SURVEYS

ADMINISTRATIVE LAW AND PROCEDURE

This discussion focuses on six administrative law cases decided by the Fifth Circuit during the survey period. Although these cases are primarily significant in the procedural area of administrative law, some of the cases affect substantive rules.

I. MAKING POLICY BY MEANS OF ADJUDICATION

Several Supreme Court decisions define the extent to which a federal agency may adopt new policies or reverse prior policies by adjudication, avoiding the Administrative Procedure Act's[1] (APA) rulemaking procedure.[2] In *SEC v. Chenery Corp.*,[3] the Court enunciated a balancing test to be applied in ascertaining whether policies adopted by adjudication may be given retroactive effect.[4] In

1. 5 U.S.C. §§ 551-556, 701-703 (1976 & Supp. IV 1980).

2. The Administrative Procedure Act designates a rulemaking procedure to be followed by federal agencies. *Id.* § 553 (1976). Both the proposed and final version of a rule must be published in the Federal Register, thereby giving the public an opportunity to comment upon or contest the rule. *Id.* § 552. *See* K. DAVIS, ADMINISTRATIVE LAW § 6.01 (3d ed. 1972). A rule is an agency statement of future effect which is designed to implement, interpret, or prescribe law or policy. 5 U.S.C. § 551(4) (1976). Adjudication, on the other hand, is the agency process by which an order is formulated. *Id.* § 551(7). An order is a final disposition of an agency in a matter other than rulemaking. *Id.* § 551(6). These two procedures provide an interesting contrast. For example, a rule is designed to fit all cases at all times and is not particularized to special facts as is an order. *See* NLRB v. Wyman-Gordon Co., 394 U.S. 759, 777 (1969) (Douglas, J., dissenting). For the purpose of formulating policy affecting large numbers of people, the rulemaking procedure is superior to adjudication because it allows input from a larger number of people. K. DAVIS, *supra*, § 6.03.

3. 332 U.S. 194 (1947).

4. *Id.* at 203. Making agency policy by adjudication is justified when dealing with unforeseeable problems, specialized problems, or problems as to which the agency lacks the experience required to adopt a rule. *Id.* at 202-03. Applying a policy adopted by means of adjudication will often have a retroactive effect; a party could be expected to conform to a requirement that had not been foreseeable. Only when this burden of retroactivity outweighs the mischief of producing a result that is contrary to statutory design will the courts declare the policy void and require the agency to utilize the rulemaking procedures. *Id.* at

NLRB v. Wyman-Gordon Co.,[5] the Court held that policies established through adjudication have prospective effect only to the extent that they operate as precedent.[6] Within these limits the administrative agency may determine whether to establish a policy, by rulemaking or adjudication, subject to review by the courts for abuse of discretion.[7]

Agencies and courts have struggled to limit the prejudicial effect of an adjudicative reversal of an established agency policy. For example, in *Safarik v. Udall*,[8] the D.C. Circuit held that an agency may give prospective application to an adjudicatory order[9] and, in *Retail, Wholesale & Department Store Union v. NLRB*,[10] the same court found that courts may order agencies to limit application of policies adopted through adjudication to acts occurring after the date of the adjudication.[11] Eventually it was determined that a court may order an agency to give prospective effect to an adjudicative policy. In *D.E. Pack*[12] the Interior Board of Land Appeals reversed a longstanding Bureau of Land Management (BLM) policy regarding qualification of applicants for federal oil and gas

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203.

5. 394 U.S. 759 (1969).

6. *Id.* at 765-66. The NLRB had purported to adopt a "rule" in a prior adjudication without applying it to the parties in that prior adjudication. *Id.* at 763. The Court noted that since the policy established in the prior adjudication was not applied to the parties therein, it had no precedential effect as to the *Wyman-Gordon* parties. *Id.* at 766. The Court did permit the NLRB to impose a new policy on the *Wyman-Gordon* parties, however, on the basis that the parties themselves were presented with a valid adjudicatory order which adopted the policy. *Id.*

7. *See* NLRB v. Bell Aerospace Co., 416 U.S. 267, 294 (1974).

8. 304 F.2d 944 (D.C. Cir.), *cert. denied*, 371 U.S. 901 (1962).

9. *Id.* at 950. The court sustained an agency practice of refusing to apply a new policy promulgated by adjudication to parties who relied on prior agency adjudications of the same issue where the prior adjudications were to the opposite effect. *Id.* at 947. There was no indication that the policy finally adopted through adjudication was not applied to the parties in that final adjudication. *Id.* at 950. The APA rulemaking procedures were not discussed.

10. 466 F.2d 380 (D.C. Cir. 1972).

11. *Id.* at 389-90. The court cited Stovall v. Denno, 388 U.S. 293 (1967), for the proposition that there are valid reasons why a new adjudicatory policy should be applied to parties to the adjudicatory proceeding in which the policy is first announced, but not to parties in subsequent proceedings. 466 F.2d at 390. The D.C. Circuit noted that article III of the Constitution requires that issues be resolved only in actual cases and controversies, and that applying new adjudicative policy to parties in the litigation encourages litigants to challenge outdated decisions. *Id.* These considerations were determined to be irrelevant in adjudications occurring after the new policy was initially adjudicated. *Id.*

12. 84 Interior Dec. 192 (1977).

leases.[13] In *Runnels v. Andrus*,[14] a federal district court limited application of the new leasing policy adopted in *Pack* to lease offers filed after the date of the *Pack* decision,[15] apparently precluding application to lease offers made by Pack himself.[16] However, the district court held that the *Pack* leasing policy could otherwise be applied prospectively.[17]

In *McDonald v. Watt*,[18] the Fifth Circuit considered the applicability of the *Pack* policy to a lease offer filed with the BLM prior to the date of the final decision in *Pack*.[19] The court held that the *Pack* policy applied prospectively and, therefore, could not affect the lease offer.[20] The court utilized the *Chenery* balancing test in deciding whether to limit "adjudicatory rules" to prospective application.[21] The court determined that the burden of the rule's retroactive application to the plaintiff was greater than any harm which might occur by deferring application of the *Pack* rule to a future time.[22] Citing *Safarik*, the Fifth Circuit postulated that a policy established by adjudication and not subject to the APA rulemaking procedures can be limited to its prospective effect.[23] Moreover, the Fifth Circuit declined to determine whether the *Pack* rule should be applied to the *Pack* case itself.[24]

The result in *McDonald* was correct but much of the court's rationale was faulty. First, the court misapplied the *Chenery* balancing test. The *Chenery* test was established to determine whether an agency should proceed by rulemaking or adjudication.[25] Once it has been determined that a rule can be formulated by adjudication, the *Chenery* test should not be employed to limit the

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13. *Id.* at 193-95.
14. 484 F. Supp. 1234 (D. Utah 1980).
15. *Id.* at 1240.
16. *See id.*
17. *Id.*
18. 653 F.2d 1035 (5th Cir. Aug. 1981).
19. *See id.* at 1039-41.
20. *Id.* at 1046.
21. *See id.*
22. *See id.* The court initially held that the policy change need not be accomplished through the APA rulemaking procedures. *Id.* at 1042. It was noted that *Wyman-Gordon* does not represent a general prohibition against applying new "adjudicatory rules" prospectively. *Id.* at 1042 n.17.
23. *Id.* at 1042 (citing Safarik v. Udall, 304 F.2d 944, 949-50 (D.C. Cir. 1962)).
24. 653 F.2d at 1046 n.26.
25. *See* SEC v. Chenery Corp., 332 U.S. 194, 203 (1947).

rule to prospective application. The Fifth Circuit mistakenly utilized the *Chenery* test for this purpose.[26]

Second, the Fifth Circuit's holding that an adjudicatory policy may be applied prospectively conflicts with prior decisions. *Wyman-Gordon* clearly held that an adjudicatory policy has no prospective effect other than through precedential power.[27] Thus, if *Chenery* holds that the *Pack* rule is inapplicable to plaintiff McDonald, then it is improper to apply it to any person until it is adopted through the APA rulemaking procedure. Conversely, if the *Pack* rule is properly applied to the parties in the *Pack* case, it is inconsistent to hold that it cannot be applied to plaintiff McDonald and all other persons similarly situated.

The court's reliance on *Retail* is unfortunate. *Retail* was based on the premise that since the Supreme Court gives prospective effect to its new court-made rules it is proper to permit an agency to do so. The critical distinction is that an agency, by making or changing policy by adjudication, encroaches upon a legislative rule in avoiding the APA rulemaking procedures. *Chenery* permitted this encroachment to a limited extent to insure that the letter of the APA does not unreasonably hinder an agency's operations. If an agency can defer application of the policy as to some persons, there is no reason why the policy cannot be deferred as to all persons pending rulemaking proceedings. Obviously, the administrative process will not be paralyzed. The agency which adopts the prospective application approach is simply looking for an expedient way to avoid the APA rulemaking procedure.[28] Cases like *McDonald* and *Retail* sanction this device. Hopefully, Congress or the Supreme Court will act to restore the integrity of the APA rulemaking process.

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26. *Chenery* simply recognized that there are some situations where an agency may avoid the APA rulemaking procedure. The key factor in these situations is that the delay required in implementing a rule through the APA procedures would paralyze an agency if the rulemaking procedures had to be utilized every time a policy was pronounced or changed.

27. NLRB v. Wyman-Gordon, 394 U.S. 759, 765-66 (1969). *See generally supra* notes 5-7 and accompanying text.

28. The teaching of *Chenery* is that adjudication is not a suitable substitute for rulemaking procedures.

II. Doctrine of Inherent Equitable Jurisdiction

A. *Injunction of Agency Proceedings*

Under the Freedom of Information Act[29] (FOIA) federal district courts are given "jurisdiction to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld . . . ."[30] Courts are split on whether the FOIA allows the district court to retain its equitable power to enforce orders by enjoining agency proceedings pending resolution of FOIA claims.[31]

In dictum, the Supreme Court had indicated that the district court retained the power to enjoin agency proceedings pending resolution of FOIA claims.[32] While this view was followed by some courts,[33] other courts held that the FOIA restricted the district court's jurisdiction so that it lacked the power to enjoin agency proceedings pending resolution of claims under the Act.[34]

Within this context the Fifth Circuit decided *Lewis v. Reagan*.[35] The court determined that the FOIA grants jurisdiction to

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29. 5 U.S.C. § 552 (1976 & Supp. IV 1980).

30. *Id.* § 552(a)(4)(B) (1976).

31. The traditional view of jurisdiction was that where a statute creates a right and provides a remedy, such a remedy is exclusive. Renegotiation Bd. v. Bannercraft Clothing Co., 415 U.S. 1, 18 (1974).

32. *Id.* at 19-20. The Court noted that the FOIA emphasizes disclosure and that Congress knows how to deprive a district court of the district court's broad equitable power when Congress chooses to do so. *Id.* at 19. The Court found it significant that the FOIA makes the district court the enforcement arm of the statute and indicated that the "special and exclusive remedy theory" is not applicable to FOIA cases. *Id.* at 19-20. The Court refused to sanction the injunction against the agency (Renegotiation Board) because the express purpose of the statute which set up the agency was to encourage parties to renegotiate without the interruption of judicial review. *Id.* at 22. The Court noted, however, that the purpose of the FOIA was to provide the public with information to enable the public to make informed choices, not to provide agency litigants with an additional discovery tool. *Id.* at 17, 24. Three justices would have allowed an injunction of agency proceedings pending resolution of the FOIA claim since the expertise of the agency does not relate to the FOIA claim; thus, awaiting a final agency decision as to the merits of an FOIA claim would be superfluous. *Id.* at 33 (Douglas, J., dissenting).

33. Columbia Packing Co. v. USDA, 563 F.2d 495, 500 (1st Cir. 1977) (injunction proper where probability of serious injury shown); Sears, Roebuck & Co. v. NLRB, 473 F.2d 91, 83 (D.C. Cir. 1972) (injunction proper where irreparable harm would result absent the injunction); St. Elizabeth's Hosp. v. NLRB, 407 F. Supp. 1357, 1358 (N.D. Ill. 1976) (injunction proper upon a showing of irreparable injury).

34. Hanley v. United States Dep't of Justice, 623 F.2d 1138, 1139 (6th Cir. 1980); Cell Assoc. v. National Inst. of Health, 579 F.2d 1155, 1157-60 (9th Cir. 1978).

35. 660 F.2d 124 (5th Cir. Oct. 1981).

the district court to enjoin agency proceedings pending resolution of an FOIA claim.[36] The district court refused to enjoin the agency hearing[37] and the FOIA claimant, Mrs. Lewis, requested that the Secretary of the Air Force be enjoined from adopting the board's recommendation pending release of the requested information.[38] The Fifth Circuit denied the injunction, holding that an injunction under the FOIA may issue only upon a showing of irreparable injury.[39] The court found that the mere pendency of FOIA requests and appeals from denials of the request did not constitute irreparable injury.[40]

The Fifth Circuit reached the proper conclusion in *Lewis*. Congress intended to empower district courts to enjoin agency proceedings pending resolution of an FOIA claim.[41] The evaluation of the validity of an FOIA claim is not dependent upon agency expertise. The court is the entity best suited to resolve the FOIA claim. Despite this, in most cases no harm will be done by first allowing the agency to determine the validity of the FOIA claim. If the information is improperly withheld, the courts can order that the hearing be reopened. In the rare instance where the FOIA applicant can prove that failure to enjoin the agency proceedings will result in irreparable harm, it is necessary that the courts retain the power to prevent the harm.

B. *Preliminary Relief Available to the Agency*

The scope of preliminary relief available to an agency has been the source of much litigation. The traditional view was that when a statute provided a special remedy, such a remedy was exclusive.[42] Subsequently, however, the courts adopted a more liberal view of

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36. *Id.* at 128. Mrs. Lewis, the FOIA claimant, originally sought to enjoin a hearing to review the "missing in action" status of her soldier husband pending release by the Air Force of certain information which she believed would assist her in proving that her husband was still alive. *Id.* at 126. The hearing was held and it was recommended that Mrs. Lewis' husband's status be changed to "killed in action." *Id.*

37. *Id.* at 126.

38. *Id.* at 128.

39. *Id.*

40. *Id.* at 129.

41. *See* Renegotiation Bd. v. Bannercraft Clothing Co., 415 U.S. 1, 19 (1974). Congress knows how to limit a court's broad equitable power. Here it chose not to do so. *See id.*

42. *Id.* at 18.

jurisdiction.[43] The liberal view was based upon a belief that when Congress entrusted to an equity court the responsibility of enforcing prohibitions contained in a regulatory enactment, it should be assumed that Congress acted with awareness of the historic power of equity to provide complete relief in the light of statutory purposes; thus, such broad power should be implied.[44]

The scope of the district court's jurisdiction under section 13(b) of the Federal Trade Commission Act[45] (FTCA) presented a controversial issue during the survey period. Previously, courts had held that section 13(b) empowered the district court to order defendants to hold a portion of assets acquired in a merger pending resolution of an adjudication[46] and to order notification of defendants' clients of pending adjudications (compulsory notification).[47]

In *FTC v. Southwest Sunsites, Inc.*,[48] the Fifth Circuit held

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43. *See* Mitchell v. De Mario Jewelry, Inc., 361 U.S. 288, 293-94 (1960) (under statute providing that for cause shown the district court shall have authority to restrain violations of the statute, it was held that the district court had authority to order employer to reimburse employee for lost wages caused by a discharge in violation of the statute); Porter v. Warner Holding Co., 328 U.S. 395, 397-400 (1946) (under statute providing that once agency determines that any person engaged or is about to engage in any acts which would be a violation of the statute that district court shall grant a permanent or temporary injunction or other order, it was held that the district court had authority to order that a statutory violator make restitution); Commodity Futures Trading Comm'n v. Muller, 570 F.2d 1296, 1301 (5th Cir. 1978) (under statute providing that once the agency has determined that any person has engaged or is about to engage in any statutory violation that the district court has jurisdiction to enjoin such statutory violation or to enforce compliance with the statute, the district court was held to be empowered to enjoin defendant from concealing or disposing of his assets).

44. Mitchell v. De Mario Jewelry, Inc., 361 U.S. 288, 291-92 (1960).

45. 15 U.S.C. § 53(b) (1976). The Act provides that when the Federal Trade Commission (FTC) has reason to believe that any person is violating or is about to violate any provision of law enforced by the FTC, the federal district court has jurisdiction to enter a temporary restraining order or temporary injunction restraining such act or practice (if the order is in the best interest of the public). *Id.* Section 5 of the FTCA, 15 U.S.C. § 45 (1976 & Supp. IV 1980), provides that unfair methods of competition in commerce are unlawful and that it is the FTC's duty to determine whether an unlawful act has occurred. *Id.* § 45(a)-(b). Section 19 of the FTCA, *id.* § 57(b) (1976), provides that the FTC may bring a civil action in the federal district court against violators of the Act and that the district court may grant such relief as the court finds necessary to redress injury to consumers caused by an unlawful act.

46. FTC v. Weyerhaeuser Co., 665 F.2d 1072, 1084 (D.C. Cir. 1981). The court held that § 13(b) of the FTLA empowered district courts to grant whatever equitable relief was required in each particular case. *Id.*

47. FTC v. Virginia Homes Mfg. Corp., 509 F. Supp. 51, 55 (D. Md.), *aff'd*, No. 81-1187 (4th Cir. July 14, 1981).

48. 665 F.2d 711 (5th Cir. Jan. 1982).

that section 13(b) of the FTCA authorized district courts to order escrow of defendants' assets[49] and compulsory notification of defendants' clients prior to an adjudication on the merits.[50] The panel stated that the district court could grant whatever equitable relief was required to preserve the status quo; therefore, in any future action for consumer redress the district court would be able to grant meaningful relief.[51] The court ultimately remanded the case to the district court to determine whether the requested relief was "reasonably necessary" to preserve the possibility of complete and meaningful relief at the end of litigation.[52]

The Fifth Circuit's holding in *Southwest Sunsites* followed a developing trend in the Supreme Court which assumes that Congress has conferred the full range of equitable jurisdiction upon the district court when the court is made the means of enforcing a remedial statute.[53] Section 13(b) of the FTCA is very similar to another statute that the Supreme Court found did not restrict the district court's equitable power.[54] From a public policy standpoint, it is desirable for the courts to have flexibility in enforcing statutory purposes. Flexibility is required so that the courts need not be too harsh or too lenient with statutory violators. If Congress desires to limit this broad equitable jurisdiction, it can easily do so by express statutory language.

III. SUBSTITUTE ADMINISTRATIVE LAW JUDGE

With every statutorily required adjudication determined "on

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49. *Id.* at 718-19.

50. *Id.* at 722. The FTC had not yet determined whether defendant Southwest Sunsites had engaged in an unfair method of competition. *See id.* at 715-16. The FTC had merely determined that there was reason to believe that defendant had violated the FTCA. *See id.* This is all that § 13(b) required for the district court to grant preliminary relief. *See* 15 U.S.C. § 53(b) (1976).

51. 665 F.2d at 718. Defendant Southwest Sunsites allegedly violated the FTCA by the manner in which it had conducted sales of land. *Id.* at 715. The FTC feared that defendant would dispose of its assets before a consumer redress action could be brought. *See id.* at 717. Also, compulsory notification was sought to prevent consumers from suffering further harm through payment of continuing installments. *See id.*

52. *Id.* at 722. The district court held that § 13(b) did not authorize the relief requested. *Id.* at 716. The district court determined that even if it had jurisdiction to grant the requested relief, there had been no "strong showing" of the need for such relief. *Id.* at 722. The Fifth Circuit held that "strong showing" was an improper standard and thus substituted the "reasonably necessary" standard. *Id.*

53. *See supra* notes 41-42 and accompanying text.

54. *See* Mitchell v. De Mario Jewelry, Inc., 361 U.S. 288, 293-95 (1960).

the record," certain procedures must be followed.[55] In such adjudications an employee, acting as an administrative law judge (ALJ), presides over the presentation of evidence. The ALJ makes the initial decision regarding findings of fact and conclusions of law.[56] If the ALJ becomes unavailable, another employee acts as a "substitute ALJ."[57]

Although litigants disagree as to whether a substitute ALJ can make a decision on the basis of an already existing record, or whether a de novo evidentiary hearing is required, some guidelines have been set. For example, a de novo evidentiary hearing is not required when the substitute ALJ hears all of the testimony.[58] Furthermore, even when the substitute ALJ hears only part or none of the testimony, courts have refused to mandate a de novo evidentiary hearing when credibility of witnesses is not an issue.[59] Also, the right to a de novo evidentiary hearing is waived when it is not timely requested.[60]

Cognizant of these principles, the Fifth Circuit decided *Pigrenet v. Boland Marine & Manufacturing Co.*[61] In *Pigrenet* the ALJ who heard the testimony in this employee compensation case[62] found that claimant Pigrenet was totally and permanently disabled, but failed to make a finding regarding causation.[63] When

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55. *See* 5 U.S.C. § 554(a) (1976 & Supp. IV 1980).

56. *Id.* § 554(d) (1976).

57. *See id.*

58. Appalachian Power Co. v. FPC, 328 F.2d 237, 240 (5th Cir.), *cert. denied*, 379 U.S. 829 (1964).

59. New England Coalition on Nuclear Pollution v. United States Nuclear Regulatory Comm'n, 582 F.2d 87, 100 (1st Cir. 1978); Gamble-Skogmo, Inc. v. FTC, 211 F.2d 106, 115 (8th Cir. 1954).

60. Gamble-Skogmo, Inc. v. FTC, 211 F.2d 106, 113-15 (8th Cir. 1954) (opportunity for credibility evaluation is a statutory procedural grant and not a due process requisite and thus party not entitled to de novo hearing unless requested at the agency level); NLRB v. Dixie Shirt Co., 176 F.2d 969, 970-71 (4th Cir. 1949) (where substitute ALJ offered to conduct de novo evidentiary hearing, but no party requested de novo evidentiary hearing, substitute ALJ properly rendered a decision based on the existing record). *See* W.R.B. Corp. v. Geer, 313 F.2d 750 (5th Cir. 1963). It was held that even if a substitute master appointed by the trial court to make findings and conclusions erred in failing to conduct a de novo hearing, such error could not be raised for the first time on appeal. *Id.* at 752.

61. 656 F.2d 1091 (5th Cir. Sept. 1981).

62. The claim was brought under the Longshoremen's and Harbor Workers' Compensation Act, 33 U.S.C. §§ 901-950 (1976 & Supp. 1980). 656 F.2d at 1093.

63. 656 F.2d at 1093. Causation refers to whether Pigrenet's injury was job related. *See id.* The substitute ALJ apparently thought that the causation issue had been stipulated. *Id.*

the issue was remanded, the original ALJ had died and a substitute ALJ was appointed to resolve the causation issue.[64] Pigrenet declined an opportunity to recall the witnesses, and the substitute ALJ resolved the causation issue against Pigrenet, finding that Pigrenet's own testimony was not credible.[65]

The Fifth Circuit held that even if it was error for a substitute ALJ to render a decision on the basis of an already existing record,[66] such error was waived when not raised at the fact-finding level.[67] The court relied on previous cases, ignoring a vigorous dissent[68] which argued that a waiver should not be implied.[69] Circuit Judge Hatchett, in dissent, argued that a party's right to a de novo hearing should not turn on the knowledge and tactics of the party's attorney.[70] Judge Hatchett would have remanded for a new evidentiary hearing because the ALJ who heard Pigrenet's testimony found it to be credible.[71] The judge warned that administrative litigants will lose faith in the system if ALJs are permitted to reverse each other's credibility findings on the basis of a cold record.[72]

The majority opinion in *Pigrenet* is consistent with the view of other circuits. To allow a litigant to raise procedural errors for the first time on appeal deprives the fact finder of the opportunity to correct the error. Remand for a de novo evidentiary hearing is duplicitous and should be permitted only when constitutionally mandated procedures are omitted. The fate of a litigant's case is frequently at the mercy of his attorney's skill and Judge Hatchett's argument is unpersuasive. His argument regarding the reversal of credibility findings, although original, might carry more weight were it not for the fact that Pigrenet declined an offer to recall witnesses. Furthermore, the ALJ who heard the testimony only found Pigrenet's testimony regarding the disability issue credible; he expressed no finding as to the credibility of Pigrenet's testimony regarding causation. Thus, the substitute ALJ did not re-

64. *Id.* at 1094.
65. *Id.* at 1094-95.
66. The Fifth Circuit did not determine whether the substitute ALJ had erred. *See id.* at 1095.
67. *Id.*
68. *See id.* at 1094-96.
69. *Id.* at 1096-1101.
70. *Id.* at 1096 (Hatchett, J., dissenting).
71. *Id.* at 1098.
72. *Id.*

verse any prior findings regarding credibility.

IV. STATUTORY INTERPRETATION

The Federal Food, Drug and Cosmetic Act[73] (Act) provides that before a "new drug" can be introduced into interstate commerce it must be submitted to a "new drug" application (NDA) procedure conducted by the Food and Drug Administration (FDA).[74] Because the process can be expensive and time consuming,[75] a great deal of litigation has arisen regarding the statutory definition of the term "new drug."[76]

The general rule of statutory construction is that an agency charged with enforcement of a statute should be granted deference in its construction; however, the courts need not defer to an agency's interpretation if it is inconsistent with congressional intent.[77] In cases raising issues of fact outside the realm of judicial expertise, the courts should defer to an agency determination.[78] The practical interpretation of an ambiguous statute by an agency charged with its enforcement should not be disturbed by the courts except for important reasons.[79]

In *Premo Pharmaceutical Laboratories, Inc. v. United States*,[80] the Second Circuit was presented with the question of whether generic drugs[81] were subject to the NDA process.[82] In

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73. 21 U.S.C. §§ 301-392 (1976 & Supp. IV 1980).

74. *Id.* § 355(a) (1976).

75. United States v. Generix Drug Corp., 654 F.2d 1114, 1114 (5th Cir. 1981).

76. The Act defines "new drug" as any drug the composition of which is not generally recognized by experts as safe and effective for use as described in its labelling *or* any drug which is so recognized as safe and effective as a result of investigations but which has not been used to a material extent or for a material time. 21 U.S.C. § 321(p) (1976). A drug which is recognized as safe and effective by experts is nevertheless a "new drug" if it has not been used to a material extent or for a material time. Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 631 (1973). After it has been so used it loses its "new drug" status. *Id.*

77. Espinoza v. Farah Mfg. Co., 414 U.S. 86, 94-95 (1973).

78. Far E. Conference v. United States, 342 U.S. 570, 574 (1952). The Supreme Court has held that since the issue as to whether a given substance is a "new drug" depends on expert knowledge and experience, Congress intended that the FDA resolve the issue subject to review by the courts. Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645, 652-53 (1973).

79. Brewster v. Gage, 280 U.S. 327, 336 (1930).

80. 629 F.2d 795 (2d Cir. 1980).

81. A generic drug is a copy of the active ingredient of another manufacturer's drug product, such active ingredient having been proven safe and effective. United States v. Generix Drug Corp., 654 F.2d 1114, 1115 (5th Cir. Sept. 1981).

82. *See* 629 F.2d at 799.

Premo the generic drug manufacturer argued that a drug's inactive ingredient[83] was not a proper consideration in the "new drug" determination.[84] The court deferred to the FDA's determination requiring all generic drugs to undergo the NDA process unless their active and inactive ingredients were identical to drugs already approved.[85]

In *United States v. Generix Drug Corp.*,[86] a generic drug manufacturer claimed, as had Premo, that its generic drug products were not "new drugs."[87] Generix also relied on the argument that a drug's inactive ingredient was not a proper consideration in the "new drug" determination.[88] Refusing to defer to the FDA's view,[89] the Fifth Circuit held that only a drug's active ingredient was relevant to the "new drug" determination.[90] The court noted that the Act defines "drug" as any article listed in specified books, including "articles intended for use as a component of any [listed article, but excepting] devices or their components, parts, or accessories."[91] The Fifth Circuit also observed that the FDA's statutory interpretation would frustrate congressional intent (manifested in other legislation) of increasing competition within the drug industry by promoting the manufacture of generic drugs.[92] Finally, the

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83. The active ingredients in the drugs in issue had previously been determined safe and effective by the FDA through participation in the NDA process and copied drugs of other manufacturers containing such active ingredients which had been in sufficient use such that they were no longer considered "new drugs" by the FDA. *Id.* at 798. The drugs in issue contained different inactive ingredients (excipients) than did the copied drugs already recognized by the FDA as safe and effective. *Id.*

84. *Id.* at 799.

85. *See id.* at 803-04. The FDA took the position that a drug's safety and effectiveness are affected by its inactive ingredients. *Id.* at 798-800. The FDA contended that a drug's inactive ingredient affects its bioavailability (the rate and extent to which the drug's active ingredients are absorbed). *Id.*

86. 654 F.2d 1114 (5th Cir. Sept. 1981).

87. *Id.* at 1115-16.

88. *Id.* The drugs in issue were copies of drugs whose active ingredients were already found safe and effective by the FDA. *See id.*

89. The FDA argued, as it had in *Premo*, that both active and inactive drug ingredients are relevant to the "new drug" issue. *See id.* at 1115.

90. *Id.*

91. *Id.* at 1116 (quoting 21 U.S.C. § 321(g)(1) (1976)).

92. 654 F.2d at 1117-19. The court found that to subject each generic drug whose inactive ingredients differ from FDA-approved drugs to the NDA process would burden the growth of the generic drug industry. *Id.*

Fifth Circuit explained that the Act provides other means by which the FDA can regulate the safety and effectiveness of generic drugs.[93]

The Fifth Circuit holding in *Generix* is highly questionable. The portions of the Act defining "drug" and "new drug" are at best ambiguous. From the plain language it is impossible to determine whether inactive ingredients are relevant to a determination of what constitutes a "new drug." The statutory language clearly reveals congressional intent that drugs not be distributed unless they are safe and effective. The courts should defer to the FDA, the agency charged with enforcing the Act, in construction of the ambiguous Act where there is evidence to support the agency interpretation.

The Fifth Circuit's argument regarding congressional intent to promote competition within the drug industry is unimpressive. In the absence of express language, it is poor public policy to assume that Congress intended to increase competition at the expense of public safety. Also, the fact that the FTC has an alternative means by which to regulate a drug's safety and effectiveness should not render the NDA process any less available.

V. Agency Manual: Equitable Defense

The extent to which agency operations manuals create legal obligations has been hotly contested. The Supreme Court has held that for an agency policy to have the force and effect of law, and thus be enforceable by or against the agency, it must be a substantive rule[94] and be promulgated in accordance with procedural requirements of the APA.[95] The APA requires that federal agencies publish in the *Federal Register* "substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability formulated and adopted by the agency . . . ."[96]

These principles generated controversies regarding what obli-

93. *Id.* at 1119. The Act provides the FDA with authority to prevent the distribution of adulterated drugs. 21 U.S.C. § 351 (1976). A drug is adulterated if mixed with another substance so as to reduce its quality or strength. *Id.* § 351(d).

94. Substantive rules are those which affect individual rights and obligations. Morton v. Ruiz, 415 U.S. 199, 232 (1974).

95. Chrysler Corp. v. Brown, 441 U.S. 281, 301, 303 (1979).

96. 5 U.S.C. § 552(a)(1) (1976).

gations lender-mortgagees and agencies owed to borrower-mortgagors under federal lending programs. Courts have held that the failure to follow provisions of a HUD loan servicing manual, neither published nor required to be published in the *Federal Register*, gives rise to neither a cause of action for obtaining damages[97] nor for enjoining foreclosure.[98] Similarly, it has been held that VA loan servicing manual provisions created no duty to service loans in the recommended manner.[99]

In *United States v. Harvey*,[100] the Fifth Circuit grappled with whether a manual created any legal rights. The court held that provisions of the VA loan servicing manual created no rights in a borrower-mortgagor that could be asserted as a defense to a foreclosure on a VA direct loan.[101] The mortgagee relied on a section providing that after establishing reasons for default, "indulgence may be extended for a reasonable time to a worthy borrower who is unable immediately to begin the liquidation of his arrearage."[102] The borrower-mortgagor alleged that this language imposed a duty on the VA to extend, reamortize, or forebear on its loans prior to foreclosing.[103] The court noted that the language of the loan servicing provision in question was permissive rather than mandatory[104] and concluded that the manual's provisions were not formal agency regulations since the manual was neither published nor required to be published in the *Federal Register*.[105]

The holding of the Fifth Circuit in *Harvey* is proper. The permissive nature of the manual's language indicates that the VA was not attempting to prescribe a rigid procedure to be mandatorily

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97. Brown v. Lynn, 392 F. Supp. 559, 562 (N.D. Ill. 1975). In dictum the court noted that federal district courts could, in exercise of their equity powers, refuse to grant foreclosures in situations where mortgagees have flagrantly disregarded HUD loan servicing provisions. *Id.*

98. Roberts v. Cameron-Brown Co., 556 F.2d 356, 360-61 (5th Cir. 1977).

99. Rank v. Nimmo, 677 F.2d 692, 697-98 (9th Cir. 1982). The Ninth Circuit held that provisions in the loan servicing manual were neither published nor required to be published in the *Federal Register*. *Id.* at 698. The court determined that the VA intended that the manual serve merely as a general guide to its employees and to hold the manual binding on the VA would seriously hamper the VA's ability to communicate with its employees by written directive. *Id. See also* Simpson v. Cleland, 640 F.2d 1354 (D.C. Cir. 1981).

100. 659 F.2d 62 (5th Cir. Oct. 1981).

101. *Id.* at 63.

102. *Id.*

103. *Id.*

104. *Id.* at 64.

105. *Id.*

followed by VA employees. The determination that the manual lacks the force and effect of law is consistent with the development of case law. From a public policy standpoint it is sensible to allow an agency flexibility in carrying out its statutory mandate, especially where neither Congress nor the agency has bound the agency to fixed procedures. If an agency treats persons similarly situated in an inconsistent manner, the proper remedy should lie in a constitutional claim.

VI. Conclusion

The cases selected for treatment will have a substantial impact on administrative law. During the survey period the Fifth Circuit joined other courts in disregarding fundamental principles of administrative rulemaking. In the decisions regarding jurisdiction, the court gave agencies freedom to function, while defining broad perimeters of judicial management. The court exercised judicial restraint in limiting the ALJ holding to the issue of timely objection, but in contrast usurped agency functions in the area of statutory interpretation. The court's refusal to rigidly bind the agency to internal guidelines will foster intraagency communication. In summary, the cases signify that the Fifth Circuit is willing to take an independent approach in resolving significant questions.

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