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Antibiotics Certification--Evidentiary Hearing (Pfizer, Inc. v. Richardson)

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The impact of such a decision is great. The very purpose of labeling an investigation non-public is undercut.[28] If the agency must release transcripts to witnesses and witnesses have no privilege of secrecy once the transcript is in their hands, then the agency's privilege of confidentiality will, in effect, be greatly decreased. The court has thus interpreted the federal statute on transcript disclosure to effectuate a significant piercing of the agency's veil of secrecy.

ANTIBIOTICS CERTIFICATION — EVIDENTIARY HEARING

The right of an aggrieved party to an evidentiary hearing of an administrative action is not an absolute one.[29] It has often been held that where a hearing is not a matter of right by statute,[30] the party must establish some valid basis for its request.[31] The Second Circuit Court of

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situation because the effectiveness of the Census Bureau was dependent upon a guarantee of confidentiality, whereas in the SEC investigation a person is under a subpoena to testify and thus is testifying not as a result of a promise of confidentiality but on penalty of contempt.

[28] Nonpublic investigations have traditionally retained their aura of inaccessibility due to the realization that they

> might be thwarted in certain cases if not kept secret, and that if witnesses were given a copy of their transcript, suspected violators would be in a better position to tailor their own testimony to that of the previous testimony, and to threaten witnesses about to testify with economic or other reprisals.

438 F.2d at 451, *quoting* Commercial Capital Corp. v. SEC, 360 F.2d 856, 858 (7th Cir. 1966).

[29] The courts have differed on the question of whether an individual affected by administrative action is entitled to a hearing. Some courts have warned against agency action without an evidentiary hearing. *See, e.g.*, Pennsylvania Gas & Water Co. v. Federal Power Comm'n, 427 F.2d 568 (D.C. Cir. 1970), where the court stated that an agency should exercise restraint against the temptation to take action without notice and a hearing. In the same vein, courts have discussed the question of a hearing by stating, "[T]he need for administrative flexibility does not of itself preclude an agency hearing or judicial review." Hahn v. Gottlieb, 430 F.2d 1243, 1246 (1st Cir. 1970). Other courts, however, have reiterated the traditional maxim that "[A] hearing is not constitutionally compelled in all cases where individual rights may be impaired." *See* Drown v. Portsmouth School Dist., 435 F.2d 1182 (1st Cir. 1970).

[30] A hearing before an agency is a right when required by statute or when the agency's action may deprive an individual of due process. Where there is no mandatory statutory requirement of a hearing, the courts will evaluate such factors as: the nature of the interest effected, the availability of judicial review, and the immediacy of the case. *See* Cafeteria & Restaurant Workers Union v. McElroy, 367 U.S. 886 (1961). *See* Note, *Summary Removal of Drugs from the Market: The Specter of the Heavy Bureaucratic Hand*, 24 SW. L.J. 880, 881 n.11 (1970).

[31] In discussing the question of an evidentiary hearing, the courts generally make a distinction between whether the agency's action had involved adjudication or rule-making. As a general rule, the agencies are not permitted to act adjudicatively without a hearing, whereas in rule-making, a hearing is not required. Adjudicative facts are those which concern the parties involved, *i.e.*, they answer the question of "who did what, where, when, how, why and with what motive or intent." Rule-making (or legislative) facts do no concern the immediate parties, but are general facts which are used to assist in establishing policy and discretion. These distinctions, however, are often unsatisfactory in various respects, as shall be seen in the instant case. 1 K. DAVIS, ADMINISTRATIVE LAW TREATISE 412-13 (1958).

Appeals in *Pfizer, Inc. v. Richardson*,[32] has reiterated this precept and expanded its applicability to the area of revocation of antibiotic certifications by the Food and Drug Administration (FDA). In this case, the court held that it was not a deprivation of due process to require the manufacturer affected to state reasonable grounds for the holding of an evidentiary hearing by the agency when the manufacturer's antibiotics were about to lose their certification by the FDA.

The crux of Pfizer's argument was that since the particular antibiotics[33] (the so-called "old drugs") had been certified under an earlier statute[34] which had required only that the drug be safe, it was an infringement on the corporation's right to due process to repeal the regulations which had certified the drugs on the grounds of failure to show *safety and effectiveness* without an opportunity to hold an evidentiary hearing.[35]

Pfizer claimed that it had met the "substantial evidence"[36] require-

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32 434 F.2d 536 (2d Cir. 1970).

33 The antibiotics involved were two Signemycin products which had been certified by the agency in the 1950's.

34 The drugs had originally been certified under section 505 of the Federal Food, Drug & Cosmetic Act of 1938, (21 U.S.C. § 355 (1970)) which prohibited the introduction into interstate commerce of any drug unless it had been certified as safe. Under section 505, the drug's certification could be withdrawn upon a finding by the Secretary of Agriculture that the tests available to him did not demonstrate "whether or not such drug is safe for use under the conditions prescribed. . . ." 21 U.S.C. § 355(d) (1970).

Section 505 was amended by Congress in 1962 to require that the manufacturer show both that the drug was safe and that it has "the effect it purports or is represented to have under the conditions of use prescribed . . ." in order to be approved by the Secretary of Health, Education and Welfare. 21 U.S.C. § 355(d) (1970). However, the withdrawal of approval by the Secretary could be effected under the new statute only "after due notice and opportunity for hearing to the applicant." 21 U.S.C. § 355(e) (1970).

35 At the same time as Congress amended section 505, it also amended section 507 (21 U.S.C. § 357 (1970)) which was now to include antibiotic drugs formerly certified under section 505 for safety alone. The Pfizer drug fell into this category. The drugs were to be certified

> if such drug has such characteristics of identity and such batch has such characteristics of strength, quality & purity, as the Secretary prescribes in such regulations as necessary to adequately insure safety and efficacy of use . . . .

21 U.S.C. § 357(a) (1970).

To review these drugs for effectiveness which had only been certified as safe, the FDA enlisted the aid of the National Academy of Sciences-National Research Council (NAS-NRC). The council made recommendations on those drugs it found to fail the efficacy test. Under section 507(f), the Secretary would then give notice to the corporation involved to present its views on the proposed revocation of certification of the drug. The new statute provided for a specific procedure:

> At any time prior to the thirtieth day after such action is made public, any interested person may file objections to such action, specifying with particularity the changes desired, stating *reasonable grounds therefor*, and requesting a public hearing upon such objections . . . .

21 U.S.C. § 357(f) (1970) (emphasis added).

The right to a public hearing which had been mandatory under section 505 was now conditional upon the manufacturer's showing of "reasonable grounds therefor."

36 The regulations established the criteria for "substantial evidence" as being "derived

ment of effectiveness by presenting clinical data which proved that the drug was effective as prescribed. The FDA held that the evidence presented had not been substantial and that Pfizer had not stated reasonable grounds[37] for objections to the agency finding. The corporation was thus precluded from an evidentiary hearing and the agency subsequently repealed the regulations upon which the certification had been based.

The court in *Pfizer* refused to make a determination as to whether this was a case of adjudication or rule-making.[38] It was concerned instead with the fact that Congress had expressly established the showing of reasonable grounds as a condition precedent for holding an evidentiary hearing by the agency.[39] Had it intended to maintain the mandatory hearing requirement prior to revocation of a drug's certification, the court felt that Congress would have done so. The court further stated that there was no reason to place the pre-1962 "old drugs" on a

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from adequate and well-controlled clinical investigations in support of promotional claims." 434 F.2d at 541. These regulations and the criteria contained therein had been upheld in Pharmaceutical Mfrs. Ass'n v. Richardson, 318 F. Supp. 301 (D. Del. 1970). That case, however, did not pertain to the "old drugs" which had been certified under section 505, as exemplified by those in *Pfizer*.

37 The repealing of certification for certain combination drugs without an evidentiary hearing had been upheld in Upjohn Co. v. Finch, 422 F.2d 944 (6th Cir. 1970), which directly preceded *Pfizer*. In that case, the court held that the manufacturer had failed to present "substantial evidence" of the drug's efficacy and that the FDA had properly revoked the certification without a hearing when "reasonable grounds therefor" had not been established by the manufacturer. Since the Upjohn drugs had been certified in 1956, they fell into the "old drugs" classification.

The FDA had decided to give the manufacturers notice of proposed rule-making and an opportunity for comment as a result of an earlier case, Pharmaceutical Mfrs. Ass'n v. Finch, 307 F. Supp. 858 (D. Del. 1970), which held that it was error not to give an adequate opportunity for comment.

38 In the *Upjohn* case, the Sixth Circuit Court of Appeals had similarly refused to make such a distinction. Upjohn had contended this was an adjudicatory case and thus they were entitled to a hearing. *See* Philadelphia Co. v. SEC, 175 F.2d 808, 816 (D.C. Cir. 1948), *vacated as moot*, 337 U.S. 901 (1949), which stated,

> It is elementary that the action of an administrative tribunal is adjudicatory in character if it is particular and immediate, rather than, as in the case of legislative or rulemaking action, general and future in effect.

On the other hand, the FDA had contended that the case involved rule-making and thus requires no evidentiary hearing, citing Federal Power Comm'n. v. Texaco, 377 U.S. 33 (1964), which held that the agency's promulgation of regulations establishing a pricing provision in utility contracts was permissible without a hearing.

The *Upjohn* court refused to make such a distinction. It merely stated that the history of the interpretations of the Food, Drug & Cosmetic Act did not require an evidentiary hearing as a right.

39 In discussing the Congressional intent, the court stated:

> When it [Congress] brought antibiotics under a separate section of the statute in 1945, it chose not to copy the "after due notice and opportunity for hearing to the applicant" language of § 505(e), . . . but to demand as a prerequisite to a hearing that those filing objections to the Secretary's action state "reasonable grounds therefor."

434 F.2d at 542.

separate status than the post-1962 drugs. What was permissible for the one should also be permissible for the other, in spite of the fact that the "old drugs" had been certified on lesser criteria than the post-1962 drugs.[40]

Although earlier Second Circuit cases have held that there is no absolute right to an evidentiary hearing by an aggrieved party,[41] and that the agency may require the party to establish a reason for holding such a hearing,[42] the *Pfizer* case is the first one in this circuit dealing with the hearing requirement in revocation of drug certifications. The court is generally following the trend of other circuits in the drug certification cases. However, the practical impact of such a holding is quite significant. If the *Pfizer* holding is upheld in future cases, it seems clear that the FDA will be able to decide that a drug is ineffective and to repeal its certification without granting a single hearing. Through its requirement of a showing of "reasonable grounds" for the granting of a hearing, the FDA has been permitted to apply to all antibiotics, both "old" and "new," a standard which, for all practical purposes, can be met only if the agency says it has been met.[43]

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[40] On the subject of requirements of the two drug groups, the court noted:
> [W]e would hardly be justified in finding, on so scant a basis, a Congressional mandate requiring the FDA to employ a double standard of efficacy in evaluating antibiotics, all of which were now subject to § 507.

Id. at 545.

[41] *See* NLRB v. Joclin Mfg. Co., 314 F.2d 627 (2d Cir. 1963) wherein the court stated,
> Recognizing the need for expedition in certification matters justifies the Board in imposing reasonable conditions to the allowance of a hearing on objections

Id. at 633 [footnotes omitted].

[42] "When a hearing before an administrative agency is not a matter of right, a party seeking such a hearing must establish some valid basis for its request." *See* Note, *Summary Removal of Drugs from the Market: The Specter of the Heavy Bureaucratic Hand*, 24 Sw. L.J. 880, 881-82 (1970).

[43] For a discussion of the impact of *Upjohn*, *Pfizer* and similar holdings, *see* Phelps, *After Panalba, Whither*, 26 FOOD DRUG COSM. L.J. 186 (1971).