UNITED STATES ET AL. *v.* RUTHERFORD ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

No. 78-605. Argued April 25, 1979—Decided June 18, 1979

Terminally ill cancer patients and their spouses brought this action to enjoin the Government from interfering with the interstate shipment and sale of Laetrile, a drug not approved for distribution under the Federal Food, Drug, and Cosmetic Act (Act). Section 505 of the Act prohibits interstate distribution of any "new drug" unless the Secretary of Health, Education, and Welfare approves an application supported by substantial evidence of the drug's safety and effectiveness. Section 201 (p) (1) of the Act defines a "new drug" to include "any drug . . . not generally recognized . . . as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling." Finding that Laetrile, in proper dosages, was nontoxic and effective, the District Court ordered the Government to permit limited purchases of the drug by one of the named plaintiffs. While not disturbing the injunction, the Court of Appeals instructed the District Court to remand the case to the Food and Drug Administration (FDA) for determination whether Laetrile was a "new drug" under § 201 (p) (1), and, if so, whether it was exempt from premarketing approval under either of the Act's two grandfather clauses. After completion of administrative hearings, the Commissioner of the FDA found that Laetrile constituted a "new drug" as defined in § 201 (p) (1) and fell within neither grandfather provision. On review of the Commissioner's decision, the District Court concluded that Laetrile was entitled to an exemption from premarketing approval under the Act's 1962 grandfather clause and, alternatively, that the Commissioner had infringed constitutionally protected privacy interests by denying cancer patients access to Laetrile. The Court of Appeals, without addressing either the statutory or constitutional rulings of the District Court, held that the Act's "safety" and "effectiveness" standards have "no reasonable application" to terminally ill cancer patients and approved intravenous injections of Laetrile for such individuals.

Held: The Act makes no express exception for drugs used by the terminally ill and no implied exemption is necessary to attain congressional objectives or to avert an unreasonable reading of the terms "safe" and "effective" in § 201 (p) (1). Pp. 551-559.

(a) Nothing in the legislative history suggests that Congress intended protection only for persons suffering from curable diseases. Moreover, in implementing the statutory scheme, the FDA has never exempted drugs used by the terminally ill. The construction of a statute by those charged with its administration is entitled to substantial deference particularly where, as here, an agency's interpretation involves issues of considerable public controversy, and Congress has not acted to correct any misperception of its statutory objectives. Pp. 552–554.

(b) The Court of Appeals erred in concluding that the safety and effectiveness standards of § 201 (p) (1) could have "no reasonable application" to terminal patients. For purposes of § 201 (p) (1), the effectiveness of a drug does not necessarily denote capacity to cure; in the treatment of any illness, terminal or otherwise, a drug is effective if it fulfills, by objective indices, its sponsor's claims of prolonged life, improved physical condition, or reduced pain. Nor is the concept of safety under § 201 (p) (1) without meaning for terminal patients; a drug is unsafe for the terminally ill, as for anyone else, if its potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit. Finally, construing § 201 (p) (1) to encompass treatments for terminal diseases does not foreclose all resort to experimental cancer drugs by patients for whom conventional therapy is unavailing. That § 505 (i) of the Act makes explicit provision for carefully regulated use of certain drugs not yet demonstrated to be safe and effective reinforces the conclusion that no exception for terminal patients may be judicially implied. Pp. 554–559.

582 F. 2d 1234, reversed and remanded.

MARSHALL, J., delivered the opinion for a unanimous Court.

Solicitor General McCree argued the cause for the United States et al. With him on the briefs were *Assistant Attorney General Shenefield, Deputy Solicitor General Barnett, Elinor Hadley Stillman, Barry Grossman,* and *Richard M. Cooper.*

Kenneth Ray Coe argued the cause for respondents. With him on the brief were *Kirkpatrick W. Dilling* and *Dennis M. Gronek.**

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*Briefs of *amici curiae* urging reversal were filed by *Francis X. Bellotti,* Attorney General, and *Jonathan Brant,* Assistant Attorney General, for the

MR. JUSTICE MARSHALL delivered the opinion of the Court.

The question presented in this case is whether the Federal Food, Drug, and Cosmetic Act precludes terminally ill cancer patients from obtaining Laetrile, a drug not recognized as "safe and effective" within the meaning of § 201 (p)(1) of the Act, 52 Stat. 1041, as amended, 21 U. S. C. § 321 (p)(1).

I

Section 505 of the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1052, as amended, 21 U. S. C. § 355, prohibits interstate distribution of any "new drug" unless the Secretary of Health, Education, and Welfare approves an application supported by substantial evidence of the drug's safety and effectiveness.[1] As defined in § 201 (p)(1) of the Act, 21 U. S. C. § 321 (p)(1), the term "new drug" includes

"[a]ny drug . . . not generally recognized, among experts

Commonwealth of Massachusetts et al.; and by *Grace Powers Monaco* for the American Cancer Society, Inc.

Briefs of *amici curiae* urging affirmance were filed by *David H. Gill II* for the Committee for Freedom of Choice in Cancer Therapy; by *Stephen Tornay* for the McNaughton Foundation of California; by *Kirkpatrick W. Dilling* and *Dennis M. Gronek* for the National Health Federation; and by *Daniel H. Smith* for the Northwest Academy of Preventive Medicine.

Briefs of *amici curiae* were filed by *George Deukmejian,* Attorney General, *Robert Philibosian,* Chief Assistant Attorney General, *Daniel J. Kremer,* Assistant Attorney General, and *Harley D. Mayfield* and *Robert M. Foster,* Deputy Attorneys General, for the State of California; by *Dennis S. Avery* for the American Academy of Medical Preventics; by *David Laufer* for the Cancer Control Society; and by *David S. King* for the Save the United States Movement, Improving Public Health and Physical Fitness of the United States Citizens.

[1] Section 505, as set forth in 21 U. S. C. § 355, provides in part:

"(a) . . . No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug.

"(b) . . . Any person may file with the Secretary an application with re-

qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling . . . ."

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spect to any drug subject to the provisions of subsection (a) of this section. Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use . . . .

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"(d) . . . If the Secretary finds . . . that (1) the investigations . . . required to be submitted to the Secretary . . . do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; . . . (4) . . . he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) . . . there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. . . . As used in this subsection . . . , the term 'substantial evidence' means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

. . . . .

"(i) . . . The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. . . ."

The Secretary has delegated his approval authority to the Commissioner of the Food and Drug Administration. See 21 CFR § 5.1 (a)(1) (1978).

Exemptions from premarketing approval procedures are available for drugs intended solely for investigative use [2] and drugs qualifying under either of the Act's two grandfather provisions.[3]

In 1975, terminally ill cancer patients and their spouses brought this action to enjoin the Government from interfering with the interstate shipment and sale of Laetrile, a drug not approved for distribution under the Act.[4] Finding that Laetrile, in proper dosages, was nontoxic and effective, the District Court ordered the Government to permit limited purchases of the drug by one of the named plaintiffs. 399 F.

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[2] The requirements for investigative use are set forth in § 505 (i) of the Act, 21 U. S. C. § 355 (i). See n. 1, *supra*.

[3] In the Federal Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1041, Congress exempted from the definition of "new drug" any drug that was subject to the Pure Food and Drug Act of 1906, ch. 3915, 34 Stat. 768, if its labeling retained the same representations concerning conditions of use made prior to 1938. This exemption is currently contained in § 201 (p) (1) of the Act, as codified in 21 U. S. C. § 321 (p) (1). The Drug Amendments of 1962 added a second grandfather clause, which provides:

"In the case of any drug which, on the day immediately preceding the enactment date [October 10, 1962], (A) was commercially used or sold in the United States, (B) was not a new drug as defined by section 201 (p) of the basic Act as then in force, and (C) was not covered by an effective [new drug] application under section 505 of that Act, the amendments to section 201 (p) made by this Act shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day." § 107 (c) (4), 76 Stat. 789.

[4] The suit was originally instituted by a cancer patient, Juanita Stowe, and her husband, Jimmie Stowe. After Ms. Stowe's death, two other patients, Glen L. Rutherford and Phyllis S. Schneider, and Ms. Schneider's husband, filed an amended complaint on behalf of a class composed of all cancer patients and spouses responsible for the costs of treatment. By order entered April 8, 1977, the District Court certified a class consisting of terminally ill cancer patients. 429 F. Supp. 506 (WD Okla.). The Government did not seek review of that order.

Supp. 1208, 1215 (WD Okla. 1975).[5] On appeal by the Government, the Court of Appeals for the Tenth Circuit did not disturb the injunction. However, it instructed the District Court to remand the case to the Food and Drug Administration for determination whether Laetrile was a "new drug" under § 201 (p)(1), and, if so, whether it was exempt from premarketing approval under either of the Act's grandfather clauses. 542 F. 2d 1137 (1976).

After completion of administrative hearings,[6] the Commissioner issued his opinion on July 29, 1977. 42 Fed. Reg. 39768 (1977). He determined first that no uniform definition of Laetrile exists; rather, the term has been used generically for chemical compounds similar to, or consisting at least in part of, amygdalin, a glucoside present in the kernels or seeds of most fruits. *Id.*, at 39770–39772. The Commissioner further found that Laetrile in its various forms constituted a "new drug" as defined in § 201 (p)(1) of the Act because it was not generally recognized among experts as safe and effective for its prescribed use. See 42 Fed. Reg. 39775–39787 (1977). In so ruling, the Commissioner applied the statutory criteria delineated in *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U. S. 609, 629–630 (1973), and concluded that there were no adequate well-controlled scientific studies of Laetrile's safety or effectiveness. 42 Fed. Reg. 39775–39787 (1977).[7]

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[5] The District Court subsequently entered similar orders for other individuals who submitted affidavits averring their membership in the certified class of terminally ill cancer patients. See App. 1–6.

[6] The Commissioner initiated proceedings with an announcement in the Federal Register seeking public comment. 42 Fed. Reg. 10066–10069 (1977). Notice was also afforded to certain known proponents of Laetrile. See *id.*, at 39785–39786.

[7] The Act does not define what constitutes general recognition of a drug's safety and effectiveness under § 201 (p)(1). However, based on the structure and purpose of the statutory scheme, this Court in *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U. S., at 629–634,

Having determined that Laetrile was a new drug, the Commissioner proceeded to consider whether it was exempt from premarketing approval under the 1938 or 1962 grandfather provisions. On the facts presented, the Commissioner found that Laetrile qualified under neither clause. See *id.*, at 39787–39795. First, there was no showing that the drug currently known as Laetrile was identical in composition or labeling to any drug distributed before 1938. See 21 U. S. C. § 321 (p)(1); n. 3, *supra*. Nor could the Commissioner conclude from the evidence submitted that, as of October 9, 1962, Laetrile in its present chemical composition was commercially used or sold in the United States, was generally recognized by experts as safe, and was labeled for the same recommended uses as the currently marketed drug. See § 107 (c)(4), 76 Stat. 789; n. 3, *supra*.

On review of the Commissioner's decision, the District Court sustained his determination that Laetrile, because not generally regarded as safe or effective, constituted a new drug under § 201 (p)(1). 438 F. Supp. 1287, 1293–1294 (WD Okla. 1977). The court also approved the Commissioner's denial of an exemption under the 1938 grandfather clause. However, concluding that the record did not support the Commissioner's findings as to the 1962 grandfather provision, the District Court ruled that Laetrile was entitled to an exemption from premarketing approval requirements. *Id.*, at 1294–1298. Alternatively, the court held that, by denying cancer patients the right to use a nontoxic substance in connection with their personal health, the Commissioner had infringed constitutionally protected privacy interests. *Id.*, at 1298–1300.

The Court of Appeals addressed neither the statutory nor the constitutional rulings of the District Court. Rather, the

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interpreted § 201 (p)(1) to require an "expert consensus" on safety and effectiveness founded upon "substantial evidence" as defined in § 505 (d) of the Act, 21 U. S. C. § 355 (d). See n. 1, *supra*.

Tenth Circuit held that "the 'safety' and 'effectiveness' terms used in the statute have no reasonable application to terminally ill cancer patients." 582 F. 2d 1234, 1236 (1978). Since those patients, by definition, would "die of cancer regardless of what may be done," the court concluded that there were no realistic standards against which to measure the safety and effectiveness of a drug for that class of individuals. *Id.*, at 1237. The Court of Appeals therefore approved the District Court's injunction permitting use of Laetrile by cancer patients certified as terminally ill. However, presumably because the Commissioner had found some evidence that Laetrile was toxic when orally administered, see 42 Fed. Reg. 39786–39787 (1977), the Court of Appeals limited relief to intravenous injections for patients under a doctor's supervision. 582 F. 2d, at 1237. In addition, the court directed the FDA to promulgate regulations "as if" the drug had been found " 'safe' and 'effective' " for terminally ill cancer patients. *Ibid.*

We granted certiorari, 439 U. S. 1127 (1979), and now reverse.

II

The Federal Food, Drug, and Cosmetic Act makes no special provision for drugs used to treat terminally ill patients. By its terms, § 505 of the Act requires premarketing approval for "any new drug" unless it is intended solely for investigative use or is exempt under one of the Act's grandfather provisions. See nn. 2, 3, *supra*. And § 201 (p)(1) defines "new drug" to encompass "[a]ny drug . . . not generally recognized . . . as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling." See *supra*, at 546–547.

When construing a statute so explicit in scope, a court must act within certain well-defined constraints. If a legislative purpose is expressed in "plain and unambiguous language, . . . the . . . duty of the courts is to give it effect according to its terms." *United States* v. *Lexington Mill & Elevator Co.*, 232 U. S. 399, 409 (1914). See *Andrus* v. *Sierra Club*, *ante*, p. 347.

Exceptions to clearly delineated statutes will be implied only where essential to prevent "absurd results" or consequences obviously at variance with the policy of the enactment as a whole. *Helvering* v. *Hammell,* 311 U. S. 504, 510–511 (1941). See *TVA* v. *Hill,* 437 U. S. 153, 187–188 (1978); *United States* v. *Key,* 397 U. S. 322, 324–325 (1970); *United States* v. *American Trucking Assns.,* 310 U. S. 534, 543–544 (1940). In the instant case, we are persuaded by the legislative history and consistent administrative interpretation of the Act that no implicit exemption for drugs used by the terminally ill is necessary to attain congressional objectives or to avert an unreasonable reading of the terms "safe" and "effective" in § 201 (p)(1).

A

Nothing in the history of the 1938 Food, Drug, and Cosmetic Act, which first established procedures for review of drug safety, or of the 1962 Amendments, which added the current safety and effectiveness standards in § 201 (p)(1),[8] suggests that Congress intended protection only for persons suffering from curable diseases. To the contrary, in deliberations preceding the 1938 Act, Congress expressed concern that individuals with fatal illnesses, such as cancer, should be shielded from fraudulent cures. See, *e. g.,* 79 Cong. Rec. 5023 (1935) (remarks of Sen. Copeland, sponsor of the Act); 83 Cong. Rec. 7786–7787, 7789 (1938) (remarks of Reps. Phillips and Lea). Similarly, proponents of the 1962 Amendments to the Act, including Senator Kefauver, one of the bill's sponsors,

[8] Under the 1938 Act, a "new drug" was one not generally recognized by qualified experts as safe for its recommended use. § 201 (p)(1), 52 Stat. 1041. The Drug Amendments of 1962, Pub. L. 87–781, 76 Stat. 789, redefined the term to include drugs not generally recognized as effective or safe for their intended use. § 201 (p)(1), 21 U. S. C. § 321 (p)(1). See *supra,* at 546–547, 551. In addition, the Amendments provided that no new drug application may be approved absent substantial evidence that the drug is effective as well as safe under prescribed conditions. § 505 (d), 21 U. S. C. § 355 (d). See n. 1, *supra.*

indicated an understanding that experimental drugs used to treat cancer "in its last stages" were within the ambit of the statute. See, *e. g.*, 108 Cong. Rec. 17399 (1962) (remarks of Sen. Kefauver); *id.*, at 17401 (comments of Sen. Eastland). That same understanding is reflected in the Committee Reports on the 1962 Amendments. Both Reports note with approval the FDA's policy of considering effectiveness when passing on the safety of drugs prescribed for "life-threatening disease." [9]

In implementing the statutory scheme, the FDA has never made exception for drugs used by the terminally ill. As this Court has often recognized, the construction of a statute by those charged with its administration is entitled to substantial deference. *Board of Governors of FRS* v. *First Lincoln-*

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[9] The Senate Report states:

"The Food and Drug Administration now requires, in determining whether a 'new drug' is safe, a showing as to the drug's effectiveness where the drug is offered for use in the treatment of a life-threatening disease, or where it appears that the 'new drug' will occasionally produce serious toxic or even lethal effects so that only its usefulness would justify the risks involved in its use. In such cases, the determination of safety is, in the light of the purposes of the new drug provisions, considered by the Food and Drug Administration to be inseparable from consideration of the drug's effectiveness. The provisions of the bill are in no way intended to affect any existing authority of the Department of Health, Education, and Welfare to consider and evaluate the effectiveness of a new drug in the context of passing upon its safety." S. Rep. No. 1744, 87th Cong., 2d Sess., pt. 1, p. 15 (1962).

See also H. R. Rep. No. 2464, 87th Cong., 2d Sess., 3 (1962).

The FDA's practice was further amplified by HEW Secretary Ribicoff in testimony on the bill that ultimately became the 1962 Amendments:

"If the drug is offered for treatment of progressive or life-threatening diseases, such as cancer, . . . we now consider its effectiveness. In such cases the determination of safety is, in the light of the purpose of the new drug provisions, inseparable from consideration of the drug's effectiveness." Hearings on S. 1552 before the Subcommittee on Antitrust and Monopoly of the Senate Committee on the Judiciary, 87th Cong., 1st Sess., 2588 (1961).

wood Corp., 439 U. S. 234, 248 (1978); *Bayside Enterprises, Inc.* v. *NLRB*, 429 U. S. 298, 304 (1977); *Udall* v. *Tallman*, 380 U. S. 1, 16 (1965). Such deference is particularly appropriate where, as here, an agency's interpretation involves issues of considerable public controversy, and Congress has not acted to correct any misperception of its statutory objectives. See *Red Lion Broadcasting Co.* v. *FCC*, 395 U. S. 367, 381 (1969); *Zemel* v. *Rusk*, 381 U. S. 1, 11–12 (1965).[10] Unless and until Congress does so, we are reluctant to disturb a long-standing administrative policy that comports with the plain language, history, and prophylactic purpose of the Act.

B

In the Court of Appeals' view, an implied exemption from the Act was justified because the safety and effectiveness

[10] To be sure, it may not always be realistic to infer approval of a judicial or administrative interpretation from congressional silence alone. See, *e. g.*, *Helvering* v. *Hallock*, 309 U. S. 106, 119–121 (1940); *Toucey* v. *New York Life Ins. Co.*, 314 U. S. 118, 140–141 (1941). But once an agency's statutory construction has been "fully brought to the attention of the public and the Congress," and the latter has not sought to alter that interpretation although it has amended the statute in other respects, then presumably the legislative intent has been correctly discerned. *Apex Hosiery Co.* v. *Leader*, 310 U. S. 469, 487–489 (1940). See *United States* v. *Bergh*, 352 U. S. 40, 46–47 (1956). See, *e. g.*, Pub. L. 94–295, 90 Stat. 575; Pub. L. 94–278, 90 Stat. 411; and Pub. L. 91–513, 84 Stat. 1281 (amending § 201 of the Act, 21 U. S. C. § 321).

The issue presented in this case plainly has not escaped public or legislative notice. Whether Laetrile should be freely accessible to cancer patients has been a frequent subject of political debate. Seventeen States have legalized the prescription and use of Laetrile for cancer treatment within their borders, and similar statutes have been defeated in 14 other States. See CCH F. D. Cosm. L. Rep. ¶ 42,292 (1978); Comment, Laetrile: Statutory and Constitutional Limitations on the Regulation of Ineffective Drugs, 127 U. Pa. L. Rev. 233, 234 n. 8 (1978). That Congress is aware of the FDA's policy concerning Laetrile is evident from Senate Subcommittee hearings on the Commissioner's 1977 ruling. See Hearing before the Subcommittee on Health and Scientific Research of the Senate Committee on Human Resources, 95th Cong., 1st Sess. (1977).

standards set forth in § 201 (p)(1) could have "no reasonable application" to terminally ill patients. 582 F. 2d, at 1236. We disagree. Under our constitutional framework, federal courts do not sit as councils of revision, empowered to rewrite legislation in accord with their own conceptions of prudent public policy. See *Anderson* v. *Wilson,* 289 U. S. 20, 27 (1933). Only when a literal construction of a statute yields results so manifestly unreasonable that they could not fairly be attributed to congressional design will an exception to statutory language be judicially implied. See *TVA* v. *Hill,* 437 U. S., at 187–188. Here, however, we have no license to depart from the plain language of the Act, for Congress could reasonably have intended to shield terminal patients from ineffectual or unsafe drugs.

A drug is effective within the meaning of § 201 (p)(1) if there is general recognition among experts, founded on substantial evidence, that the drug in fact produces the results claimed for it under prescribed conditions. See *Weinberger* v. *Hynson, Westcott & Dunning, Inc.,* 412 U. S., at 629–634; n. 7, *supra.* Contrary to the Court of Appeals' apparent assumption, see 582 F. 2d, at 1236, effectiveness does not necessarily denote capacity to cure. In the treatment of any illness, terminal or otherwise, a drug is effective if it fulfills, by objective indices, its sponsor's claims of prolonged life, improved physical condition, or reduced pain. See 42 Fed. Reg. 39776–39786 (1977).

So too, the concept of safety under § 201 (p)(1) is not without meaning for terminal patients. Few if any drugs are completely safe in the sense that they may be taken by all persons in all circumstances without risk.[11] Thus, the Commissioner generally considers a drug safe when the expected therapeutic gain justifies the risk entailed by its use.[12] For

[11] See L. Goodman & A. Gilman, The Pharmacological Basis of Therapeutics 325–339 (5th ed. 1975).

[12] See statement of Dr. Theodore Klumpp, Chief, Drug Division, FDA, June 23, 1941, CCH F. D. Cosm. L. Rep. ¶ 71,053.59 (1977); n. 13, *infra.*

the terminally ill, as for anyone else, a drug is unsafe if its potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit. Indeed, the Court of Appeals implicitly acknowledged that safety considerations have relevance for terminal cancer patients by restricting authorized use of Laetrile to intravenous injections for persons under a doctor's supervision. See 582 F. 2d, at 1237; *supra,* at 551.

Moreover, there is a special sense in which the relationship between drug effectiveness and safety has meaning in the context of incurable illnesses. An otherwise harmless drug can be dangerous to any patient if it does not produce its purported therapeutic effect. See 107 Cong. Rec. 5640 (1961) (comments of Sen. Kefauver). But if an individual suffering from a potentially fatal disease rejects conventional therapy in favor of a drug with no demonstrable curative properties, the consequences can be irreversible.[13] For this reason, even before the 1962 Amendments incorporated an efficacy standard into new drug application procedures, the FDA considered effectiveness when reviewing the safety of drugs used to treat terminal illness. See nn. 8, 9, *supra.* The FDA's practice also reflects the recognition, amply supported by expert medical testimony in this case, that with diseases such as cancer it is often impossible to identify a patient as terminally ill except in retrospect.[14] Cancers vary considerably in behavior

[13] See, *e. g.,* 42 Fed. Reg. 39768, 39787 (1977) (statement of Dr. Carl Leventhal, Deputy Director of the Bureau of Drugs, FDA, and Assistant Professor of Neurology and Pathology at Georgetown University) ("The safety of a drug for human use depends, in large measure, on the therapeutic effectiveness of the particular drug. . . . In the case of cancer, treatment with an ineffective drug will . . . inexorably lead to the patient's death"); *ibid.* (statement of Dr. George J. Hill II, Chairman of the Department of Surgery at Marshall University School of Medicine, W. Va.) (Ineffectual treatment can lead to delay in accepted modes of therapy and needless deaths; thus, "[i]n the absence of scientific evidence of effectiveness, no drug intended for use in treating cancer can be regarded as safe").

[14] See, *e. g., id.,* at 39805 (statement of Dr. Peter Wiernik, Chief of the

and in responsiveness to different forms of therapy. See 42 Fed. Reg. 39777 (1977).[15] Even critically ill individuals may have unexpected remissions and may respond to conventional treatment. *Id.*, at 39777, 39805. Thus, as the Commissioner concluded, to exempt from the Act drugs with no proved effectiveness in the treatment of cancer "would lead to needless deaths and suffering among . . . patients characterized as 'terminal' who could actually be helped by legitimate therapy." *Id.*, at 39805.

It bears emphasis that although the Court of Appeals' ruling was limited to Laetrile, its reasoning cannot be so readily confined. To accept the proposition that the safety and efficacy standards of the Act have no relevance for terminal patients is to deny the Commissioner's authority over all drugs, how-

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Clinical Oncology Branch of the National Cancer Institute's Baltimore Research Center) ("[N]o one can prospectively define the term 'terminal' with any accuracy. A patient can be said to be terminal only after he dies. Many patients who are critically ill respond to modern day management of cancer"); *ibid.* (statement of Dr. Joseph Ross, Professor of Medicine, University of California School of Medicine at Los Angeles) ("[T]he distinction of 'terminal' patients from 'non-terminal' patients may not be reliably determined and an assumption that Laetrile may be given to ['terminal'] patients with impunity may deprive such patients of therapeutic measures which could help them").

[15] The Commissioner noted that these unexpected behavior patterns may account for anecdotal claims of Laetrile's effectiveness. Users of Laetrile who experience spontaneous remissions or delayed responses to conventional therapy after its abandonment may ascribe their improvement to Laetrile without any objective basis for that attribution. See, *e. g.*, *id.*, at 39777 (statement of Dr. Daniel S. Martin, researcher in cancer immunology and chemotherapy); *id.*, at 39800 (statement of Dr. Emil J. Frereich, Chief of the Division of Oncology at University of Texas Medical School at Houston); *ibid.* (statement of Dr. Melvin Krant, Director of Cancer Project at the University of Massachusetts Medical Center). Particularly since accepted cancer treatments such as chemotherapy and radiation often have painful side effects, the Commissioner concluded that patients who subjectively perceive improvement after substituting Laetrile for these modes of therapy may erroneously believe that their condition has been arrested or ameliorated. See *id.*, at 39777, 39799–39800.

ever toxic or ineffectual, for such individuals. If history is any guide, this new market would not be long overlooked. Since the turn of the century, resourceful entrepreneurs have advertised a wide variety of purportedly simple and painless cures for cancer, including liniments of turpentine, mustard, oil, eggs, and ammonia; peat moss; arrangements of colored floodlamps; pastes made from glycerin and limburger cheese; mineral tablets; and "Fountain of Youth" mixtures of spices, oil, and suet.[16] In citing these examples, we do not, of course, intend to deprecate the sincerity of Laetrile's current proponents, or to imply any opinion on whether that drug may ultimately prove safe and effective for cancer treatment. But this historical experience does suggest why Congress could reasonably have determined to protect the terminally ill, no less than other patients, from the vast range of self-styled panaceas that inventive minds can devise.

We note finally that construing § 201 (p)(1) to encompass treatments for terminal diseases does not foreclose all resort to experimental cancer drugs by patients for whom conventional therapy is unavailing. Section 505 (i) of the Act, 21 U. S. C. § 355 (i), exempts from premarketing approval drugs intended solely for investigative use if they satisfy certain preclinical testing and other criteria.[17] An application for clinical testing of Laetrile by the National Cancer Institute is now pending before the Commissioner. Brief for United States

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[16] CCH Fed. F. D. Cosm. L. Admin. Reps., 1907–1949, p. 745 (1951); *id.*, at 1408; *id.*, at 1170–1171, 1298–1299; *id.*, at 224; FDA Ann. Reps., 1950–1974, pp. 309, 464; *id.*, at 45; *id.*, at 412.

[17] See n. 1, *supra*. At present, some 300 experimental drugs are available to critically ill cancer patients at authorized institutions. See Brief for United States 34 n. 23; National Cancer Institute, Extramural Clinical Trial Programs of the Division of Cancer Treatment, General Overview and Scope of Contract-Supported Activities (1979). During 1977, over 90,000 cancer patients participated in investigative programs under the auspices of the National Cancer Institute or the Veterans' Administration. Brief for United States 35 n. 23.

35 n. 23. That the Act makes explicit provision for carefully regulated use of certain drugs not yet demonstrated safe and effective reinforces our conclusion that no exception for terminal patients may be judicially implied. Whether, as a policy matter, an exemption should be created is a question for legislative judgment, not judicial inference.

The judgment of the Court of Appeals is reversed, and the case is remanded for further proceedings consistent with this opinion.[18]

So ordered.

[18] Respondents urge that we consider the District Court's rulings on the constitutional and grandfather clause questions as alternative bases for sustaining the judgment below. However, since the Court of Appeals addressed neither issue, we remand the case for further consideration of respondents' claims. See *Vermont Yankee Nuclear Power Corp.* v. *National Resources Defense Council, Inc.*, 435 U. S. 519, 549 (1978); *Arlington Heights* v. *Metropolitan Housing Dev. Corp.*, 429 U. S. 252, 271 (1977).