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.[108]

Compliance With APA Requirements in FDA Rule Making

In *Pharmaceutical Manufacturers Association v. Finch*[109] 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.[110] Substantial evidence was defined vaguely as "adequate and well-controlled investigations, including clinical investigations, by experts."[111] 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.[112] 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.[113] When the regulations were made operative immediately upon publication in the *Federal Register*,[114] the Pharmaceutical Manufacturers

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.

Association sought a preliminary injunction to restrain the Commissioner from acting in reliance upon the regulations and from applying them retroactively, contending that the regulations were invalid because issued without notice and an opportunity for comment in violation of sections 4(b) and 4(c) of the Administrative Procedure Act.[115] In response, the Commissioner claimed the regulations to be "interpretive," rather than "legislative," and therefore within the exception to notice and hearing of section 4(b) of the APA.[116] The Commissioner asserted that the regulations were interpretive since they were the direct result of the substantial evidence of effectiveness requirements of the 1962 amendments and merely particularized an existing statutory standard. The court decided that the Commissioner's characterization was not conclusive and that the general policy considerations behind sections 4(b) and 4(c) compelled notice and hearing to avoid undue hardship, regardless of the type of regulation involved. In holding the September regulations invalid because issued without notice and opportunity to comment, the court did not rule on the validity of the regulations *per se* but granted a preliminary injunction to allow the pharmaceutical companies an opportunity to present their grievances to the FDA.

Section 4(b) of the APA exempts "interpretive" regulations from the requirements of pre-adoption notice and opportunity for comment;[117] yet "interpretive" regulations are neither defined nor distinguished from "legislative" regulations within the Act. The Supreme Court has never attempted to articulate the differences between the two types of regulations, despite controversies over their meanings,[118] but lower courts frequently have so characterized regulations and made the characterization a dispositive factor.[119] Legislative regulations create law and are regulations which the administrator is expressly empowered to make by statute. They receive statutory force when promulgated,[120] for legislative regulations

115. 5 U.S.C. § 553(b), (c) (Supp. V, 1970).

116. *Id.* § 553(b), which states that: "Except when notice or hearing is required by statute, this subsection shall not apply to interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice . . . ."

117. *Id.*

118. 1 K. DAVIS, ADMINISTRATIVE LAW TREATISE § 5.03 (1958) [hereinafter cited as DAVIS].

119. *See* Allstate Ins. Co. v. United States, 329 F.2d 346, 349 (7th Cir. 1964); American President Lines, Ltd. v. FMC, 316 F.2d 419 (D.C. Cir. 1963); *In re* Chin Thloot Har Wong, 224 F. Supp. 155, 165 (S.D.N.Y. 1963).

120. REPORT OF THE ATTORNEY GENERAL'S COMMITTEE ON ADMINISTRATIVE PROCEDURE, S. DOC. No. 8, 77th Cong., 1st Sess. 100 (1941); *see* Davis, *Administrative Rules—Interpretative, Legislative, and Retroactive*, 57 YALE L.J. 919, 936 (1948).

are often necessary to implement an existing statute. Because there is a presumption that Congress delegated finality as to the substance of legislative regulations to the agencies rather than to the courts, reviewing courts are reluctant to overturn them.[121] When a delegation of power is explicit, courts find authority for an agency to promulgate legislative regulations;[122] otherwise, regulations are presumed to be interpretive. Interpretive regulations—agency statements concerning the meaning of existing statutes, legislative rules, other interpretive regulations, and administrative decisions—do not propose new law and are not entitled to statutory force. The validity of interpretive regulations is subject to challenge in a judicial proceeding,[123] and they often are invalid when issued without notice and a hearing.[124]

Not only is the distinction between the two types of regulations uncertain, but the relevance of the distinction to the issue of reviewability is questionable. The assumption that legislative regulations are not reviewable, while interpretive regulations are, underlies the exemption from notice and hearing for interpretive regulations embodied in section 4(b) of the APA. The rationale behind the exemption seems to be that since judicial review will be readily available for interpretive regulations and these regulations are not legally binding, the principal remedy will lie with the courts rather than with the agencies.[125] The majority of courts, however, have ignored the distinction when granting review,[126] for review has been denied even when regulations were interpretive.[127] The validity of a regulation now rarely depends upon the type of regulation involved. Since the Supreme Court has held that an agency is not the proper party to define either its delegated power or the nature of the regulations issued pursuant to that power,[128] courts no longer defer to

121. DAVIS § 5.03, at 299.

122. *See, e.g.*, Boynton v. Pedrick, 136 F. Supp. 888, 890 (S.D.N.Y. 1954), *aff'd*, 228 F.2d 745 (2d Cir. 1955).

123. REPORT OF THE ATTORNEY GENERAL'S COMMITTEE ON ADMINISTRATIVE PROCEDURE, *supra* note 120, at 100.

124. *See* United States v. 353 Cases, 247 F.2d 473 (8th Cir. 1957), *cert. denied*, 358 U.S. 834 (1958).

125. *See* S. DOC. No. 248, 79th Cong., 2d Sess. 18 (1946). The Senate Committee indulged in this fictitious distinction of reviewability by describing "interpretive" rules as subject to plenary review, whereas legislative rules involve a maximum of administrative discretion.

126. Columbia Broadcasting Sys., Inc. v. United States, 316 U.S. 407 (1942); B.C. Morton Int'l Corp. v. FDIC, 305 F.2d 692 (1st Cir. 1962).

127. American President Lines, Ltd. v. FMC, 316 F.2d 419 (D.C. Cir. 1963), *criticized in* DAVIS § 5.03 (Supp. 1970); Helco Prods. Co. v. McNutt, 137 F.2d 681 (D.C. Cir. 1943).

128. Addison v. Holly Hill Fruit Prods. Co., 322 U.S. 607, 616 (1944). *See generally* DAVIS § 5.05, at 317.

the label placed upon a regulation by an agency.[129] Practical considerations, such as whether skills and knowledge particularly unique to the agency rather then to the court are necessary for formulating the regulation[130] and the adverse effect of a regulation upon a party seeking review,[131] often prevail over definitions. Yet, the most important factor in upholding any type of regulation is the amount of power granted to the administrator by Congress and the degree to which the administrator may have exceeded this power.

The Food, Drug and Cosmetic Act has been regarded as an outstanding example of a statute providing ample due process safeguards.[132] Denials of hearings and lack of notice by the Food and Drug Administration were unusual prior to the late 1960's.[133] Inherent in the 1938 Act was the importance of a hearing before regulations could become effective,[134] and, although the Act imposed no real limitation on the procedures used to issue guidelines and interpretive regulations, explicit procedures were to be followed for the issuance of legislative regulations.[135] Sentiment for the rights of notice and hearing abated in 1954, resulting in the enactment of the Hale Amendment[136] to alleviate procedural burdens for food standard regulations by denying public hearings on noncontroversial questions.[137] Despite the Hale Amendment, hearings were still granted liberally, and the limited number of cases between 1954 and 1962 indicated that most controversies were being resolved through the administrative process rather than through litigation.[138]

129. *See* NLRB v. Wyman-Gordon Co., 394 U.S. 759, 764 (1969); Columbia Broadcasting Sys., Inc. v. United States, 316 U.S. 407, 416 (1942). "The particular label placed upon it by the Commission is not necessarily conclusive, for it is the substance of what the Commission has purported to do and has done which is decisive." *Id.* at 416. *See also* National Motor Freight Traffic Ass'n v. United States, 268 F. Supp. 90, 95-97 (D.D.C. 1967); Seaboard World Airlines, Inc. v. Gronouski, 230 F. Supp. 44, 46 (D.D.C. 1964).

130. *See, e.g.*, ICC v. Service Trucking Co., 186 F.2d 400, 402 (3d Cir. 1951).

131. Abbott Labs. v. Gardner, 387 U.S. 136, 140 (1967); Bantam Books, Inc. v. Sullivan, 372 U.S. 58, 66-67 (1963).

132. *See* DAVIS § 6.06.

133. *But cf.* Dyestuffs & Chems., Inc. v. Flemming, 271 F.2d 281 (8th Cir. 1959), *cert. denied*, 362 U.S. 911 (1960).

134. In its original form, the Federal Food, Drug and Cosmetic Act § 701(e), ch. 7, 52 Stat. 1040, 1055 (1938), provided: "The Secretary, on his own initiative or upon application of an interested industry or substantial portion thereof, shall hold a public hearing upon a proposal to issue, amend, or repeal any regulation . . . ."

135. *Id.*

136. Federal Food, Drug and Cosmetic Act §§ 401, 701(e), 21 U.S.C. §§ 341, 371(e) (1964), *amending* 21 U.S.C. §§ 341, 371(3) (1938).

137. S. REP. No. 1060, 83rd Cong., 2d Sess. 2 (1954).

138. *See* Certified Color Indus. Comm. v. Secretary, 283 F.2d 622 (2d Cir. 1960); Dyestuffs & Chems., Inc. v. Flemming, 271 F.2d 281 (8th Cir. 1959); United States v. 353 Cases, 247 F.2d 473 (8th Cir. 1957).

In the late 1950's, after an exhaustive investigation of the drug industry by Senator Kefauver's subcommittee on Antitrust and Monopoly encouraged reform in the procedure for approving drugs,[139] Congress took notice of the dangers of unsafe and ineffective drugs and began to formulate legislation to revise the procedures. The Kefauver-Harris Amendments of 1962 authorized the FDA, after giving notice and an opportunity for a hearing, to withdraw approval or deny an application for any drug if there was a lack of evidence that the drug would have its represented effect.[140] The FDA then contracted with the National Academy of Sciences-National Research Council (NAS-NRC) to review the effectiveness of both approved and new drugs and promptly gave notice of this arrangement to the drug industry.[141] Drug regulations were issued with greater frequency, but it was not until *Abbott Laboratories v. Gardner*[142] that the Supreme Court acknowledged the procedural problems surrounding the issuance of regulations by granting pre-enforcement review when the adverse effect of a regulation upon a party was "sufficiently direct and immediate."[143]

The court in *Pharmaceutical Manufacturers Association* followed *Abbott Laboratories* by declining to make its own determination of the interpretive or legislative nature of the Commissioner's regulations and by adhering instead to the general purposes underlying sections 4(b) and 4(c) of the APA. The court held that the distinction between the two types of regulations did not determine the applicability of sections 4(b) and 4(c), for the central objective of the APA was to provide notice and an opportunity for comment in any case where a proposed regulation would have a substantial impact upon the regulated industry or an important class of the members or the products of that industry.[144] By making the regulation effective upon publication in the *Federal Register,* the Commissioner had neither given the required general notice of proposed rule making nor complied with the APA requirement of a thirty-day period for

139. *See* Upjohn Co. v. Finch, 422 F.2d 944, 946, 960-61 (6th Cir. 1970).

140. 21 U.S.C. § 355(e) (1964), *amending* 21 U.S.C. § 355 (1938). However, 21 U.S.C. § 357(f) requires persons objecting to the removal of certain antibiotics to file a petition stating "reasonable grounds" for obtaining a hearing. If the Secretary decides "reasonable grounds" for a hearing do not exist he can deny the petition.

141. 31 *Fed. Reg.* 9426 (1966).

142. 387 U.S. 136 (1967); *see* Gardner v. Toilet Goods Ass'n, Inc., 387 U.S. 167 (1967). *But cf.* Toilet Goods Ass'n, Inc. v. Gardner, 387 U.S. 158 (1967).

143. 387 U.S. 136, 152 (1967).

144. 307 F. Supp. at 863.

comment by interested parties before making the regulations effective.[145] The court attacked the substance of the regulations by emphasizing the hardship that such a drastic departure from past testing procedures would have on the drug industry. According to the court, the regulations were pervasive enough to jeopardize more than two thousand previously marketed drugs by making them subject to immediate removal from the market if they did not meet the new standards. Historical control, or the consensus of medical experience and usage as an indicator of effectiveness, would be available only in special circumstances, while exacting clinical investigations would be preferred.[146] Such a change was considered patently unfair by the court, for there had been no precise understanding as to proof of effectiveness prior to the 1969 regulations.[147] The court believed that under the new standards companies would not be able to employ the additional research investigators needed to perform the required tests since many trained clinicians would not be interested in testing drugs which had already been marketed and accepted as effective by the medical profession. The court also observed that the regulations involved a fundamental public policy decision, for testing resources are extremely scarce, and the regulations would require the reallocation of these resources and their removal from the critical areas of research and development. Therefore, the court concluded that the Commissioner was obligated, both to the pharmaceutical companies and to the public dependent upon drug research, to provide notice and opportunity for comment before effectuating such pervasive regulations.

Pharmaceutical Manufacturers Association should prompt the FDA to implement the policies of fairness and compliance with due process inherent in the Federal Food, Drug and Cosmetic Act and in the APA when promulgating pervasive regulations directed at the

145. 5 U.S.C. § 553(b)(Supp. V, 1970).

146. 34 *Fed Reg.* 14596 (1969).

147. 307 F. Supp. at 865. The 1969 Regulations challenged in *Pharmaceutical Manufacturers Association* were republished after interested parties had an opportunity to comment. When, pursuant to the republished regulations, the Commissioner denied hearings on the removal of drugs because of a lack of sufficient evidence of effectiveness, two companies challenged the validity of the regulation.

In both cases, the court upheld the regulations stating that the Commissioner, pursuant to his rule-making powers, could, after giving interested parties opportunity to comment, deny an evidentiary hearing unless "reasonable grounds" therefore are first established. Upjohn Co. v. Finch, 422 F.2d 944 (6th Cir. 1970); Pfizer, Inc. v. Richardson, 434 F.2d 536 (2d Cir. 1970).

entire pharmaceutical industry.[148] Although the FDA's primary responsibility is the protection of the consumer,[149] the September regulations questioned in *Pharmaceutical Manufacturers Association* would deprive not only the drug industry, but the public as well, of the statutory right to comment and object to the substance of the regulations. The FDA was required to remove ineffective drugs from the market by the 1962 amendments; if notice and opportunity for comment had been provided before the promulgation of the September regulations, unnecessary litigation might have been avoided and the designated drugs removed from the market much sooner. When litigation occurs, testing by the NAS-NRC often ceases, and the regulations are placed in abeyance pending the outcome of litigation. Fair procedure in such cases can encourage cooperation between the drug industry and the FDA, resulting in less reluctance on the part of the drug manufacturers to comply with subsequent drug regulations. Rule-making proceedings are not merely confrontations between the FDA and the manufacturers but are proceedings in which all interests should be considered,[150] such as the interest of consumers in not paying substantially higher prices for drugs to cover the companies' added expenses for what may be unnecessary testing. Sections 4(b) and 4(c) of the APA were enacted to ensure public participation in the rule-making process, for broader participation enables agencies to educate themselves before establishing procedures and rules which will have a substantial impact on the public and on the industries regulated.[151] A denial of notice and the opportunity to comment may facilitate the enforcement of agency policy in the short-run, but it is the rule of law and the public interest which eventually will suffer when procedural safegurards are circumscribed.

IV. ADJUDICATION

The Evolving Right To Counsel In Social Security Hearings

In the past year a small, but perhaps important, change has

148. The obvious effect of *Pharmaceutical Manufacturers Association* can be observed in the republishing of the September regulations in February, 1970, in full compliance with the APA.

149. *See* United States v. Two Bags, 147 F.2d 123, 127 (6th Cir. 1945), which gives as the purpose of the Federal Food, Drug and Cosmetic Act the protection of the ultimate consumer.

150. 21 U.S.C. § 371(e)(3) (1964).

151. *See* Texaco, Inc. v. FPC, 412 F.2d 740 (3d Cir. 1969).