, other agencies have customarily participated and do not like to be excluded. At the same time the statutory time limit does not exert the same time pressure on these referral agencies as it does on the agency that administers the program. Officials at the Office of Export Administration know how rapidly applications must be processed in order to comply with the time limit and are aware that they will be held to account for the program's track record. Officials at the referral agencies, on the other hand, are not subject to the same scrutiny and there is a danger that they will treat referrals as a secondary matter to be handled when they get around to it. The Department of Defense, for example, does not have a tracking system such as that in the Office of Export Administration to insure that a superior official is notified of applications that have been delayed for more than 30 days. While Section 3(h) grants the Defense Department only 30 days in which to recommend to the President that he reject a license application on military grounds, the Department knows that it need not act within 30 days because under present practice its concurrence is needed for a consensus decision. It thus appears

---

183. 50 U.S.C. App. §2409 (1970 & Supp. V 1975).

to take more than a nonenforceable statutory time limit to change the present system in the sensitive area of national security export controls. Likewise, suggestions to eliminate the COCOM review or to conduct it simultaneously with the interagency review involve major policy changes that may be meritorious but are not likely to be implemented simply to achieve compliance with the statutory time limit.

Despite the unquestioned impact of the statutory time limit in the 1974 Export Administration Amendments, Congress continues to be unhappy about delays in the processing of licensing applications.<sup>184</sup> The Export Administration Amendment of 1977<sup>185</sup> amended the statutory time limit in subsection 4(g) of the Act to provide that an application "shall be *deemed* to be approved and the license shall be issued" at the expiration of the 90-day period unless the Secretary of Commerce "finds that additional time is required and notifies the applicant in writing of the specific circumstances requiring such additional time and the estimated date when the decision will be made." This tightened time limit primarily requires the Office of Export Administration to develop a fool-proof tracking system to prevent an application from slipping through at the end of the 90-day period before the Office has acted on it. The Department of Commerce still retains the authority to extend the time limit upon giving reasons for doing so. The Department successfully resisted a more radical change proposed by a number of Congressmen for the automatic approval of applications still pending at the end of 90 days without authorizing the Department to extend the 90-day period. The Department argued that this provision would force it to choose between the unpleasant alternatives of approving an application that might endanger our national security or denying it because there was insufficient time to evaluate it.

#### CASE STUDY NO. 4

##### *Special Imports Program Division in the Domestic and International Business Administration (DIBA) in the Department of Commerce — Applications for Duty Free Importation of Articles of Scientific Value*

Under section 6 of the Educational, Scientific and Cultural Materials Act of 1966,<sup>186</sup> non-profit organizations may apply to the Secretary of the Treasury (i.e., to the Customs Service) for the duty-free importation of articles of scientific value not available on the domestic market. The Secretary must promptly forward the application to the Secretary of Commerce for a determination whether an instrument or apparatus of equivalent scientific value is manufactured in this country. Section 6(c) provides that the

---

184. S. Rep. 95-104, 95th Cong., 1st Sess. 11-12 (1977).

185. Pub. L. 95-52, §107, 91 Stat. 235 (1977). Similar legislation passed both Houses in 1976 but enactment was blocked when Congress adjourned before either House could act on the Conference Report.

186. Pub. L. 89-651, 80 Stat. 897 (1966) (uncodified).



Secretary of Commerce shall promptly report his finding to the Secretary of the Treasury. That section requires an addition that the Secretary of Commerce shall publish in the Federal Register his finding, with a statement of reasons therefor, before the ninetieth day after the filing of the application with the Secretary of the Treasury.

The Secretary of Commerce has delegated his authority under the Act to the Industry and Trade Administration (ITA) (formerly the Domestic and International Business Administration) (DIBA) which administers the program through its Statutory Import Programs Staff (formerly Special Import Programs Division). The program itself is a comparatively small one; and ITA now receives between four hundred and five hundred applications per year covering goods worth between twenty and thirty million dollars. The application process is a simple one; the importer completes a blank form distributed by the Customs Service and supplies documentation (e.g., bill of sale) on the article purchased abroad for importation. While a non-profit organization may apply for duty-free importation before committing itself to purchase abroad an article of scientific value, few take advantage of the opportunity to apply in advance of actual order of the article.

The Statutory Import Programs Staff has only three professional employees, the Director (who splits his time among three statutory programs) and two technical people. Two administrative assistants and two typists are also assigned to this function. However, section 6(c) of the Act requires the Department of Commerce to consider the written advice of the Department of Health, Education and Welfare on applications. Applications involving biomedical end uses undergo a scientific review at the National Institutes of Health within HEW or, if that agency does not have competence in the research or educational purposes for which the article covered by an application is intended to be used, the application will be referred to experts in other governmental agencies, such as the National Bureau of Standards or the National Oceanic and Atmospheric Administration within the Department of Commerce itself. Section 6(c) also requires that the Department of Commerce publish notice of an application in the Federal Register to afford a reasonable opportunity for public comment. ITA customarily allows only twenty days for the submission of comments.

ITA normally receives an application from the Customs Service within five days after it has been accepted for filing by the Service. ITA then allots fifteen days to complete its own initial review of the application. In a small percentage of cases, ITA determines that the application contains a deficiency which prevents its consideration on the merits. Under its regulations,<sup>187</sup> ITA may deny at the initial review stage the application without prejudice (DWOP) and notify the applicant in writing what additional information about the imported article, comparable domestic article

---

187. 15 CFR 301.8 (1976).

or his intended end uses is required for it to make an equivalency determination. (Generally, however, ITA waits for the technical advice from the consulting agencies, as described below, before "DWOPing" an application). The DWOP becomes final if the applicant does not resubmit its application within 90 days. A resubmission triggers anew the running of the 90-day statutory time limit. If, on the other hand, ITA determines that the application is complete, it prepares a public notice summarizing the application for publication in the Federal Register.

The initial review by ITA generally culminates in the publication of a Federal Register notice. While ITA almost always meets its target of completing this review in fifteen days, delays in the insertion of notices in the Federal Register normally result in a twenty to thirty day time span between the agency's receipt of an application and the appearance of a Federal Register notice. All Federal Register notices and decisions are signed by the director of the Statutory Import Programs Staff without any higher level review. Letters of denials without prejudice issued at the initial review stage are also almost always dispatched within fifteen days of receipt of an application or very soon thereafter. The program is neither big enough nor complex enough to develop a significant backlog.

The Federal Register notices prompt comments from interested persons on roughly ten percent of the applications. An application rarely attracts more than one comment. The commentators are invariably domestic manufacturers who claim to manufacture equivalent scientific equipment. Copies of any comments received and the applications are transmitted to the appropriate consulting agency within five days of the expiration of the comment period. ITA must then wait for the completion of the scientific review by its consultant agencies which ITA requests be returned within thirty days. While the statute does not explicitly preclude ITA from acting on its own once the comment period closes, counsel in the Department has advised that for legal sufficiency the ITA decision requires a supporting scientific evaluation from a consulting agency. Moreover, ITA does not have the technical competence to evaluate the entire range of instruments which may be covered by applications in terms of the specific research or educational end uses (a statutory requirement). Once ITA receives the written report of the scientific reviewer, it allots thirty days for its final review and decision. Cases involving policy issues or denial decisions are also referred to the ITA Office of General Counsel for review. Once again it almost always meets this self-imposed deadline. Five to ten days may elapse before the Federal Register publishes the required notice of the decision. Approximately ninety percent of the applications finally decided are approved; and in most instances the approval is relatively routine and straightforward.

The chief delays in processing applications occur at the National Institutes of Health (NIH) and, to a lesser extent, at the National Bureau of Standards (NBS). The evaluation of applications at NIH is not a funded activity or a high priority item. The task at both NBS (which is reimbursed by

ITA for the evaluation service) and NIH is remote from the central missions of the reviewing scientists or technicians. The Statutory Import Programs staff does not have much leverage to require these agencies to submit their reports within the required thirty-day period given the ITA policy that decisions cannot be rendered by the staff without a supporting technical evaluation. Moreover, the staff does not have much incentive to do so since it is not itself subject to any significant pressure from applicants to make timely decisions. There is also a concern among the professional staff that to pressure consultants may result in incomplete or unsatisfactory evaluations. It is therefore common for ITA to receive a report on the scientific review of an application two or three months after the application is transmitted to NIH even though the review itself may consume only a single staff day at the Institute. A sample of applications reviewed by the National Institutes of Health during late 1976 and early 1977 disclose an average review of sixty-three days.

ITA therefore misses the 90-day statutory deadline in the majority of cases. While there are no statistics available on the number of applications acted on after the expiration of 90 days, the average processing time for all applications filed since July, 1972 (excluding denials without prejudice) is 176 days. There are also normally between fifty and one hundred applications in process that have been pending over 90 days. It is a good estimate that the agency misses the statutory deadline on ninety percent of the applications.

These delays have distressed no one, except possibly the professional staff at the Department of Commerce who do not like to be cast in the role of potential lawbreakers. Importers of scientific equipment do not pay any duty at the time of entry if they file a claim for duty-free entry prior to the entry of the article. They only pay the duty (without any obligation for interest) if their application is ultimately denied and therefore they have little incentive to force a timely decision. Occasionally the approaching expiration of a budget year or a reversion of grant funds may prompt an importer to inquire whether a decision on its application may soon be forthcoming. In these instances ITA gives the application priority treatment by expediting its own review and by contacting its scientific reviewers to request them to give special attention to the application because the applicant needs a prompt answer.

This case study raises doubts about the need for the statutory time limit in section 6(c) of the Educational, Scientific and Cultural Materials Act. It is difficult to ascertain what purpose it serves since the affected private parties do not really need its protection. While the time limit does operate to expedite the processing of applications at ITA, it lacks sufficient force or reason to expedite the process of interagency scientific review. While its provisions may otherwise be harmless, does that fact justify a statutory command that an agency official "shall" do something within 90 days that he does not have at his disposal the means to obey?

## CASE STUDY NO. 5

*Consumer Product Safety Commission (CPSC)—Promulgation of Consumer Product Safety Rules*

The Consumer Product Safety Act of 1972<sup>188</sup> established a five-member independent regulatory commission known as the Consumer Product Safety Commission to protect the public against unreasonable risks associated with consumer products. Section 9 of the Act<sup>189</sup> authorized the Commission to promulgate consumer product safety rules which may take the form either of consumer product safety standards or of consumer product bans. In order to promulgate a safety standard for a consumer product, the Commission must find that the standard's requirements are in the public interest and are "reasonably necessary to eliminate or reduce an unreasonable risk of injury" associated with the consumer product;<sup>190</sup> a product ban is authorized only if the Commission finds that "no feasible consumer product safety standard under this chapter would adequately protect the public from the unreasonable risk of injury" associated with the consumer product.<sup>191</sup>

Congress also transferred to the Commission in the 1972 Act jurisdiction to administer a number of older safety statutes that had approached the problem in a piecemeal fashion. These statutes included the Flammable Fabrics Act, the Poison Prevention Packaging Act, and the Federal Hazardous Substances Act. Section 30(d) of the original Act<sup>192</sup> provided that a risk of injury associated with a consumer product that could be eliminated or reduced to a sufficient extent by Commission action taken under the transferred Acts may not be regulated under the Consumer Product Safety Act. In 1976, Congress amended section 30(d)<sup>193</sup> to allow the Commission to regulate under the Consumer Product Safety Act rather than under one of the transferred acts any risk of injury associated with a consumer product if it determined that it was in the public interest to do so.

The Consumer Product Safety Act of 1972 contained a number of significant procedural innovations applicable to rulemaking under the Act.<sup>194</sup> Section 7 of the Act<sup>195</sup> required the Commission to utilize private offerors to develop proposed safety standards prior to the Commission's

---

188. Pub. L. 92-573, 86 Stat. 1207 (1972), codified at 15 U.S.C. §§2051-81. The Consumer Product Safety Commission Improvements Act of 1976, Pub. L. 94-294, 90 Stat. 503 (1976), amended various sections of the original Act.

189. 15 U.S.C. §2058 (Supp. II 1972).

190. Section 9(c)(2)(A), 15 U.S.C. §2058(c)(2)(A) (Supp. II 1972).

191. Section 9(c)(2)(C), 15 U.S.C. §2058(c)(2)(C) (Supp. II 1972).

192. 15 U.S.C. §2079(d) (Supp. II 1972).

193. Pub. L. 94-294, §16, 90 Stat. 510 (1976). See n.188, *supra*.

194. See generally, Scalia and Goodman, Procedural Aspects of the Consumer Product Safety Act, 20 *U.C.L.A. Law Rev.* 899, (1973).

195. 15 U.S.C. §2056 (Supp. II 1972).

publication of a notice of proposed rulemaking under section 553 of the Administrative Procedure Act. The purpose of this pre-rulemaking procedure was to permit the maximum use of the expertise available in the private sector and to permit maximum participation by industry and consumer interests in the standard-setting process while maintaining the ultimate authority of the Commission to determine the final standard.<sup>196</sup> Section 10 of the Act<sup>197</sup> also recognized the right of "any interested person" to petition the Commission to initiate a rulemaking proceeding and to obtain judicial review of the Commission's refusal to do so. That section defined interested person to include "consumer or consumer organization." Finally, sections 7 through 10 of the Act<sup>198</sup> contained numerous time limits, normally extendable for good cause, applicable to each stage of the rulemaking process.

The 1970 Report of the National Commission on Product Safety provided the impetus for the passage of the Consumer Product Safety Act. The Act itself largely derived from a proposed statute drafted by the Commission for submission to Congress.<sup>199</sup> Section 8 of the Commission's draft contained two major time limits. First, private offerors were allotted a maximum of 180 days to develop a proposed safety standard during which time the Consumer Product Safety Commission was required to suspend its own rulemaking activities. Second, the Commission was required to promulgate a final safety standard or terminate the rulemaking proceeding within 60 days after proposing a standard. Both time limits were extendable by the Commission for good cause. The 180-day time-frame was selected because it was the normal period of time required by private standard-setters to develop a new safety standard. No consideration was apparently given to whether it was realistic to expect the Consumer Product Safety Commission to promulgate a final standard in 60 days. The Report did emphasize the importance of procedural flexibility,<sup>200</sup> and the new Commission's authority to extend the time limit evidently made it unnecessary to consider whether 60 days was a sufficient period of time. The National Commission on Product Safety did criticize other federal agencies for undue delay in promulgating safety standards.<sup>201</sup> The delays were attributed to unnecessary procedural obstacles and inadequate funding. The Commission's response to these difficulties was to propose the creation of an independent commission with

---

196. H.R. Rep. No. 1153, 92nd Cong., 2nd. Sess. 33 (1972).

197. 15 U.S.C. §2059 (Supp. II 1972).

198. 15 U.S.C. §§2056 to 2059 (Supp. II 1972).

199. The proposed statute may be found at the end of the Commission's Report. See National Commission on Product Safety, *Final Report* (June, 1970).

200. *Id.* at 114.

201. The criticism was documented in the Heffron Report prepared for the Commission. The agencies singled out for criticism were the National Highway Traffic Safety Administration, the Federal Trade Commission, and the Food and Drug Administration. See Heffron Report, *Federal Consumer Safety Legislation: A Study of the Scope and Adequacy of the Automobile Safety, Flammable Fabrics, Toys and Hazardous Substances Programs* (June 1970).

broad powers whose sole responsibility was to protect the consuming public from hazardous products.

The Senate Committee on Commerce refined the draft prepared by the National Commission on Product Safety, and the Committee's bill (S.3149) was largely enacted into law. The Committee added time limits during which the Consumer Product Safety Commission was required to respond to rulemaking petitions (within 120 days) and during which the Commission, after the receipt of a proposed standard developed by a private offeror, was required either to publish a notice of proposed rulemaking or to terminate the proceeding (within 60 days). Only the latter time limit was extendable for good cause. The Committee's lengthy report did not explain the latter addition but did explain that the former addition was necessary to transform a right to petition for rulemaking (proposed by the National Commission on Product Safety and already provided by section 553(e) of the Administrative Procedure Act) into a right to bring a mandamus suit to challenge agency inaction.<sup>202</sup> A deadline was established for Commission action in order to permit a consumer to challenge inaction in court after that date. There was no discussion whether 120 days was a realistic time limit for responding to petitions.

As of early September 1977, the Consumer Product Safety Commission had promulgated under the Consumer Product Safety Act three safety standards (swimming pool slides,<sup>203</sup> architectural glazing materials<sup>204</sup> and matchbooks)<sup>205</sup> and three product bans (unstable refuse bins,<sup>206</sup> chlorofluorocarbons<sup>207</sup> and lead-containing paint and consumer products bearing lead-containing paint<sup>208</sup>). It had proposed one additional safety standard (power lawn mowers<sup>209</sup>) and two additional product bans (extremely flammable contact adhesives<sup>210</sup> and certain products containing respirable asbestos<sup>211</sup>). The Commission had also initiated three section 7 proceedings (television receivers,<sup>212</sup> public playground equipment<sup>213</sup> and

---

202. S. Rep. 92-749, 92nd Cong., 2nd Sess. 20-21 (1972). S. 3149 was jointly reported to the Senate by the Committee on Commerce and the Committee on Labor and Public Welfare.

203. 41 FR 2741 (Jan. 19, 1976).

204. 42 FR 1427 (Jan. 6, 1977).

205. 42 FR 22656 (May 4, 1977).

206. 42 FR 30296 (June 13, 1977).

207. 42 FR 42779 (Aug. 24, 1977).

208. 42 FR 44192 (Sept. 1, 1977).

209. 42 FR 23052 (May 5, 1977).

210. 42 FR 35984 (July 13, 1977).

211. 42 FR 38782 (July 29, 1977).

212. 40 FR 8592 (Feb. 28, 1975).

213. 40 FR 10706 (March 13, 1976). Technically, the standard for public playground equipment will ultimately be promulgated under the Federal Hazardous Substances Act, but the Commission has decided to utilize the offeror procedures in the Consumer Product Safety Act for its development.

miniature Christmas tree lights<sup>214</sup>) for the development of proposed safety standards by private offerors. The Commission had until recently actually utilized its rulemaking authority under the transferred acts more frequently and successfully than its rulemaking authority under the Consumer Product Safety Act. It had placed in effect at least six substantive standards or bans under the Federal Hazardous Substances Act (full size cribs, bicycles, vinyl chloride monomer as an aerosol propellant, toy testing, non-full size cribs and fireworks) and at least one each under the Flammable Fabrics Act (children's sleepwear) and the Poison Prevention Packaging Act (ethylene glycol).<sup>215</sup>

The Commission therefore conducts some rulemaking proceedings that are subject to statutory time limits and some that are not. Any preference by the Commission for utilizing the transferred acts is not attributable to a desire to avoid the time limits for rulemaking under the Consumer Product Safety Act. The time limits, as will be seen, are too readily extendable to have that impact. The explanation lies more in the cumbersome offeror process that distinguishes proceedings under the latter Act from proceedings under the transferred Acts.<sup>216</sup> Sections 9(c)(1)(C) and (D) of the Consumer Product Safety Act also require the Commission to make difficult determinations on the economic impact of safety standards that it is not required to make for rules promulgated under the transferred acts. These differences between rulemaking under the transferred acts and rulemaking under the Consumer Product Safety Act preclude any comparative study on the effect of statutory time limits.

The applicability of statutory time limits to only a portion of the Commission's proceedings poses the danger that the Commission will be unable

---

214. 42 FR 17154 (Mar. 31, 1977). In November, 1975, the Commission also solicited offers to develop a proposed standard for home aluminum wiring. No acceptable offers were received; and commission efforts to develop a standard have not yet produced a proposal. A court recently ruled that the Commission lacked jurisdiction because home wiring was not a consumer product. *Kaiser Aluminum v. CPSC*, 428 F. Supp. 177 (D. Del. 1977).

215. Hearings on Department of Housing and Urban Development - Independent Agencies Appropriations for 1978 before a Subcommittee of the House Committee on Appropriations, 95th Cong., 1st Sess. 48 (1977) (letter to committee by Commissioner R. David Pittle) (hereafter cited as House Hearings on 1978 Appropriations). Commissioner Pittle's statistics date from early February, 1977. The Commission's much publicized subsequent ban on children's sleepwear treated with the flame-retardant chemical TRIS was also taken under the Federal Hazardous Substances Act.

216. Former Commission Chairman Richard O. Simpson shared this negative assessment of the offeror process for developing proposed standards and sought its repeal. Hearings on Regulatory Reform before the Subcommittee on Oversight and Investigations of the House Committee on Interstate and Foreign Commerce, 94th Cong., 2nd Sess., Volume IV, 10-12 (1976) (hereafter cited as Hearings on Regulatory Reform). The present Commission has decided to live with the basic section 7 offeror process. The Commissioners are divided on its relative merits, but Commissioner Franklin in particular believes that it can be made to work. See House Hearings on 1978 Appropriations, *supra* n.215, at 114, 118-119. The Commission, however, does favor an amendment of section 7 that would give it greater flexibility to make mandatory a previously voluntary standard without utilizing the offeror process.

rationally to determine its own priorities but will find it necessary to assign priority to those proceedings subject to a time limit. Rulemaking proceedings under the Consumer Product Safety Act do not necessarily have a greater priority than other Commission proceedings not subject to statutory time limits such as rulemaking proceedings under the transferred acts or adjudicatory proceedings against individual products that do not violate any safety standard but constitute a substantial product hazard. Congress did not make any such priority determinations when it enacted the Consumer Product Safety Act in 1972. While the Commission has in part avoided this problem by missing or freely extending statutory deadlines,<sup>217</sup> the statutory time limits have made it difficult for the Commission to develop its own priorities. This adverse impact is particularly apparent in the context of rulemaking petitions.

#### *A. Time Limits Applicable to Rulemaking Petitions*

Section 10(a) of the Act<sup>218</sup> provides that any interested person, including a consumer or a consumer organization, may petition the Commission to commence a proceeding for the issuance, amendment, or revocation of a consumer product safety rule. The rules covered by this provision include both safety standards for consumer products and bans of hazardous consumer products. Section 10(b) requires that the petition shall set forth 1) facts which it is claimed establish the "necessity" of the requested rule and 2) "a brief description" of the rule. Section 10(c) authorizes the Commission to hold a public hearing on a petition and to conduct such investigation or proceeding as it deems appropriate. Section 10(d) provides that the Commission shall either grant or deny a petition within 120 days after it is filed with the Commission. Unlike other time limits in the Act, this time limit for acting on petitions is not extendable by the Commission for good cause. If the Commission grants a rulemaking petition, it "shall promptly commence an appropriate proceeding under section 7 (standards) or 8 (bans)." If the Commission denies a petition, it shall publish its reasons for the denial in the Federal Register.

For petitions filed more than three years after the date of the Act's enactment (i.e. after October 27, 1975), section 10(e) provides a unique judicial remedy to petitioners if the Commission denies a petition or fails to grant or deny it within the requisite 120 days. The petitioner may commence, within 60 days after the Commission's denial of the petition or

---

217. However, the worst instance of delay at the Commission did not involve a proceeding subject to a statutory time limit. The Commission's failure in the five years of its existence to promulgate generic toy regulations under the Federal Hazardous Substances Act is well described in Senate Committee on Governmental Affairs, *Study on Federal Regulations: Delay in the Regulatory Process (Volume IV)* 17-20 (June, 1977). In the summer of 1977, the Commission withdrew product bans proposed by it in January, 1975 and proposed new technical requirements for toys with sharp points and edges. 42 FR 39647 (August 4, 1977); 42 FR 44160 (Sept. 1, 1977). Proposed standards on small parts are still to appear.

218. 15 U.S.C. §2059(a) (Supp. II 1972).



within 60 days after the expiration of the 120-day period if the Commission fails to grant or deny the petition within that time, a civil action in a United States District Court to compel the Commission to initiate the requested rulemaking proceeding. The court shall order the Commission to do so if the petitioner demonstrates "by a preponderance of evidence in a de novo proceeding" that a "consumer product presents an unreasonable risk of injury, and that the failure of the Commission to initiate a rulemaking proceeding under section 7 or section 8 of this title unreasonably exposes the petitioner or other consumers to a risk of injury presented by the consumer product."<sup>219</sup> This provision not only authorizes judicial review of the Commission's failure to commence a rulemaking proceeding but also contains an unusually strict standard for that review. Even if the Commission's refusal to do so was a rational one (i.e. it was not arbitrary or capricious) and even if it was supported by substantial evidence, the court must order the Commission to initiate the requested rulemaking proceeding if the court finds that the preponderance of the evidence is the other way. Section 10 of the Consumer Product Safety Commission Improvements Act of 1976<sup>220</sup> further strengthened this judicial remedy by adding a new section 10(e)(4) to authorize the District Court in the interests of justice to award the petitioner the costs of the suit, including reasonable fees for attorneys and for expert witnesses.

The Commission's Petition Log lists eighty-two petitions filed under section 10 of the Consumer Product Safety Act from the Commission's inception through April 20, 1977. A typical petition requests the Commission to initiate a rulemaking proceeding for the development of a safety standard for a particular consumer product. In a clear majority of cases the Commission did not grant or deny the petition within the required 120 days. As of March 12, 1976, the Commission had received fifty-six petitions. It had acted on only twelve of those petitions within 120 days, while on twenty-one of the petitions it had acted subsequent to the expiration of the 120 days. The average response time for the thirty-three petitions on which the Commission had acted was 201 days. The average age of the twenty-three petitions still pending was 323 days.<sup>221</sup> Since March, 1976 the situation has improved somewhat, especially with respect to the backlog of long-pending petitions; but only seven of the twenty-two petitions acted on by the Commission between March, 1976 and late August, 1977 had been pending less than 120 days.<sup>222</sup> While this record does reflect in part the clearing of old

---

219. 15 U.S.C. §2059(e)(2) (Supp. II 1972).

220. See n. 188, *supra*.

221. Hearings on Regulatory Reform, *supra* n.216, at 169-170.

222. Author's computations based on Commission's Petition Log.

petitions, the commission is still not able to process within 120 days petitions to initiate standard-setting for additional products.<sup>223</sup>

There are a number of explanations for the Commission's poor record in complying with the statutory time limit. First and foremost there is the problem of management inefficiency. In its four short years of existence the Commission has had seven Acting Executive Directors but it has never had a permanent one. Staff morale and performance have suffered as a result. At least four of the five present Commissioners agree that the lack of effective permanent leadership to give direction to the Commission's staff is in part responsible for the Commission's difficulties in administering the Consumer Product Safety Act.<sup>224</sup> A constant turnover of top level staff has resulted in a large backlog of pending matters that simply do not receive attention regardless of statutory time limits.

The statutory time limit for acting on rulemaking petitions also raises more basic difficulties. The Commission commences a rulemaking proceeding for the development of a safety standard by publishing in the Federal Register a notice under section 7(b) of the Act identifying a consumer product and the risks of injury associated with the product and stating the Commission's determination that a safety standard is necessary to reduce or eliminate the risk of injury. This section 7(b) notice solicits offers from private persons to develop a proposed safety standard and sets in motion a rulemaking proceeding whose every stage is subject to its own statutory time limit.<sup>225</sup>

Former Commission Chairman Richard O. Simpson, in his presentation to the Senate Appropriations Committee in February, 1976, estimated that the Act required the Commission to promulgate at least one hundred mandatory safety standards. The one hundred standards would address approximately seventy-five percent of the standard - preventable injuries.<sup>226</sup> Obviously the Commission cannot develop one hundred standards simultaneously. It costs \$3,000,000 to \$4,000,000 to develop a typical safety

---

223. See, for example, the Federal Register for August 9, 1977 where the Commission denied petitions to develop safety standards for ventilation fans and belt-driven grinders. Both petitions were filed in December, 1976 and formally denied by the Commission on August 3, 1977. 42 FR 40232-33.

224. House Hearings on 1978 Appropriations, *supra* n.215, at 43-75 (letters to the Subcommittee by Commissioners Pittle, Kushner, Franklin, and Garrett).

225. The Commission may omit the section 7(b) notice and the private offeror process for developing a proposed standard when it proposes a product ban under section 8. However, in many instances the Commission will be unable to determine that a ban is necessary because no safety standard is feasible to protect the public unless there has first been an effort at standard development under section 7.

226. Hearings on the Department of Housing and Urban Development and Certain Independent Agencies Appropriations for 1977 before a Subcommittee of the Senate Committee on Appropriations, 94th Cong., 2nd Sess. 7-10 (1976) (statement of Richard O. Simpson, Chairman, Consumer Product Safety Commission) (hereafter cited as Senate Hearings on 1977 Appropriations).

standard, and the Commission's total annual budget is approximately \$40,000,000.<sup>227</sup> Given its limited resources, must the Commission grant a rulemaking petition simply because the requested standard is among the one hundred or so standards that ultimately should be promulgated? The Commission initially responded to this question in the affirmative and denied a petition only if it determined that there was no unreasonable risk of injury associated with the product which necessitated the development of a safety standard. Conversely, the Commission believed that it had no choice but to grant a petition and promptly commence a rulemaking proceeding by publishing a section 7(b) notice if it determined that a safety standard was reasonably necessary to eliminate or reduce an unreasonable risk of injury associated with a consumer product.<sup>228</sup> This interpretation of section 10 certainly discouraged the Commission from ruling on petitions since it would soon find itself involved in far more rulemaking proceedings than it could handle. The Commission's response was to temporize. It relied on the three year grace period in section 10(e)<sup>229</sup> and hoped that it could avoid suits by petitioners after its expiration by explaining to them in an above-board fashion what it was doing with their petitions and why it had not acted on them within the 120-day time limit.<sup>230</sup>

At the Commission's Senate Appropriations hearings in February, 1976, Senator Proxmire sharply criticized the Commission's interpretation of its responsibility to rule on petitions under section 10 of the Act.<sup>231</sup> He argued that the Commission must establish its own priorities on which standards to develop first and not allow its priorities to be set by the order in which persons outside the agency filed petitions. At the time of the hearing the Commission had just promulgated its first consumer product safety standard for swimming pool slides; and the Senator reacted with considerable merriment to the inconsequentiality of the standard and the trivialities of its provisions. He noted that the standard for swimming pool slides had been developed and promulgated in response to a petition, the first one filed under section 10 of the Consumer Product Safety Act. Chairman Simpson agreed that the petitioning process had largely controlled the agency's priorities but argued that the Commission had no choice unless section 10 was amended or repealed. Simpson had previously submitted in January, 1976 a chart to Representative Moss's oversight hearings that contrasted the importance of petition-generated and self-generated rulemaking proceedings. Ten proceedings at the Commission generated by petitions granted under section 10 of the Act addressed only 155,000 preventable

---

227. *Id.* at 19 (testimony of Woodson W. Bercaw, Director, Budget and Operations Division, Consumer Product Safety Commission).

228. *Id.* at 21 ff.

229. See text at n.219 *supra*.

230. House Hearings on 1978 Appropriations, *supra* n. 215, at 135 (testimony of S. John Byington, Chairman, Consumer Product Safety Commission).

231. Senate Hearings on 1977 Appropriations, *supra* n. 226, at 19-22, 58-59, 67-73.

injuries, while ten self-selected Commission proceedings addressed 1,230,000 injuries.<sup>232</sup> While this chart is not fully informative on the Commission's allocation of priorities,<sup>233</sup> it is plain that the Commission's actions under the 1972 Act have been more reactive than planned. Of the twelve safety standards or bans presently in effect or under active development, only two were Commission-generated (matchbooks and television receivers). The remaining ten (swimming pool slides, architectural glazing material, power lawn mowers, public playground equipment, miniature Christmas tree lights, unstable refuse bins, chlorofluorocarbons, lead-containing paint, contact adhesives, and asbestos products) were all petition-generated.

The Commission responded to Senator Proxmire's criticism by establishing priorities for Commission action. It adopted on July 2, 1976, an interim policy statement which established eight criteria for determining agency priorities.<sup>234</sup> While the Commission's criteria are necessarily somewhat general, they do provide a basis for determining which safety standards to develop first. The Commission subsequently promulgated in September, 1976, interim rules on procedures for rulemaking petitions which specifically applied the Commission's priorities to the disposition of section 10 petitions.<sup>235</sup> In deciding whether to grant or deny a petition the Commission will consider "the risk of injury associated with the product about which the petition has been filed and the Commission's resources available for rulemaking activity with respect to that risk of injury."<sup>236</sup> In September 1977, the Commission actually listed twenty-nine high priority projects which it intended to complete as quickly as possible and seventeen medium-priority projects which it intended to complete as soon as possible thereafter.<sup>237</sup> These rankings were subject to continuing review.

The Commission's present approach makes it more practicable for it to grant or deny rulemaking petitions within the 120-day time limit. The Commission has collected nationwide data on product-related injuries and has conducted (or could easily conduct) in-depth investigations on most major products to determine the precise cause of a statistically significant sample of those injuries. This information should afford the Commission an adequate factual basis for acting on petitions. While the preparation of a section 7(b) notice requires additional time and is the crucial step in the offeror

---

232. Hearings on Regulatory Reform, *supra* n. 216, at 13.

233. The chart does not identify specific proceedings. It also does not indicate the staff hours spent on the two types of proceedings. Despite the Commission's initial interpretation of section 10, it has granted petitions on which it has subsequently invested very little in the way of resources. For example, on October 9, 1973, it granted a petition to develop a safety standard for extension cords but it has yet to publish a section 7(b) notice in that proceeding.

234. 41 FR 27960 (July 8, 1976), codified at 16 CFR 1009.8 (1977).

235. 41 FR 43125 (Sept. 29, 1976), codified at 16 CFR 1110.11 (1977).

236. *Id.* at 43129, codified at 16 CFR 1110.22(b) (1977).

237. 42 FR 47859 (Sept. 22, 1977).

process,<sup>238</sup> the Commission need not complete that step before granting the petition. The Commission may first grant the petition and sometime thereafter "promptly commence" a rulemaking proceeding by publishing a section 7(b) notice. Oddly, the publication of the section 7(b) notice is the only stage of the Commission rulemaking that is not subject to a specific statutory time limit but only to a more general requirement of "promptness". Significant delays have occurred at that stage. In two instances dating from 1973 and 1974, the Commission granted rulemaking petitions for safety standards on extension cords (petition granted on October 9, 1973) and space heaters (petition granted on October 31, 1974) but has not yet formally commenced proceedings through the publication of a section 7(b) notice.

The Commission is still hesitant to deny rulemaking petitions on the basis of its priorities. It did so for the first time on August 3, 1977 when it denied a petition to develop a safety standard for belt-driven grinders.<sup>239</sup> There is some apprehension that the courts will rule that the Commission's present approach conflicts with section 10 and that the Commission must grant meritorious petitions rather than deny them on the basis of inadequate resources.<sup>240</sup> So far only one petitioner has sued the Commission.<sup>241</sup> In that case the Commission had failed to grant or deny within the 120-day time limit a petition to commence a proceeding for the development of a safety standard for Christmas tree lights. The petitioner had obtained a patent for a type of Christmas tree light whose safety features he believed should be the subject of a mandatory safety standard. He sought a court order directing the Commission to initiate the requested proceeding through the publication of a section 7(b) notice. After unsuccessfully contending that the plaintiff's mailgram to the Commission did not constitute a petition under the Commission's rules, the Commission settled the case in early 1977 and published a section 7(b) notice in which the court allowed the Commission to limit to miniature Christmas tree lights. While the Commission in its pleadings and briefs did not advance a defense based on its newly established priorities, the court made it quite clear to the parties that the Commission was required to initiate a rulemaking proceeding once it recognized, as it did, that Christmas tree lights were amenable to regulation by a consumer product safety standard.

The determination of Commission priorities involves more than the question which petition to grant and which standard to develop first. There

---

238. See text at p. 128 below.

239. For the published denial, see 42 FR 40232 (Aug. 9, 1977).

240. There is a difficult issue of statutory construction whether section 10(e)(2) allows the Commission to deny a petition on the grounds that the risk of injury to which the petitioner or other consumers are exposed is a matter of low priority. For a statement of the competing argument, see Hearings on Regulatory Reform, *supra* n.216, at 95-126.

241. *Lorch v. Consumer Product Safety Commission*, Civil Action No. C-76-11174-SW(CD Calif) (filed June 19, 1976).

is a broader issue of what priority to assign to mandatory safety rules. The primary mission of the Commission is to reduce injuries caused by hazardous products. To accomplish that goal it must of course identify and analyze the hazards associated with consumer products. Once it has done so the Commission has available to it four distinct strategies to reduce those hazards: 1) it may promulgate mandatory safety rules of general applicability; 2) it may proceed against particular defective products through formal adjudicatory proceedings or through seizure action in the courts; 3) it may monitor voluntary standards development; and 4) it may conduct or support information and education programs directed to consumers.<sup>242</sup> Plainly the draftsmen of the Consumer Product Safety Act contemplated that the Commission would adopt some mix of these strategies since the Act authorized the Commission to pursue all of them. The Act did not determine the precise nature of the mix but left that determination to the Commission, subject to Congressional review through the annual appropriations process.

The Commission, like most federal agencies, has devoted only a portion of its resources to rulemaking. In fiscal 1977, 136.6 positions and \$7,713,000 were allocated to the Commission's Regulatory Development Program out of a total appropriation of \$39,974,000. The Information and Education Program had 79.5 positions and \$4,479,000, while the Compliance and Enforcement Program had the largest share, 286 positions and \$9,785,000.<sup>243</sup> Surely, an allocation of a greater share of the Commission's

---

242. House Hearings on 1978 Appropriations, *supra* n.215, at 55 (letter of Commissioner Kushner to subcommittee).

243. The complete figures for fiscal 1977 are as follows:

Program Activity	Positions	Funds
Hazard Identification	164.5	\$ 7,845,000
Hazard Strategy Analysis	29.1	2,063,000
Regulatory Development	136.6	7,713,000
Information and Education	79.5	4,479,000
Compliance and Enforcement	286.0	9,785,000
Administration	194.3	8,049,000
Reimbursable Programs		40,000
		<u>\$39,974,000</u>

House Hearings on 1978 Appropriations, *supra* n.215, at 175.

An undetermined portion of the Compliance and Enforcement budget supports the enforcement of mandatory safety standards. That portion is relatively small since the number of mandatory standards is low and since the Commission in its budget submission, reproduced above, pruned the Compliance and Enforcement budget by allocating to Regulatory Development over twenty positions and \$1,000,000 that had formerly been treated as part of the Compliance and Enforcement budget. The transferred functions included programs for achieving compliance with new standards.

limited funds to rulemaking would result in an improvement in the Commission's record in responding to petitions and in completing rulemaking proceedings in a timely fashion. The statutory time limits seemingly have not had an effect on the composition of the mix and have not caused a greater allocation of resources to the rulemaking strategy than would otherwise be the case.

It is fortunate that the time limits have not had a greater impact on agency priorities. Whether the Commission has devoted adequate resources to rulemaking is of course a matter of dispute.<sup>244</sup> Certainly the act placed a strong emphasis on rulemaking but it did not require the Commission to rely exclusively or even primarily on mandatory standards to protect the consuming public. The determination of the appropriate mix is a difficult task which should not be dictated by outside petitioners. The Commission should be able to tell a petitioner that the subject of his petition is not an appropriate matter for rulemaking at the present time. Of course, the Commission should allocate sufficient resources to review petitions and to respond to them in a timely fashion. Section 10 of the Act requires at a minimum that it do so. This requirement is a desirable one since it insures that the agency will at least consider suggestions from the public. Perhaps the Commission's response should be subject to judicial review for arbitrariness, but the broader judicial review provided in section 10(e) is undesirable if it is interpreted to allow a court to order the Commission to commence a rulemaking procedure even if the Commission has made a rational determination not to do so.

The Commission also receives rulemaking petitions under the transferred acts now administered by it. Petitions filed under these statutes are not subject to the 120-day statutory time limit in section 10 of the Consumer

---

The breakdown within the Regulatory Development Program for fiscal 1977 is as follows:

Activity	Positions	Funds
Mandatory Rules	94.0	\$5,818,000
Voluntary Standards	19.0	863,000
Petitions	21.6	971,000
Reporting on New Products	1.6	61,000
	<u>136.6</u>	<u>\$7,713,000</u>

*Id.* at 177.

244. Commissioner Pittle has long maintained that the Commission has not devoted sufficient resources to the development of mandatory consumer product rules and has spent too much money on education and information campaigns and on the development of voluntary standards. House Hearings on 1978 Appropriations, *supra* n.215, at 52 (letter of Commissioner Pittle to subcommittee).

Product Safety Act. Despite this fact, the Commission's Petition Log indicates that the commission has responded more promptly in granting or denying these petitions than it has to section 10 petitions. For example, the average response time for petitions acted on by the Commission under the Federal Hazardous Substance Act and Poison Prevention Packaging Act through March, 1976 was 170 days and 178 days respectively, as compared with 201 days under the Consumer Product Safety Act. The Commission even granted or denied thirty-two of the sixty-eight petitions filed under the Poison Prevention Packaging Act within 120 days.<sup>245</sup> The differences between section 10 and non-section 10 petitions explain this apparent discrepancy. The Commission inherited from the transferor agencies a substantial body of regulations promulgated by them under the transferred acts. The great majority of petitions under the transferred acts therefore request modification of an existing standard, a waiver of the standard, or an extension of a deadline in a standard. The issues are narrow and technical and normally do not require the Commission to make the difficult determination whether or not to develop a new safety standard.<sup>246</sup>

### *B. Development of Proposed Consumer Product Safety Standards*

Section 7 of the Consumer Product Safety Act (as amended by the Consumer Product Safety Commission Improvements Act of 1976) contains time limits for the development of proposed consumer product safety standards. The House Conference Committee Report on the 1976 Act describes as follows the time limits in the amended section 7:

First, the Commission under section 7(b) issues the notice of determination of need for a consumer product safety standard and invites offerors to submit proposals for the development of a standard. (Offers must be submitted within 30 days.)

Second, within 60 days, the Commission must either (1) accept an offer or offers to develop a proposed standard; or (2) publish a notice in the Federal Register terminating the proceeding; or (3) itself develop a proposed consumer product safety rule. If an offer to develop a proposed standard is accepted or the Commission itself proceeds with

---

245. Hearings on Regulatory Reform, *supra* n.216, at 171-73.

246. The Commission's denial of a petition filed under the Federal Hazardous Substances Act to publish a proposed rule banning handgun ammunition did prompt a judicial challenge. *Committee for Handgun Control, Inc. v. CPSC*, 388 F. Supp. 216 (D.D.C. 1975). Section 3(a)(2) of the Federal Hazardous Substances Act, 15 U.S.C. §1262(a)(2) (1970), provides that proceedings for the issuance, amendment or repeal of a rule shall be governed by the provisions in section 701(e) to (g) of the Food, Drug and Cosmetic Act of 1938, 21 U.S.C. §371(e)-(g) (1970). That section in turn provides that the Secretary shall publish a proposed rule on his own initiative or "by petition of any interested person, showing reasonable grounds therefor." The court determined that the petitioner had shown reasonable grounds for banning handgun ammunition and ordered the Commission to publish a proposed rule to that effect within 60 days. Congress subsequently withdrew ammunition from the Commission's jurisdiction.



the development of the proposal, 150 days are allotted for such development.

Third, at the expiration of the 150 day period, either (1) the offeror must submit his proposal to the Commission; or (2) if the Commission itself has proceeded to develop the standard, the Commission must, by notice published in the Federal Register, withdraw the notice of determination of need or it must publish a proposed consumer product safety rule.

If an offeror has submitted a proposal for a consumer product safety standard, the Commission must, within 60 days (i.e. 210 days after the acceptance of the offer), proceed to publish a proposed consumer product safety rule or terminate the proceedings.

While the Commission is authorized to extend each of the above time periods by a notice published in the Federal Register stating good cause therefor, time is of the essence in the development of product safety standards and such extensions should not be made lightly.<sup>247</sup>

The only substantial difference between the time limits in the amended section 7 and in the original section 7 is the time allotment for an offeror or the Commission to develop a proposed standard. Under the original section, the offeror or the Commission was required to develop the proposal within 150 days of the original section 7(b) notice. Under the present section 7, the 150-day period does not start to run until the Commission accepts an offer to develop a proposed standard or commences development itself. Under the former section, the maximum time period for standard development was 210 days from the publication of the initial notice until the publication in the Federal Register of a proposed standard. The present section allows 210 days from the acceptance of an offer. Since the Commission must accept an offer within 60 days of the original notice, the maximum period for developing a proposed standard is now 270 days from the initial notice published by the Commission. The Commission may lengthen this overall time period by extending for good cause any of the intermediate deadlines in the standard development process.

The Commission has so far conducted six offeror proceedings for the development of proposed safety standards. The chart on the following page discloses the Commission's record in those proceedings, which were largely conducted under the time limits in the 1972 Act.

In all six proceedings the statutory time limits were consistently exceeded; and in five of the six proceedings the time limits were missed by wide margins. Only in the proceeding to develop a proposed standard for swimming pool slides did the Commission come close to completing the proceeding within the 210 days allowed under the 1972 Act. Of course, the Commission "complied" with all the statutory time limits in the Act by

---

247. House Conference Report 94-1022 to accompany S.644, 94th Cong., 2nd Sess. 20-21 (1976), reprinted in (1976) U.S. Code Cong. & Ad. News 1509, 1538-39.

TIME CHART FOR DEVELOPMENT OF PROPOSED CONSUMER PRODUCT SAFETY STANDARDS

Stage of Proceeding and Applicable Time Limit: Standard	Submission of Offers (30 days) (non-extendable)	Commission Evaluation of Offers (30 days)	Development of Standard by Offeror (90 or 150 days)	Commission Evaluation of Offeror's Proposed Standard (60 days)	Total Elapsed Time from Section 7(b) Notice until Publication of Proposed Standard (210 or 270 days)
Swimming Pool Slides — (Section 7(b) notice on 10/29/74)	30 days	42 days	144 days	108 days (proposed standard published in Federal Register on 9/15/75)	324 days
Architectural Glazing Material (Section 7(b) notice on 5/28/74)	30 days	40 days	171 days	383 days (proposed standard published in Federal Register on 2/11/76)	624 days
Matchbooks (Section 7(b) notice on 9/4/74)	30 days	20 days	100 days	524 days (proposed standard published in Federal Register on 4/1/76)	624 days
Power Lawn Mowers (Section 7(b) notice on 7/7/74)	30 days	40 days	290 days	655 days (proposed standard published in Federal Register on 5/5/77)	1015 days
Television Receivers (Section 7(b) notice on 2/23/75)	30 days	49 days	413 days	(ongoing for 1 year as of July 6, 1977)	—
Public Playground Equipment (Section 7(b) notice on 3/7/75)	30 days	20 days	318 days	(ongoing for one year as of May 1, 1977)	—

*Notice:* The figures in this chart derive from an internal Commission study of the offeror process. The chronology of section 7 proceedings may also be found in Hearings on Department of Housing and Urban Development — Independent Agencies Appropriations for 1977 before a Subcommittee of the House Committee on Appropriations, 94th Cong., 2nd Sess. 20-26 (1976). The figures are unfortunately not broken down into days in the House Hearings.

extending them for "good cause" whenever a deadline approached. It is nevertheless apparent that the time limits did not serve as measuring rods or guideposts for each stage of the process. Any difficulty which arose in the development of a standard provided the basis for a "good cause" extension of the time limit. The majority of extensions were for periods of at least two or three months. In one instance the Commission extended at one time for an additional ten months the period during which it must either publish a proposed safety standard for power lawn mowers or terminate the section 7 proceeding by withdrawing its initial notice.<sup>248</sup>

There are of course a number of explanations for these delays. Management inefficiency is surely high on the list and may explain why in at least four of the proceedings it took the Commission longer to evaluate an offeror's proposed standard than it took the offeror to develop it. In addition, the Commission has often found an offeror's work product to be inadequate because it lacks the necessary technical and economic support and does not state the requirements of the proposed standard in performance terms, as required whenever feasible by section 7(a)(1) of the Act. In the television receiver proceeding, for example, the offeror submitted little more than a voluminous collection of standards previously developed by it.<sup>249</sup> Finally, the Commission has imposed unnecessary burdens on offerors by failing accurately to identify in the section 7(b) notice the risks of injury which the safety standard should address. As a result of the commission's over-inclusion of risks in its section 7(b) notices, offerors have been forced to address product hazards for which there is no injury data or no apparent remedy. Offerors have then complained that they must do too much work with too little in the way of resources<sup>250</sup> or information from the Commission. The American National Standards Institute and the American Society for Testing and Materials have both complained that the 150-day time limit in the 1972 Act proved to be much too short for the development by an offeror of an all-inclusive standard.<sup>251</sup> All these explanations for the delays that did occur are valid, but it is still significant that the extendable statutory time did not operate to force the Commission to overcome these difficulties.

---

248. In the Federal Register notice published on July 6, 1976, 41 FR 27997, the Commission extended the period until April 30, 1977. The offeror in the power lawn mower proceeding had submitted its proposed standard to the Commission one year earlier on July 17, 1975.

249. House Hearings on 1978 Appropriations, *supra* n.215, at 113 (testimony of Commissioner Pittle).

250. There is considerable controversy over the adequacy of Commission funding of offerors.

251. Hearings on Medical Devices Amendments of 1975 before the Subcommittee on Health and Environment of the House Committee on Interstate and Foreign Commerce, 94th Cong., 1st Sess. 451-461 (1975) (testimony of Association officials opposing similar time limits for the development of performance standards for medical devices).

### C. *Promulgation of Final Consumer Product Safety Rules*

Section 9(a) of the Consumer Product Safety Act provides that within 60 days of the publication of a proposed consumer product safety standard or consumer product ban, the Commission shall either promulgate a final rule or withdraw by rule the notice of the proceeding. The Commission may extend the 60-day time limit for good cause. While the Commission may utilize the informal rulemaking procedures in section 553 of the Administrative Procedure Act, it is required to give interested persons "an opportunity for the oral presentation of data, views or arguments in addition to an opportunity to make written submissions."<sup>252</sup>

The 60-day time limit is an unrealistic one for promulgating major rules. The Commission normally allows 60 days for public comment and schedules a public hearing mid-way in the comment period. The notice of proposed rulemaking routinely extends the deadline for promulgating the final rule until at least 30 days after the close of the comment period.<sup>253</sup> Subsequent extensions have consistently been made.

The following chart depicts the Commission's time record in promulgating final consumer product safety rules:

#### STAGE OF PROCEEDING AND APPLICABLE TIME LIMIT—PROMULGATION OF FINAL RULE (60 DAYS)

Standard or Ban		Public Participation
Swimming Pool Slides (safety standard)	126 days	Twenty-four written and seven oral presentations
Architectural Glazing Materials (safety standard)	329 days	Extensive
Matchbooks (safety standard)	395 days	226 written comments; two days of public hearing
Unstable Refuse Bins (product ban)	157 days	Sixteen written and oral comments; one day of public hearing
Lead Containing Paint and Consumer Products Bearing Lead Containing Paint (product ban)	386 days	fifty-eight comments
Power lawn mowers (safety standard)	Not yet promulgated (extended so far to cover 150 days)	public hearing in process

252. Section 9(a)(2), 15 U.S.C. §2058(a)(2) (Supp. II 1972).

253. See, e.g., the notice of proposed rulemaking on the power lawn mower standard, 42 FR 23052 (May 5, 1977).

Once again the statutory time limit has not served as an effective measuring rod for the time normally necessary to complete the task. The Commission has missed the 60-day goal by a wide margin in all six proceedings. While the time limit is an unrealistically tight one, the time actually taken by the Commission to promulgate final rules in the architectural glazing, matchbooks and lead proceedings far exceeds the 60-day norm. In these proceedings the level of public participation was far lower than in major rulemaking proceedings at FDA, OSHA, and EPA. The rulemaking records were accordingly much smaller. The number of issues in these proceedings are also fewer and they appear to be less complex. The Commission nevertheless consistently found it necessary to extend the time periods for completing the proceedings. The Federal Register notices are often uninformative on the reasons for the extensions but merely cite the complexity of the issues.<sup>254</sup>

#### CASE STUDY NO. 6

##### *The Occupational Safety and Health Administration (OSHA) in the Department of Labor — Promulgation of Occupational Safety and Health Standards*

In the Occupational Safety and Health Act of 1970,<sup>255</sup> Congress delegated to the Secretary of Labor authority to develop and administer uniform occupational safety and health standards. Section 6(b) of the Act<sup>256</sup> contains three separate time limits for the promulgation of standards. First, section 6(b)(1)<sup>257</sup> provides that if the Secretary requests the recommendations of an advisory committee after he has determined that a rule should be promulgated, the advisory committee shall submit to the Secretary its recommendations regarding the rule within 90 days from the date of its appointment or within such longer or shorter period prescribed by the Secretary, but in no event for a period which is longer than 270 days. Second, section 6(b)(2)<sup>258</sup> provides that when an advisory committee is appointed to make recommendations regarding a rule, the Secretary shall publish the proposed rule within 60 days after the submission of the advisory committee's recommendations or the expiration of the period prescribed by the Secretary for such submission. Third, section 6(b)(4)<sup>259</sup> requires that the Secretary shall promulgate, modify or revoke an occupational safety or

---

254. See, e.g., the Federal Register notice extending for seven and one-half months from September 15, 1976 to May 1, 1977 the period for promulgating a matchbook standard. The notice cites only the complexity of the issues without further specification. 41 FR 39041 (Sept. 14, 1976).

255. Pub. L. 91-596, 84 Stat. 1593, codified at 29 U.S.C. §§ 650 et seq. (1970).

256. 29 U.S.C. §655(b) (1970).

257. 29 U.S.C. §655(b)(1) (1970).

258. 29 U.S.C. §655(b)(2) (1970).

259. 29 U.S.C. §655(b)(4) (1970).

health standard, or make a determination that a standard should not be issued, within 60 days after the completion of any hearing held on a proposed standard. In addition, section 6(c) of the Act<sup>260</sup> authorizes the Secretary to promulgate emergency temporary standards, effective immediately upon publication in the Federal Register, if he determines that the publication of an emergency standard is necessary to protect employees from "grave danger." Upon the promulgation of an emergency temporary standard, the Secretary shall commence a rulemaking proceeding in accordance with section 6(b) and shall promulgate a permanent standard "no later than six months after publication of the emergency standard."<sup>261</sup>

The Act's legislative history discloses very little about the purpose of these statutory time limits. The debate over the Act's rulemaking provisions focused on the issues of who should promulgate rules and what procedures should be required for rulemaking. The Administration's bill, which passed the House provided for formal on-the-record rulemaking by an independent Board. The Senate bill, favored by the Democratic leadership in the Congress, delegated rulemaking authority to the Secretary of Labor and allowed him to utilize more informal rulemaking procedures. The Secretary could promulgate rules through informal notice and comment proceedings but was required in addition to hold a "public hearing" on "written objections" to a proposed rule if the person submitting an objection stated the "grounds" for the objection and requested a public hearing. The House Committee on Education and Labor had reported to the House a bill similar to that subsequently passed by the Senate but had been overruled by the full House. In the Conference Committee, however, the House receded and the Senate bill largely became law.

Both the Administration's bill and the bill supported by the Congressional leadership provided for the use of advisory committees composed primarily of representatives of industry and labor to develop safety and health standards. The bill reported by the House Committee on Education and Labor (H.R. 16785) required the Secretary to obtain the recommendations of an advisory committee before proposing a new standard.<sup>262</sup> While the Senate bill (S. 2193) allowed the Secretary to propose standard without first obtaining the recommendations of an advisory committee, the Senate Committee on Labor and Public Welfare expected that he would only do so where the subject matter was non-controversial.<sup>263</sup> The insertion of this new step in the rulemaking process evidently prompted the inclusion of statutory time limits. The addition of this "pre-rulemaking" stage for the development of proposed standards aroused concern that the promulgation of new standards would take too long. Time limits were therefore placed in what

---

260. 29 U.S.C. §655(c) (1970).

261. 29 U.S.C. §655(c)(3) (1970).

262. H.R. 91-1291, 91st Cong., 2nd Sess. (1970).

263. S.Rep. 91-1282, 91st Cong., 2nd Sess. (1970), reprinted in [1970] U.S. Code Cong. & Ad. News 5177, 5183

became section 6(b) of the Act to guarantee prompt decision-making by advisory committees and the Secretary in the development of safety and health standards.<sup>264</sup> Even with the addition of time limits, some Congressional critics believed it would take years to promulgate new standards through the cumbersome advisory committee process.<sup>265</sup> H.R. 16785 (the Committee bill) and H.R. 19200 (the Administration's bill passed by the House) both contained longer time limits than did the Senate bill (S. 2193) that was ultimately enacted. The House bills allowed an advisory committee a maximum period of one year and three months (rather than 270 days) to submit its recommendations to the Secretary (or independent Board in the case of the Administration's bill) and allowed the Secretary or Board four months (rather than 60 days) to respond to those recommendations. The legislative history does not indicate how these time frames were selected. The House receded generally to the rulemaking provisions in the Senate bill without any specific consideration of the differences in the time limits.<sup>266</sup>

The time limit in section 6(c)(3) for the promulgation of a permanent standard after the issuance of an emergency temporary standard has a different background and purpose. While the Committee reports do not address the purpose of the six months time limit in section 6(c)(3), it is apparent that the serious consequences of permitting the Secretary to issue an enforceable standard without any prior notice and hearing require that the Secretary promptly afford notice and hearing to interested persons. An emergency temporary standard, like other forms of summary action, is only valid for a limit period of time during which the agency must evaluate more precisely and with the aid of public input the need for a permanent standard.<sup>267</sup>

OSHA's experience in administering the 1970 Act has not fulfilled Congressional expectations for swift action in promulgating standards. Since the adoption in 1971 without public proceedings of a large batch of national consensus standards and established federal standards (primarily in the safety field), OSHA has completed less than a dozen major standard-setting proceedings and has encountered major delays in developing health standards on workers' exposure to carcinogens and other toxic substances.<sup>268</sup>

---

264. H.R. 91-1291, 91st Cong., 2nd Sess. 19 (1970) (Report of Committee on Education and Labor).

265. *Id.* (minority views favoring development and promulgation standards by independent Board).

266. Conf. Rep. 91-1765, 91st Cong., 2nd Sess. (1970), reprinted in [1970] U.S. Code Cong. & Ad. News 5228.

267. The Senate Committee on Human Resources recognized this rationale for the time limit in section 6(c) when it proposed in S. 717, 95th Cong., 1st Sess., a nine month time limit for the promulgation of a permanent mine safety or health standard after the issuance of an emergency temporary standard to protect miners from grave danger. S. Rep. 95-181, 95th Cong., 1st Sess. 24 (1977). S. 717, the Federal Mine Safety and Health Act of 1977, passed the Senate in late June 1977.

268. See generally, Comptroller General of the United States, *Delays in Setting Workplace Standards for Cancer-Causing and Other Dangerous Substances* (May 10, 1977) (hereinafter referred to as the Comptroller General's Report).

*The Causes of Delay at OSHA*—A large number of factors appear to have contributed to these delays, including industry resistance to change and bureaucratic lethargy or indifference in compelling it. While these factors are endemic in regulatory programs, a high dosage of both accompanied OSHA's efforts to secure safe and healthy workplaces for American workers. The resources assigned to the standard-setting task have also been surprisingly limited. In recent years less than eight percent of OSHA's overall budget has been allocated for the development and promulgation of mandatory safety and health standards.<sup>269</sup> The great majority of the agency's budgeted funds were allocated to enforcement.<sup>270</sup> From 1973 through 1976, the Office of Standards Development in OSHA employed a maximum of seventy professionals, forty in safety and twenty-nine in health. That Office has now been divided into separate Directorates for Health Standards Programs and Safety Standards Programs, but the number of professionals in the crucial health area had in fact decreased to twenty-six in June, 1977. The problem of resources is not entirely a budgetary one because there have consistently been vacant positions which OSHA has been unable to fill with competent safety or health experts. The Solicitor's Office, which supplies OSHA with legal assistance in promulgating standards, employs seventeen or eighteen attorneys in its standards division. These attorneys spend sixty to seventy percent of their time on standards development; the remainder of their time is apportioned between Freedom of Information Act requests, variance petitions, standards interpretation, and report preparation. In 1975, there were only thirteen lawyers, while in 1972 and 1973 the number of attorneys went as low as four and never exceeded seven.

The complexity of the rulemaking task also contributes importantly to the delays in promulgating safety and health standards. OSHA's proposed standard on lead,<sup>271</sup> for example, raises at least twelve major issues: 1) what is a safe level of exposure to airborne lead, 2) what is a safe level of lead in the bloodstream, 3) what is the relationship between these two levels, 4) which level is more significant healthwise, 5) what engineering controls are technologically feasible to control airborne lead, 6) what are the costs of these controls, 7) what is the economic burden of the standard on the affected industries, 8) what monitoring of the air will be required to enforce

---

269. The Department of Labor's 1978 budget request included \$8,692,000 for OSHA's program of safety and health standards out of a total OSHA budget of \$134,640,000. Hearings on Departments of Labor and Health, Education and Welfare Appropriations for 1978 before a Subcommittee of the House Committee on Appropriations, 95th Cong., 1st Sess. 1283, 1384 (1977). Congressional appropriations in prior years reflected a similar allocation. Those figures, of course, do not include appropriations for standard development by the National Institute for Occupational Safety and Health in the Department of Health, Education and Welfare.

270. OSHA requested in its fiscal 1978 budget \$94,756,000 for its compliance program. *Id.* at 1287.

271. OSHA proposed a lead standard in October, 1975. 40 FR 45934 (Oct. 3, 1975).



the standard, 9) what medical surveillance of employees will be required to enforce the standard, 10) what job protection will be given to employees who face transfer because of past exposure to lead, 11) what is a safe level of exposure to protect the human fetus in pregnant workers, and 12) what subclinical effects on human health are caused by exposure to lead. OSHA must resolve all of these issues and more (e.g., the environmental and inflationary impact of the standard) in the rulemaking proceeding. The issues are hotly controverted and cannot be disposed through boiler-plate language in the standard accompanied by a routine explanation in the preamble. Creative work and draftsmanship are necessary. Judicial decisions on informal rulemaking require that OSHA afford interested persons notice of the issues in a notice of proposed rulemaking and then respond to public comment on the issues in the statement of basis and purpose which accompanies the final rule.<sup>272</sup> As a result it is not unusual for preambles to proposed and final rules to exceed thirty or forty triple-spaced Federal Register pages. The preamble to the recently promulgated coke oven emissions standard consumed 43 Federal Register pages.<sup>273</sup> (On the other hand, the entire proposed lead standard required only 14 pages.)<sup>274</sup>

Congress has also imposed procedural requirements on standard setting by OSHA that exceed the minimum procedures required for informal rulemaking by sections 553 (b)-(d) of the Administrative Procedure Act. Section 6(b)(3) of the Act<sup>275</sup> provides that any interested person may file written objections to a proposed rule, stating the grounds therefore and requesting a public hearing on the objections. If objections are filed, the Secretary of Labor shall within 30 days after the final date for filing objections specify the time and place for the requested hearing. In section 6(f) of the Act,<sup>276</sup> Congress also provided, in connection with judicial review of standards, that the "determinations" of the Secretary shall be conclusive only if supported by substantial evidence on the record as a whole. OSHA implemented these two requirements by enacting regulations<sup>277</sup> which afforded objectors a hearing which the agency described as an informal or legislative-type hearing but which in fact contained some of the attributes normally associated with the adjudicatory or formal rulemaking model. The Department apparently believed that a more formal hearing was necessary in order to supply the reviewing court with a record for the application of the statutorily mandated substantial evidence test.<sup>278</sup> The

---

272. *National Welfare Rights Organization v. Mathews*, 533 F.2d 637 (D.C. Cir. 1976); *Rodway v. Department of Agriculture*, 514 F.2d 809 (D.C. Cir. 1973).

273. 41 FR 46742 (Oct. 22, 1976).

274. 40 FR 45934 (Oct. 3, 1975).

275. 29 U.S.C. §655(b)(3) (1970).

276. 29 U.S.C. §655(f) (1970).

277. 36 FR 17506 (Sept. 1, 1971), 29 CFR 1911.15 (1976).

278. *Industrial Union Department, AFL-CIO v. Hodgson*, 499 F.2d 467, 472-73 (D.C. Cir. 1974).

regulations therefore provided that a section 11 hearing examiner (now retitled an administrative law judge) with authority to administer oaths shall preside at the rulemaking hearing, that the presiding officer shall permit cross examination on "crucial issues", and that a verbatim transcript of the hearing shall be prepared. The Court of Appeals for the District of Columbia Circuit has upheld the Department's hybrid approach to rulemaking;<sup>279</sup> and it is unlikely that it would allow the Department to cut back on it in light of the recent judicial trend to impose additional procedural formalities on agency rulemaking which, unlike rulemaking at OSHA, is subject only to section 553(b)-(d) of the Administrative Procedure Act.<sup>280</sup>

Rulemaking hearings at OSHA have become increasingly protracted. While the public hearing in 1972 on the proposed asbestos standard lasted only four days, recent hearings have consumed three to six weeks. There were twenty-six days of testimony on the recently promulgated coke oven emissions standard and over thirty days on the proposed lead standard. The proposed cotton dust standard consumed over twenty hearing days while the sulfur dioxide and beryllium standards are likely to require somewhat fewer hearing days. These standards (except for the coke oven emissions standard) affected many industries and prompted objections from manufacturers and workers who wished to present the particular problems of their industry. OSHA is reluctant to limit or discourage public participation; and on major proposals such as the lead and the cotton dust standards it even holds regional hearings in areas of the country other than Washington. While reviewing courts have complained about mammoth hearing records cluttered with duplications in testimony and irrelevant exhibits,<sup>281</sup> lawyers from the Solicitor's Office who represent the Department of Labor at the hearings believe that it is generally not worth the effort to attempt to cut-off the presentation of a public participant. The Department has also weakened its authority to do so in a number of proceedings by itself scheduling a hearing at the time it publishes a proposal rather than awaiting the filing of objections. The hearing is therefore on the entire rule and is not limited to the specific grounds raised in the objections. While the Department's policy does broaden the scope of the hearing, it also may serve to expedite its scheduling since there is no need to await the end of the initial comment period before setting a hearing date. This approach makes sense on major or controversial proposals where OSHA anticipates a broad range of objections.

---

279. *Id.*

280. On hybrid rulemaking, see *NRDC v. NRC*, 547 F.2d 633 (D.C. Cir. 1976); Williams, "Hybrid Rulemaking" under the Administrative Procedure Act: A Legal and Empirical Analysis, 42 *U. Chi. L. Rev.* 401 (1975).

281. Justice Clark complained when reviewing the vinyl chloride standard: "The examination of the 4000 page record in this case has been a prodigious task, aggravated by duplication of testimony, irrelevant exhibits and letters, almost illegible copies of documents, and a general blunderbuss approach in petitioner's [the industry's] briefs." *Society of the Plastics Industry v. OSHA*, 509 F.2d 1301, 1303 (2nd Cir. 1975).

*The Impact of the Statutory Time Limits*—The statutory time limits in section 6(b) of the Act have had at best a marginal impact on reducing delay in rulemaking proceedings that are not proceeded by the issuance of an emergency temporary standard.<sup>282</sup> OSHA has found the statutory deadlines difficult to meet and has not normally met them. Proceedings to promulgate permanent standards after the issuance of an emergency temporary standard provide a partial exception to these generalizations. In those proceedings OSHA has found the time limits in section 6(b) and in section 6(c)(3) difficult to meet but has experienced greater success in complying with them.

The statutory time limits in section 6(b) have threatened to undermine OSHA's efforts to determine its own priorities by forcing it to concentrate its resources on rulemaking proceedings that are subject to statutory deadlines. This danger has remained more potential than real largely because OSHA has not complied with statutory time limits at the expense of what it believes to be higher priority proceedings. While all rulemaking at OSHA is subject to section 6(b) of the Act, the time limits in that section do not apply to all stages of the rulemaking process. The focus of the time limits is on the completion of rulemaking proceedings and they do not affect the timing of OSHA's decision to initiate rulemaking or the amount of time OSHA allows for public hearing and comment on a proposed rule. Under section 6(b), the Secretary may commence the development of a standard or propose a standard whenever on the basis of the information available to him he determines that a rule should be promulgated in order to serve the objectives of the Act. Section 6(g) of the Act further recognizes the Secretary's discretion in initiating rulemaking proceedings. That section provides:

In determining the priority for establishing standards under this section, the Secretary shall give due regard to the urgency of the need for mandatory safety and health standards for particular industries, trades, crafts, occupations, businesses, work places or work environments. . . .<sup>283</sup>

At the very least this provision authorizes the Secretary to make choices about which standards to develop first and which standards to defer.<sup>284</sup> Similarly, while section 6(b)(3) of the Act requires the Secretary within 30 days after the close of the period for filing objections to a proposed standard to schedule a public hearing on the objections, there are no time constraints on when he schedules the hearing or how long he allows it to continue.

---

282. Professor Currie reached a similar conclusion in his recent study of OSHA. Currie, OSHA, 1976 *Am. Bar. Foundation Res. J.*, 1107, 1125 n.107.

283. Section 6(g), 29 U.S.C. §655(g) (1970).

284. *National Congress of Hispanic American Citizens (El Congreso) v. Usery*, 554 F.2d 1196 (D.C. Cir. 1977). See text at n.58 for further discussion of section 6(g).

The worst delays at OSHA have occurred at the stage of the initial decision to commence rulemaking and at the hearing stage. Neither of these stages is subject to a statutory time limit. This phenomenon indicates that the statutory time limits may shift delays from those stages of the proceeding subject to a statutory deadline to those that are not so subject. While the time limits may expedite those phases of rulemaking to which they directly apply, they have little appreciable effect on the overall process.

OSHA normally initiates standard development in response to a criteria document containing a recommended standard prepared by the National Institute for Occupational Safety and Health (NIOSH) in the Department of Health, Education and Welfare. There is no time limit during which OSHA must respond to a NIOSH criteria document, and the Comptroller General has found that some of the longest delays in the standard-setting process occurred at this juncture. As of September 30, 1976, NIOSH had submitted to OSHA criteria documents with recommended health standards on fifty-three substances. OSHA had promulgated final standards on only two of these substances (asbestos and vinyl chloride) and had proposed standards for nine of the remaining fifty-one substances. OSHA had had the remaining fifty-one criteria documents for an average of eighteen months. In the nine instances where OSHA had proposed but not yet promulgated a standard, it had taken an average of twenty-six months from the receipt of the criteria document to the publication of OSHA's proposal.<sup>285</sup> Since the cut-off date of the Comptroller General's study, OSHA has promulgated one standard (coke oven emissions) and proposed two additional standards (cotton dust and benzene) for which there are NIOSH criteria documents.

There is likewise no time limit applicable to OSHA's making of the grave danger determination that provides the basis for the issuance of an emergency temporary standard. Courts have indicated that OSHA may take a considerable period of time to determine whether or not employees are subject to grave danger from exposure to substances that are toxic or physically harmful.<sup>286</sup> The preparation of an emergency temporary standard is in fact time-consuming because the courts have required that a statement of reasons accompany the standard and that the record contain substantial evidence to support OSHA's grave danger determination.<sup>287</sup> However, the actual drafting of the emergency standard and accompanying documentary support can be accomplished within a comparatively brief time span once OSHA decides to act. In the case of benzene, for example, NIOSH and OSHA had studied the relationship between exposure to benzene and leukemia for many years. On October 27, 1976, NIOSH

---

285. Comptroller General's Report, *supra* n.268, at 11-12.

286. *Dry Color Mfrs. Ass'n v. Department of Labor*, 486 F.2d 98, 108 n.15 (3rd Cir. 1973).

287. *Florida Peach Growers Ass'n v. Department of Labor*, 489 F.2d 120 (5th Cir. 1974) (pesticides standard).

strongly recommended that OSHA promulgate an emergency temporary standard on exposure to benzene. OSHA remained unconvinced on the need for an emergency standard until sometime in the early spring of 1977 when OSHA officials learned of the results of a new epidemiological study which established an incidence of leukemia in workers exposed to benzene at a particular plant at least five times the expected incidence. OSHA then promptly issued an emergency standard on April 29, 1977.<sup>288</sup> A similar chronology accompanied the issuance of an emergency standard on exposure to vinyl chloride in late March, 1974.<sup>289</sup> A number of specific items of new information prompted the issuance of the standard after years of study and a growing awareness of the risks posed by vinyl chloride. In both instances OSHA assigned priority to the task of drafting an emergency standard and completed it within a month.

Significant delays have also occurred at the hearing stage. In October and November 1975 OSHA proposed six major health standards (beryllium,<sup>290</sup> lead,<sup>291</sup> toluene,<sup>292</sup> trichloroethylene,<sup>293</sup> sulfur dioxide<sup>294</sup> and ammonia<sup>295</sup>). The notices of proposed rulemaking solicited public comment but did schedule in advance a public hearing on the anticipated objections. In each proceeding OSHA extended the initial 60 days allowed for public comment for an additional 30 to 60 days. Each proposed standard prompted a significant number of objections and requests for a public hearing (e.g., forty-five in the beryllium proceeding). However, no public hearings were held on these standards until the early spring of 1977 when OSHA conducted lengthy hearings in Washington, St. Louis and San Francisco on the proposed lead standard. During the summer of 1977 OSHA held in Washington shorter hearings lasting several days on the proposed sulfur dioxide and beryllium standards. As of September, 1977, OSHA had not yet scheduled hearings on the remaining standards and had closed the hearing record only on the lead standard.

These delays are attributable in part to the amount of work that OSHA must do in preparation for a public hearing. The primary cause for the delays, however, was the new requirement that OSHA evaluate the inflationary impact of its standards. Executive Order 11821, issued in late 1974, required OSHA and other executive branch agencies to identify major proposals that may have a significant impact on inflation and to prescribe procedures for evaluating that impact. OSHA had not evaluated the inflationary impact of the major health standards it proposed in 1975. It did not

---

288. 42 FR 22515 (May 3, 1977). The effective date of the standard was May 21, 1977.

289. 39 FR 13944 (April 4, 1974).

290. 40 FR 48814 (Oct. 17, 1975).

291. 40 FR 45934 (Oct. 3, 1975).

292. 40 FR 46206 (Oct. 6, 1975).

293. 40 FR 49032 (Oct. 20, 1975).

294. 40 FR 54520 (Nov. 24, 1975).

295. 40 FR 54684 (Nov. 25, 1975).

schedule hearings on the six standards it proposed in October and November 1975 primarily because it realized that hearings should await the preparation of an inflationary impact statement. OSHA had to reopen the hearings that had already been held on three major health standards (noise, inorganic arsenic, and coke oven emissions) proposed by it in late 1974 and early 1975 in order to allow public participation on the issue of inflationary impact. It took OSHA an average of twelve months to complete its first four inflationary impact statements on its standards for coke oven emissions, cotton dust, inorganic arsenic and noise.<sup>296</sup> OSHA has required even longer periods of time to complete inflationary impact statements for the six health standards first proposed in October and November 1975 that are just now going to hearing.

*Time Limits Applicable to Rulemaking Following the Promulgation of an Emergency Temporary Standard*—Once OSHA issues an emergency standard, section 6(c)(3) of the Act requires that it promulgate a permanent standard within six months. OSHA has so far issued only six emergency standards for 1) asbestos, 2) organophosphorous pesticides, 3) a group of fourteen carcinogens, 4) vinyl chloride, 5) commercial diving and 6) benzene. OSHA subsequently promulgated permanent standards for asbestos, thirteen of the fourteen carcinogens, vinyl chloride and commercial diving. The benzene proceeding is now in process; and October 29, 1977 is the deadline for the promulgation of a permanent benzene standard. OSHA met the statutory deadline for promulgating permanent standards for asbestos and vinyl chloride and missed it by only a month in the proceeding involving the fourteen carcinogens. OSHA personnel expect to meet the deadline for promulgating the benzene standard. The commercial diving standard was invalidated on judicial review prior to the expiration of the six month period.<sup>297</sup> While OSHA ultimately promulgated a diving standard thirteen months after the issuance of the emergency standard,<sup>298</sup> the statutory time limit in section 6(c)(3) did not apply to the proceeding because OSHA had abandoned any effort to enforce the emergency standard after it was invalidated by the court. OSHA also abandoned its emergency standard for pesticides and successfully defended a suit to require it to promulgate a permanent standard on the grounds that EPA had exclusive jurisdiction to regulate pesticides.<sup>299</sup>

OSHA's success in complying with the six month time limit in section 6(c)(3) is largely attributable to crash efforts to complete the proceedings on time. Very little is done to change the decisional process for rulemaking except greater efforts are made to maintain control over the public hearing.

---

296. Comptroller General's Report, *supra* n. 268, at 64.

297. *Taylor Diving and Salvage Co. v. Department of Labor*, 536 F.2d 819 (5th Cir. 1976).

298. 42 FR 37560 (July 22, 1977).

299. *Organized Migrants v. Brennan*, 520 F.2d 1161 (D.C. Cir. 1975).

While it is evidently possible to complete the complex standard-setting process under section 6(b) within six months, it can only be done if there is a significant commitment of agency resources. It is necessary to assign full time to the rulemaking proceeding two to four health officers from OSHA itself and two or three attorneys from the Solicitor's Office. These individuals must draft a notice of proposed rulemaking,<sup>300</sup> conduct the public hearing, draft issue papers for internal agency review, and prepare a final standard. While working on a permanent standard, they must also respond to questions and provide interpretative advice on the emergency standard. It is also likely that they will be asked to assist in the Department's defense in the courts of the emergency standard.

The Department of Labor has allocated these resources to rulemaking proceedings subject to the time limit in section 6(c)(3) largely because of its interpretation that an emergency temporary standard expires at the end of the six month statutory period. At that point the agency lacks an enforceable standard if it has not yet promulgated a permanent standard.<sup>301</sup> While this "sanction" for missing a statutory deadline has effectively spurred OSHA to meet it, it also explains in part the agency's limited use of emergency temporary standards. OSHA does not issue an emergency standard until it has done the front-end work sufficient to defend the standard in court and to complete the standard-setting process within six months. Otherwise OSHA enforcement personnel are likely to find themselves at the end of a limb which the statutory time limit proceeds to saw off. OSHA has announced its intention to expand its use of section 6(c) by issuing emergency temporary standards immediately upon NIOSH's classification of a substance as a confirmed carcinogen.<sup>302</sup> Department officials frankly concede, however, that this program cannot be accomplished with existing resources.

*Time Limits Applicable to Rulemaking not Preceded by an Emergency Temporary Standard*—Section 6(b)(3) requires that the Secretary initiate a rulemaking proceeding by publishing a proposed rule within 60 days after the submission of an advisory committee's recommendations. It is unclear whether the Secretary may respond to a committee's recommendations by proposing not to issue a rule. The purpose of the statutory time limit is also

---

300. While section 6(c)(3) provides that the emergency standard shall serve as the proposed rule, OSHA normally finds it necessary to provide additional notice of the issues by publishing a notice of proposed rulemaking a month or so after the issuance of an emergency standard. The proposed permanent standard usually is stricter than the emergency standard.

301. The Comptroller General has recently questioned the Department's interpretation. See Comptroller General's Report, *supra* n. 268, at 30-31. While the legislative history of the 1970 Act is inconclusive on this issue, the Senate Committee on Human Resources clearly stated its interpretation of the time limit in section 6(c)(3) when it imposed a similar nine-month time limit on the promulgation of mine safety and health standards. See n. 267, *supra*. The Committee clearly stated at p. 24 that an emergency temporary standard was to remain in effect for only nine months regardless of whether the agency promulgated a permanent standard during that period.

302. 3 CCH *Employment Safety and Health Guide* ¶10, 745 (Jan. 24, 1977).

unclear. The Secretary is not required by law to request the recommendations of an advisory committee except with respect to construction standards. He also controls the timing of any referral to an advisory committee. Why then must he respond to the recommendations of a committee by publishing a proposed rule within 60 days? That time limit is often difficult to meet because the recommendations of an advisory committee are not in the form of a proposed standard and require substantial rewriting by the OSHA project officer. Advisory committee recommendations also do not consider the compliance aspects of rulemaking, nor do they include the economic or environmental analysis required for a notice of proposed rulemaking. One to two additional months of drafting work are usually required to transform an advisory committee recommendation into a proposed rule. The proposed rule is then subject to technical compliance and legal review before it is signed by the Assistant Secretary and published in the Federal Register.

While it is possible to complete these tasks within 60 days if OSHA has closely monitored the work of the advisory committee and done some advance work before formally receiving the committee's recommendations, it is hard to justify priority treatment for this segment of the rulemaking process. Recommendations of advisory committees vary widely in quality, thoroughness of preparation, and importance. Of course, OSHA should not appoint an advisory committee unless it is willing and ready to proceed with rulemaking, but many in the Department do not believe that OSHA should be forced in all instances to publish a proposed rule within 60 days after receiving the recommendations of an advisory committee. OSHA's much criticized proposal on field toilets and washing facilities for agricultural workers was an ill-considered response to recommendations of an over exuberant Agricultural Advisory Committee.

The problems created by the 60-day statutory time limit in section 6(b)(1) do not encourage the use of advisory committees, and OSHA presently makes only limited use of them. There are only two standing advisory committees (construction and agriculture); and no more than three ad hoc (specially appointed) advisory committees (hazardous materials labelling, coke oven emissions and noise) have functioned in recent years. There are no advisory committees working on new health standards. The Hazardous Materials Labelling Advisory Committee submitted its recommendations to OSHA in June, 1975 but two years later the agency, which assigned the matter a low priority, still had not published a proposed standard. Public Citizen has now petitioned OSHA to do so, but interestingly it did not cite the statutory time limit in its petition. The agency, on the other hand, did assign top priority to the development of its coke oven emissions standard<sup>303</sup> and published a proposed standard exactly two

---

303. For the chronology of the coke oven emissions standard, see the preamble to the final standard in 41 FR 46742 (Oct. 22, 1976).



months (sixty-five calendar days) after receipt of the recommendation of the Coke Oven Emissions Advisory Committee.<sup>304</sup>

Section 6(b)(1) limits the work life of an advisory committee to a maximum period of 270 days. The section provides that the advisory committee shall submit its recommendations within 90 days of its appointment but that the Secretary may extend that period to no more than 270 days. This time limit is also a difficult one to meet. Logistical problems aggravate the situation. The part-time representatives of industry and labor who serve on advisory committees must be collected from around the country and must be supplied with adequate information. OSHA has experienced difficulty in extracting timely recommendations from its advisory committees. Committee members have trouble assembling at one time and complain that they do not have enough information or are unable to agree on recommendations. Of course, the deadline can be met; and the Coke Oven Emissions Advisory Committee submitted its recommendations within the 270 days allowed to it. The statutory time limit also gives OSHA increased leverage in demanding prompt action from its advisory committees.

The time limit which creates the most serious problem in the utilization of advisory committees is the six month time limit in section 6(c)(3) for the promulgation of a permanent standard after the issuance of an emergency temporary standard. It is very difficult to compress within that period a referral to an advisory committee, which the courts have held must precede the publication of a proposal for public comment.<sup>305</sup> When OSHA issued an emergency standard for commercial diving, it was required by law to obtain the recommendations of the Construction Advisory Committee on a permanent standard. The delays involved in obtaining the committee's recommendations were one of the reasons that OSHA personnel did not anticipate meeting the tight section 6(c)(3) deadline in that proceeding. Missing the deadline was averted solely by reason of a court decision which invalidated the emergency standard prior to the expiration of the six months period.

Section 6(b)(4) specifically provides a deadline for the completion of rulemaking proceedings. The Secretary shall issue a final rule, or make a determination that a rule should not be issued, within 60 days after the close of the comment period or within 60 days after the close of any public hearing on the proposed rule. OSHA's regulations provide that the 60-day time limit is triggered by the close of the comment period if there is no public hearing or upon certification of the hearing record by the presiding officer to the Assistant Secretary if there is a public hearing.<sup>306</sup> The latter event may take place two to three months after the close of the hearing itself since there is a period allowed for post hearing comments and briefs and for the

---

304. 40 FR 32268 (July 31, 1973).

305. *Synthetic Organic Chemical Mfrs. Ass'n. v. Brennan*, 506 F.2d 385 (3rd Cir. 1974).

306. 29 CFR 1911.18 (1976).

presiding officer to assemble the record.<sup>307</sup> While the triggering event is potentially subject to manipulation by the agency, there is no evidence that this has occurred. The presiding officer does announce in advance when the period of post hearing comment ends and when he expects to certify the record. This announcement affords the Department some lead time in excess of the statutory 60 days to commence work on the final rule.

With the advantage of this lead time it is at least possible to meet the 60-day time limit for promulgating a final rule, but it is unlikely that OSHA will ever do so for a major standard. In the coke oven emissions and lead proceedings, the transcripts exceeded five thousand pages. There were also 143 written comments on the coke oven proposal and nearly three hundred on the lead proposal. Many of the comments were lengthy and contained detailed, well-articulated objections. Four safety officers and three attorneys had worked nearly full time on the lead standard ever since the drafting of a notice of proposed rulemaking in the fall of 1975. There was a similar commitment of resources to the coke oven emissions standard. The safety officers are responsible for drafting issue papers responding to the issues raised by the comments. These drafts are reviewed by the Associate Solicitor and the Assistant Secretary for Occupational Safety and Health. The amount of writing involved is very great, but the task can be completed within the statutory time limit if the draftsmen have taken advantage of the lead time afforded them and if all goes smoothly.

The time limit in section 6(b)(4) has had a significant impact in expediting the promulgation of final rules. After the hearing ends Department officials formulate a schedule for meeting the deadline to which they strive to adhere. It is nearly inevitable, however, that snags will develop. The Assistant Secretary normally wishes personally to acquaint himself with a major standard because he is expected to defend it publicly. If he or his staff questions the resolution of a particular issue or the reasons advanced in support of it, there must be a referral back to the original draftsmen or technical people. Rewriting of the preamble of the rule may also be required to state clearly and simply the complex issues involved. Despite herculean efforts by the agency, there will be proceedings which the agency cannot complete in a manner satisfactory to it within the requisite 60 days. The coke oven emissions proceeding, for example, took almost three months to complete after the presiding officer certified the record to the Assistant Secretary. In that proceeding there was no question of the Department's commitment to promulgate a standard promptly and, if at all possible,

---

307. In the coke oven emissions proceeding, the principal hearing ended January 8, 1976 but the presiding officer did not certify the record until July 28, 1976. Part of the delay is attributable to the fact that OSHA's inflationary impact statement was not ready for inclusion in the record until March 12, 1976. A second, briefer public hearing was held on the statement in mid-May. In the more typical lead proceeding, there was only a two month gap between the completion of the hearing and the certification of the record.

within the statutory time limit. There was also the overriding concern that after expending years of effort on the development of the standard the agency finish the job right even if it took a few more days than Congress saw fit to allow. An analogous situation has developed in the lead proceeding where the Assistant Secretary has decided to reopen the proceeding for additional comment and a public hearing solely on the issue of the appropriate job protection for workers transferred from areas of lead exposure under the standard's medical surveillance program.<sup>308</sup> The reopening occurred after the expiration of the 60-day time limit for promulgating a final rule.

*Potential Distortion of Agency Priorities*—Each of the three statutory time limits in section 6(b) applies to a particular stage of rulemaking. Their focus is on the completion of that stage; an advisory committee must make its recommendations within 270 days after the Secretary requests it to do so; the Secretary must propose a rule within 60 days after the submission of an advisory committee's recommendations; and the Secretary must promulgate a rule within 60 days after the close of the rulemaking record. There is no time limit or series of time limits that control the overall process from OSHA's receipt of a NIOSH criteria document containing a recommended standard until OSHA's promulgation of a final standard. The longest delays take place in those segments not governed by a statutory time limit. Two years or more may elapse between OSHA's receipt from NIOSH of a recommended standard and its decision to propose a standard or request an advisory committee to recommend a standard. Likewise, the hearing process itself may consume one or two years from the publication of a proposal to the closing of the record. The statutory time limits have apparently operated to shift delays from one stage of the process to another without necessarily expediting the overall process.

To the extent that this shift has occurred, one might ask why it is desirable to give priority to those stages of the proceeding subject to statutory time limits. While it is desirable for an agency to complete a rulemaking proceeding once it has devoted a substantial amount of time and resources to the proceeding, other priorities may suddenly arise. NIOSH or some other outside group may inform OSHA that there is alarming new evidence on the carcinogenicity of a substance widely found in workplaces. OSHA must respond promptly by determining whether there is a grave danger to justify an emergency standard. It also must consider the need to propose a health standard and what standard to propose. If one assumes that all the health and safety officers and attorneys at OSHA are fully employed, some work is going to have to stop for a time in order to accommodate the new priority. The Assistant Secretary might determine that the best way to free an adequate number of competent persons would be to

---

308. 42 FR 56547 (Sept. 16, 1977).

withdraw them from the lead proceeding even though this would delay by a month or so the final promulgation of the lead standard. While the Assistant Secretary might withdraw personnel from a standard that was then still in hearing and not subject to a statutory time limit (e.g., the sulfur dioxide or noise standard), this action might disrupt a previously announced schedule for public participation. Should a statutory time limit requiring the promulgation of a final rule within 60 days after the close of the record preclude OSHA from determining that the earlier stages of another proceeding deserved a higher priority? Common sense says no.

The situation described above is a hypothetical one but it closely resembles an actual situation which confronted OSHA in 1974 and 1975. During those years in proceedings to develop agricultural standards OSHA missed by wide margins a significant number of statutory deadlines. In late 1972, for example, the Agricultural Advisory Committee recommended a roll over protection standard but OSHA did not propose the recommended standard until February 4, 1974<sup>309</sup> — approximately eleven months after the end of the statutory 60-day period. OSHA promulgated the final rule on April 25, 1976<sup>310</sup> — about six months late. Similar delays occurred in the promulgation of the farm machinery guarding standard and in various stages of the yet unpromulgated noise, nuisance dust, field sanitation, and personal protective equipment standards for agricultural workers. The Raza Association of Spanish Speaking Americans (subsequently renamed the National Congress of Hispanic American Citizens) sued to enforce the statutory time limits and obtained a decree from the District Court in the District of Columbia ordering the Secretary of Labor to comply with them.<sup>311</sup> The Court of Appeals reversed,<sup>312</sup> adopting the Department's contention that it retained discretion to order its own priorities. The Department had argued that during 1974 and 1975 it had rationally assigned priority to vinyl chloride and other suspected carcinogens and therefore had deferred further action on the development of agricultural standards. The court held that the Secretary had authority rationally to alter priorities and reallocate resources even if his actions resulted in missing statutory deadlines. The court based its holding on section 6(g) of the Act,<sup>313</sup> which it interpreted to authorize the Secretary to determine priorities not only for the initiation of standard-setting proceedings but also for their completion. While relying on section 6(g) for its holding, the court also stated more broadly that it would make "an absurdity of the Act and a fool out of Congress" to interpret the Act to require literal compliance with the time limits

---

309. 39 FR 4535 (Feb. 4, 1974).

310. 40 FR 18253 (Apr. 25, 1975).

311. *Raza Association of Spanish Speaking Americans v. Brennan*, 425 F.Supp. 900 (1976).

312. *National Congress of Hispanic American Citizens (El Congreso) v. Usery*, 554 F.2d 1196 (D.C. Cir. 1977) (opinion by Justice Clark).

313. See text at n. 283, *supra*.

in section 6(b) regardless of the consequences to higher priority items.<sup>314</sup> The court also echoed a fear repeated many times by OSHA officials that the initiation of rulemaking would be discouraged if the statutory time limits precluded the deferral of final action on a rule once the process was inexorably set into motion.

*National Congress* (El Congreso) thus limits the relief available to aggrieved persons if OSHA misses a statutory deadline. A court may not simply order OSHA to comply with the statutory time limits but must inquire whether OSHA has "honestly and fairly"<sup>315</sup> exercised its discretion in ordering its priorities. The *National Congress* court required OSHA to submit to the District Court reports and timetables on its processing of the remaining agricultural standards. If the District Court was not satisfied with the sincerity of the agency's efforts, "it should take such action as the circumstances require."<sup>316</sup> The relief available does not seem much broader than that available under section 706(1) of the Administrative Procedure Act when a court compels agency action unlawfully withheld or unreasonably declared. Of course, the *National Congress* court treated OSHA's missing a statutory deadline as sufficient to trigger the judicial scrutiny of the agency's performance without any further inquiry into the unlawfulness or unreasonableness of the delay.

*New Legislation on Mine Safety and Health*—Congress recently reviewed the statutory time limits in the Occupational Safety and Health Act of 1970 when both Houses considered various bills transferring responsibility for mine safety and health from the Department of the Interior to the Department of Labor. Under these bills a new Assistant Secretary of Labor for Mine Safety and Health would have authority to promulgate safety and health standards for mines in accordance with procedures similar to those now followed by OSHA. S.1302, which died in the Senate at the close of the Second Session of the 94th Congress, adopted the time limits found in the present section 6(b) of the Occupational Safety and Health Act. H.R. 13555, which passed the House in the 94th Congress on July 28, 1976, did not contain any time limits for agency action. S.717, which was introduced in the 95th Congress and passed the Senate in late June, 1977, retains the statutory time limits but makes a number of significant changes. Section 102(b) extends the time limit for promulgating a permanent standard after the issuance of an emergency temporary standard from six to nine months, while section 102(a)(4) extends the time limit for promulgating a final standard from 60 to 90 days after the close of the record. Section 102(a)(1), on the other hand, reduces the maximum period the Secretary may allow an advisory committee to make its recommendations from 270 to 180 days. More important than these minor changes are the bill's imposition of time limits on other stages of the rulemaking process. If NIOSH

---

314. *National Congress*, *supra* n. 312, at 1199.

315. *Id.* at 1200.

316. *Id.*

recommends a standard, section 102(a)(1) provides that the Secretary of Labor must within 60 days refer the matter to an advisory committee, publish a proposed standard, or publish reasons for a determination not to issue a proposed standard. Likewise, section 102(a)(3) provides that any public hearing on a proposed standard must commence within 60 days after the publication of the notice of proposed rulemaking. These new time limits apply to stages in the rulemaking process where OSHA has encountered serious delays.

These bills reflect Congressional dissatisfaction with the Department of the Interior's administration of the Federal Metal and Non-Metallic Mine Safety Act of 1966<sup>317</sup> and the Federal Coal Mine Health and Safety Act of 1969.<sup>318</sup> In the opinion of the Senate Committee on Human Resources<sup>319</sup> and the House Committee on Education and Labor,<sup>320</sup> the Department of the Interior had not been sufficiently active in developing safety and health standards to protect miners. The Senate Committee stated: "The nearly non-existent rate for promulgating improved health standards under the Coal Act has been a great disappointment to the Committee, and demonstrates that the procedure for promulgating health standards is one of the basic flaws in the standard-making mechanism of that Act."<sup>321</sup> The Committee responded by shifting rulemaking authority to an agency that it believed would be more responsive to concern over the safety and health of miners and by imposing statutory time limits on most all stages of the rulemaking process.

#### CASE STUDY NO. 7

##### *National Highway Traffic Safety Administration (NHTSA) in the Department of Transportation — Rulemaking and Defect Petitions*

In 1974, Congress amended the National Traffic and Motor Vehicle Safety Act of 1966 by adding a new section 124<sup>322</sup> on agency responsibility in granting or denying petitions. The new section covers two categories of petitions: petitions to commence a rulemaking proceeding under section 103 of the Act<sup>323</sup> to issue, amend or revoke a federal motor vehicle safety standard; and petitions to commence a defect proceeding under section 152(b) of

317. Pub. L. 89-577.

318. Pub. L. 91-153.

319. S. Rep. 95-181, 95th Cong., 1st Sess. (1977) (Report on S. 717, Federal Mine Safety and Health Act of 1977).

320. H. Rep. 95-312, 95th Cong., 1st Sess. (1977) (Report on H.R. 4287, the Federal Mine Safety and Health Act of 1977). H.R. 4287 is a revised version of H.R. 16555 which passed the House in the previous session.

321. S. Rep. 95-181, *supra* n. 318, at 15.

322. 15 U.S.C. §1410a (Supp. V 1975). The 1974 amendments (Pub. L. 93-492) are referred to as the Motor Vehicle and Schoolbus Safety Amendments of 1974.

323. 15 U.S.C. §1392 (1970).

the Act<sup>324</sup> to determine whether any motor vehicle or item of replacement equipment does not comply with an applicable federal motor vehicle safety standard or contains a defect which relates to vehicle safety. NHTSA<sup>325</sup> must grant or deny all such petitions within 120 days after filing. If NHTSA grants a petition, it shall “promptly commence the proceeding requested in the petition.”<sup>326</sup> If it denies the petition, it shall publish in the Federal Register its reasons for the denial.<sup>327</sup>

The legislative history of section 124 gives no clear indication why Congress required NHTSA to respond to petitions within 120 days. The Committee reports simply summarize the section. The House Committee on Interstate and Foreign Commerce, which drafted the 1974 amendments to the National Traffic and Motor Vehicle Safety Act, did criticize in other portions of its report the delays or “slippage” that often occurred between the initiation of rulemaking and the effective date of a motor vehicle safety standard.<sup>328</sup> Section 202 of the 1974 amendments<sup>329</sup> responded to this concern by requiring NHTSA to propose within six months and promulgate within fifteen months motor vehicle safety standards for school buses in eight specific performance areas. The new standards were to go into effect within twenty-four months.<sup>330</sup> Section 124, however, only dealt with NHTSA’s responsibility to respond to petitions to commence proceedings and did not impose time limits for the completion of proceedings. On the former matter, the House Committee had brought to its attention one instance where the Insurance Institute for Highway Safety had received a brushoff from NHTSA after it had devoted more than two months to the preparation of a petition to upgrade the existing motor vehicle safety standard for fuel tanks.<sup>331</sup>

324. 15 U.S.C. §1412(b) (1970).

325. Section 124 assigned this responsibility to the Secretary of Transportation, who has in turn delegated it to the Administrator of NHTSA. 49 CFR 1.51 (1976).

326. Section 124(c), 15 U.S.C. §1410a(d) (Supp. V 1975).

327. *Id.*

328. H.R. 93-1191, 93rd Cong., 1st Sess. 1974, reprinted in (1974) U.S. Code Cong. & Ad. News 6046.

329. 15 U.S.C. §1392(i)(1)(A) (Supp. V 1975).

330. NHTSA successfully met these deadlines for proposing and promulgating school bus safety standards. See 40 FR 48352 (Oct. 15, 1975); 41 FR 2391 (Jan. 16, 1976); and 41 FR 3872 (Jan. 27, 1976). NHTSA was able to do so because it had either issued or was in the process of developing standards in seven of the eight specified areas before the 1974 amendments were enacted. See Hearings on H.R. 9291 (National Traffic and Motor Vehicle Safety Act Amendments of 1976) before the Subcommittee on Consumer Protection and Finance of the House Committee on Interstate and Foreign Commerce, 94th Cong., 2nd Sess. 203 (1976) (testimony of Administrator James Gregory). In other words, NHTSA had already done the front-end work in developing the standards and Congress only acted to force their timely promulgation. Congress itself acted in 1976 to delay still further the effective date of the new rules.

331. Hearings on Amendments to the National Traffic and Motor Vehicle Safety Act before the Subcommittee on Commerce and Finance of the House Committee on Interstate and Foreign Commerce, 93rd Cong., 1st Sess. 969ff (1973).

Section 124 became effective on December 22, 1974. During the fourteen months between that date and early March, 1976, NHTSA received twenty-five rulemaking petitions and seven defect petitions.<sup>332</sup> Roughly the same rate of filings has continued into 1977. Approximately one-third of the rulemaking petitions are granted. No defect petitions were granted until May, 1977 when NHTSA granted two.<sup>333</sup> The Technical review of rulemaking petitions is done by the two standard-setting offices (the Office of Crash Avoidance and the Office of Crashworthiness) within NHTSA's Division of Motor Vehicle Programs, while defect petitions are reviewed by the Office of Defect Investigation within the same division. Surprisingly, almost all of the rulemaking petitions have been filed by manufacturers of vehicles and automotive equipment who are seeking technical amendments to existing standards. Defect petitions have largely been filed by disgruntled consumers who believe that the malfunctioning of their automobiles indicates that the manufacturer's products somehow violate federal standards.

NHTSA has a near-perfect record in granting or denying all petitions covered by section 124 within the requisite 120 days. There are a number of explanations for this success. First, the number of petitions has remained low. Second, NHTSA has taken its responsibility seriously. The Office of Chief Counsel has monitored the review process and everyone is aware of the date that a response is due. Third, and most important, NHTSA has adopted an interpretation of the statutory requirement that upon granting a petition it "promptly commence a proceeding" which greatly lessens the work which NHTSA must do within the 120-day time period. NHTSA's regulations provide that the standard for granting a petition is whether there is a "reasonable possibility" that the requested rule or order will issue.<sup>333A</sup> The petitioner is specifically informed in most instances that the granting of a petition and the commencement of a rulemaking or defect proceeding does not signify that the rule or order in question will issue but only that the decision to promulgate a rule order will be made on the basis of all available information developed in the course of the rulemaking or defect proceeding. In other words, NHTSA's granting of a petition does not commit it to promulgate or even propose the requested rule or order. It does no more than indicate that NHTSA believes the petitioner has a good idea that deserves further consideration or investigation. NHTSA therefore "commences" a rulemaking proceeding (it has not yet had any significant experience with petition-generated defect proceedings) by assigning to it a public docket number within the Office of Crash Avoidance or the Office of Crashworthiness, the two standard-setting offices within the agency. Those

---

332. Hearings, *supra* n.330, at 299, 362.

333. 42 FR 22215 (May 2, 1977) (Ambassador Leather Products Child Safety Harness); 42 FR 27705 (May 31, 1977) (Capri Stabilizer bars).

333A. 49 CFR 55218 (1976).



offices then proceed with standard development in accordance with their own priorities on the utilization of agency resources.<sup>334</sup>

NHTSA's interpretation of the phrase "commence a proceeding" does not appear to be unreasonable in the rulemaking context. Informal notice and comment rulemaking does not "commence" with the publication of a notice of proposed rulemaking or even an advanced notice of proposed rulemaking or notice of intent. An agency must first develop a proposal that has objective factual support before submitting it to public comment.<sup>335</sup> It is unrealistic to expect an agency to develop within 120 days the factual support for all new ideas presented to it. There is no clear indication that Congress intended NHTSA to do so by requiring it to publish a proposed rule in the Federal Register upon granting a petition.

The limited relief available under section 124 explains in large part the low volume of petitions, especially by safety and public interest representatives. A brief reference to the history of NHTSA's safety standards program supports this position. After an initial burst of regulatory activity in the late 1960's and early 1970's (twenty-nine major vehicle safety standards were issued in the first three years of the program), there followed a slowdown or "stagnation" in rulemaking.<sup>336</sup> Excluding the new school bus standards expressly mandated by Congress, NHTSA issued only two new standards in the three years from 1974 through 1976 and promulgated only a handful of significant amendments to existing standards. What NHTSA did not do is more significant than what it did since the agency was engaged in major rulemaking efforts in many areas (passive restraints, external protrusions, flammability of interior material, etc.), where it did not promulgate any new or amended standards. Whatever the reason for this situation, whether it was the complexity of the issues, industry resistance, consumer apathy, or political interference from the White House as contended by the Moss Report on Regulatory Reform,<sup>337</sup> it was not remedied by the statutory time limit found in section 124. In fact, at least one rulemaking petition by the Center for Auto Safety was specifically *granted* on the ground that the agency was already at work developing a rulemaking proposal in the same area.<sup>338</sup> While the petitioner obtained the relief it requested, the granting of the petition did not otherwise expedite the publication of NHTSA's proposed rule.

---

334. NHSTA recently announced that it will publish annually in the Federal Register a brief description of all significant rulemaking actions anticipated within the succeeding five years. 42 FR 12284 (March 3, 1977). These notices should enable interested persons to comment on the agency's priorities with respect to ongoing rulemaking.

335. *National Welfare Rights Organization v. Mathews*, 533 F.2d 637 (D.C. Cir. 1976).

336. Subcommittee on Oversight and Investigations of the House Committee on Interstate and Foreign Commerce, *Report on Federal Regulation and Regulatory Reform*, 94th Cong., 2nd Sess. 166ff (1976) (Moss Report).

337. See n.336, *supra*.

338. Hearings, *supra* n.330, 358.

The effect of the time limit in section 124 has thus been quite modest because it only applies to one stage of the rulemaking process. That section has placed a small but by no means unreasonable burden on NHTSA's resources. However, the petitioning process has not been heavily used, nor has it had a substantial impact on the agency's regulatory activity. There are no identifiable adverse consequences, and petitioners do receive the courtesy of a timely response to their ideas. If a petitioner is dissatisfied with the reasons for a denial, he may seek judicial review. While section 124 does not specifically provide for judicial review of denials, it seemingly is available under section 706 of the Administrative Procedure Act where the standard of review would be whether the denial was arbitrary or capricious.

#### CASE STUDY NO. 8

##### *Environmental Protection Agency (EPA)*

Congress has delegated to EPA<sup>339</sup> broad authority to protect the nation's environment from the adverse effects of air pollution, water pollution, noise, unsafe drinking water, pesticides and solid waste. At the same time Congress has subjected the major portion of EPA's regulatory activity to statutory time limits. These time limits reflect the prevailing Congressional and public sentiment that the federal government should do something right away to prevent further degradation of the environment. In the Clean Air Amendments of 1970,<sup>340</sup> Congress adopted the approach that EPA (originally the Department of Health, Education and Welfare prior to EPA's formation) should establish "rational goals on the basis of the best information available" and not await the results of further research on the environmental and economic effects of air pollution.<sup>341</sup> Congress retained this decision-forcing philosophy in subsequently enacted major pieces of environmental legislation. Time limits similar to those found in the Clean Air Amendments of 1970 were also included in the Federal Water Pollution Control Amendments of 1972,<sup>342</sup> the Noise Control Act of 1972,<sup>343</sup> the Safe Drinking Water Act of 1974,<sup>344</sup> and the Resource Conservation and Recovery Act of 1976.<sup>345</sup>

---

339. Congress normally has delegated authority to the Administrator of the Environmental Protection Agency who acts on behalf of the agency. For purpose of simplicity, this study uses the term "EPA" throughout rather than the term "Administrator."

340. Pub. L. 91-604, 84 Stat. 1676 (1970), amending the Clean Air Act of 1963, codified at 42 U.S.C. §§1857 et seq. (1970).

341. S. Rep. 91-1196 on S. 4358, 91st Cong., 2nd Sess. 11 (1970), reprinted in 1 *Legislative History of the Clean Air Amendments of 1970* 411.

342. Pub. L. 92-500, 86 Stat. 816 (1972), amending the Federal Water Pollution Control Act of 1956, codified at 33 U.S.C. 661251 et seq. (Supp. V 1975).

343. Pub. L. 92-574, 86 Stat. 1234 (1972), codified at 42 U.S.C. §§4901 et seq. (Supp. V 1975).

344. Pub. L. 93-523, 88 Stat. 1660 (1974), codified at 42 U.S.C. §§300f et seq. (Supp. V. 1975).

345. Pub. L. 94-580, 90 Stat. 2795 (1976), to be codified at 42 U.S.C. §§6901 et seq. The Act superceded the earlier Solid Waste Disposal Act of 1965.

The time limits found in these statutes generally take one of three forms. The first type requires EPA to identify or list within a prescribed period the pollutants or sources of pollution that it intends to regulate under a particular statutory provision. Normally EPA must compile its initial list within so many days (30, 90 or 180 days) of the statute's enactment, but it may subsequently revise its list through deletions or by adding new pollutants or sources of pollutants which it subsequently decides to regulate. The listing of a pollutant or source of pollution usually triggers a second type of statutory time limit. This type of time limit requires EPA to develop a proposed standard to regulate a pollutant or source of pollution within so many days after it has identified or listed the pollutant or source. For some standards (e.g., standards for safe drinking water), the first stage is eliminated and EPA is simply required to develop proposed standards within so many days of the statute's enactment. A third type of statutory time limit requires EPA to promulgate a final standard within so many days after it has proposed a standard. This type of deadline forces EPA to make a decision on the basis of its present knowledge without awaiting the gathering or evaluation of additional data. A related type of time limit requires EPA to act within a set number of days on petitions by private parties (e.g., a petition by an automobile manufacturer to suspend for one year automobile emission standards).

The statutory time limits applicable to EPA do not allow it to extend a deadline for good cause or with the agreement of interested parties. Courts have uniformly interpreted them to be mandatory.<sup>346</sup> EPA has nevertheless very rarely complied with a statutory time limit for regulatory action. This poor record reflects the tremendous difficulties EPA has encountered in implementing its numerous statutory responsibilities. Charged with enforcing a half-dozen or so major new statutes enacted in rapid fire succession in the early 1970's, EPA has encountered stiff resistance from industry and from within the Executive Branch itself. As a new agency it had to develop its own expertise and constituency in areas that had previously been unregulated. By 1975 it found itself staggering under the burden of some 125 uncompleted rulemaking proceedings and nearly five hundred pending law suits.<sup>347</sup>

#### A. *The Impact of Statutory Time Limits at EPA*

The magnitude of the task confronting EPA has influenced the attitude of EPA officials toward statutory time limits. EPA officials have consistently supported statutory time limits for agency action even though they recognize that EPA will not be able to comply with most of them. The prevailing view has been that EPA would rather miss a statutory deadline

---

346. See the cases discussed in Part B of this case study.

347. Comment, *Wasting Away: The Attack on EPA Authority to Regulate Beverage Containers Used at Federal Facilities*, 5 *Envir. Law Rep.* (PLI) 10197 n. 1 (1975).

than to have no statutory deadline to serve as a target or to have authority itself to extend a deadline. EPA has not asked Congress to change statutory time limits that have proved unrealistic or unattainable and has preferred to live with the Acts as originally enacted rather than open them up for amendment.<sup>348</sup> While it appears that the new EPA Administrator Douglas Costle may modify the latter approach and may request Congress to amend statutory provisions that EPA finds unworkable,<sup>349</sup> Costle has at the same time strongly reaffirmed EPA's support of the concept of statutory deadlines. "(I)n so many of our programs the only way that you establish a benchmark against which to plan is to establish a date, and the only way that you can in fact achieve enforcement is to work against an established date."<sup>350</sup>

The actual impact of statutory time limits is nevertheless difficult to evaluate. The enactment of a deadline for agency action does not insure that the EPA will meet it or even strive to meet it. A prime example often cited at EPA is the time limit in section 318 of the Federal Water Pollution Control Act<sup>351</sup> for promulgating standards on the discharge of pollutants into approved aquaculture projects. That section, added by the 1972 amendments to the Federal Water Pollution Control Act, required EPA to promulgate final standards by January 1, 1974, roughly fifteen months after the section's enactment. EPA finally promulgated the standards on May 17, 1977,<sup>352</sup> nearly three and one-half years late. The aquaculture regulations are among the simpler ones issued by EPA, but their promulgation was nevertheless delayed well beyond the statutory deadline because no one inside or outside the agency really cared about them. Other water quality proceedings plainly deserved higher priority; and no one objected when EPA deferred the development of section 318 regulations. Deferral was possible because the statutory time limit was not self-enforcing. EPA officials did

---

348. For a critical discussion of EPA's general reluctance to ask Congress to amend unworkable statutes, see 2 Committee on Environmental Decisionmaking, National Academy of Sciences - National Research Council, *Decisionmaking in the Environmental Protection Agency* 2 (1977).

349. In the late spring of 1977, EPA asked Congress to amend section 306 of the Federal Water Pollution Control Act, 33 U.S.C. §1317 (Supp. V 1975). That section requires EPA to develop a proposed effluent standard for a toxic pollutant within six months of listing the pollutant. A final standard is due within six months after the publication of the proposal. EPA must also hold a public hearing on the proposal. EPA supported an amendment extending the statutory time limits from six months to 270 days. This extension of the time limits is only a small part of the proposed amendment, which is intended to give EPA more flexibility in controlling toxic pollutants. The present section requires EPA to promulgate health-based standards on a pollutant-by-pollutant, source-by-source approach. EPA has found that method of control to be unworkable in dealing with the health hazards posed by hundreds of toxic pollutants. See 8 *Envir. Rep. (BNA)* (June 17, 1977).

350. 8 *Envir. Rep. (BNA)* 50 (May 13, 1977) (remarks at annual meeting of ABA environmental law standing committee).

351. 33 U.S.C. §1328 (Supp. V 1975).

352. 42 FR 25478 (May 17, 1977).

not face any sanction for missing the statutory deadline, and there was no serious doubt about EPA's authority to promulgate effective regulations after the deadline had passed. The statutory time limit was ineffective because there was no outside pressure to enforce it and because EPA recognized that it did not reflect a Congressional judgment on the agency's priorities. In the case of EPA, Congress has imposed time limits so widely and indiscriminately that they cannot be interpreted to represent a Congressional determination that EPA should give priority to proceedings subject to a time limit.

Section 2(c) of the Safe Drinking Water Act of 1974<sup>353</sup> provides another example of a statutory time limit applicable to a proceeding that obviously has a comparatively low priority. That section required EPA to publish proposed national secondary drinking water regulations within 270 days after the date of its enactment (December 16, 1974) and to promulgate final standards within 90 days thereafter. Unlike the primary standards, the secondary standards are non-enforceable and advisory only. The development of secondary standards remained on the back-burner at EPA for several years while the agency wrestled with the development of the mandatory, health-related primary standards. Proposed secondary standards did not appear in the Federal Register until March 31, 1977.<sup>354</sup>

The absence of a statutory time limit, on the other hand, may encourage foot dragging by EPA. The example commonly cited where this did occur is the promulgation of guidelines for the management of solid waste under the amended section 209 of the Solid Waste Disposal Act of 1965.<sup>355</sup> That section, as amended in 1970, required EPA to promulgate guidelines "as soon as practicable" after October 26, 1970, the date of the amended section's enactment. The guidelines were intended to provide guidance to the states on solid waste management but were binding and enforceable against federal facilities. EPA did not issue any guidelines until August, 1974 when it promulgated guidelines for incinerators and sanitary landfills.<sup>356</sup> That action was prompted by a suit filed by environmental groups to force EPA to obey the statutory mandate to promulgate guidelines as soon as practicable.<sup>357</sup> EPA did not really contest the lawsuit but informally agreed to issue guidelines under judicial surveillance. When EPA encountered further delays in early 1976 in promulgating a controversial guideline on returnable beverage containers, the court specifically ordered it to do so by September 17, 1976.<sup>358</sup> EPA met that deadline and promulgated a guideline which required a minimum five-cent returnable

---

353. 42 U.S.C. §300g(c) (Supp. V 1975).

354. 42 FR 17143 (Mar. 31, 1977).

355. Section 209, formerly codified at 42 U.S.C. §3254c(a) (1970), was repealed by the Resource Conservation and Recovery Act of 1976. See n.345 *supra*.

356. 39 FR 29328 (Aug. 14, 1974).

357. *Natural Resources Defense Council v. Train*, No. C-74-1202 (N.D. Cal. filed 1974).

358. 6 *Envir. Rep. (BNA)* 1878 (Mar. 5, 1976).

deposit on all carbonated beverage containers sold at federal installations.<sup>359</sup> In this instance the court did grant relief against agency foot dragging despite the absence of a statutory time limit. However, EPA did not really contest the relief sought. The delay in promulgating the guideline on returnable beverage containers did not result from EPA's unwillingness to make a timely decision but from EPA's inability to overcome the objections of other federal agencies to the decision it had made. A statutory deadline might have assisted EPA to overcome these "political" obstacles without the need for a lawsuit to force agency action.

These two examples indicate that monitoring by outside interest groups has an important impact on the promptness of EPA decision-making. A statutory time limit that is not monitored may have little impact, while monitoring may have an impact even if there is no statutory time limit. The citizen suit provisions found in most environmental legislation have aided the monitors by allowing virtually any interested member of the public to sue EPA to force it to perform its duty of promulgating specific regulations. Former Deputy Administrator John Quarles has described this activity of citizen groups as a new form of oversight that has had a major impact at EPA.<sup>360</sup>

Another example which supports these generalizations is EPA's promulgation of new source performance standards under section 111 of the Clean Air Act added by the Clean Air Amendments of 1970.<sup>361</sup> That section required EPA to publish within 90 days of the date of enactment (December 31, 1970) and subsequently to revise a list of all categories of stationary sources which it determines contribute significantly to air pollution which causes or contributes to the endangerment of public health or welfare. The section required EPA to propose a performance standard within 210 days after it lists a stationary source and to promulgate a performance standard within 90 days thereafter. Thus, performance standards for sources on EPA's initial list were due 300 days after enactment, while the rulemaking period for subsequently listed sources was 210 days. EPA listed five stationary sources in its initial list and promulgated performance standards for them on December 23, 1971, slightly less than two months late. It has subsequently listed an additional nineteen new sources for which it has promulgated performance standards. The final standards curb seventeen major industries. EPA has adopted the practice of simultaneously listing a new stationary source and proposing performance standards for that source. Courts have upheld this practice which in effect "skips" the 120 days allotted for the development of a proposed standard.<sup>362</sup> Whether that 120

---

359. 41 FR 41201 (Sept. 21, 1976) (signed by Administrator on Sept. 10, 1976).

360. See the remarks by Quarles in Proceedings of the Administrative Law Sec's 1976 Bicentennial Institute - Oversight and Review of Agency Decisionmaking, 29 *Ad. L. Rev.* 569, 730 (1976).

361. 42 U.S.C. §1857c-6 (1970).

362. *National Asphalt Paving Ass'n v. Train*, 539 F.2d 775 (D.C. Cir. 1976).

days may be tacked onto the 90 days allowed to promulgate the final standard is not clear. Even allowing EPA to do so, it has never promulgated a performance standard within 210 days of publishing a proposed standard. It proposed seven standards on June 11, 1973 and promulgated them on March 8, 1974. It proposed an additional twelve standards in October, 1974 and promulgated five of them in August, 1975, one in September, 1975, five in January, 1976, and one in May, 1976.

EPA's record in promulgating these standards was not closely monitored by outside interest groups. The standards involved technical issues on which most environmental and public interest organizations lacked expertise. In the early 1970's those organizations chose to focus their attention on monitoring EPA's approval of state implementation plans for achieving national ambient air quality standards. The National Resources Defense Council (NRDC), whose Project Clean Air made it the major public interest organization in this area, sued to enforce the statutory time limit during which EPA was required either to approve a state implementation plan or to promulgate a federal plan for the state.<sup>363</sup> Meanwhile, EPA established its own pace for promulgating performance standards for new stationary sources. Public participation in these proceedings was largely limited to the industries involved. There was no real pressure at EPA to meet the statutory deadlines. It was recognized that new source performance standards were only a small part of the battle against air pollution; the review of state implementation plans and the lowering of automobile emissions both deserved higher priority. On the other hand, there was no incentive for industry or EPA to delay the proceedings. Section 111 defined a "new" stationary source to include all sources constructed or expanded after the date EPA published in the Federal Register a proposed performance standard for that category of sources. This provision operated as a built-in disincentive against delay. EPA therefore completed these proceedings with reasonable dispatch even though it missed the statutory deadline by at least two months in all instances. It probably could have met the statutory deadline in all these proceedings if there had been real pressure for it to do so. Each proceeding only involved a small number of issues, no public hearings were required or held, and the number of comments was small. EPA also favored proposing and promulgating a group of standards as a package even though this approach required parts of the package to be held up while other parts were completed. In sum, the timely promulgation of new source performance standards simply did not justify a back-breaking all-out-effort when it was plain that many other projects at EPA (some of them not subject to statutory deadlines) did justify that effort.

Section 311 of the Federal Water Pollution Control Act<sup>364</sup> provides another comparison between agency action subject to a statutory time limit

---

363. *NRDC v. EPA*, 475 F.2d 968 (D.C. Cir. 1973); *City of Riverside v. Ruckelshaus*, 3 *Envir. Law Rep. (PLI) 20043* (C.D. Calif. 1972).

364. 33 U.S.C. §1321 (Supp. V 1975).

and agency action not subject to a statutory time limit. That section, added by the 1972 amendments, required EPA to designate by regulation hazardous substances and to determine "as soon as possible" after the date of enactment (October 27, 1972) what quantities of discharge are harmful. EPA proposed a list of hazardous substances on December 30, 1975 and at the same time proposed harmful quantity determinations for those substances.<sup>365</sup> Final regulations have still not been promulgated, although EPA expects to do so before the end of 1977.<sup>366</sup> Section 311(b)(2)(B)(iv) required that EPA establish penalty schedules for discharges of a hazardous substance within 180 days after it designates the hazardous substances. EPA proposed penalty schedules for discharges at the same time it published its proposed list of hazardous substances.<sup>367</sup> While this tactic makes the statutory time limit technically inapplicable, EPA has not complied with its intent by developing penalty schedules within 180 days. Regulations on penalties have proven to be difficult to draft and are presently holding up the entire package of final regulations on the discharge of hazardous substances.

EPA, as indicated above, is subject to three types of statutory time limits. The first type of time limit applicable to the initial listing of pollutant or sources of pollution to be regulated has had only a limited impact at EPA, since in most instances the time limit has not affected EPA's authority to determine the contents of the initial list. Of course, EPA's decision to regulate a pollutant or source of pollution by listing it triggers EPA's duty to propose and then promulgate standards to control it within the prescribed statutory time periods. Statutory time limits applicable to EPA's publication of an initial list have generally been interpreted to require EPA promptly to commence regulatory activity by listing something within a short time after a new Act's enactment. It is not expected that EPA will regulate everything at once by publishing a comprehensive list at the outset. This legislative intent is clearer in some sections than in others. For example, section 112 of the Clean Air Act,<sup>368</sup> as added by the Clean Air Amendments of 1970, required the Secretary of Health, Education and Welfare (subsequently the Administrator of EPA) to develop national emission standards for hazardous air pollutants. Within 90 days of enactment the Secretary was required to publish "a list which includes each hazardous air pollutant for which he intends to establish an emission standard under this section."<sup>369</sup> The Secretary was instructed to revise the list from time to time. The Senate Committee on Public Works recognized that these provisions left the timing of control over hazardous air pollutants to the discretion of

---

365. 40 FR 59962, 59982 (Dec. 30, 1973).

366. 8 *Envir. Rep.* (BNA) 363 (July 1, 1977).

367. 40 FR 59999 (Dec. 30, 1975).

368. 42 U.S.C. §1857c-7 (1970).

369. 42 U.S.C. §1857c-7(b)(1)(H) (1970).



the Secretary.<sup>370</sup> The initial list, published in timely fashion by the Administrator of EPA, contained only three hazardous air pollutants (asbestos, beryllium and mercury).

A statutory time limit of the first type may have an undesirable effect on EPA's ability to determine its own priorities if it requires EPA to regulate too much at one time. For example, section 306(b)(1)(A) of the Federal Water Pollution Control Act,<sup>371</sup> added by the 1972 amendments, listed twenty-seven different categories of point sources which it required EPA to regulate. The 1972 amendments imposed tight statutory time limits on EPA for proposing and promulgating effluent limitation guidelines, new source performance standards, and pretreatment standards for those twenty-seven categories of point sources and for any other categories added to the list by EPA. This task proved far too much for EPA to accomplish; its inability to do so prompted a suit by the Natural Resources Defense Counsel to enforce the statutory time limits.<sup>372</sup>

Section 17 of the Noise Control Act of 1972<sup>373</sup> provides another, albeit minor, example of a statute that required EPA to regulate too much at one time. That section required EPA to regulate "noise emissions resulting from the operation of the equipment and facilities of surface (rail) carriers." Proposed noise emission standards were due within nine months of the date of enactment and final standards were due within ninety days thereafter. EPA missed these deadlines by wide margins; it also limited its final standards to cover only noise emissions resulting from the operation of locomotives and railroad cars. In *Association of American Railroads v. Costle*,<sup>374</sup> the court held that EPA had failed to perform a statutory duty since its noise standards covered only some of the equipment and none of the facilities of rail carriers. Section 17 did not allow EPA to "phase in" regulation by promulgating first those emission standards that affected major sources of noise and by deferring action on other standards until a later date. The court ordered EPA to promulgate within one year of the decision final noise emission standards for all railroad equipment and facilities.

In this instance, as in the regulation of discharges from point sources, a number of factors tempered the impact of the statutory time limit on EPA's priorities. EPA did not commence rulemaking activity in all areas at once but concentrated its resources initially in those areas which it was best prepared to regulate (point sources on which it had adequate information) or which it considered most in need of regulation (locomotives and railroad cars). The court did not interfere with EPA's determination of priorities,

---

370. S. Rep. 1196, *supra* n. 3, at 18, reprinted in *1 Legislative History of the Clean Air Amendments of 1970* 418.

371. 33 U.S.C. §1316(b)(1)(A) (Supp. V 1975).

372. See the discussion of the effluent guidelines litigation at p.185, *infra*.

373. 42 U.S.C. §4916 (Supp. V 1975).

374. 562 F.2d 1310 (D.C. Cir. 1977).

and probably could not have interfered, until after the statutory deadline had passed. While the court did order EPA fully to comply with the statute by regulating lower-priority areas, the dates scheduled for EPA action were far later in time than the original statutory deadline.

The second and third types of statutory time limits applicable to the publication of proposed standards and the promulgation of final standards have had a greater impact at EPA. The litigation discussed in Part B of this case study indicates that outside monitors have on occasion used the time limits to invoke the assistance of the courts to force EPA to act sooner than EPA would have acted on its own. Once again other factors have tempered the impact of the statutory time limits. EPA retains considerable discretion in many areas over what it regulates and over when it initiates regulation. Even if it does not, it still concentrates rulemaking activity in areas of its choice. Court orders enforcing statutory deadlines can do little more than order EPA to catch up in areas where it has been laggard. Finally, many EPA rulemaking proceedings do not attract citizen monitors who are willing to sue if EPA misses a statutory deadline.

The extent of EPA's discretion to determine what and when it shall regulate under a particular statutory provision is often a difficult and controversial issue, but the resolution of that issue is not affected by the presence of a statutory time limit. For example, section 108(a)(1) of the Clean Air Act,<sup>375</sup> added by the Clean Air Amendments of 1970, required EPA within 30 days after the enactment of the amendments to publish a list which included six designated or "criteria" pollutants and such additional pollutants which in EPA's judgment have "an adverse effect on public health or welfare" and "the presence of which in the ambient air results from numerous or diverse mobile or stationary sources." Section 108(a)(1) also provided that EPA "shall from time to time thereafter revise the list." Section 109(a)(1) required that within twelve months of listing an additional pollutant, the EPA shall propose national primary and secondary ambient air quality standards for that pollutant.

EPA had not listed any air pollutants in addition to the six designated or "criteria" pollutants until August 10, 1976, when NRDC obtained a court order requiring it to list atmospheric lead.<sup>376</sup> The court also ordered EPA to publish proposed air quality standards for lead by the statutory deadline of August 10, 1977. NRDC in its suit did not invoke the long-passed 30-day time limit for publishing the initial list but successfully contended that atmospheric lead met the statutory definition of an "air pollutant" in section 108 and that EPA therefore had a legal duty to establish national ambient air quality standards for it.

The court-ordered listing of atmospheric lead did trigger the running of

---

375. 42 U.S.C. §1857c-3(a)(1) (1970).

376. *NRDC v. Train*, 411 F.Supp. 864 (S.D.N.Y. 1976), *aff'd*. 545 F.2d 320 (2d Cir. 1976).

the one year statutory time limit for developing proposed national air quality standards for lead. EPA encountered considerable difficulty complying with that deadline. The Lead Subcommittee of its Scientific Advisory Board twice recommended rejection of EPA's draft proposal on the grounds that it did not sufficiently address the health dangers of airborne lead. In the early summer of 1977, it was recognized that if EPA accepted this recommendation, the additional work required to redo the proposal would force EPA to miss the statutory and court-enforced deadline of August 10, 1977. Counsel for NRDC expressed that organization's willingness to allow EPA a reasonable amount of additional time beyond the August 10th deadline if the delay would result in substantial improvements in the proposal.<sup>377</sup> NRDC preferred that EPA miss the statutory deadline rather than publish an inadequate proposal which NRDC would be forced to challenge in court if it became the basis for the final rule. Subsequently, NRDC and EPA entered an agreement which was approved by the court stipulating to an extension of the deadline for proposing a lead standard from August 10, 1977 to December 2, 1977.<sup>378</sup>

NRDC's position in the lead proceeding is similar to the approach taken by other participants in EPA rulemaking proceedings. Participants whose interests are at stake are not so much concerned about the timely completion of the rulemaking proceeding as they are about its completion in their favor. Participants will gladly afford EPA additional time or allow it to miss a statutory deadline if the delay is likely to result in a better product or in a product more to their liking. The example of this phenomenon frequently cited at EPA involved the promulgation of interim primary drinking water standards under section 2(a) of the Safe Drinking Water Act of 1974.<sup>379</sup> That section required EPA to propose regulations within 90 days of the date of enactment (December 16, 1974) and to promulgate regulations within 180 days of that date. EPA met the first deadline by publishing proposed standards on March 14, 1975,<sup>380</sup> but found it impossible to complete the rulemaking proceeding within the remaining 90 days. The 90-day period was an exceptionally short one for promulgating major rules; and the proposed rules raised difficult issues about the detection and treatment of organic chemical contaminants. The participants in the rulemaking proceeding (mainly environmental groups and municipalities) informally agreed to allow EPA additional time to prepare the final rule. The comment period on the proposal closed in mid-April, 1975; and it was recognized that EPA could not promulgate a final rule by the mid-June deadline. The environmentalists and the municipalities, who were at loggerheads over a number of issues, both hoped that the delay would work to their advantage.

---

377. 8 *Envir. Rep.* (BNA) 409-410 (July 8, 1977); 686 (Sept. 2, 1977).

378. *Id.* at 586 (Aug. 19, 1977).

379. 42 U.S.C. §1412(a) (Supp. V 1975).

380. 40 FR 11911 (Mar. 14, 1975).

EPA finally promulgated its interim primary drinking water standards on December 24, 1975,<sup>381</sup> over six months late. The Environmental Defense Fund, aggrieved by EPA's deletion of standards for all but six organic chemicals, immediately petitioned the Court of Appeals for the District of Columbia to review the regulations.<sup>382</sup> In other rulemaking proceedings EPA has told the participants that it could not do what they wanted unless it had more time than the statute allowed.<sup>383</sup>

EPA's difficulties with the statutory time limit in the lead proceeding derive in large part from the fact that the proceeding was forced upon EPA by the court. EPA had not done the front-end work which it normally does before listing a pollutant or source of pollution. EPA, for example, is now conducting a major research effort costing \$94,000,000 on the environmental effects of sulfates and expects by 1983 to propose under section 108 of the Clean Air Act national ambient air quality standards for sulfates.<sup>384</sup> The Sierra Club has so far been unsuccessful in its efforts to compel EPA to list sulfates now under section 108(a)(1).<sup>385</sup> If EPA retains control over the timing of the decision to list sulfates as an air pollutant for which national ambient air quality standards are required, it is likely to encounter less difficulty in meeting the one-year time limit for developing proposed standards than if it is ordered to list sulfates by a court, since it will presumably have done sufficient front-end work at the time it lists the pollutant to permit it to complete the proceeding within one year. EPA did meet the statutory deadlines for promulgating air quality standards for the initial six "criteria" pollutants designated in the Clean Air Amendments of 1970 (sulfur oxides, particulate matter, carbon monoxide, photochemical oxidants, hydrocarbons, and nitrogen dioxide) because its predecessor agencies had completed the front-end work on the standards prior to the enactment of the amendments. EPA thus met its first major statutory deadline; it has met very few since that time.

### *B. Judicial Relief When EPA Misses a Statutory Deadline*

As indicated in Part A, the effectiveness of a statutory time limit in reducing delay at EPA depends in large part on the presence of outside pressure or monitoring. In at least four major instances outside monitors have obtained judicial relief when EPA missed a statutory deadline. The statutory time limits which were the bases of these suits were all of the third type requiring EPA to promulgate a final rule within a prescribed period of time. The relief granted by the courts in these cases had a substantial impact

---

381. 40 FR 59565 (Dec. 24, 1975).

382. 6 *Envir. Law Rep.* (PLI) 10006 (Jan. 1976). The suit is now in the process of settlement. The controversy involves how much regulation EPA can delay until the promulgation of final primary drinking water standards in 1977/1978.

383. See the discussion, *infra*, of the effluent guidelines proceedings.

384. 7 *Envir. Rep.* (BNA) 1717 (March 11, 1977).

385. *Id.*

on the speed but not necessarily on the process of decisionmaking at EPA. (The discussion in this part is largely descriptive. The desirability of oversight of agency performance through citizen suits is discussed in section D of the Introduction.)

The first two challenges to missed statutory deadlines involved the Clean Air Act. Section 110 of that Act,<sup>386</sup> added by the Clean Air Amendments of 1970, required each state, within nine months of EPA's promulgation of national ambient air quality standards, to submit to EPA a plan to limit emissions within the state in order to insure the timely attainment of the federal standards. Section 110(a)(2) provided that EPA shall approve or disapprove state implementation plans within four months of the date they were required to be submitted. If a state did not submit an approvable plan, EPA was required within an additional two months to promulgate its own implementation plan for the state. Municipalities and environmental groups in two separate law suits successfully challenged EPA's permitting the states to postpone for two years the submission of approvable transportation control plans.<sup>387</sup> Both courts held that the statutory deadlines for approving or promulgating implementation plans were mandatory and that EPA could not authorize a two-year delay in the submission of approvable transportation control plans. These decisions resulted in the prompt approval or promulgation of transportation control plans for all fifty states. While the judicial enforcement of the statutory time limits did result in quicker action by EPA than otherwise would have occurred, there is considerable controversy whether this speed-up ultimately helped or retarded progress toward clean air. Some of the transportation control plans were politically unrealistic if not draconian. They aroused widespread opposition and remain largely unenforced. It is doubtful, however, that a two-year delay in their appearance would have made much difference in the long run.<sup>388</sup>

EPA's failure to meet the statutory time limits in section 112 of the Clean Air Act<sup>389</sup> has also been the subject of a judicial challenge. That section, added by the Clean Air Amendments of 1970, required EPA to publish an initial list of the hazardous air pollutants it intended to regulate within 90 days of the date of enactment (December 31, 1970). A hazardous air pollutant is defined to mean an air pollutant for which no national ambient air quality standard is applicable and which, in the judgment of EPA, may cause or contribute to an increase in mortality or to an increase in serious irreversible illness or incapacitating reversible illness. EPA must publish proposed standards for a hazardous air pollutant within 180 days

---

386. 42 U.S.C. §1857c-5 (1970).

387. *City of Riverside v. Ruckelshaus*, 3 *Envir. Law Rep.* (PLI) 20043 (C.D. Calif. 1972); *NRDC v. EDF*, 475 F.2d 968 (D.C. Cir. 1973).

388. On the effects of this judicially enforced speed-up, see Stewart, *The Development of Administrative and Quasi-Constitutional Law in Judicial Review of Environmental Decisionmaking: Lessons from the Clean Air Act*, 62 *Iowa L. Rev.* 713, 725-727 (1977).

389. 42 U.S.C. §1857c-7 (1970).

after it lists the pollutant and final standards within 180 days thereafter. EPA published in timely fashion in March, 1971 its initial list of three hazardous pollutants (asbestos, beryllium and mercury) and proposed emission standards for these pollutants on December 7, 1971, almost three months later. When EPA did not promulgate final standards within the prescribed 180 days, the Environmental Defense Fund (EDF) invoked the citizen suits provision in section 304 of the Clean Air Act<sup>390</sup> to compel EPA to act. On January 29, 1973, a court held that the promulgation of a final standard within 180 days following the publication of a proposed standard was mandatory and ordered EPA to promulgate final standards for the three pollutants within 60 days.<sup>391</sup> EPA did so; and the final standards were published in the Federal Register on April 6, 1974.<sup>392</sup> EPA's delay in promulgating the final standards had evidently not resulted from any shortage of resources available for the proceedings but from substantive doubts about some of the proposed standards.<sup>393</sup> EDF's lawsuit did not enforce a time limit as much as it forced agency action that otherwise might not have been forthcoming at all.

EPA recently promulgated a fourth hazardous emission standard for vinyl chloride. The vinyl chloride proceeding further demonstrates the limited effectiveness of statutory time limits in the absence of outside monitoring and enforcement. On December 24, 1975, EPA determined that vinyl chloride was a hazardous air pollutant and added it to its list of hazardous air pollutants. On the same day it proposed a national emission standard for vinyl chloride. EPA thus followed its usual practice of compressing into one stage the listing of a pollutant and the publication of a proposed standard for its control. A final emission standard for vinyl chloride was promulgated by EPA on October 12, 1976 and published in the Federal Register on October 20, 1976.<sup>394</sup> While EPA did, as required by section 112, promulgate an emission standard within one year after it determined that vinyl chloride was a hazardous air pollutant, it did not comply with the statutory time limit of 180 days between proposal and final rule. The prevailing view at EPA is that the agency therefore missed the statutory deadline for promulgating the final standard.<sup>395</sup> EPA, in other words, can-

---

390. 42 U.S.C. §1857h-2 (1970).

391. 3 *Envir. Law Rep.* (PLI) 20173 (D.C. D.C. 1973).

392. 38 FR 8820 (April 6, 1974).

393. The asbestos standard, for example, applied to demolition work. Some officials at EPA questioned whether EPA should regulate demolition activity through an emission standard.

394. 40 FR 46565 (Oct. 20, 1976).

395. 8 *Envir. Rep* (BNA) 159 (June 3, 1977) (statement of EPA Administrator Douglas Costle). Costle made his statement upon granting EDF's petition to list benzene as a hazardous air pollutant. Costle at that time expressed his doubt that it was feasible for EPA to develop a proposed benzene standard within the required six month time frame. He cited the need to assess the health risks of benzene, to identify the sources of benzene to be controlled, and to determine the extent of control necessary.

not tack the unused 180 days for developing a proposal onto the 180 days allowed for promulgating a final standard.

The 180-day statutory time limit was a realistic one in the vinyl chloride proceeding. EPA held a one-day hearing on the proposed standard on February 3, 1976; and the comment period closed on February 23, 1976. The standard affected only a limited number of industrial establishments and only fifty comments were received. Industry representatives contended that EPA should apply a cost-benefit analysis rather than the best available technology in formulating a standard, while environmentalists argued for a health-based standard and for a zero discharge level where substitute products were available. EPA readily rejected these contentions. Except for the coverage of small emission sources, the proceeding raised no other issues of significance. The final standard filled eight Federal Register pages; there were five pages of preamble. Despite the comparative simplicity of the proceeding, there was nevertheless a seven month gap between the close of the comment period and the promulgation of the standard. The statutory time limit was not effective in forcing an earlier decision. The explanation for the delay apparently lies in the Quality of Life Review to which the Office of Management and Budget subjected all EPA regulations in the mid-1970's. This form of interagency review followed the public comment period and consumed an average of 104 days.<sup>396</sup> It has now been substantially abandoned by the new Administration.<sup>397</sup>

The two remaining major challenges to EPA's failure to meet a statutory deadline both involved the Federal Water Pollution Control Act. The time limits in the 1972 amendments to that Act have had a greater impact on EPA than have the time limits in other statutes. EPA's record in meeting the statutory deadlines have been closely monitored by environmental groups and have been the subject of two major lawsuits. The first suit involved the promulgation under section 304(b) of the Act<sup>398</sup> of effluent limitations guidelines for point sources. That section required EPA to promulgate final guidelines within one year of the date of enactment (October 18, 1972). The guidelines were to require the application of the best practicable control technology by 1977 and of the best available control technology economically achievable by 1983. Unlike other environmental statutes, it did not delegate to EPA the task of listing the sources of pollution which EPA would then control. Section 306(b)(1)(A)<sup>399</sup> specifically listed twenty-seven categories of point sources for which EPA was required to promulgate guidelines within one year. The statutory listing was not intended to be all-inclusive but established minimum requirements for EPA regulation. EPA was expected to control discharges from an undetermined

---

396. 7 *Envir. Rep* (BNA) 693.

397. 8 *Envir. Rep*. (BNA) 699 (Sept. 9, 1977).

398. 33 U.S.C. §1314(b)(Supp. V 1975).

399. 33 U.S.C. §1316(b)(1)(A) (Supp. V 1975).

number of additional categories of point sources. EPA's initial list of additional categories was due within 90 days of enactment and was subject to subsequent revision by the agency.

Although EPA had not opposed the inclusion of the one-year time limit in section 304, it soon discovered that the October 27, 1973 deadline for promulgating final guidelines was a highly unrealistic one. EPA found itself confronted by a mammoth information gap of the type that often accompanies new programs. For most categories of point sources EPA simply did not know what substances were being discharged, what control technologies were available, and what was the cost of control. EPA found it necessary to utilize private contractors to develop the technical and economic bases for the guidelines. Soliciting proposals consumed several months; and the private contractors required six months to complete their reports. Industry proved recalcitrant and generally did not cooperate in the furnishing of information. When it became apparent that the deadline could not be met even for the twenty-seven categories of point sources listed in the statute, EPA decided to promulgate first those guidelines which covered the greatest number of major discharges. Dissatisfied with EPA's progress in promulgating effluent limitation guidelines, NRDC sued on August 14, 1973 to obtain a declaratory judgment that EPA had a non-discretionary duty under section 304(b) to promulgate guidelines for all categories of point sources by October 27, 1973. The District Court for the District of Columbia granted summary judgment to NRDC on November 15, 1973, and on November 27, 1973, the statutory deadline having passed without the promulgation of a single guideline, ordered EPA to promulgate guidelines under a court-approved time schedule.<sup>400</sup>

On December 5, 1974, in *NRDC v. Train*,<sup>401</sup> the Court of Appeals affirmed the greater part of the District Court's order. It held that the statutory deadline of October 18, 1973, only applied to the twenty-seven categories of point sources specifically listed in section 306(b)(1)(A). For all other categories of point sources (roughly fifteen in number), the deadline for promulgating guidelines was December 31, 1974, which was the last date on which a permit was not required for a discharge into navigable waters. The Court of Appeals specifically approved as a proper response to a missed deadline the decision of the District Court to incorporate into its order a time table for agency action in promulgating guidelines. With respect to the December 31, 1974 deadline, the court refused to order EPA to promulgate all guidelines by that time and recognized that manpower or methodological constraints might justify further extensions. The case was remanded for the District Court to rule on any justifications for further delay presented by EPA and to impose its own time schedule in cases of non-compliance with the December 31, 1974 deadline.

---

400. 6 *Envir. Rep. Cases* (BNA) 1033 (D.C.D.C. 1973).

401. 510 F.2d 692 (D.C. Cir. 1973).



By September, 1976 EPA had promulgated under judicial supervision regulations governing forty industrial point source categories. While effluent limitation guidelines have not yet been proposed for some industries, EPA has basically completed the task of promulgating the initial guidelines. It is no longer subject to the November 17, 1973 order of the District Court. The regulations promulgated by EPA include not only effluent limitation guidelines for existing sources based on the 1977 and 1983 technology standards but also standards of performances for new sources issued under section 306(b) of the Act and pretreatment standards for new and existing sources issued under section 307(b) of the Act. Since each industrial category is subdivided into various subcategories, the total package of regulations includes several thousand effluent limitations. The statutory deadline, monitored by NRDC and enforced by the court, provided EPA an important stimulus for this herculean task.

The schedules which the court ordered EPA to follow in promulgating effluent limitation guidelines were in part determined by negotiations between the parties and in part by the court itself. On at least four separate occasions the court made major modifications in its order at the request of EPA. While extensions of the court-ordered deadlines were possible, EPA officials recognized the importance of complying with the court's schedule. Court-ordered deadlines, unlike statutory ones, are enforceable through the contempt power. Judge Leventhal for the court of Appeals had indicated that a federal court should not hold a government official in contempt if it was convinced that he was in good faith employing the utmost diligence in discharging his statutory duties.<sup>402</sup> It was nevertheless apparent that any foot dragging at EPA would result in NRDC seeking contempt sanctions. The court-ordered promulgation dates had an impact on work schedules at EPA because everyone knew that the court and NRDC meant business.

Time constraints had an impact on EPA's decisional process in the effluent guidelines proceedings but the impact was quite limited. It prompted small but helpful changes like the simultaneous rather than seriatim review of Federal Register documents by EPA Assistant Administrators. EPA never promulgated a regulation with which it was not satisfied. EPA's general approach was still to do the job right and not just to do it within the time limit. In late 1975, when difficulties arose in promulgating guidelines for the iron and steel, pulp and paper and other major industries, Deputy Administrator John Quarles directly intervened and convinced NRDC that EPA needed more time to do things right and that the only alternative was for EPA to leave things out and promulgate incomplete, inadequate regulations. EPA also promulgated seven guidelines in interim form without prior public notice of a proposal and opportunity comment thereon. It invoked the time constraints of the court order as good cause for dispensing with the provisions for public participation in sections 553(b)-(c) of the Administrative Procedure Act. This departure from normal rulemaking

---

402. *NRDC v. Train*, 510 F.2d 692,713 (D.C. Cir. 1973).

procedure was of limited practical significance because EPA developed guidelines in the open; industry and environmental groups kept themselves informed and were able to communicate their views to EPA. EPA also shortened the rulemaking process by eliminating Steering Committee review at the outset of the process and by shortening or eliminating interagency review at the end. Again these changes were of limited significance in the context of promulgating effluent limitation guidelines. Steering Committee review enables the various bodies within EPA to participate in decisions to initiate rulemaking. It permits the agency to coordinate and prioritize its activities but naturally has little role to play when the court has ordered the agency to proceed. Interagency review also has a lesser role to play when a court has ordered the agency to promulgate regulations, and EPA was able to utilize the court-imposed time constraints to eliminate or reduce the delays associated with interagency review.

The effluent guidelines case (*NRDC v. Train*) discussed above involved EPA's "first round" of regulations under the Federal Water Pollution Control Act. A second round case is now in the courts. This suit originated after EPA's failure to meet the statutory time limit for promulgating effluent standards for toxic pollutants under section 307(a) of the Act.<sup>403</sup> That section, added by the 1972 amendments, required EPA to publish an initial list of toxic pollutants within 90 days from the date of enactment (October 27, 1972). EPA was required to propose an effluent standard or prohibition for a toxic pollutant within 180 days from the date it lists the pollutant on its initial list or a revision thereof. Final standards are due within six months after the publication of proposed ones. EPA published its initial list of nine toxic pollutants on September 7, 1973,<sup>404</sup> over eight months late, and proposed effluent standards for those pollutants on December 27, 1973.<sup>405</sup> NRDC promptly sued EPA, contending that it had arbitrarily omitted at least twenty-three toxic pollutants from the list.<sup>406</sup> When no final standards for the nine listed toxic pollutants were forthcoming in 1974, NRDC and Citizens for a Better Environment sued to compel promulgation of the standards that were already long overdue.<sup>407</sup>

The parties to these lawsuits finally settled the cases in June, 1976.<sup>408</sup> The court-approved consent agreement provided that EPA would regulate, according to a predetermined schedule, sixty-five toxic pollutants discharged by twenty-one categories of industrial sources. Regulation of all but six of the toxic pollutants would be on the basis of technology-based

---

403. 33 U.S.C. §1317(a) (Supp. V 1975).

404. 38 FR 24344 (Sept. 7, 1973).

405. 38 FR 35388 (Dec. 27, 1973).

406. Civil Action No. 73-2153 (D.C. D.C.). See also *NRDC v. Train*, 519 F.2d 287 (D.C. Cir. 1975).

407. Civil Actions No. 75-172 and No. 75-1698 (D.C. D.C.).

408. 8 *Envir. Rep. Cases* (BNA) 2120 (D.C. D.C. 1976).

effluent limitations under section 304 of the Act. EPA did agree, however, to control six of the original nine toxic pollutants by health-based standards under section 307(a). It agreed to republish those proposed standards promptly and to promulgate final standards for the six toxic pollutants within six months. It did so on January 12, 1977.<sup>409</sup> The previous delays during 1974 and 1975 were primarily caused by EPA's reluctance to promulgate health-based standards for toxic pollutants under section 307. Section 307 allowed industry only one year to bring itself into compliance with an emission standard, and EPA feared that many plants would have to close if it promulgated the health-based standards it had proposed in 1973.<sup>410</sup> EPA, industry, and environmental groups wrestled with the problem of how to control toxics for almost two years prior to the court's approval of the settlement agreement in June, 1976. In that settlement EPA's position that toxic pollutants should be controlled by technology-based effluent guidelines promulgated under section 304 largely prevailed. EPA is now developing these second-round regulations under a court-approved schedule. However, industry representatives who were excluded from the settlement have obtained a decision from the Court of Appeals that the District Court improperly refused to allow them to intervene.<sup>411</sup> While the "second round" of toxics case originated with EPA's failure to promulgate regulations within the time prescribed, the issues in the case soon broadened to include the scope of EPA's discretion to choose the form regulation will take. By 1976, the lawsuit and settlement discussions no longer focused on the statutory time limits but on the appropriate form of regulation.

#### CASE STUDY NO. 9

##### *Office of Education (OE) in the Department of Health, Education and Welfare*

Congress has on several occasions expressed dissatisfaction with rulemaking (or the lack thereof) at the Office of Education. Congressional displeasure has taken the form of statutory provisions that impose special requirements on rulemaking at the Office of Education. Among these provisions is section 431(g) of the General Education Provisions Act<sup>412</sup> enacted in 1974 which allows the Office a maximum of 240 days (extendable by joint action of the House Committee on Education and Labor and the Senate Committee on Labor and Public Welfare) to promulgate rules for newly authorized or revised aid-to-education programs. The Office interpreted

---

409. 42 FR 2588 (Jan. 12, 1977).

410. La Pierra, *Technology Forcing and Federal Environmental Protection Statutes*, 62 *Iowa L. Rev.* 771, 803 (1977).

411. *NRDC v. Costle*, 561 F.2d 904 (D.C. Cir. 1977).

412. Pub. L. 93-380, §509(a)(2), 88 Stat. 566 (1974), 20 U.S.C. §1232(g) (Supp. IV 1974).

section 431(g) as originally enacted to require only that the Office issue proposed rules within the 240-day time frame, but Congress in 1976 amended section 431(g) to make explicit that the deadline applied to the promulgation of final rules.<sup>413</sup>

The special statutory provisions applicable to rulemaking at the Office of Education can only be understood in light of the administrative practices that prompted their enactment. The Office was established by statute in 1867 but it played a relatively minor role in the federal bureaucracy until the enactment of the Elementary and Secondary Education Act of 1965 initiated a massive program of grants-in-aid to state and local educational institutions and agencies.<sup>414</sup> Numerous other programs of federal aid to education quickly followed. By the late 1960's the Office of Education, now located in the Department of Health, Education and Welfare, annually disbursed billions of dollars in federal grants-in-aid. The Department<sup>415</sup> did not normally allow public participation in the formulation of standards for aid-to-education programs but invoked the exemption in section 553(a)(2) of the Administrative Procedure Act which permits an agency to eliminate public proceedings for rulemaking relating to government grants. In addition, the standards or rules adopted by the Office normally appeared in the form of guidelines, handbooks and even internal memoranda; they were not published in the Federal Register nor codified in the Code of Federal Regulations.

In 1970 Congress responded to this situation by enacting the Green and Pucinski Amendments to the General Education Provisions Act. The Green Amendment<sup>416</sup> provided that "rules, regulations, guidelines or other published interpretations or orders" issued by the Office shall contain immediately following each substantive provision a citation to the legal authority upon which the provision is based. Congress viewed the Green Amendment as a device for maintaining some measure of control over the Office of Education's interpretation of aid-to-education statutes.<sup>417</sup> The Pucinski Amendment,<sup>418</sup> on the other hand, required the Office to publish in the Federal Register any "standard, rule, regulation, or requirement of

---

413. Pub. L. 94-482, §405(g), 90 Stat. 2321, 20 U.S.C. §1232(g) (Supp. VI 1976).

414. Bailey & Mosher, *ESEA; The Office of Education Administers a Law* 17-19 (1968).

415. The Office of Education and the National Institutes of Education comprise the Education Division within the Department of Health, Education and Welfare. 20 U.S.C. §1221a(a)-(b) (Supp. V 1975). The Office is headed by the Commissioner of Education. 20 U.S.C. §1221c(b) (Supp. V 1975). General rulemaking authority rests with the Secretary of Health, Education and Welfare. While the General Education Provisions Act frequently refers to the promulgation of rules by the Commissioner of Education, the Secretary has not delegated to the Commissioner the authority to promulgate final rules. Rulemaking at the Office of Education is therefore subject to the direction and control of the Secretary.

416. Pub. L. 91-230, §401(a)(10), 84 Stat. 169 (1970), 20 U.S.C. §1232(a) (1970).

417. Sky, *Rulemaking in the Office of Education*, 26 *Ad. Law Rev.* 129, 132 (1974).

418. Pub. L. 91-230, §401(a)(10), 84 Stat. 169 (1970), 20 U.S.C. §1232(b) (1970).

general applicability prescribed for the administration of any applicable program” and provided for a minimum hold period of thirty days before the requirement became effective. The apparent purpose of the Amendment was to afford members of Congress and interested members of the public an opportunity to express their views to the Office before a new requirement went into effect.<sup>419</sup>

The Pucinski Amendment did not require the Office of Education to allow public comment on a proposed rule or to adopt notice and comment procedures for rulemaking. In early 1971, the Department of Health, Education and Welfare, acting in response to a recommendation of the Administrative Conference, waived the exemption in section 553(a)(2) of the Administrative Procedure Act for rulemaking relating to government grants and voluntarily adopted notice and comment procedures for grant-related rulemaking by offices within the Department, including the Office of Education.<sup>420</sup> The Department by early 1974 had also committed itself to publish objective criteria for judging applicants for federal financial assistance.<sup>421</sup> Congress subsequently enacted the former procedure into law when in 1974 it revised the Pucinski Amendment to convert it from a thirty-day hold on regulations into a directive that the Office utilize the public procedures in section 553 of the Administrative Procedure Act when promulgating rules for the administration of aid-to-education programs.<sup>422</sup> Congress had previously required in 1972 that the Office of Education reenact, after affording an opportunity for public comment and hearing, all its rules, regulations, guidelines, or other published interpretations or orders affecting an aid-to-education program.<sup>423</sup> The Office was expected to complete this task within eighteen months but found it impossible to do so. Five years later, the Office has now nearly finished the mammoth undertaking of reenacting all its rules. The end product fills so far six hundred pages of the Code of Federal Regulations. While Congress never officially extended the original eighteen month deadline, it is apparently satisfied with the Office’s progress.

The statutory and administrative requirements surveyed above have on balance had a salutary impact at the Office of Education. In the late 1960’s

---

419. Sky, *supra* n. 417, at 130-131.

420. 36 FR 2532 (Feb. 5, 1971).

421. See the directive of HEW Secretary Casper Weinberger at 39 FR 34700 (Sept. 27, 1974).

422. Pub. L. 93-380, §509(a)(1), 88 Stat. 566 (1974), codified at 20 U.S.C. §1232(b)(2) (Supp. V 1975). The revised Pucinski Amendment provides that during the minimum thirty-day hold period “the Commissioner shall, in accordance with the provisions of section 553 of Title 5, offer any interested party an opportunity to make comment upon, and take exception to, such regulation and shall reconsider any such regulation upon which comment is made or to which exception is taken.” 20 U.S.C. §1232(b)(2)(A) (Supp. V 1975).

423. Section 503 of Pub. L. 92-318, 86 Stat. 346 (1972), reprinted as an Appendix to 20 U.S.C.A. §1232.

the Office badly needed to upgrade the quality (and quantity) of its rules. In response to the new requirements the Office has developed and promulgated a large body of program rules which furnish authoritative guidance to applicants for financial assistance, confine agency discretion in disbursing grants, and reflect the impact of substantial public participation in their formulation.<sup>424</sup> The present situation is therefore a marked improvement over the situation in the late 1960's when the Office lacked published rules for disbursing grants.

The desirability of two more recent statutory requirements is less clear. In these instances Congress has sought to assert greater control over rulemaking at the Office of Education. In 1974, Congress amended section 431 of the General Education Provisions Act<sup>425</sup> to subject most rules adopted by the Office of Education to a legislative veto. Affected rules were to be transmitted to Congress and were to take effect forty-five days later unless disapproved in the meantime by concurrent resolution of both Houses for inconsistency with statutory authority. The Department has complied with this requirement despite doubts about its constitutionality. Congressional review is limited to questions of legality, and neither House has so far disapproved a regulation.<sup>426</sup> (The Administrative Conference opposes the legislative veto on policy grounds.)<sup>427</sup>

At the same time Congress adopted the legislative veto it enacted a new section 431(g) of the General Education Provisions Act<sup>428</sup> which required the Office of Education, within sixty days after the enactment of a statute authorizing a new aid-to-education program or affecting the administration of a previously authorized program, to submit to the House Committee on Education and Labor and the Senate Committee on Labor and Public Welfare a schedule for the publication of implementing regulations. The schedule must provide for the promulgation of all regulations within 180 days after its submission (i.e., within 240 days after enactment). Departures from the schedule must be approved by both committees and are allowed only "for circumstances unforeseen at the time of the submission of any such schedule." The Office of Education initially interpreted section 431(g) to require only the issuance of proposed rules within 240 days of a program's authorization, but Congress in 1976 amended section 431(g)<sup>429</sup> to clarify its intent to require the promulgation of final regulations within the statutory time limit.

424. On the advantages of published rules, see Sky, *Rulemaking and the Federal Grant Process in the United States Office of Education*, 62 *Va. L. Rev.* 1017, 1028 n. 27 (1976).

425. Pub. L. 93-380, §509(a)(1), 88 Stat. 566, 20 U.S.C. §1232(d)-(e) (Supp. V 1975).

426. On the experience of the Office of Education with this legislative veto provision, see Bruff and Gellhorn, *Congressional Control of Administrative Regulation: A Study of Legislative Vetoes*, 90 *Harv. L. Rev.* 1369, 1385-1390 (1977).

427. See 1 C.F.R. §308.7. -1.

428. See n. 412, *supra*. The relevant Senate committee is now the Senate Committee on Human Resources.

429. See n. 413, *supra*.

The 240-day time limit is a subsidiary feature of section 431(g). The primary purpose of that section was not to reduce delay but to force the promulgation of additional regulations.<sup>430</sup> Prior to 1974, the Office of Education had developed regulations for a newly authorized program only if the President intended to include appropriations for the program in his budget requests. This policy angered the Congress because Congress believed that this policy undermined its authority to determine which authorized programs to fund. If the Office of Education had not developed regulations for a program, a Congressional decision to appropriate funds for the program often could not be implemented during that fiscal year. Congress was also forced to make the appropriations decision without knowing how the agency intended to implement the authorized program. As a result, Congress directed the Office of Education to promulgate implementing regulations for all authorized programs and not just for funded programs or programs the Office wanted funded. The 240-day statutory time limit was simply selected as a device for insuring agency compliance with this directive.

Congress normally enacts education legislation in the form of massive biennial Education Amendments which clear both Houses near the end of each Congress in the fall of even-numbered years. This phenomenon aggravates the impact of section 431(g) at the Office of Education since the Education Amendments reflect two years of Congressional effort in program development. The Education Amendments of 1974 and of 1976 each required over forty packages of regulations to implement an equivalent number of newly authorized or revised programs. Congress rarely authorizes aid-to-education programs in separate legislation.<sup>431</sup> The single enactment date therefore triggers the 240-day statutory time limit which runs simultaneously for all new programs. The Office must promulgate regulations for all programs within 240 days and cannot defer the development of less important regulations to a later date.

For programs that are authorized and funded in the same year, the Office often has less than 240 days available to promulgate final rules if it is to award grants under those rules before the end of the fiscal year. Both the authorization and appropriation acts are unlikely to pass until fall, and the Office must disburse its grants by the close of the fiscal year on the succeeding June 30th (now September 30) to avoid a reversion of funds. The Office must allow at least forty-five days for preeffectiveness legal review of its rules by Congress under sections 431(d)-(e) of the General Education Provisions Act. That forty-five day period is further extended if Congress is

---

430. On the legislative history of section 431(g), see S. Rep. 93-763 93d Cong., 2d Sess. 95-96 (1974) (Education Amendments of 1974).

431. One prominent exception is the separate act (P.L. 94-142) amending the Education of the Handicapped Act. See n. 435, *infra*. Those amendments passed in November, 1975. The only separate act enacted in 1976 authorizing a new aid-to-education program was the Indo-china Refugee Act.

not in session, and with summer adjournments in mind the Office must plan for a typical review period between fifty to sixty days. The Office of Education may therefore have available to it substantially less than 240 days to promulgate final rules for programs that are funded in their first year. In these instances time pressures have forced the Office to solicit grant applications against proposed rules although it recognizes that this policy provides a substantial disincentive to the making of changes in the final rules.<sup>432</sup> The Department of Health, Education and Welfare has also invoked the good cause exception in section 553(b)(3)(B) of the Administrative Procedure Act to avoid the delays of notice and comment procedures for rulemaking. While this has not occurred recently, in June, 1975 the Department promulgated final regulations for four new programs authorized in the mammoth Education Amendments of 1974 without first publishing a notice of proposed rulemaking in order to award grants before the end of the fiscal year on June 30th. The Department also eliminated public procedures under section 553 in promulgating final regulations for the Right to Read program in late May, 1976.<sup>433</sup> Those regulations implemented a late statutory change enacted in December 1975. With the anticipated late summer, pre-election Congressional recess, the regulations could not have become effective before the end of the fiscal year on September 30, 1976 unless immediately promulgated. Of course, the elimination of section 553 procedures does not necessarily mean there is no public participation in the promulgation of the final rules; and in all the above proceedings there was public notice on the crucial issues through notices of intent or through prior, related rulemaking proceedings.

Section 431(g) imposes a similar tight schedule on the promulgation of rules for all authorized programs. Much of the rulemaking activity mandated by its provisions may prove to be unnecessary or premature since many authorized programs are never funded or only funded in subsequent years. The section also reduces the advantages of providing a one year gap between authorization and funding during which the Office of Education can develop program regulations before soliciting grant applications. If it were not for section 431(g), the Office would have between twelve and eighteen months to promulgate the regulations in order to prepare for the award of grants in the following year. Of course, rulemaking activity that hindsight determines was unnecessary or premature is not necessarily wasteful since Congress may believe that these costs are worth bearing in order to retain Congressional control over funding decisions. So far, however, Congress has not exercised an independent role in funding education programs not included in the President's budget.

The costs of excessive rulemaking are beyond the confines of this study which focuses on the effectiveness and desirability of statutory time limits

---

432. Sky, *supra* n. 417 at 1033-1034.

433. 41 FR 21453 (May 26, 1976).



as a device for reducing administrative delays. More central to the focus of the study is the tension between the statutory time limit in section 431(g) and the procedural requirements of modern rulemaking. In the case of the Office of Education this tension has been aggravated by former Secretary Mathews's Memorandum on Regulatory Policies.<sup>434</sup> That Memorandum, which could be more properly styled a directive, established rulemaking procedures for the principal operating components (POCs) in the Department (excluding only the Food and Drug Administration). Before initiating rulemaking activity, a POC was required to formulate a regulation development plan for approval by the Secretary. The POC was normally expected to include in the plan provisions for a notice of intent to engage in rulemaking, for public hearings before and after the publication of a notice of proposed rulemaking, and for a minimum comment period of at least forty-five days on the proposed rule.

The purpose of Secretary Mathews's requirement was to increase public participation in rulemaking by the Department and to produce rules that could be read and understood by ordinary people. In major rulemaking proceedings the Department has sought to defuse controversy by bringing the adversaries together at public hearings throughout the country. It has also retained outside laymen to assist it in drafting regulations that are written in plain English.<sup>435</sup> While the thrust of the Memorandum is consistent with the procedural requirements imposed by the courts on agency rulemaking, its specific provisions and its application in practice no doubt exceed what the courts have required. It also continues the Departmental policy of centralizing rulemaking authority in the Secretary, who must approve regulation development plans and sign all notices of intent, notices of proposed rulemaking, and final rules for the operating components within the Department, including the Office of Education.

The rulemaking procedures adopted by the Department under former Secretary Mathews are on collision course with the statutory time limit in section 431(g). More than 240 days are normally required to complete a rulemaking proceeding on the Secretary's model. Officials at the Office of Education have estimated that 318 days is the minimum time required. It is

---

434. 41 FR 34811 (Aug. 17, 1976).

435. See, for example, the extensive public participation and drafting efforts described in the preamble to the proposed rules on the incentive grants program for the education of handicapped children. 41 FR 56965 (Dec. 30, 1976). Those regulations implemented Pub. L. 94-142, the 1975 amendments to the Education of the Handicapped Act. Pub. L. 94-142, enacted on November 29, 1975 required the Department to promulgate the implementing regulations by January 1, 1977. Once again the Department interpreted the requirement to apply only to proposed regulations. While this interpretation seems strained, there was no real need to promulgate final regulations by the statutory deadline since Pub. L. 94-142 did not become effective until October 1, 1977. Until that time earlier statutes and regulations remained in effect. The Department issued proposed rules on the last day before the statutory deadline. In order to promulgate final rules by that time, it would have been necessary to sacrifice public participation and agency efforts at conciliation.

obvious that the statutory time limit did not prevent the adoption of rulemaking procedures that made compliance with the time limit difficult if not impossible. There is considerable evidence that not everyone at the Office of Education favored the new procedures and some even invoked the statutory time limit as a reason for dispensing with notices of intent and lengthy comment periods and for delegating authority to the Commissioner of Education to issue Federal Register notices and even to promulgate some final rules.

There is an underlying tension between the timely promulgation of regulations and Secretary Mathews's goals of increased public participation in rulemaking proceedings and of clarity in drafting rules. Secretary Mathews placed emphasis on improving the quality of regulations and was not primarily concerned with the problem of regulatory delay. Whether his Memorandum on Regulatory Policies has engendered undue delay in rulemaking proceedings is a matter of some controversy. Critics of the Secretary contend that the policies in the Memorandum added unnecessary steps to the rulemaking process which delayed the promulgation of final rules. Public participation became repetitive since the Department solicited comments on the same issue on more than one occasion.<sup>436</sup>

Secretary Califano has now adopted his own policy statement on the Reform of Departmental Procedures for Writing Regulations.<sup>437</sup> The new policy emphasizes the timely promulgation of regulations at the expense of some public participation. Whether it strikes the right balance is unknown at this time. Under the new policy statement there are three different models for rulemaking within the Department. For technical regulations that involve no policy changes the Department follows streamlined procedures that involve no more than the bare minimum required by section 553 of the Administrative Procedure Act. For major regulations (no more than fifteen proceedings per year), the Department continues to follow Secretary Mathews's model. For the large intermediate class of policy significant regulations, a review panel determines on a proceeding by proceeding basis what procedures to follow in addition to the minimum requirements of section 553. The review panel decides whether to use notices of intent, to hold public hearings before or after a notice of proposed rulemaking, or to lengthen comment periods. Authority to issue Federal Register notices may also be delegated to the head of the principal operating component.

---

436. Secretary Mathews's decision to issue a notice of intent to engage in rulemaking to implement section 504 of the Rehabilitation Act of 1973 encountered a barrage of criticism. That section prohibits discrimination against the handicapped by recipients of federal assistance. Commentators representing the interests of the handicapped condemned the notice as an unnecessary step and demanded that the Department immediately publish a notice of proposed rulemaking. For the notice of intent that provoked the hostile comment see 41 FR 20296 (May 17, 1976).

437. 42 FR (Oct., 1977).

*Experience Under the Education Amendments of 1976*

Pub. L. 94-482 (the Education Amendments of 1976) was the first authorizing legislation subject to the amended section 431(g) which required the Office of Education to promulgate final implementing regulations within 240 days. The President signed the Amendments on October 12, 1976, and the Office of Education dutifully submitted its schedule to the appropriate Congressional committees on the sixtieth day, December 11, 1976. The schedule listed thirty-seven packages of regulations implementing newly authorized or revised aid-to-education programs. All regulations were to be promulgated by June 9, 1977, the 240th day after enactment. At least thirteen of the packages involved new budget authorizations for which there were no funds in fiscal 1977 and, in most instances, no significant likelihood of funding in fiscal 1978. Two of these authorizations (Research Library Resources and Teacher Centers) required major rulemaking efforts.

Before transmitting its schedule to the committees, the Office of Education negotiated with Secretary Mathews's office some modifications in the Secretary's Memorandum on Regulatory Policies. For rulemaking packages that only involved minor technical amendments, the Secretary did not require the approval of a regulation development plan or the publication of a notice of intent to engage in rulemaking. For all other rulemaking packages, the Secretary delegated to the Commissioner of Education the authority to issue notices of intent. Where new authorizations only required the amendment of existing regulations, the minimum comment period following the issuance of a notice of proposed rulemaking was reduced in most proceedings from forty-five to thirty days. The Secretary's Office also committed itself to clear all notices of proposed rulemaking and final rules within either ten or fifteen days. These changes in Departmental policy were plainly prompted by the need to comply (or at least make an effort to comply) with the 240-day time limit in section 431(g).

The Office of Education did not have much success in complying with its initial schedule. By June 9, 1977, it had promulgated only four final regulations and one interim regulation and had issued an additional fifteen notices of proposed rulemaking. On June 27, 1977, the Commissioner of Education transmitted a new schedule to the Congressional committees which provided for the promulgation of forty additional packages of regulations by December 31, 1977. The revised schedule was computed by ascertaining where each package was in the rulemaking process and by allowing for its completion the number of days the Office's prototype or model for rulemaking allocated to the remaining stages of the process. In no case, however, was a promulgation date scheduled for later than the end of the calendar year.

The experience under the Education Amendments of 1976 discloses several major difficulties with section 431(g). First, the Commissioner is authorized to submit a new schedule extending the 240-day deadline only if he finds that he cannot comply with a previously submitted schedule "due

to circumstances unforeseen at the time of the submission.” This requirement that the causes of delay be “unforeseen” is difficult to take seriously. When the Commissioner submitted his initial schedule in December, 1976, everyone familiar with the situation could easily foresee that not all of the regulations could be promulgated by June 9, 1977. The number of regulations involved and the procedures required to promulgate them made it extremely unlikely that many final rules would appear within the remaining 180 days of the 240-day period. During fiscal 1977 the Office also had in process sixty-two other packages of program regulations that were not subject to the provisions of section 431(g). These rulemaking packages, which revised existing regulations that were not affected by the authorizations in the Education Amendments of 1976, represent an effort by the Office of Education to improve and clarify its programs. The “time critical” date for their promulgation was in many instances the early summer of 1977 since they affected funded programs where grant decisions had to be made before the end of the fiscal year on September 30th. From the Office’s perspective it was more important to promulgate these regulations than regulations for unfunded programs. While the Office of Education did proceed in good faith in attempting to meet the 240-day deadline,<sup>438</sup> there was never a significant likelihood that it would promulgate many regulations within that time period. The Commissioner’s June letter to the Congressional committees described the “unforeseen circumstances” responsible for the slippage beyond the 240-day deadline only in the most general terms (i.e., the change in Administrations, the number of policy issues, the swell of public participation, difficulties in drafting clear regulations, and the need to promulgate other program regulations).<sup>439</sup>

The second difficulty revealed by the Office’s experience under the Education Amendments of 1976 is the failure of the Congressional committees to act on or otherwise approve the new schedules submitted to them by the Commissioner of Education. Neither committee has so far responded to the Commissioner’s June submission, nor have they responded to any prior schedule submitted by the Commissioner under section 431(g). While it may well be inappropriate for Congressional committees to review the managerial decisions of administrators in the scheduling of rulemaking proceedings, section 431(g) plainly requires them to do so. A new schedule of promulgation dates is ineffective under section 431(g) unless both committees notify the Commissioner of their approval. In the absence of such

---

438. The Office of Education began work on implementing regulations when Pub. L. 94-482 (the Education Amendments of 1976) was still before the Congress. Two major notices of intent covering all major new authorizations appeared shortly after its enactment. 41 FR 51549 (Nov. 25, 1976); 41 FR 52410 (Nov. 29, 1976).

439. It is hard to see how the need to promulgate other program regulations, such as the regulations implementing the 1975 amendments to the Education of the Handicapped Act (see n. 435, *supra*), was “unforeseen” at the time the initial schedule was submitted in December 1975.

approval the old schedule remains in effect and the Office is vulnerable to suits to enforce that schedule or the 240-day deadline in section 431(g). So far, however, only one lawsuit has been filed, and that suit did not involve the Education Amendments of 1976.<sup>440</sup>

The Office of Education has, it appears, genuinely committed itself to comply with the revised schedule of promulgation dates submitted to Congress. The date that a final rule is due is known to everyone in the Department who is working on the rule. The Office has also established its own deadlines for intermediate steps in each rulemaking proceeding to insure satisfactory progress towards promulgation. Slippage has nevertheless occurred and the Department has missed the majority of the deadlines on the revised schedule. So far no deadline has been missed by more than two months, and in most instances the delay after the deadline passed was less than a month.

There are two principal reasons why the Office of Education has been unable to comply with the schedule. First, there is the sheer magnitude of the rulemaking activity within the Office. So many rulemaking proceedings are taking place simultaneously that it is simply not possible in many instances to meet a target date set long in advance. Too much is going on at once and upper echelon policymakers who must approve the final rules have only so much time available. In order to allow the Office to catch up on its rulemaking the Commissioner on July 29, 1977 declared a moratorium on all non-essential rulemaking. The moratorium, however, does not apply to rulemaking subject to section 431(g). Similar bottlenecks have occurred in the Office of the Secretary where the Executive Secretariat processes rules from throughout the Department for approval by the Secretary or Undersecretary. Again the sheer number of rules is very great. The only rules subject to a statutory time limit are those from the Office of Education. The Office of the Secretary has committed itself to a turn-around time of ten days on minor rules and fifteen days on major ones but is not now meeting those self-imposed deadlines. While the Office of the Secretary is aware of the scheduled date for promulgating a final rule, its priorities for ordering rulemaking from throughout the Department must take into account a broader range of considerations than does the Office of Education when it submits a schedule to Congress. The Office of the Secretary may therefore defer action on a rule until after the scheduled due date.<sup>441</sup>

---

440. In November, 1975, the American Council of the Blind sued to force the issuance of proposed confidentiality criteria for protecting the identity of handicapped children in state and local schools. The regulations were required under the Education Amendments of 1974. Section 431(g) as then interpreted only required that the Office of Education issue proposed rules within 240 days. The Office had failed to do so and had inadvertently omitted the confidentiality rules from the new schedule it submitted to the Congressional committees. The Office promptly issued a notice of proposed rulemaking pursuant to a consent decree that settled the case. *American Council of the Blind v. Mathews*, Civ. No. 75-10901 (D.C. D.C. 1975).

441. See, e.g., the regulations for the student Incentive Grant Program which were scheduled for promulgation by July 20, 1977. The Commissioner of Education signed the regulations on July 7, 1977, but the Under Secretary did not do so until September 3, 1977. The

There is a second, more basic reason why the Office of Education has been unable to comply with the schedules for promulgating rules under the Education Amendments of 1976. The promulgation dates are in effect target dates which the Office expects to meet if everything goes smoothly. Self-imposed intermediate deadlines enable the Office to determine whether a rulemaking proceeding is "on target". Slippage inevitably occurs whenever a difficulty or something unusual arises. The Office's monitoring system enables the Regulations Development Division in the Office of the Commissioner to identify quickly the source of delay and to correct it as speedily as possible. It therefore is to be expected that the Office will not meet most target dates. Missing a target date does not mean that there has been an unnecessary delay. If the Office misses a scheduled promulgation date by a month or two, the target date may nevertheless have served its function of expediting the rulemaking process.

The new Vocational Education Regulation<sup>442</sup> provides an example of this phenomenon. In less than one year the Office developed and promulgated major amendments to its regulations on vocational education to implement sections 201 and 202 of the Education Amendments of 1976. The Department first published a notice of intent on November 12, 1976, with a sixty-five day comment period. The notice identified fifteen major substantive issues and prompted over six hundred comments. The Office also held sixty-six public meetings through the country that were attended by over six thousand persons. The Department then published a notice of proposed rulemaking on April 7, 1977 with a thirty-day comment period. The Office of Education in late April held ten well attended public meetings on the proposal at the Department's regional centers. Over seven hundred persons filed written comments. The Commissioner's June letter to the Congressional committees scheduled the promulgation of the final rule for July 29, 1977, but the Department did not meet this deadline. The Office of Education simply required more time to analyze and respond to the massive public input in the proceeding. Despite the unexpected heavy workload, the Office of Education completed its work on the regulation and the Commissioner signed it on August 18, 1977. The Secretary signed it on September 26, 1977 and it appeared in the Federal Register on October 3, 1977. A major issue arose near the end of the proceeding when it was discovered that the notice of proposed rulemaking contained an error in statutory interpretation on

---

proposed rules had prompted no public comments. The final rules appeared in 42 FR 46040 (Sept. 14, 1977). The regulations for the Student Financial Assistance Training Program provide another example. Scheduled promulgation date was August 1, 1977. The Commissioner of Education signed the regulations on July 19, 1977, but the Under Secretary did not do so until September 2, 1977. The preamble to the final regulations was less than one page. See 42 FR 46047 (Sept. 14, 1977). In both instances the regulations could have been promulgated on time if the Office of the Secretary had met its goal of ten-day turn-around time for minor rules.

442. 42 FR 53821 (Oct. 3, 1977).

the funding formula. Extra time was needed to consult with Congress and to determine what to do in the case of states that had submitted plans in conformity with the funding formula in the proposed regulation.

While the vocational education proceeding demonstrates the effectiveness of deadlines, it does not demonstrate the effectiveness of the statutory time limit in section 431(g). The Office of Education had originally scheduled the promulgation of the vocational education regulation for June 1, 1977. That date, which was just eight days before the expiration of the 240-day period allowed for rulemaking under section 431(g), was the statutory deadline for promulgating the regulation. The Congressional committees never approved the extension of the deadline until July 29, 1977 and the Office of Education did not request a further extension. After June 1, 1977, the Office was vulnerable to a suit to enforce the legal requirement that it promulgate a regulation by that date. This vulnerability continued despite the Office's comparatively rapid progress toward promulgating a final rule. While the Office missed by four months the statutory deadline of June 1, 1977 (and by two months the revised target date of July 29, 1977), it is far more significant that the Office promulgated a major regulation eleven months after a notice of intent and five months after a notice of proposed rulemaking. That track record compares favorably with standard times at other agencies for rulemaking proceedings.<sup>443</sup>

While deadlines may operate to expedite rulemaking proceedings, more refined provisions for their use are necessary than those found in section 431(g). First, that section does not allow the Office of Education adequate flexibility to distinguish between high-priority and low-priority proceedings. It requires the Office to promulgate all rules implementing the Education Amendments within 240 days and permits extensions only for "unforeseen circumstances". The major new regulations required to implement the unfunded Research Library Resources and Teacher Center programs do not deserve the same priority as do the major amendments to the vocational education regulations that affected a funded program. While the Office of Education was able to work first on the development and promulgation of the vocational education regulation, the statutory time limit also required that it begin simultaneously on the other regulations. Second, section 431(g) treats the statutory time limit as a legal deadline and not a target date. While the Department (and perhaps the Congress) has in fact treated the deadline as a target date, the Office of Education is still unnecessarily vulnerable to suit.

---

443. In 1973 and 1974 the average time lapse at six independent agencies between the publication of a notice of proposed rulemaking and the promulgation of a final rule was almost three hundred days. Senate Comm. on Governmental Affairs, *Study on Federal Regulations: Delay in the Regulatory Process*, 95th Cong., 1st Sess. 29 (1977).

[The page contains extremely faint, illegible text, likely bleed-through from the reverse side of the document. The text is arranged in approximately 25 horizontal lines across the page.]