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## Summary Removal of Drugs from the Market: The Spector of the Heavy Bureaucratic Hand

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of an agency determination carries with it the right to intervene in the proceeding on which the determination is based. But, unlike the former, the latter right is not absolute once it attaches.<sup>50</sup> Hopefully the courts will continue to recognize this distinction as they are called upon to scrutinize the intervention practices and procedures of administrative agencies. Such a distinction is imperative lest the right to intervene become the right to interfere.

*Paul D. Schoonover*

## Summary Removal of Drugs from the Market: The Specter of the Heavy Bureaucratic Hand

In 1966, the Drug Efficacy Study Group formed by the National Academy of Sciences—National Research Council (NAS-NRC) commenced an evaluation of all drugs on the market which had been certified as safe and effective by the Food and Drug Administration (FDA) between 1938 and 1962.<sup>1</sup> During the course of its investigations, the Study Group reported to the Commissioner of the FDA that the Upjohn Company's claims concerning the antibiotic drugs Panalba, Albamycin-T, and Albamycin G.U. were unwarranted, that the drugs were ineffective, and that no "well-controlled"<sup>2</sup> studies had been found to support Upjohn's claims. Upjohn submitted testimonials of physicians and statistics on the widespread use of the drugs to support its claims, but the Commissioner ruled

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who might otherwise apply for intervention and serves to expedite the administrative process.'" 429 F.2d at 739. The court further stated:

To the extent that appellees are apprehensive of chaos and confusion as an incident to this enlarged right, we remind that they have already recognized the right of appellants to be present at the hearings and to be heard through counsel. Reliance for proper control of the hearings and the orderly compilation of the hearing record must, of course, be on the hearing examiner. He is fully authorized to be the arbiter of the relevance of proffered testimony and of the proper scope of cross-examination, and to insist that all parties address themselves to the business at hand with dignity and dispatch.

*Id.* at 739 n.46.

<sup>50</sup> See note 49 *supra*.

[M]any factors affect [the right of intervention] and not [the right to judicial review]. . . . The central problem of intervention is usually the disadvantage to the tribunal and to other parties of extended cross-examination; judicial review involves no such problem. Adequate protection for interests obliquely affected may often be afforded through limited participation; no such compromise concerning judicial review is customary.

3 K. DAVIS, ADMINISTRATIVE LAW TREATISE § 22.08, at 241 (1958).

<sup>1</sup> In 1959, the Subcommittee on Antitrust and Monopoly of the Senate Judiciary Committee began a comprehensive investigation of the drug industry. This investigation resulted in the enactment of several amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-92 (1964). The sections amended in whole or in part in 1962 were: §§ 321, 331-32, 348, 351-53, 355, 357-58, 360, 372, 374, 376, and 381. To implement the 1962 amendments, the Food and Drug Administration requested the National Academy of Sciences—National Research Council to establish a Drug Efficacy Study Group to review the claims of effectiveness of the estimated 4,000 drugs then certified. Notice of this agreement between the FDA and the NAS-NRC was published in the Federal Register. 31 Fed. Reg. 9426 (1966).

<sup>2</sup> Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(d) (1964).

such evidence insufficient to justify the granting of an evidentiary hearing.<sup>3</sup> The denial of a hearing was based on the failure of Upjohn to produce "substantial evidence" of the effectiveness of the drugs as required for retention of certification by 21 U.S.C. section 355(e).<sup>4</sup> Finally, citing the results of an additional report by the NAS-NRC Study Group which further described the ineffectiveness and undesirable side effects of the drugs, the Commissioner published an order revoking their certificates of safety and effectiveness.<sup>5</sup> Before the order could become effective, Upjohn obtained an injunction in a federal court, delaying enforcement of the order until thirty days after the Commissioner took action on Upjohn's pending motion for an evidentiary hearing.<sup>6</sup> The Commissioner then published a thorough review of the evidence submitted, again concluding that Upjohn had failed to show grounds for an evidentiary hearing.<sup>7</sup> A final order was published on September 19, 1969, revoking the certificates of the drugs.<sup>8</sup> Simultaneously, interpretive regulations describing the standards for the granting of an evidentiary hearing and detailing the essentials of an "adequate and well-controlled clinical investigation" were published.<sup>9</sup> Upjohn appealed in accordance with 21 U.S.C. section 355(h).<sup>10</sup> *Held, affirmed*: The action of the Commissioner and the interpretive regulations correctly reflect the intent of Congress that the "substantial evidence" standard of 21 U.S.C. section 355(e) requires a genuine and substantial issue of fact as a prerequisite to the granting of an evidentiary hearing. *Upjohn Co. v. Finch*, 422 F.2d 944 (6th Cir. 1970).

#### I. HEARING BEFORE AN ADMINISTRATIVE AGENCY WHEN NOT A MATTER OF RIGHT

When a hearing before an administrative agency is not a matter of right,<sup>11</sup> a party seeking such a hearing must establish some valid basis for

<sup>3</sup> Simultaneously, the Commissioner published notice of his intent to withdraw certification of the drugs. 33 Fed. Reg. 19203-04 (1968).

<sup>4</sup> Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(e) (1964).

<sup>5</sup> 34 Fed. Reg. 7687 (1969).

<sup>6</sup> *Upjohn Co. v. Finch*, 303 F. Supp. 241 (W.D. Mich. 1969).

<sup>7</sup> 34 Fed. Reg. 12958-68 (1969).

<sup>8</sup> 34 Fed. Reg. 14598 (1969).

<sup>9</sup> 21 C.F.R. § 130.12 (Supp. 1970).

<sup>10</sup> Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(h) (1964).

<sup>11</sup> A hearing before an administrative agency is a right when required by statute or when the action of the agency will deprive the claimant of "life, liberty, or property, without due process of law" in violation of the fifth amendment of the United States Constitution. In the absence of statutory requirement, factors to be evaluated in determining whether a hearing is a matter of right are: (1) the nature of the action of the administrative agency; (2) the nature of the interest affected by agency action; (3) the availability of judicial review; and (4) the need for immediate action. See *Cafeteria & Restaurant Workers Union v. McElroy*, 367 U.S. 886 (1961); *Phillips v. Commissioner*, 283 U.S. 589 (1931); *Auffmordt v. Hedden*, 137 U.S. 310 (1890).

Agency action may be characterized as either rule-making or adjudicatory. Rule-making action is manifested in a rule or regulation which is general in application and future in effect, while adjudicatory action is particular in application and immediate in effect. The particularity of focus of adjudicatory action generally requires that a hearing be held prior to the taking of such action. *Prentis v. Atlantic Coast Line*, 211 U.S. 210, 226 (1908); *Philadelphia Co. v. SEC*, 175 F.2d 808, 816 (D.C. Cir.), *vacated as moot*, 337 U.S. 901 (1949).

The interest affected by agency action may be either a right or a privilege. It is generally held that due process standards do not apply if only a privilege is to be affected. Application of this distinction depends upon the feasibility of characterizing an interest as either right or privilege.

its request.<sup>12</sup> Generally, reasons advanced may not be "frivolous or inconsequential,"<sup>13</sup> but must raise issues "material to the questions involved."<sup>14</sup> Administrative agencies are not required to perform "useless or unfruitful tasks."<sup>15</sup> The public interest in the continued efficient functioning of the agency is closely related to the requirement for legally sufficient grounds for a hearing. Agencies will not grant individual hearings in numbers which would seriously impair their work.<sup>16</sup>

There is dictum to the effect that a factor in the grant or denial of a hearing should be the amount of power conferred upon the agency,<sup>17</sup> and that "fair play"<sup>18</sup> or the acuteness of the effect on the interests involved<sup>19</sup> should also be considerations. However, none of these essentially subjective elements standing alone has ever been held to be sufficient to invalidate the denial of a hearing. Similarly, the fact that conflicting evidence is presented is not decisive.<sup>20</sup> On the other hand, the denial of a hearing has been held to be error when the agency acted without explicit authorization,<sup>21</sup> took action which was clearly adjudicatory,<sup>22</sup> or acted on the basis of information which was secretly collected and not disclosed to the affected party.<sup>23</sup>

To delineate standards for the granting of a hearing, administrative agencies promulgate interpretive regulations. These regulations are not

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However, a clear distinction is not possible in many instances, for example, where the grant of a license has led to substantial investment of money or other reliance which would be adversely affected by summary agency action. See K. DAVIS, ADMINISTRATIVE LAW § 7.20, at 143 (1959).

The availability of judicial review is a requirement of the Administrative Procedure Act, 5 U.S.C. § 702 (Supp. IV, 1966), and has been held to exist even in the absence of specific statutory authorization. Thus, statutes authorizing administrative agency action invariably include a specific provision making judicial review available and specifying the procedures to be followed in obtaining it. See, e.g., Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(h) (1964).

Immediate action by an administrative agency is occasionally necessary when an issue must be resolved prior to a hearing or other formality. Summary action would be justified, for example, when public health or welfare was at stake. See *Phillips v. Commissioner*, 283 U.S. 589 (1931).

<sup>12</sup> *United States v. Storer Broadcasting Co.*, 351 U.S. 192, 205 (1956).

<sup>13</sup> *Dyestuffs & Chemicals, Inc. v. Flemming*, 271 F.2d 281, 286 (8th Cir.), cert. denied, 362 U.S. 911 (1959).

<sup>14</sup> *Id.*

<sup>15</sup> *Id.*

<sup>16</sup> This rationale was employed in *Air Line Pilot's Ass'n v. Quesada*, 276 F.2d 892 (2d Cir. 1960), in which some 18,000 air line pilots were adversely affected by a regulation, adopted by the Federal Aviation Agency without a hearing, requiring them to retire at age sixty. The *Quesada* court stated: "Administrative regulations often limit in the public interest the use that persons may make of their property without giving each one affected an opportunity to present evidence upon the fairness of the regulation." *Id.* at 896.

<sup>17</sup> *Ohio Bell Tel. Co. v. PUC*, 301 U.S. 292, 304 (1937).

<sup>18</sup> *Morgan v. United States*, 304 U.S. 1, 14-15 (1938); *Chicago, M. & St. P. Ry. v. Polt*, 232 U.S. 165, 168 (1914).

<sup>19</sup> *National Broadcasting Co. v. FCC*, 362 F.2d 946, 953 (D.C. Cir. 1966).

<sup>20</sup> *ICC v. Louisville & N. Ry.*, 227 U.S. 88 (1913); *In re Electric Bond & Share Co.*, 95 F. Supp. 492 (S.D.N.Y.), cert. denied, 341 U.S. 950 (1951).

<sup>21</sup> *Greene v. McElroy*, 360 U.S. 474 (1959) (Army-Navy-Air Force Personnel Security Board revoked security clearance of employee of government contractor without explicit authorization of either the President or Congress).

<sup>22</sup> See *Philadelphia Co. v. SEC*, 175 F.2d 808 (D.C. Cir.), vacated as moot, 337 U.S. 901 (1949); note 11 *supra*.

<sup>23</sup> *Ohio Bell Tel. Co. v. PUC*, 301 U.S. 292 (1937) (PUC ordered Bell to refund excess earnings to customers; Commission had determined excessiveness of earnings by its own evaluation of the value of Bell's property and price trends and had not revealed this information to Bell); *Morgan v. United States*, 304 U.S. 1 (1938) (Secretary of Agriculture established maximum rates to be charged by stockyard commission men without a hearing and without revealing studies upon which action was based).

new law, since the power to make law may not be delegated by the legislature,<sup>24</sup> but are merely statements as to what the head of the agency thinks the law to be.<sup>25</sup> Therefore, the regulations must be in harmony with the statute they interpret, and must be reasonable.<sup>26</sup> Although the agency's interpretation of the law is not conclusive, it is entitled to the highest respect,<sup>27</sup> particularly if the statute involved is relatively new.<sup>28</sup>

## II. SECTIONS 355(d) AND 355(e) AND THE ASSOCIATED INTERPRETIVE REGULATIONS

Sections 355(d) and 355(e)<sup>29</sup> were enacted as part of the 1962 amendments to the Food, Drug, and Cosmetic Act.<sup>30</sup> Section 355(e) describes the procedures and standards for withdrawing the certification of drugs previously certified by the FDA. It provides that certification may be withdrawn "on the basis of new information . . . with respect to such drug, evaluated together with evidence available . . . when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have . . . ."<sup>31</sup> "Substantial evidence," as used in section 355(e), is defined in section 355(d) as "evidence consisting of well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved . . . ."<sup>32</sup>

Section 355(e) makes no clear statement as to the grounds for granting a hearing on de-certification of a drug; it simply provides that after "notice and opportunity for a hearing"<sup>33</sup> the Secretary may withdraw certification of a drug if there is a lack of "substantial evidence" as to its effectiveness. The standards for the grant of a hearing under section 355(e) are contained in the interpretive regulations issued by the Commissioner on September 19, 1969.<sup>34</sup> These regulations state that an applicant must submit "a well-organized and full factual analysis of the clinical and other investigational data he is prepared to prove . . . . A request for a

<sup>24</sup> *Schechter Poultry Corp. v. United States*, 295 U.S. 495, 529 (1935) ("The Congress is not permitted to abdicate or transfer to others the essential legislative functions with which it is thus vested.").

<sup>25</sup> *R.H. Macy & Co. v. United States*, 255 F.2d 884 (2d Cir.), cert. denied, 358 U.S. 880 (1958).

<sup>26</sup> *Commissioner v. Clark*, 202 F.2d 94 (7th Cir. 1953).

<sup>27</sup> *International Chem. Workers Union v. Planters Mfg. Co.*, 259 F. Supp. 365 (N.D. Miss. 1966).

<sup>28</sup> *McLeod v. AFTRA*, 234 F. Supp. 832 (S.D.N.Y. 1964), aff'd, 351 F.2d 310 (2d Cir. 1965) (per curiam).

<sup>29</sup> Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 355(d), (e) (1964).

<sup>30</sup> 21 U.S.C. §§ 301-92 (1964); see note 1 *supra*.

<sup>31</sup> Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(e) (1964).

<sup>32</sup> *Id.* § 355(d).

<sup>33</sup> *Id.*

<sup>34</sup> 21 C.F.R. §§ 130.12, 130.14, 130.27, 130.31, and 146.1 (Supp. 1970). In *Pharmaceutical Mfrs. Ass'n v. Finch*, 307 F. Supp. 858 (D. Del. 1970), these regulations were declared invalid because of the failure of the Commissioner to provide notice and opportunity to comment in accordance with the Administrative Procedure Act, 5 U.S.C. § 553 (Supp. IV, 1966). The Commissioner immediately proposed to re-promulgate the regulations after complying with the requirement for notice and opportunity to comment. 35 Fed. Reg. 3073 (1970). The regulations were re-promulgated with minor changes in wording, effective May 8, 1970. 35 Fed. Reg. 7250-53 (1970).

hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing."<sup>35</sup> In the absence of a "genuine and substantial issue of fact," the Commissioner is authorized to make findings on the basis of the data submitted, without holding a hearing. The interpretive regulations also describe the essentials of a clinical study, detailing such provisions as selection of subjects, comparison of test and control groups, placebo control, and standardization. It is specifically stated that "uncontrolled studies or partially controlled studies are not acceptable evidence to support claims of effectiveness."<sup>36</sup> The requirement of section 355 (e) that a manufacturer demonstrate the effectiveness of his product by "substantial evidence" is thus defined by section 355 (d) and the interpretive regulations as a requirement that the manufacturer raise "a genuine and substantial issue of fact" by means of clinical studies as a prerequisite to the grant of an evidentiary hearing on the effectiveness of the drug.

### III. UPJOHN CO. V. FINCH

Upjohn attacked the application of the "substantial evidence" standard by claiming that: (1) the FDA could not apply it because there was no new information or evidence establishing the ineffectiveness of the drugs involved; (2) the standard was only applicable to drugs which had been certified after 1962; and (3) even if the standard were applicable, the testimonials and statistics submitted by Upjohn established its claims by "substantial evidence." The court held, with little substantive discussion, that the FDA's new information, collected after 1962, was sufficient to establish that the drugs involved were ineffective. The court then construed the applicability of section 355 (e) in the broadest sense, holding that it applied to drugs certified before, as well as after, 1962, and that information acquired subsequent to certification could be used in evaluating the effectiveness of the drug.<sup>37</sup> The court agreed with the Commissioner that the evidence submitted by Upjohn, consisting of testimonials of physicians and statistics on the widespread use and prior certification of the drug, was not sufficient to meet the "substantial evidence" test. The popularity of the drugs was accounted for in an extended polemic against the advertising practices of the drug industry. The court also held that the interpretive regulations of the FDA, defining the "substantial evidence" test of section 355 (e) in terms of a "genuine and substantial issue of fact," correctly reflected the intent of Congress.<sup>38</sup>

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<sup>35</sup> 21 C.F.R. § 130.14 (Supp. 1970).

<sup>36</sup> 21 C.F.R. § 130.12(7)(c) (Supp. 1970).

<sup>37</sup> The court cited the policy considerations enunciated in *Bell v. Goddard*, 366 F.2d 177 (7th Cir. 1966). In *Bell* the court had noted that the FDA study "drew together clinical experience in a manner not previously attempted," and to prevent the application of this new information because it was assimilated subsequent to certification "would do violence to the paramount interest in protecting the public from unsafe drugs." *Id.* at 181.

<sup>38</sup> Senator Kefauver was quoted: "This section 355(d) would require . . . a showing by substantial evidence, by experts who are experienced in making investigations of the drug involved, that the drug not only will be safe but also will have the effect it purports or is represented to

Upjohn also alleged that it would suffer irreparable injury as a result of de-certification. The company noted that over 750 million doses of these drugs had been prescribed since 1957, and that they accounted for twelve per cent of the company's business, or \$30 million per year. The court did not discuss the implied contention that the substantial investment of Upjohn in the manufacture of these drugs rendered the retention of their certification more in the nature of a vested right than a privilege.<sup>39</sup> The logic of this contention is appealing, but it is squarely opposed by the nature and purpose of the Food, Drug, and Cosmetic Act. Considering the pervasive provisions of the Act for the evaluation and licensing of drugs, it cannot be said that Upjohn has a right to market them, or that the company has a right to compensation after being forced to withdraw them from the market. The most that can be said is that Upjohn has a privilege without protection beyond the normal standards of administrative due process.

Filing a brief as amicus curiae, the Pharmaceutical Manufacturers Association<sup>40</sup> contended that Congress did not intend that the 1962 amendments be applied to drugs certified prior to 1962, and that the NAS-NRC panels did not apply the same standards demanded of manufacturers in making the determination that the drugs were ineffective.<sup>41</sup> The first of these contentions was refuted by the court by its broad construction of section 355 (e). The second contention, however, is the strongest in favor of the drug industry. The court stated only that the Commissioner had before him "the unanimous conclusion of thirty experts in antimicrobial therapy" that the drugs were ineffective.<sup>42</sup> No mention is made of a clinical study on the part of the Study Group, and analysis of the composition and procedures of the panels indicates that there was substantial reliance upon personal experience and opinions.<sup>43</sup> The Group had reviewed some 2,800 drugs as of February 1970; individual attention in the form of a clinical

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have." 108 Cong. Rec. 16,307 (daily ed. Aug. 23, 1962) (remarks of Senator Kefauver, member of the Judiciary Committee).

<sup>39</sup> See note 10 *supra*.

<sup>40</sup> The Pharmaceutical Manufacturers Association is a non-profit Delaware corporation composed of some 130 drug companies, which account for approximately 90% of drugs manufactured and distributed in interstate commerce. *Pharmaceutical Mfrs. Ass'n v. Finch*, 307 F. Supp. 858, 859 n.1 (D. Del. 1970).

<sup>41</sup> Whyte, *Effectiveness of the NAS-NRC Drug Effectiveness Review*, 25 *FOOD DRUG COSM. L.J.* 91 (1970). See also Kleinfeld, *Reasonable Grounds, Substantial Evidence, and Law and Order*, 25 *FOOD DRUG COSM. L.J.* 210 (1970).

<sup>42</sup> *Upjohn Co. v. Finch*, 422 F.2d 944, 951 (6th Cir. 1970).

<sup>43</sup> The effectiveness evaluations were performed by twenty-seven panels, with six members each. Individual drugs were assigned to the various panels on the basis of therapeutic groupings. The members of the panels were selected by the Policy Committee of the study in consultation with the chairmen of the individual panels. The panels were instructed to make the following judgments on the indications set forth for a drug in its labeling—effective; probably effective; possibly effective; or ineffective . . . . The panels were to base their judgments on factual information available in the scientific literature; factual information available from the FDA, the manufacturer or other sources; or on the experience and informed judgment of the members of the panel . . . . In all, 237 firms submitted material on 2,824 drug preparations.

Whyte, *Effectiveness of the NAS-NRC Drug Effectiveness Review*, 25 *FOOD DRUG COSM. L.J.* 91, 92-93 (1970).

study for each one was a practical impossibility.<sup>44</sup> The operating guidelines for the Study Group do not require a clinical study to be made.<sup>45</sup> Thus, the FDA has based its action upon the opinions of experts, a type of evidence deemed insufficient when proffered by the manufacturer.

#### IV. CONCLUSION

*Upjohn* makes clear that the "substantial evidence" test of section 355(e) will be applied to all drugs considered for de-certification. This will include drugs certified before and after 1962, and evidence acquired after 1962 may be used in making a determination of the efficacy of a particular drug. The most serious impact of *Upjohn*, however, is that a given drug may be removed from the market by summary action of the Commissioner of the FDA if the "substantial evidence" test is not met. This action will be taken without regard for the financial interest of the manufacturer in the production of the drug. While *Upjohn* represents the most oppressive fact situation yet found in terms of the amount of money involved, it is not difficult to imagine situations of even greater financial magnitude in which the FDA could take summary action. Section 355(e) places the burden of proof squarely on the manufacturer, but the wide disparity in standards of proof, coupled with the substantial economic effect on *Upjohn*, must give rise to concern. These factors would seem to indicate that something more than summary action is called for. *Upjohn* states that they do not. Thus, although a dormant power of the FDA has been realized and used successfully, the limits of this power remain undefined.

*Charles H. Waters, Jr.*

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<sup>44</sup> *Id.*

<sup>45</sup> *Pharmaceutical Mfrs. Ass'n v. Finch*, 307 F. Supp. 858, 865 (D. Del. 1970); *Upjohn Co. v. Finch*, 303 F. Supp. 241, 259-60 (W.D. Mich. 1970).