4/8/86

June 10, 1986

MEMORANDUM FOR DRS. GREER AND GRINSPOON

George and Lester:

The enclosed case was decided by the D.C. Court of Appeals on April 8, 1986. It shows the difficulty of getting the DEA Administrator reversed, even with a decision by the ALJ in your favor.

Richard Cotton

Enclosure

6. Drugs and Narcotics ⇐46

Drug Enforcement Agency Administrator's definition of term chemical similarity, which was sufficiently broad so that presence of opiate's skeleton in another substance's structure established requisite chemical similarity to support conclusion that substance was derivative of opiate, was sufficiently reasonable to warrant judicial deference, considering Administrator's authority to fashion such definition and expertise that Administrator presumably brought to bear on issue. Comprehensive Drug Abuse Prevention and Control Act of 1970, § 102(16), 21 U.S.C.(1982 Ed.) § 802(16).

7. Drugs and Narcotics ⇐46

In determining whether drug was derivative of opiate and thus, narcotic drug under Controlled Substances Act [Comprehensive Drug Abuse Prevention and Control Act of 1970, §§ 101–1016, 21 U.S.C.A. §§ 801–966], Administrator of Drug Enforcement Agency was authorized to accept expert testimony, even though administrative law judge previously rejected such testimony. 5 U.S.C.A. § 557(b).

8. Drugs and Narcotics ⇐46

Testimony of expert witness was sufficient to support finding of Administrator of Drug Enforcement Agency that buprenorphine was chemically similar to thebaine, in determining whether buprenorphine was derivative of thebaine and thus, narcotic drug under Controlled Substances Act [Comprehensive Drug Abuse Prevention and Control Act of 1970, §§ 101–1016, 21 U.S.C.A. §§ 801–966]. Comprehensive Drug Abuse Prevention and Control Act of 1970, § 102(16), 21 U.S.C.(1982 Ed.) § 802(16).

Petition for Review of an Order of Drug Enforcement Administration.

Thomas O. Henteleff, Washington, D.C., with whom Peter R. Mathers, Washington, D.C., was on brief for petitioner.

Gary Schneider, Atty., Dept. of Justice, with whom Stephen E. Stone, Associate Chief Counsel, Dept. of Justice, and Charles E. Pazar, Sr. Atty., Drug Enforcement Administration, Washington, D.C., were on brief for respondent.

Robert A. Dormer, with whom Robert T. Angarola, Washington, D.C., was on brief for intervenor.

Before ROBINSON, Chief Judge, and MIKVA and SILBERMAN, Circuit Judges.

Opinion for the Court filed by Circuit Judge SILBERMAN.

SILBERMAN, Circuit Judge:

This is a petition for review of an order of the Administrator of the Drug Enforcement Agency maintaining the classification of the drug buprenorphine as a narcotic under the Controlled Substances Act, 21 U.S.C. §§ 801–966 (1982). The petitioner, Reckitt & Colman, Ltd., complains that the DEA Administrator's designation of buprenorphine as a narcotic rests on an improper determination that buprenorphine is a derivative of the opiate drug thebaine. Because we conclude that the Administrator's definition of the statutory term "derivative" represents a permissible construction of the Act, and that substantial record evidence supports the Administrator's conclusion that buprenorphine falls within this definition, we affirm the Administrator's decision.

I.

The Controlled Substances Act is a comprehensive regulatory measure that divides the universe of hazardous drugs into different schedules subject to varying degrees of control. *See* 21 U.S.C. § 812 (1982). The Act also designates certain substances as "narcotic drugs." *See id.* § 802(16). In general, the severity of restrictions imposed on the marketing of controlled drugs depends more on what schedule a drug is placed in than on whether it is designated a narcotic. Classification as a narcotic, however, does circumscribe the manner and extent of a drug's importation and exportation, *see id.* §§ 952–53, and its use in drug detoxification programs, *see id.* § 823(g). Moreover, criminal penalties for violations of the Act are harsher if a narcotic sub-

stance is involved. *See id.* § 841(b)(1). And, in practical terms, the DEA's classification of a drug as a narcotic may be expected to impair a drug manufacturer's marketing freedom.

Under the Act, any "derivative" of opium or an opiate is classified as a narcotic drug.[1] Buprenorphine is a relatively new drug, produced from the opium constituent thebaine, that has been developed for medical use as a pain reliever. Although buprenorphine is marketed in many foreign countries, Reckitt & Colman has attempted to introduce it into the United States only recently. In May 1982, the Department of Health and Human Services notified the DEA Administrator that a new drug application for buprenorphine had been approved. HHS recommended that the DEA Administrator modify buprenorphine's status as a Schedule II controlled substance under the Act to the less restricted status of Schedule V. HHS also recommended, however, that buprenorphine continue to be classified as a narcotic drug on the ground that it is a thebaine derivative.

[1] In September 1982, the Administrator issued a notice of proposed rulemaking indicating that buprenorphine would be transferred to Schedule V but would retain its classification as a narcotic. 47 Fed.Reg. 41,401 (1982). Reckitt & Colman objected, urging that buprenorphine should be entirely decontrolled and that it should not be designated a narcotic. The matter was set for an on-the-record hearing before an administrative law judge. In October 1984, the ALJ issued an opinion essentially agreeing with Reckitt & Colman's position. The DEA Administrator, however, rejected the ALJ's conclusions and issued a final order placing buprenorphine in Schedule V and retaining its designation as a narcotic. 50 Fed.Reg. 8104 (1985). Although Reckitt & Colman has abandoned its objection to the placement of buprenorphine in Schedule V, it challenges that part of the Administrator's order maintaining buprenorphine's narcotic classification. This court has jurisdiction pursuant to 21 U.S.C. § 877 (1982).[2]

II.

Reckitt & Colman contends that in maintaining buprenorphine's narcotic classification, the DEA Administrator adopted an unprecedented and improper definition of the statutory term "derivative." To be sure, this is a fairly unusual case. In the course of the administrative proceedings, it became apparent that the derivative status of a substance is a more complicated and uncertain matter than previously thought by the agency. Buprenorphine had heretofore been considered a derivative of thebaine simply because it is prepared from thebaine. Under modern technological methods, however, it is possible to prepare aspirin, acetaminophen (Tylenol), and, apparently, even water from thebaine. Thus, a more refined (and restrictive) definition of "derivative" was obviously needed. But neither the Act nor its legislative history purport to define what a derivative is. Under these circumstances, the Administrator indicated that the agency would regard as a derivative of a drug any substance (1) prepared from that drug, (2) which chemically resembles that drug, and (3) which

1. The Act defines a "narcotic drug" as
> any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:
> (A) Opium, coca leaves, and opiates.
> (B) A compound, manufacture, salt, derivative, or preparation of opium, coca leaves, or opiates....

21 U.S.C. § 802(16) (1982).

An opiate, in turn, is "any drug or other substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability." *Id.* § 802(17).

It is not disputed that thebaine is an "opiate."

2. Intervenor McNeil Pharmaceutical asserts that only actions scheduling or rescheduling drugs are made appealable to this court by 21 U.S.C. § 877 and thus the Administrator's action with respect to buprenorphine's narcotic designation is not appealable. We reject this contention. 21 U.S.C. § 877 refers to "[a]ll final determinations, findings, and conclusions of the Attorney General under this subchapter"; nothing in that provision remotely suggests that it is limited to scheduling actions.

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has some of the adverse effects of that drug. *See* 50 Fed.Reg. 8104, 8107 (1985). The Administrator then concluded, "Buprenorphine possesses sufficient opiate-like actions and does so resemble the structure of its parent, thebaine, that it must be considered to be a derivative thereof...." *Id.*

[2] Reckitt & Colman argues that the Administrator's construction of the Act is flawed because it defines the term "derivative" too broadly. In the petitioner's view, a substance may rightly be regarded as a derivative of another only if it can be produced from it in only one or two chemical operations. (Buprenorphine is produced from thebaine in six or seven steps). The Administrator rejected this narrow "two-step" definition. He felt that "[t]o attribute great significance to the actual number of chemical steps is misleading"—that what is important, rather, is the overall chemical similarity of the product to its parent. *Id.* We conclude that this aspect of the Administrator's definition is "sufficiently reasonable" to warrant judicial deference. *Federal Election Comm'n v. Democratic Senatorial Campaign Comm.*, 454 U.S. 27, 39, 102 S.Ct. 38, 46, 70 L.Ed.2d 23 (1981). Although the Administrator was not necessarily required to follow a strictly scientific definition, *cf. United States v. An Article of Drug ... Bacto-Unidisk....*, 394 U.S. 784, 792, 798, 89 S.Ct. 1410, 1418, 22 L.Ed.2d 726 (1969),[3] the definition he adopted is nevertheless consistent with that employed by chemists.[4]

[3] Reckitt & Colman also argues that the Administrator erred in considering a substance's pharmacological effects as an aspect of the definition of "derivative." Reckitt & Colman maintains that whether one substance is a derivative of another is solely a question of the two substance's chemical relationship. Under the Act, substances with addictive potential comparable to morphine are classified as "opiates," 21 U.S.C. § 802(17) (1982), and hence narcotics, *id.* § 802(16)(A). Thus, the petitioner contends, the statute's reference to "opiates" exhausts the range of situations in which a substance's pharmacological attributes bear on whether it is a narcotic. We find this argument uncompelling. Nothing in the Act dictates that the Administrator must blind himself to the abusive consequences associated with a drug short of effects comparable to morphine. Given the Act's overarching purpose of controlling the distribution of harmful drugs, *id.* § 801, we think it quite reasonable that the Administrator sought to confirm the theoretical chemical similarity of buprenorphine to thebaine by examining its real-world effects. As the Administrator noted, "It is quite clear that addicts recognize buprenorphine as a narcotic and utilize it as a heroin substitute. They clearly understand that buprenorphine is not aspirin or [Tylenol]." 50 Fed.Reg. 8104, 8107 (1985).

[4] In short, the Administrator has drawn upon his expertise to fashion an interpretation of an undefined and potentially ambiguous statutory term. Because that interpretation is reasonable and consistent with the Act's purposes, we are obliged to defer to it. *See Chevron, U.S.A., Inc. v. Natural Resources Defense*

3. Reckitt & Colman contends that because criminal liability may turn on whether a substance is a "derivative" of another, Congress must have intended that the Administrator adopt a narrow and precise definition. This argument is misconceived. Congress has expressly restricted criminal liability to knowing or intentional violations of the Act, *see, e.g.*, 21 U.S.C. § 841 (1982), and so has obviated any potential due process problems implicated by a vague definition of statutory terms such as "derivative." The degree of precision required in formulating such definitions, then, depends upon what means of enforcing the Act the Administrator chooses.

4. The Administrator relied upon *Van Nostrand's Scientific Encyclopedia* (5th ed. 1976), which defines a "derivative" as:

> A term used in organic chemistry to express the relation between certain known or hypothetical substances and the compound formed from them by simple chemical processes in which the nucleus or skeleton of the parent substance exists. Usually the term applies to those compounds where the resulting compound is formed in one step, *although a chain of steps may be involved in some cases depending essentially upon how easy it is to identify the "derivative" within the parent substance*
> ....

50 Fed.Reg. 8104, 8105 (1985) (emphasis added).

Council, Inc., 467 U.S. 837, 104 S.Ct. 2778, 2782, 81 L.Ed.2d 694 (1984); *Federal Election Comm'n*, 454 U.S. at 37; *Morton v. Ruiz*, 415 U.S. 199, 231, 94 S.Ct. 1055, 1072, 39 L.Ed.2d 270 (1974); *Red Lion Broadcasting Co. v. FCC*, 395 U.S. 367, 380–82, 385–86, 89 S.Ct. 1794, 1801–02, 1804, 23 L.Ed.2d 371 (1969).

III.

[5] Reckitt & Colman also argues that the Administrator's conclusion that buprenorphine falls within this definition is not supported by substantial evidence. Reckitt & Colman does not contest the sufficiency of the evidence introduced regarding buprenorphine's pharmacological attributes;[5] the Administrator had before him extensive evidence about abuse associated with buprenorphine in West Germany, Australia, New Zealand, and other countries. *See* 50 Fed.Reg. 8104, 8106 (1985). Instead, Reckitt & Colman focuses its attack on the Administrator's conclusion that buprenorphine is chemically similar to thebaine. According to the petitioner, the only evidence supporting this finding was the testimony of one witness, Dr. Zelesko, who is employed by intervenor McNeil Pharmaceutical.[6] The petitioner argues that the ALJ found this witness' testimony not credible and that this determination strips the testimony of its probative force.

[6] We note that it is not entirely clear on the record before us that the Administrator treated the chemical similarity issue as one of disputed fact. The parties' dispute centered on whether the "ring structure" of buprenorphine is substantially similar to that of thebaine. All of the experts who testified (including the petitioner's) agreed that thebaine's "skeleton" is contained within that of buprenorphine but that an additional side chain of atoms is attached to this skeleton in buprenorphine. They differed over whether the addition of this side chain represented a material change in overall ring structure.[7] The Administrator concluded, without elaboration, that the presence of thebaine's skeleton in buprenorphine's structure was sufficient to establish the requisite chemical similarity. *See id.* at 8105. Thus, it may be that the Administrator simply adopted, as part of the governing legal standard, a broader definition of chemical similarity than that advanced by the petitioner. Given the Act's implicit delegation of authority to the Administrator to fashion such a definition, as well as the expertise that the Administrator presumably brings to bear on the issue, we cannot conclude that the definition adopted was so unreasonable as to be unworthy of judicial deference. *See supra* Part II.

[7, 8] Even if the question of chemical similarity were treated as a disputed factual issue, we would conclude that substantial evidence supports the Administrator's resolution of that issue. The Administrator could have accepted Dr. Zelesko's testimony even though the ALJ did not. The agency, and not the ALJ, is the ultimate factfinder. *See* 5 U.S.C. § 557(b) (1982) ("On appeal from or review of the initial decision, the agency has all the powers which it would have in making the initial decision...."); *Local 310, Int'l Bhd. of Teamsters v. NLRB*, 587 F.2d 1176, 1180–81 (D.C.Cir.1978); *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 853 (D.C.Cir.1970), *cert. denied*, 403 U.S. 923, 91 S.Ct. 2229, 29 L.Ed.2d 701 (1971). While it is true that reviewing courts must take the ALJ's findings into account as part of the record, *see Universal Camera Corp. v. NLRB*, 340 U.S. 474, 496–97, 71 S.Ct. 456, 468–69, 95 L.Ed. 2456 (1951), the significance to be ascribed to them "depends largely on the importance of credibility in

5. Reckitt & Colman does argue that no evidence was introduced supporting the Administrator's decision to include pharmacological effects within the definition of "derivative." But the substantial evidence test only applies to "[f]indings of fact." 21 U.S.C. § 877 (1982). No record evidence is necessary to support the Administrator's interpretation of the statute.

6. The Administrator's order, however, discloses that he also relied upon the statement by buprenorphine's developer that it is a thebaine derivative. 50 Fed.Reg. 8104, 8105 (1985).

7. Dr. Zelesko commented: "I don't think it is a major change.... The dog is still there, the tail is longer."

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Accordingly, the p *denied.*

TEAMSTERS LOCA affiliated with the I erhood of Team Warehousemen anc ica, Petitioner,

v.

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Bell Transit Comp

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United States Cou District of Colu

Argued Nov.

Decided April

Union petitioned for National Labor Relati

8. The intervenor's brief c partment of Justice agre that the Administrator's c norphine is a thebaine de on an alternative ground parties, HHS's initial co stated that buprenorphine tive, and the Act makes tions as to "scientific a binding on the DEA. S (1982). If that were so, it purpose the agency's c

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ko commented: "I don't think it is a ge.... The dog is still there, the tail

the particular case." *Id.* at 496, 71 S.Ct. at 469. The dispute in this case centered not on the occurrence or nonoccurrence of historical facts, or other issues for which demeanor evidence would be highly probative, but rather on matters of scientific judgment and expertise. The ALJ conceded that Dr. Zelesko was "a highly qualified and experienced chemist" but simply found the petitioner's experts more persuasive. On such matters the Administrator remains free to disagree. We conclude that the Administrator's conclusion is supported by substantial evidence.[8]

Accordingly, the petition for review is *denied.*

TEAMSTERS LOCAL UNION NO. 175, affiliated with the International Brotherhood of Teamsters, Chauffeurs, Warehousemen and Helpers of America, Petitioner,

v.

NATIONAL LABOR RELATIONS BOARD, Respondent,

Bell Transit Company, Intervenor.

No. 84–1584.

United States Court of Appeals, District of Columbia Circuit.

Argued Nov. 15, 1985.

Decided April 15, 1986.

Union petitioned for review of order of National Labor Relations Board finding that employer did not commit an unfair labor practice when it unilaterally reduced wage rate of bargaining unit employees because bargaining was at an impasse. The Court of Appeals, Harry T. Edwards, Circuit Judge, held that decision of Board was not supported by substantial evidence.

Reversed and remanded.

1. Labor Relations ⇐680

National Labor Relations Board's determination of impasse involves a judgment on factual issues that are peculiarly within Board's expertise and a reviewing court may not disturb the Board's evaluation unless the finding is irrational or unsupported by substantial evidence.

2. Labor Relations ⇐574

Decision of National Labor Relations Board finding that negotiations were at an impasse, and thus employer did not commit an unfair labor practice when it unilaterally reduced wages, was not supported by substantial evidence; there was no evidence to suggest that either union or employer's negotiator viewed negotiations as deadlocked; moreover, Board's conclusion that an impasse and tentative agreement could exist simultaneously was both inconsistent with prevailing law and incomprehensible.

Petition for Review of an Order of the National Labor Relations Board.

Wilma B. Liebman, with whom Robert M. Baptiste, Washington, D.C., was on brief, for petitioner.

8. The intervenor's brief contends, and the Department of Justice agreed at oral argument, that the Administrator's conclusion that buprenorphine is a thebaine derivative can be upheld on an alternative ground. According to these parties, HHS's initial communication to DEA stated that buprenorphine is a thebaine derivative, and the Act makes HHS's recommendations as to "scientific and medical matters" binding on the DEA. *See* 21 U.S.C. § 811(b) (1982). If that were so, it is difficult to see what purpose the agency's on-the-record hearing served in this case. Certainly the Administrator did not appear to regard his independent findings on "scientific and medical matters" as superfluous. While we entertain doubts about the soundness of the Justice Department's interpretation of the Act—Section 811(b) could be read to indicate only that the DEA must follow HHS's recommendations on the specified matters in deciding whether to *initiate* scheduling actions—our disposition of this case renders it unnecessary for us to decide the point.