

by a motion to quash under the same rule.<sup>46</sup> Although the term "adjudication" encompasses many informal administrative activities,<sup>47</sup> the request for an order requiring an eligibility list clearly demands a higher level of action. *Wyman-Gordon* focused primarily on the invalidity of the "Excelsior Rule" *qua* rule and approved the requirement only in the interest of expediting that particular case. The error of that decision is demonstrated in *Delaware Valley Armaments* which transformed expediency into unassailable doctrine. Once the Court recognizes that there is no "rule" requiring this list and that an order requiring it can be issued only after a formal adjudication of that issue, it will increase the pressure on the NLRB to conform to the legislative intent that rule making be the primary means for the determination of policy. The Board will then be faced with a clear choice between conducting rule-making proceedings or properly adjudicating the issue anew in each case.

#### *Requirement of Notice and Hearing in Rate-Making Proceeding*

In *Moss v. CAB*<sup>48</sup> the Court of Appeals for the District of Columbia Circuit held that certain fare increases approved by the Civil Aeronautics Board, which the Board claimed were carrier-made and within its power to allow,<sup>49</sup> had actually been prescribed by the Board and were illegal because granted without fulfillment of the public notice and hearing requirements applicable to fare increases specified and imposed by the Board itself.<sup>50</sup> The petitioners, 32 Congressmen, had complained to the CAB on several occasions about its practice of holding *ex parte* meetings with air carrier representatives concerning the need for increased fares. Following a series of such meetings the carriers filed tariffs with the Board, proposing new rates to take effect after 30 days.<sup>51</sup> While its decision on these rates was pending, the Board held another *ex parte* meeting with the carriers,<sup>52</sup> after which it announced that it would hold a

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46. *Id.*

47. See note 12 *supra*.

48. 430 F.2d 891 (D.C. Cir. 1970).

49. See Federal Aviation Act § 1002(g), 49 U.S.C. § 1482(g) (1964) (if the Board does not suspend proposed fare increases within thirty days after filing, they become effective); *Id.* § 403(d), 49 U.S.C. § 1373(d).

50. *Id.* § 1002(d), 49 U.S.C. § 1482(d).

51. The carriers were following the procedure prescribed in 49 U.S.C. § 1373(c) (1964). See notes 64-68 *infra* and accompanying text.

52. Congressman Moss requested, but was denied, admission to this meeting. 430 F.2d at 894 & n.12.

public meeting on the advisability of exercising its statutory power<sup>53</sup> to suspend the proposed rate changes. Petitioners refused to participate in the hearing on the ground that it would be solely *pro forma*. Shortly after the hearing the Board suspended the proposed rate increases, pending an investigation. In its order, however, the Board set forth in detail a new rate structure from which “anyone could have . . . computed the acceptable coach fares”<sup>54</sup> and indicated that it would permit implementation of new tariffs filed in accordance with this structure without exercising its suspension powers.<sup>55</sup> The carriers promptly withdrew the tariffs filed initially and filed new tariffs based on the suggested rate structure. Petitioners applied for reconsideration of the Board’s order and opposed the new rate filings, but the Board permitted the new proposed tariffs to stand and the rate increases specified therein to take effect.<sup>56</sup> On appeal, the court invalidated the new rate increases and remanded the case for further proceedings.

Tariffs containing rate schedules must be submitted to the Board by every air carrier subject to CAB jurisdiction.<sup>57</sup> After a carrier is operating and fares have been established, rates may be changed by two methods. The first requires that the carrier file and give notice of a proposed increase or decrease in any fare.<sup>58</sup> Such a carrier-made fare will take effect in 30 days unless the Board decides to hold a hearing or to suspend temporarily the proposed changes pending an investigation and hearing.<sup>59</sup> A third party may petition to restrain any rate change thus proposed,<sup>60</sup> but the Board may dismiss such a petition without hearing if facts are not stated which warrant action or an investigation.<sup>61</sup> Thus, carrier-made rate increases of this type may become effective without a hearing, so long as they are properly filed 30 days in advance.

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53. 49 U.S.C. § 1482(g) (1964).

54. 430 F.2d at 896.

55. CAB Order of Investigation and Suspension, No. 69-9-68, Docket 21322 (Sept. 12, 1969), at 9 reported at 34 *Fed. Reg.* 14665, 68 (1969).

56. CAB Order Denying Reconsideration, No. 69-9-150, Docket 21322 (Sept. 30, 1969) reported at 34 *Fed. Reg.* 15428 (1969).

57. 49 U.S.C. § 1373(a) (1964).

58. *Id.* § 1373(c).

59. *See id.* § 1482(g).

60. 14 C.F.R. § 302.501 (1970).

61. *Flying Tiger Line, Inc. v. CAB*, 350 F.2d 462, 465 (D.C. Cir. 1965), *cert. denied*, 385 U.S. 945 (1966); 49 U.S.C. § 1482(a) (1964); 14 C.F.R. § 302.503 (1970). According to Professor Davis, the CAB disposes of most petitions without hearing. I K. DAVIS, *ADMINISTRATIVE LAW TREATISE* § 6.13, at 151 (Supp. 1965).

The second method by which rates may be changed is through Board action, taken upon its own initiative, although no carrier has filed an amended tariff.<sup>62</sup> After notice and a hearing the Board may modify any existing rate determined to be improper.<sup>63</sup> Notice and hearing must also be provided if the Board has invoked its suspension power.<sup>64</sup> It is clear, therefore, that when a rate is Board-made, the CAB must provide notice and hold a public hearing.

Whether rates are carrier- or Board-made is important for several reasons in addition to determining if a hearing is required. First, if the CAB permits new tariffs to become effective without a hearing or without exercise of its suspension power, only a limited record will be available for judicial review, making such review difficult and ineffective. Indeed, in such cases the Board's refusal to suspend and investigate carrier-made tariffs is reviewed only to ascertain whether there has been an abuse of discretion.<sup>65</sup> Second, the requirement of notice and hearing in the rate-making procedure also affects the propriety of *ex parte* communications. With respect to petitions which can be granted only after notice and hearing, the Board's rules prohibit *ex parte* contacts from the time of the filing of the petition; with respect to other matters, *ex parte* communications are forbidden after the Board gives notice that such matters will be determined upon a record after hearing.<sup>66</sup> But regardless of whether rates are carrier- or Board-made, the Federal Aviation Act, unlike the Interstate Commerce Act, does not provide for reparations by carriers in case

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62. 49 U.S.C. § 1482(d) (1964).

63. *Id.* Under the APA ratemaking is considered a rule-making or legislative function, 5 U.S.C. §§ 551(4) & 551(5) (Supp. V, 1970), requiring that interested persons be given notice and an opportunity to participate through "submission of written data, views or arguments with or without opportunity for oral presentation." *Id.* § 553(c).

64. 49 U.S.C. § 1482(g) (1964). At the time of exercising its suspension power the Board must indicate the reasons for so doing in writing. *Id.* Among the statutory criteria which the Board must take into account when holding such a hearing, or otherwise exercising rate-making powers, are the public interest in adequate service at the lowest possible cost, the character and quality of service, and the need of the carriers for sufficient revenue to operate effectively. *Id.* § 1482(e).

65. *Transcontinental Bus System, Inc. v. CAB*, 383 F.2d 466, 488 (5th Cir. 1967). *Flight Engineers' Int'l Ass'n v. CAB*, 332 F.2d 312 (D.C. Cir. 1964); *Pan American Grace Airways, Inc. v. CAB*, 178 F.2d 34 (D.C. Cir. 1949). *But see Trailways of New England, Inc. v. CAB*, 412 F.2d 926 (1st Cir. 1969).

66. 14 C.F.R. § 300.2 (1970) (hearing cases; improper influences). *Cf.* REPORT OF THE SPECIAL COMMITTEE ON REVISION OF THE ADMINISTRATIVE PROCEDURE ACT OF THE AMERICAN BAR ASSOCIATION, Resolution No. 4 (1970), which would expressly prohibit most *ex parte* communications.

fares are determined to be excessive or unlawful,<sup>67</sup> a factor indicating the importance of proper rate-making procedure.

Examination of the procedures of the Interstate Commerce Commission are instructive since the CAB's regulatory functions are largely patterned after those of the ICC.<sup>68</sup> In rate-making cases arising under the Interstate Commerce Act, whether rates are carrier-made or Commission-made is critical in determining a carrier's liability for unreasonable or illegal rates. If a tariff indicating rate increases is properly filed by the carrier and permitted to take effect by the ICC without further action, the increased rate will be legal, but the carrier will be liable for reparations of excess charges if subsequently it can be shown that the rates charged were unreasonable; thus, the carrier's rates could have been legal but still unreasonable.<sup>69</sup> On the other hand, if rates are specifically prescribed by the Commission, or prescribed to the extent that maximum or minimum rates are established, such rates are considered Commission-made, and the carrier is entitled to rely thereon without liability.<sup>70</sup> In *ICC v. Inland Waterways Corp.*<sup>71</sup> the Supreme Court reversed a district court's decision and upheld the Commission's vacation of a suspension order<sup>72</sup> in which the Commission indicated that the rates it was permitting to stand were "just and reasonable

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67. Sections 8 and 9 of the Interstate Commerce Act, 49 U.S.C. §§ 8 & 9 (1964), provide for the recovery of damages if a carrier charges excessive rates in violation of the Act. *See also id.* § 304a (Supp. V, 1970).

68. The Federal Aviation Act of 1958, 72 Stat. 731, insofar as its provisions for economic regulation of carriers was concerned, was a substantial reenactment of the Civil Aeronautics Act of 1938, ch. 601, 52 Stat. 973. The provisions of the Civil Aeronautics Act relating to economic regulations in turn were patterned after similar provisions of the Interstate Commerce Act. C. RHYNE, *CIVIL AERONAUTICS ACT ANNOTATED* xiii-iv (1939). For this reason there was little debate concerning the intent of Congress with respect to the provisions so modeled, and a sizable body of case law was incorporated into such provisions. *Id.* at xiv-xv; *see* Aitchison, *The Evolution of the Interstate Commerce Act 1887-1937*, 5 GEO. WASH. L. REV. 289, 304 & n.34 (1937). This is important because the Federal Aviation Act of 1958 was not intended to be a legislative endorsement of prior administrative or judicial decisions with respect to provisions which had already been in effect that were reenacted in the same or identical language, but rather "an absolute neutral factor in any question of interpretation." H.R. REP. NO. 2360, 85th Cong., 2d Sess. 10-11 (1958). Consequently, to gauge congressional intent with respect to the Federal Aviation Act it may still be necessary to consider the provisions of the Interstate Commerce Act and pertinent case law as they existed in 1938.

69. *Arizona Grocery Co. v. Atchison, T. & S.F. Ry.*, 284 U.S. 370, 383-84 (1932).

70. When making rates, the Commission is speaking in a quasi-legislative capacity. *Id.* at 386-88. *See also* *United States v. Illinois Cent. Ry.*, 263 U.S. 515, 524 (1924).

71. 319 U.S. 671 (1943).

72. The ICC, like the CAB, has the power to suspend tariffs. 49 U.S.C. § 15(7) (1964); *see* *Arrow Transp. Co. v. Southern Ry.*, 372 U.S. 658 (1963).

and are not shown to be otherwise unlawful.”<sup>73</sup> Notwithstanding this language, the Court held that the rates in question were carrier-made and not “approved” or “prescribed” by the Commission, so that the carriers would still be liable for reparations if the rates were subsequently found unreasonable.<sup>74</sup> A similar result occurred in a case<sup>75</sup> in which the ICC suspended tariffs which had been filed by carriers but at the same time explained a plan of “carefully selected moderate” increases which it would accept.<sup>76</sup> These increases were set forth in detail in an appendix to the Commission’s order with which the carriers were left free to comply by filing new tariffs.<sup>77</sup> Nevertheless, the Commission made it clear that compliance with its proposed increases would be “permissive in character” and that the resulting rates would be considered carrier-made.<sup>78</sup> In *Public Utilities Commission v. United States*,<sup>79</sup> another case involving facts similar to those in the principal case, the court followed the precedents decided under the Interstate Commerce Act. The FCC<sup>80</sup> had held *ex parte* meetings over a period of months with representatives of the Bell System. Following these meetings the Commission issued a public notice indicating that there would be major reductions in interstate telephone rates. Subsequently, Bell filed tariffs complying precisely with the rates indicated in the Commission’s notice. The utilities commission filed a request for rehearing, claiming that the FCC’s informal meetings had been a “proceeding” and that it had been denied the opportunity to be heard in violation of sections 204 and 205 of the Communications Act.<sup>81</sup> The court, however, upheld the Commission’s claim that the informal meetings had not been a rule-making proceeding, inasmuch as the carrier was not *required* to file the tariff in question, and held the new rates to be carrier-made, so as not to preclude customers from later seeking damages.<sup>82</sup> Other recent

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73. 319 U.S. at 682.

74. *Id.* at 686-87. *See also* *ICC v. Mechling*, 330 U.S. 567 (1947).

75. *Algona Coal & Coke Co. v. United States*, 11 F. Supp. 487 (E.D. Va. 1935).

76. *Emergency Freight Charges*, 208 I.C.C. 4, 60 (1935).

77. 11 F. Supp. at 491.

78. *Id.* at 491. *See also* *Birmingham Slag Co. v. United States*, 11 F. Supp. 486 (N.D. Ala. 1935).

79. 356 F.2d 236 (9th Cir.), *cert. denied*, 385 U.S. 816 (1966).

80. The statutory scheme under which the FCC regulates rates for wire communications carriers is similar to those of the ICC and CAB. *See* 47 U.S.C. §§ 203-07 (1964).

81. *Id.* §§ 204 & 205 (1964).

82. 356 F.2d at 240.

decisions<sup>83</sup> have confirmed the view expressed in *Public Utilities Commission*. However, part of the justification for these decisions was that any person would still be permitted to challenge the reasonableness of any specific rate that caused him to be aggrieved,<sup>84</sup> an opportunity which would not be available in the circumstances of *Moss*.

The holding in *Moss v. CAB* is a narrow one: that the CAB had not complied with its statutory mandate to provide notice and a hearing when establishing Board-made rates. It rests on the single determination that the tariffs permitted to go into effect by the Board were Board-prescribed—not carrier-made. In making this determination the court first attempted to distinguish decisions under other statutes and noted that under the Federal Aviation Act, unlike the Interstate Commerce Act and Federal Communications Act, there is no provision for carrier reparations in case of unreasonable or illegal fares.<sup>85</sup> This, the court claimed, made it especially crucial that the public, which would pay the fares, be able to participate in rate-making proceedings. Undoubtedly this distinction is a critical one inasmuch as the rates of carriers operating under the supervision of the ICC and FCC are subject to judicial scrutiny,<sup>86</sup> whereas under the Federal Aviation Act the only remedy for the CAB's failure to suspend a tariff would be to bring a suit alleging abuse of discretion.<sup>87</sup> The court also suggested that the description of fares in the CAB's suspension order was more detailed and explicit than in any prior case, thus making this a clear case of prescription.<sup>88</sup>

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83. *Alabama Power Co. v. United States*, 316 F. Supp. 337 (D.D.C. 1969), *prob. juris. noted*, 398 U.S. 903 (1970); *Atlantic City Elec. Co. v. United States*, 306 F. Supp. 338 (S.D.N.Y. 1969) *prob. juris. noted*, 398 U.S. 903 (1970); *Florida Citrus Comm'n v. United States*, 144 F. Supp. 517 (N.D. Fla. 1956), *aff'd*, 352 U.S. 1021 (1957); *cf. Cincinnati, N.C. & T.P. Ry. v. Chesapeake & O. Ry.*, 312 F. Supp. 972 (1970). *But see* 316 F. Supp. at 339 (Wright, J., dissenting).

84. *See, e.g., Arizona Grocery Co. v. Atchison, T. & S.F. Ry.*, 284 U.S. 370, 390 (1932).

85. The determination that there is no carrier liability rests on the absence of statutory language so indicating and a Supreme Court decision that the absence of such language in the Motor Carriers Act precluded liability for reparations. *T.I.M.E., Inc. v. United States*, 359 U.S. 464 (1959); *cf. National Motor Freight Traffic Ass'n v. United States*, 268 F. Supp. 90 (D.D.C. 1967), *aff'd*, 393 U.S. 18 (1968). This reasoning is almost certainly correct. *See Tishman & Lipp, Inc. v. Delta Air Lines*, 413 F.2d 1401, 1406 n.8 (2d Cir. 1969). It is unlikely that the omission of a reparations provision from the Civil Aeronautics Act of 1938 was due to oversight since one of the concerns of Congress in adopting the Act was to promote financial stability in the commercial air carrier industry. *See C. RHYNE, supra* note 68, at 134-38. *But see* *The Wall St. Journal*, March 2, 1971, at 3, col. 2 (Eastern ed.).

86. *See* 47 U.S.C. § 207 (1964); 49 U.S.C. § 9 (1964); *id.* § 304a (Supp. V, 1970).

87. 430 F.2d at 900. *See* note 89 *infra*.

88. This distinction does not appear valid since the rates in question in two lower court decisions involving rail carriers were extremely detailed. *See* notes 75-78 *supra* and

The court also attempted to distinguish *Moss* from *Public Utilities Commission* and the decisions under the Interstate Commerce Act on the grounds that the CAB was attempting to avoid judicial review through use of its suspension powers, pointing out that the Board's suspension authority is insulated from judicial review<sup>89</sup> and that an inadequate record for review had been produced. These observations are correct, but they do not really serve to distinguish *Moss*. The Board's suspension powers are no more insulated from judicial review than are the suspension powers of the ICC or FCC.<sup>90</sup> Insofar as the record available for review is concerned, the Board did hold a hearing regarding the advisability of exercising its suspension powers, in which petitioners declined to participate. With the exception of *Public Utilities Commission*, where there was no hearing, precisely this kind of a hearing was held in other suspension cases.<sup>91</sup> Unless such a hearing were *pro forma*, as alleged in *Moss*, its failure to produce an adequate record would not seem to be a procedural defect attributable to an intentional attempt to avoid judicial review. Finally, the court distinguished *Moss* on the basis of the *ex parte* communications—the attempts to eliminate the public from the Board's proceedings—a factor that indeed differentiates *Moss* from all the cases except *Public Utilities Commission*.<sup>92</sup> This and the fact that reparations are not available under the Federal Aviation Act, both important considerations with respect to the protection of the public, are the two convincing features cited by the court which distinguish *Moss* from the precedents under the Interstate Commerce Act.

Because the Board is required to state in writing the reasons for exercising its suspension power,<sup>93</sup> a subtle problem arises. Such explanation would in all likelihood contain some entirely proper

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accompanying text. However, in the *Public Utilities Commission* decision there was no indication concerning the precision with which the allegedly prescribed rates had been set forth in the Commission's notice, 356 F.2d at 238, but even if there had been, such evidence would not have been conclusive with respect to the detail with which the rates had actually been prescribed since, as in *Moss*, it was not known what had transpired at the *ex parte* meetings.

89. 430 F.2d at 900; see *Arrow Transp. Co. v. Southern Ry.*, 372 U.S. 658 (1963). See note 65 *supra* and accompanying text.

90. But see notes 84 & 86 *supra* and accompanying text.

91. See, e.g., *Algoma Coal & Coke Co. v. United States*, 11 F. Supp. 487 (E.D. Va. 1935).

92. In *Public Utilities Commission v. United States*, there were also *ex parte* communications. However, the court hinted at disapproval of that decision. See 430 F.2d at 899 n.33.

93. 49 U.S.C. § 1482(g) (1964). See note 64 *supra*.

indication, whether direct or indirect, of the kind of fares that the Board would consider permissible. Consequently, the court did not say that the Board could not explain its reasons for suspending the tariffs initially filed by the carriers but only that it went much too far.<sup>94</sup> In reality a question of degree was involved in determining how detailed an explanation the Board should have made for exercising its suspension powers; the court, in deciding that the Board had gone too far, determined that the Board had abused its discretion. It is precisely on this point that prior judicial decisions differ.<sup>95</sup> In making this decision the court indicated clearly that it will look beyond what an agency says it has done to what it has actually done. At the same time the court attempted to demonstrate that it was not demanding the impossible from the Board—a complete general rate investigation before any action at all was taken. It indicated that action taken by the Board on an interim basis would be sympathetically considered and that its review of such interim action would be conducted on a limited basis.<sup>96</sup>

The technical holding in *Moss*, even though a question of first impression, is of limited significance, for it applies to only one agency<sup>97</sup> and relies upon a determination that the Board abused its discretion, a determination largely dependent on the specific facts in that case. But despite the narrow technical holding of the case, the court suggests that its opinion should be read more broadly. The case presents a broad, recurring question which plagues the public regulation of industry: whether regulatory agencies are unduly oriented toward the interest of the industry being regulated.<sup>98</sup> The court condemns in sweeping terms the exclusion of the public from agency proceedings and implies that it will not hesitate to use such exclusion as a basis for voiding agency action. At the same time, however, the court does not indicate any specific basis in rule or statute for prohibiting *ex parte* contracts, at least to the extent that they occurred in *Moss*. Thus, the court can find the CAB “guilty” only of bad faith toward the public.<sup>99</sup> To this extent *Moss* is

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94. 430 F.2d at 898.

95. See, e.g., cases cited at notes 74-77 *supra*.

96. 430 F.2d at 901-02. See also *Bell Lines, Inc. v. United States*, 306 F. Supp. 209, 215-16 (S.D.W. Va. 1969), *aff'd*, 397 U.S. 818 (1970).

97. The court suggests that “a somewhat different statute and a different industry” may make one case distinguishable from another. 430 F.2d at 899 n.33.

98. *Id.* at 893.

99. While a question of bad faith was not involved, the CAB has been criticized and its decision reversed for excessively informal procedure on a prior occasion. See *CAB v. Delta Air Lines, Inc.*, 367 U.S. 316 (1961).



illustrative of a growing judicial disenchantment with the procedures followed by some administrative agencies. This attitude is reflected in the increased willingness of courts to look beyond agency explanations to find that efforts were made to exclude the public,<sup>100</sup> that agencies attempted to evade judicial review,<sup>101</sup> and that agencies exhibited bad faith;<sup>102</sup> the trend is also illustrated by the increased willingness to permit representatives of the public interest to intervene in agency proceedings.<sup>103</sup> To the extent that review by skeptical courts exposes and curtails improper practices, this trend is unquestionably salutary.

However, the larger question, whether such decisions have any significant impact on the administrative process, remains unanswered. A finding that an agency has exercised bad faith, such as in *Moss*, has little precedential value. And it would seem quite easy for the CAB to violate the spirit of *Moss* simply by not setting forth specific rates in a suspension order, while continuing to communicate informally with air carriers to whatever extent it felt necessary. Moreover, there would be little a court could do about this, so long as the Board complied with the statutory prerequisites and did not violate its own rules.<sup>104</sup> Even assuming, however, that the agencies will exercise good faith in following judicial decisions, developments subsequent to the *Moss* decision illustrate how minimal the effects of a judicial decision may be. The Board filed for a partial stay of the court's mandate to permit the unlawful tariffs to stay in effect while carriers filed new tariffs free of Board compulsion.<sup>105</sup> After considering the new tariffs,<sup>106</sup> the Board suspended them all with the exception of those which proposed continuation of the fares already in effect.<sup>107</sup> Hence, after 13 months during which the rates determined by

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100. *Environmental Defense Fund, Inc. v. Ruckelshaus*, \_\_\_\_ F.2d \_\_\_\_, \_\_\_\_ (D.C. Cir. 1971).

101. *Id.*

102. See *Office of Communications of United Church of Christ v. FCC*, 425 F.2d 543, 547 (D.C. Cir. 1969). See also Comment, *Administrative Agencies, the Public Intent, and National Policy: Is a Marriage Possible?*, 59 GEO. L.J. 420, 445-46 (1970).

103. *National Welfare Rights Org. v. Finch*, 429 F.2d 725, 732-33 (D.C. Cir. 1970); *Office of Communications of the United Church of Christ v. FCC*, 359 F.2d 994, 1000 n.8 (D.C. Cir. 1966). See the discussion of *Firestone Tire & Rubber Co.*, section V, *infra*, for an example of increased agency willingness to permit public interest intervention.

104. See note 66 *supra* and accompanying text.

105. CAB Release 70-102 (July 29, 1970).

106. CAB Release 70-108 (Aug. 19, 1970).

107. CAB Release 70-123 (Sept. 24, 1970).

the court to be illegal were in effect, the Board determined that these same rates were proper and should remain in effect. The *Moss* decision and the events following it thus illustrate clearly that if significant reforms are to be made in the administrative process, efforts to achieve them must extend beyond the courts.<sup>108</sup>

#### *Compliance With APA Requirements in FDA Rule Making*

In *Pharmaceutical Manufacturers Association v. Finch*<sup>109</sup> the United States District Court for Delaware held that regulations promulgated by the Commissioner of Foods and Drugs for determining the effectiveness of drugs had an immediate and substantial impact on the pharmaceutical industry, requiring notice and an opportunity for interested parties to comment before adoption. In 1962, Congress amended the Food, Drug and Cosmetic Act to require drugs to be effective, as well as safe, and authorized the Food and Drug Administration to refuse drug applications when there was a "lack of substantial evidence" that a drug was effective for its predicated use.<sup>110</sup> Substantial evidence was defined vaguely as "adequate and well-controlled investigations, including clinical investigations, by experts."<sup>111</sup> In September, 1969, the Commissioner issued regulations detailing the criteria for "adequate and well-controlled clinical investigations" and restricting the testing procedures which could be used to prove effectiveness.<sup>112</sup> The Commission was already empowered by the 1962 amendments to remove drugs from the market for lack of substantial evidence of effectiveness. The September regulations further provided that when the Commissioner promulgated regulations removing drugs from the market, the affected drug companies could obtain a formal hearing only by convincing the Commissioner that the efficacy of the drug in question was supported by "adequate and well-controlled investigations" of the kind described in the same regulations.<sup>113</sup> When the regulations were made operative immediately upon publication in the *Federal Register*,<sup>114</sup> the Pharmaceutical Manufacturers

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108. In this context it is interesting to observe that since the *Moss* decision the CAB has established a new consumer advisory council, the function of which is to advise the Board on questions of public interest. See *Washington Post*, Oct. 22, 1970, § F at 12, col. 1.

109. 307 F. Supp. 858 (D. Del. 1970).

110. 21 U.S.C. § 355(d) (1964).

111. *Id.*

112. 34 *Fed. Reg.* 14596-97 (1969).

113. *Id.* at 14596.

114. 307 F. Supp. at 863.