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Regulating Laetrile: Constitutional and Statutory Implications

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REGULATING LAETRILE: CONSTITUTIONAL AND STATUTORY IMPLICATIONS

I. INTRODUCTION

Since Ernst T. Krebs, Sr. and Jr. claimed to have discovered it as a cure for cancer, laetrile[1] has had an unsettled status.[2] Under the Federal Food, Drug, and Cosmetic Act,[3] drugs which are "new drugs" are regulated by the Food and Drug Administration (FDA). Difficulties concerning laetrile stem from the fact that it has been classified as a "new drug" by the FDA.[4] To understand the problem in context, it is important to look at the history of the governing statutes.

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1. Although the word "laetrile" is used to describe one particular drug, it is more properly defined as "a class of cyanogenic glucosides." In fact, laetrile, although usually composed primarily of amygdalin, varies from sample to sample, with no standard proportion of amygdalin to other chemicals. Dorr & Paxinos, *The Current Status of Laetrile*, 89 ANNUALS OF INTERNAL MED. 389, 389 (1978) [hereinafter cited as *Status*].

Amygdalin occurs naturally in some fruits and vegetables, including, for example, apricot pits, clover, lima beans, peach and plum pits. *Id.* The first isolation of amygdalin was accomplished by the French chemists Robiquet and Boutron-Charlard in 1830. Greenberg, *Vitamin Fraud in Cancer Quackery*, 122 W.J. OF MED. 345, 345 (1975) [hereinafter cited as *Vitamin Fraud*]. It was first called "Laetrile" by Ernst T. Krebs, Jr. in 1952. Ernst T. Krebs, Sr. and Jr. had both worked on extracting amygdalin from apricot pits. The senior Krebs had begun work in 1926. 42 Fed. Reg. 10,066, 10,067 (1977). In 1949, they patented the formula. According to Krebs' affidavit, reprinted in the Federal Register, it is only being used investigationally as a cure for cancer. 42 Fed. Reg. 39,768, 39,789 (1977).

There is a difference in Laetrile (the patented product), and what the public recognizes as laetrile, which is being advanced as a cancer cure. Laetrile has been used interchangeably to describe various chemical entities; nitriloside, prunasin, and Sarcarcinase. It has also been called vitamin B-17 and promoted as a cure for cancer as a vitamin deficiency disease. A thorough discussion may be found in the Federal Register, 42 Fed. Reg. 39,768, 39,770-72 (1977). The common usage of the word "laetrile" is understood to include any drug which is primarily composed of amygdalin, and this comment will follow that common meaning.

2. The question of status relates to the classification of "new drugs." "New drug" is a term of art under the Federal Food, Drug, and Cosmetic Act, §§ 1-902, 21 U.S.C. §§ 301-392 (1976). *See* note 4 *infra*.

3. 21 U.S.C. §§ 301-392 (1976).

4. For the purposes of this comment, the major area of concern is that of "new drugs." First, a definition of "drug" is necessary. Under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act, a drug includes "articles intended in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." 21 U.S.C. § 321(g)(1) (1976). A "new drug" is defined as follows in the amended Act:

(p) The term "new drug" means

(1) Any drug (except a new animal drug or an animal feed bearing or containing

In 1906, Congress passed the Food and Drug Act.[5] The Act required primarily that drugs be properly labelled and not be contaminated.[6] It was repealed in 1938 and replaced by the Federal Food, Drug, and Cosmetic Act.[7] The major change made by the new Act was a requirement that a "new drug" be safe for its intended purpose.[8] Burdens of investigation were placed upon the proponent of the new drug, and evidence of testing was to be submitted with a new drug application (NDA) for approval.[9] In 1962, the latest amendment to the Act added a requirement of efficacy to the safety provision.[10] Now the proponent of a drug must show evidence that the new drug is both safe and effective for its intended use.[11]

Without approval of the FDA, a new drug may not be transported across state lines or otherwise be involved in interstate commerce.[12] Governmental authority to enforce the Act and to approve new drugs is delegated to the Secretary of HEW.[13]

Not only has laetrile been classified as a "new drug" by the FDA, but an NDA has been refused because the FDA decided that there is insufficient evidence and testing concerning safety.[14] Ordinarily, such an action does not result in strong criticism and suspicion.[15] Pro-

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a new animal drug) the composition of which is such that such drug is not generally recognized, among experts 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 thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug . . . the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

21 U.S.C. § 321(p) (1976).

5. Food and Drug Act, ch. 3915, §§ 1-13, 34 Stat. 768 (1906) (repealed 1938).

6. *Id.*

7. Federal Food, Drug, and Cosmetic Act, ch. 675, §§ 1-902, 52 Stat. 1040 (1938) (current version at 21 U.S.C. §§ 301-392 (1976)).

8. Federal Food, Drug, and Cosmetic Act, ch. 675, § 505, 52 Stat. 1052 (1938) (current version at 21 U.S.C. § 355 (1976)).

9. *Id.*

10. Drug Amendments of 1962, Pub. L. No. 87-781, § 102, 76 Stat. 781 (current version at 21 U.S.C. §§ 321, 355 (1976)).

11. 21 U.S.C. § 355(b) (1976).

12. 21 U.S.C. § 355(a) (1976).

13. *Id.*

14. 42 Fed. Reg. 39,768 (1977).

15. The parties normally seeking an NDA are drug companies, with minimal public participation.

ponents of laetrile are an active group, however, and persistent claims that the drug is helpful in treatment of cancer, one of mankind's most dreaded diseases, are not easily put to rest.

Recently, one of the most controversial cases involving laetrile was heard by the United States Supreme Court.[16] But two intriguing issues concerning laetrile were not decided by the Court: (1) whether laetrile is exempt from the Federal Food, Drug, and Cosmetic Act[17] under one of the "grandfather clauses"[18]; and (2) whether the constitutional right to privacy extends to use of an unapproved drug.[19]

This comment will deal with the application of the Federal Food, Drug, and Cosmetic Act to drugs in general, premarketing requirements of new drugs, and statutory exemptions under the "grandfather clauses."[20] The comment will also examine the constitutional right to privacy as it relates to the use of unauthorized drugs.[21] Challenges to the classification of laetrile as a "new drug" and to the consequent interstate commerce shipping ban have been based upon both statutory and constitutional grounds. The validity of these attacks will be examined.

II. FEDERAL FOOD, DRUG, AND COSMETIC ACT

A. Historical Background

The Food and Drug Act[22] was originally a policing statute, passed in 1906. It prohibited placing misbranded or adulterated drugs or foods on the market.[23] There were no other requirements in that Act.

In 1938, the Food and Drug Act was repealed, and the Federal Food, Drug, and Cosmetic Act[24] was enacted.[25] This Act included pro-

16. United States v. Rutherford, 99 S. Ct. 2470 (1979).

17. 21 U.S.C. §§ 301-392 (1976).

18. There are two "grandfather clauses" in the present Act. Each clause exempts certain drugs from compliance with the Act. 21 U.S.C. §§ 321, 355 (1976). *See* notes 40-41 *infra*.

19. The Supreme Court in the *Rutherford* case did not examine these issues because the Tenth Circuit Court had not ruled on them. The case has been remanded to that court to consider the arguments. 99 S. Ct. at 2479 n.18.

20. *See* note 18 *supra*.

21. *See* note 111 *infra*.

22. Food and Drug Act, ch. 3915, §§ 1-13, 34 Stat. 768 (1906) (repealed 1938).

23. *Id.*

24. Federal Food, Drug, and Cosmetic Act, ch. 675, §§ 1-902, 52 Stat. 1040 (1938) (current version at 21 U.S.C. §§ 301-392 (1976)).

25. The new Act was passed following a scare involving a drug called sulfanilamide, a sulfa compound. An "Elixer of Sulfanilamide" was marketed by one manufacturer, who had performed no toxicity testing prior to marketing. Approximately 100 persons died due to the drug before it was recalled. The new Act was aimed at preventing such disasters. Comment, *Drug Efficacy and The 1962 Drug Amendments*, 60 GEO. L.J. 185, 186 (1971) [hereinafter cited as *Drug Efficacy*].

visions which enabled the government to control the introduction of unsafe new drugs into interstate commerce.[26] New drugs were subject to a premarketing review.[27] Proponents had to file a new drug application (NDA) and show evidence of compliance with the safety requirement.[28] If the Secretary of HEW did not disapprove the application, it became "effective," and the drug could be produced and sold.[29]

Due to growing concern for pharmaceutical practices, Congress passed the 1962 amendment to the Federal Food, Drug, and Cosmetic Act. Several revisions were made,[30] but two of the most important changes were as follows: (1) an NDA must be affirmatively approved;[31] and, (2) a drug must be proven both safe and effective prior to marketing.[32] Since 1962, these requirements have not been changed.

Before an NDA is required, the FDA Commissioner must deter-

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26. Federal Food, Drug, and Cosmetic Act, ch. 675, § 505, 52 Stat. 1052 (1938) (current version at 21 U.S.C. § 355 (1976)).

27. *Id.*

28. *Id.*

29. *Id.* § 505(c). Governmental authority for enforcement of the Act was delegated to the Secretary of HEW. The Secretary then delegated that authority to the FDA Commissioner. 21 C.F.R. § 5.1 (1979). The FDA's organization is set forth at 21 C.F.R. § 5.100 (1979). Three methods of enforcement are currently available to the Commissioner: condemnation and seizure of unapproved drugs, 21 U.S.C. § 334 (1976); injunction against violators, 21 U.S.C. § 332 (1976); and criminal sanctions, 21 U.S.C. § 335 (1976).

30. Drug Amendments of 1962, Pub. L. No. 87-781, §§ 101-308, 76 Stat. 781 (current version at 21 U.S.C. §§ 301-392 (1976)). "In short, the purpose of this bill, as amended, is to strengthen the laws designed to keep unfit drugs off the market in the first instance and speed their removal should they reach the market." S. REP. NO. 1744, 87th Cong., 2d Sess. 2884, *reprinted in* [1962] U.S. CODE CONG. & AD. NEWS 2884, 2884.

At the time of the 1962 amendments to the Federal Food, Drug, and Cosmetic Act, cases of deformities in infants caused by the use of thalidomide were being reported. Although the drug was not being prescribed here, and the cases were occurring primarily in England, Americans were extremely concerned that such occurrences be prevented here. J. MASHAW & R. MERRILL, *FDA Implementation of the 1962 Drug Amendments*, in INTRODUCTION TO THE AMERICAN PUBLIC LAW SYSTEM 462 (1975) [hereinafter cited as MASHAW & MERRILL].

31. Drug Amendments of 1962, Pub. L. No. 87-781, § 102(c), 76 Stat. 781 (current version at 21 U.S.C. § 355 (1976)). In addition to the requirements of safety and efficacy and provisions that applications for new drugs be approved, the Secretary of HEW is required to deny approval if there is a "lack of substantial evidence" to support approval. *Id.* The Secretary is authorized to withdraw approval of any drug after notice and an opportunity for hearing if he or she discovers new information that substantial evidence is lacking, and the provision allows immediate withdrawal of approval of an NDA if there is an imminent danger to the public. 21 U.S.C. § 355(e) (1976). *See Drug Efficacy, supra* note 25, at 192-93.

32. Drug Amendments of 1962, Pub. L. No. 87-781, § 102(b), 76 Stat. 781 (current version at 21 U.S.C. § 355(b) (1976)).

mine that the drug is a "new drug."[33] Therefore, it is valuable to examine the provisions of the Act which relate to this determination.

B. "New Drug" Provision

Unapproved drugs are governed by sections 201(p) and 505 of the Federal Food, Drug, and Cosmetic Act.[34] The FDA Commissioner makes a threshold determination concerning the classification of the drug, *i.e.*, whether or not it is a new drug. There are no specific provisions concerning the manner in which this determination must be made.[35] If the Commissioner classifies the drug as a "new drug,"[36] the proponent must apply for approval before the drug may be shipped in interstate commerce, for either private use or sale.[37]

In order to be exempted from premarketing procedures, the drug must fit into one of the statutory exemptions which are known as the "grandfather clauses."[38] There are two such clauses being currently

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33. 21 U.S.C. §§ 321(p), 355 (1976). *See* note 4 *supra*.

34. 21 U.S.C. §§ 321(p), 355 (1976).

35. *See* MASHAW & MERRILL, *supra* note 30. The Supreme Court has recognized the power of the FDA to make the threshold "new drug" classification. Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645 (1973); Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609 (1973).

36. *See* note 4 *supra*.

37. 21 U.S.C. § 355(a)-(j) (1976), prescribe the process which a proponent of a new drug must follow in order to obtain approval for that drug. Unless approval is received, the drug cannot be shipped in interstate commerce. 21 U.S.C. § 355(a) (1976). The proper procedure is as follows: the proponent of the drug must file an application with the Secretary of the HEW (the designated person is now the FDA Commissioner); the proponent must submit the following with the application:

> (b)(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; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such drug.

21 U.S.C. § 355(b) (1976). After the application is filed, the Commissioner will approve or disapprove the new drug application (NDA). The proponent of the drug has the option of appealing an order of the Commissioner if the application is denied. 21 U.S.C. § 355(b), (h) (1976). The Federal Food, Drug, and Cosmetic Act does not explicitly confer jurisdiction upon anyone to determine what a "new drug" is within the meaning of the Act; however, performance of this function must be within the implied powers of the Secretary of HEW, as delegated to the Commissioner, because the approval of new drugs is subject to his or her approval. MASHAW & MERRILL, *supra* note 30, at 498.

38. *See* note 18 *supra*.

enforced.[39] One clause was part of the 1938 Act,[40] and the other was included in the 1962 amendments.[41]

A drug which had been introduced into interstate commerce prior to passage of the 1938 Act is exempted from the requirements of the Act, provided the label remained unchanged after the passage of the 1938 Act.[42] In particular, the current label must prescribe usage identical to that prescribed prior to the passage of the Act.[43]

A drug "grandfathered" under the 1962 Act is exempted from the requirements of that Act if the drug was being commercially sold or used in the United States prior to the passage of the Act, was not a "new drug" as defined by the 1938 Act,[44] and was not covered by an effective NDA under section 505 of that Act.[45] Hence, because the 1938 Act required safety, and the 1962 act required efficacy in addition to safety, the first grandfather clause exempted drugs from both requirements; the second clause exempted drugs from the efficacy requirement, but not from the safety requirement.[46] In order for the exemptions to apply, the drugs must be used for the same purposes for which they were used prior to the amendments, and the labels must contain the same representations.[47] The courts have construed the 1962

39. 21 U.S.C. § 321(p)(1); Drug Amendments of 1962, Pub. L. No. 87-781, § 107(c)(4), 76 Stat. 781 (found in notes following 21 U.S.C. § 321 (1976)).

40. Federal Food, Drug, and Cosmetic Act, ch. 675, § 201(p)(1), 52 Stat. 1041 (current version at 21 U.S.C. § 321(p)(1) (1976)), provides:

> Such a drug not so recognized shall not be deemed a "new drug" if at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use.

41. Drug Amendments of 1962, Pub. L. No. 87-781, § 107(c)(4), 76 Stat. 781. Although not codified into a section in the U.S.C., it can be found in the notes following 21 U.S.C. § 321 (1976), and provides:

> In the case of any drug which, on the day immediately preceding the enactment date, (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 application under section 505 of that Act, the amendments to section 201(p) 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.

42. *See* note 40 *supra*.

43. *Id.*

44. *See* note 41 *supra*.

45. *Id.*

46. See the discussion of the requirements of the 1938 and 1962 Act in notes 23-25 and accompanying text *supra*.

47. *See* notes 40-41 *supra*. What is passing as laetrile from Mexico not only has different labeling, but such products vary in composition from sample to sample. Recent assay results of confiscated laetrile from Mexico indicate that the amount of amygdalin in a 500 mg. tablet varied from 274 mg. to 446 mg. The injectable 3 g. ampules varied from 1.18 g. to 1.68 g. In these samples, all forms were subpotent, varying

grandfather clause as requiring a general recognition of safety by experts prior to the 1962 Act.[48]

After a drug is classified as a new drug, the proponent must file an NDA and appropriate evidence supporting the drug's efficacy and safety.[49] The FDA has promulgated rules indicating what types of testing are acceptable as proof of efficacy.[50] Enough evidence concern-

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from 46% to 55% in injectables, and 55% to 87% in tablets, from the amount stated on the label. Jee, Yoshikawa, Pont, Cheung, & Lim, *Assay of Amygdalin Dosage Forms From Mexico*, 67 J. PHARM. SCI. 438 (1978).

48. Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645 (1973); Durovic v. Richardson, 479 F.2d 242 (7th Cir. 1973), *cert. denied*, 414 U.S. 944 (1973); Hanson v. United States, 417 F. Supp. 30 (D. Minn. 1976), *aff'd*, 540 F.2d 947 (8th Cir. 1976).

49. 21 U.S.C. § 355(b) (1976).

50. That regulation states:

(a) The plan or protocal for the study and the report of the results of the effectiveness study must include the following:

(1) A clear statement of the objectives of the study,

(2) A method of selection of the subjects that

(i) Provides adequate assurance that they are suitable for the purposes of the study, diagnostic criteria of the condition to be treated or diagnosed, confirmatory laboratory tests where appropriate, and, in the case of prophylactic agents, evidence of susceptibility and exposure to the condition against which prophylaxis is desired.

(ii) Assigns the subjects to test groups in such a way as to minimize bias.

(iii) Assures comparability in test and control groups of pertinent variables, such as age, sex, severity, or duration of disease, and use of drugs other than the test drug.

(3) Explains the methods of observation and recording of results, including the variables measured, quantitation, assessment of any subjects response, and steps taken to minimize bias on the part of the subject and observer.

(4) Provides a comparison of the results of treatment or diagnosis with a control in such a fashion as to permit quantitive evaluation. The precise nature of the control must be stated and an explanation given of the methods used to minimize bias on the part of the observers and the analysts of the data. Level and methods of "blinding," if used, are to be documented. Generally, four types of comparison are recognized:

(i) no treatment: Where objective measurements of effectiveness are available and placebo effect is negligible, comparison of the objective results in comparable groups of treated and untreated patients.

(ii) Placebo control: Comparison of the results of use of the new drug entity with an inactive preparation designed to resemble the test drug as far as possbile.

(iii) Active treatment control: An effective regimen of therapy may be used for comparison, e.g., where the condition treated in such that no treatment or administration of a placebo would be contrary to the interest of the patient.

(iv) Historical control: In certain circumstances, such as those involving diseases with high and predictable mortality (acute leukemia of childhood), with signs and symptoms of predictable duration or serverity (fever in certain infections), or in case of prophylaxis, where morbidity is predictable, the results of use of a new drug entity may be compared quantitatively with prior experience historically derived from the adequately documented natural history of the disease or condition in comparable patients or populations with no treatment or with a regimen (therapeutic, diagnostic, prophylactic) the effectiveness of which is established

ing efficacy must be produced by the proponent of the new drug to indicate that a hearing is necessary; otherwise, the NDA is summarily dismissed.[51] Procedurally, this is similar to other administrative decisions,[52] and such threshold requirements have been judicially upheld.[53]

A refusal of the FDA Commissioner to approve an NDA is subject to judicial review, not unlike other final administrative agency decisions.[54] But because agencies such as the FDA are presumed to have specialized knowledge in their areas of expertise, their decisions are accorded great weight. Such decisions are not easily overturned unless a constitutional right is violated, or unless the decision is arbitrary or capricious.[55]

If the proponent of the unapproved drug wishes to obtain it in interstate commerce only for his or her own personal use, the normal procedure is to seek a preliminary injunction against the FDA Commissioner, to prevent enforcement of section 505(a) of the Federal Food, Drug, and Cosmetic Act[56] against the proponent.[57] In such

(5) A summary of the methods of anaylsis and an evaluation of data derived from the study, including any appropriate statistical methods.

21 C.F.R. § 314.111(a)(5)(ii)(*a*)(*1*)-(*5*) (1979).

51. *See, e.g.*, Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609 (1973); Durovic v. Richardson, 479 F.2d 242 (7th Cir. 1973), *cert. denied*, 414 U.S. 944 (1973); Ciba-Geigy Corp. v. Richardson, 446 F.2d 466 (2d Cir. 1971); Pfizer, Inc. v. Richardson, 434 F.2d 536 (2d Cir. 1970). These cases held that a hearing need not be given unless sufficient evidence is presented to warrant a hearing.

52. *See, e.g.* FPC v. Texaco, Inc., 377 U.S. 33 (1964); United States v. Storer Broadcasting Co., 351 U.S. 192 (1956).

53. *See* note 51 *supra*.

54. 21 U.S.C. § 355(h) (1976); Administrative Procedure Act, § 706(2), 5 U.S.C. § 706(2) (1976). Under such procedures, a person is not entitled to a hearing unless he or she can produce sufficient evidence to show that a hearing is necessary or that a fundamental right is involved. Administrative agencies do have the power to establish rules and issue orders without a hearing. *See* Bi-Metallic Inv. Co. v. Colorado, 239 U.S. 441 (1915). *See generally* B. SCHWARZ, ADMINISTRATIVE LAW, §§ 67-89 (1976).

55. This standard was not ignored by the district court in Rutherford v. United States, 438 F. Supp. 1287 (W.D. Okla. 1977), *aff'd*, 582 F.2d 1234 (10th Cir. 1978), *rev'd and remanded*, 99 S. Ct. 2470 (1979). Citing Citizens to Preserve Overton Park Inc., v. Volpe, 401 U.S. 402 (1971), the court stated it had a responsibility to inquire into the agency's decision. The court then examined the record and determined that the Commissioner's decision was "arbitrary, capricious, that it represents an abuse of discretion and is not in accordance with law." 438 F. Supp. at 1291. *See also* Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645, 654 (1973); Weinberger v. Hynson, Westcott, & Dunning, Inc., 412 U.S. 609 (1973); Far E. Conference v. United States, 342 U.S. 570, 574-75 (1952).

56. 21 U.S.C. § 355(a) (1976).

57. Rutherford v. United States, 399 F. Supp. 1208 (W.D. Okla. 1975) (order granting preliminary injunction), *aff'd and remanded*, 542 F.2d 1137 (10th Cir. 1976), *remanded*, 424 F. Supp. 105 (W.D. Okla. 1977) (remanded to FDA Commissioner for further administrative findings), 438 F. Supp. 1287 (W.D. Okla. 1977) (order granting permanent injunction), *aff'd*, 582 F.2d 1234 (10th Cir. 1978), *rev'd and remanded*, 99 S. Ct. 2470 (1979). *See also* Rizzo v. United States, 432 F. Supp. 356 (E.D.N.Y. 1977); Gadler v. United States, 425 F. Supp. 244 (D. Minn. 1977).

actions, the plaintiff must show a threat of irreparable harm and a probability of success on the merits.[58] In *Rutherford v. United States*,[59] however, the district court shifted the burden to the Commissioner, ordering him to compile an administrative record supporting the basis of his "new drug" determination.[60] This approach was a drastic departure from the routine treatment of an NDA.[61]

III. LAETRILE

A. Determination of Status

Because the "new drug" classification triggers application of the Federal Food, Drug, and Cosmetic Act,[62] it is important to examine the classification of laetrile as a "new drug." Initially, proponents of laetrile claimed it was simply not a drug.[63] The definition of "drug" under the Federal Food, Drug, and Cosmetic Act, section 201(g)(1), includes "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals."[64] Because laetrile is being promoted as a cure or mitigator in the treatment of cancer, it falls squarely within the definition.[65]

Also advanced by the proponents of laetrile is the argument that if laetrile is a drug, it is not a "new drug" under the Act.[66] To support this argument, it would be necessary for the proponents to establish that laetrile is "grandfathered" under one of the relevant statutory clauses.[67]

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58. Rizzo v. United States, 432 F. Supp. 356, 357 (E.D.N.Y. 1977).

59. 424 F. Supp. 105 (W.D. Okla. 1977).

60. *Id. Rutherford*, the major case dealing with laetrile, was a certified class action brought by a class of terminally ill cancer patients who sought to enjoin the FDA Commissioner from enforcing the Act in order to obtain laetrile for their own private use.

61. The structure of the Act forces a proponent of a drug to submit evidence showing safety and efficacy in order to be permitted to transport the drug in interstate commerce. 21 U.S.C. § 355(d) (1976). If sufficient evidence is not submitted, the NDA is not approved. The Commissioner need not seek information to prove the drug's ineffectiveness in order to deny the application. *See* note 51 *supra*.

62. 21 U.S.C. §§ 301-392 (1976).

63. Proponents claimed that it was a food, or alternatively, a vitamin (B-17). But even if laetrile is a "food," if it is sold for the mitigation of disease, it is a drug as well. *See, e.g.*, United States v. 250 Jars, Etc. of U.S. Fancy Pure Honey, 218 F. Supp. 208 (E.D. Mich. 1963), *aff'd*, 344 F.2d 288 (6th Cir. 1965). Typically, the absence of a particular vitamin results in a deficiency syndrome or a well-defined disease. It has not been proven that the absence of laetrile causes either result. Thus, claims that laetrile is a vitamin also appear unsubstantiated. An excellent discussion of the properties of vitamins contrasted with those of laetrile may be found in *Vitamin Fraud*, *supra* note 1.

64. 21 U.S.C. § 321(g)(1)(B) (1976).

65. *Id.*

66. *See* note 4 *supra*.

67. *See* notes 18 and 40-41 *supra*.

In 1977, the district court in *Rutherford* ordered the FDA Commissioner to compile a record to support the determination that laetrile was a new drug. In order to comply with the order, the FDA published a notice of rulemaking, inviting comments and submission of data.[68] After considering the submissions, the FDA published its record.[69] The agency determined that because of Ernst T. Krebs', Sr., testimony that the composition of laetrile varied during the years from 1926 to 1962, laetrile was not exempt under the 1938 grandfather clause.[70] Turning to the 1962 grandfather clause, the Commissioner conceded that laetrile was not covered by an effective new drug application at the time of the 1962 amendment to the Act.[71] Nevertheless, he concluded that laetrile was not grandfathered under the clause because of the following determinations: (1) it was not shown that the drug currently in question has the identical composition of the one produced in 1962; (2) laetrile was not in general use in 1962, but was being used only investigationally and such use is not a basis for exemption; (3) the labeling was not proven to be the same as that used in 1962; and (4) laetrile was not generally recognized as safe in 1962.[72]

B. Judicial Response to the Status Determination

Although there have been several lower court decisions concerning laetrile,[73] the only Supreme Court case which has been heard to date is *United States v. Rutherford*.[74] *Rutherford* involved a class of terminally ill cancer patients who wished to obtain laetrile in interstate commerce for their own use.[75] Those patients sought to enjoin the FDA Commissioner from enforcing the Act insofar as it interfered with their ability to obtain laetrile for personal use.

The district court in *Rutherford* examined the grandfather provisions of the Act, and determined that laetrile is exempt under the 1962 grandfather clause.[76] The court also found, with respect to the 1938 Act's requirements, that laetrile was "safe,"[77] and that, in any event,

68. 42 Fed. Reg. 10,066 (1977).
69. 42 Fed. Reg. 39,768 (1977).
70. *See* note 40 *supra*.
71. *See* note 41 *supra*.
72. 42 Fed. Reg. 39,768, 39,791-94 (1977).
73. Rizzo v. United States, 432 F. Supp. 356 (E.D.N.Y. 1977); Gadler v. United States, 425 F. Supp. 244 (D. Minn. 1977); *In re* Custody of a Minor, 4 FAM. L. REP. (BNA) 2432 (Plymouth Mass. Super. Ct., April 18, 1978).
74. 99 S. Ct. 2470 (1979).
75. Plaintiffs attacked application of the interstate shipment ban found in 21 U.S.C. § 355(a) (1976).
76. 438 F. Supp. 1287 (W.D. Okla. 1977).
77. *Id.* at 1297-98.

the terminal patient's constitutional right to privacy extends to the use of laetrile.[78]

The circuit court neither reached the constitutional issue nor examined application of the grandfather clause; instead, it focused on the requirements of "safety" and "effectiveness" imposed by the Act.[79] Holding that for a terminal cancer patient "safety" and "effec-

78. The court stated:

Plaintiffs seek to exercise final control over the handling of their own individual health-care problems. Numerous cancer patients possess extensive first-hand experience with Laetrile which had led them to believe, correctly or not, that the substance has eased their pain and prolonged their lives. Such personal convictions are not readily dispelled by government pronouncements or affidavits to the contrary. When deprived of treatment in this country, they go elsewhere, and in so doing are denied close contact with their families and family doctors.

. . . .

Doubtless FDA desires to protect the public. Such good intention, however, is not the overriding issue. Many of us allocate time and money and other resources in ways susceptible to just criticism by many standards. Nonetheless, our political ideals emphasize that the right to freely decide is of much greater significance than the quality of those choices actually made. It is never easy for one who is concerned and feels himself particularly knowledgeable to observe others exercise their freedom in ways that to him appear unenlightened.

. . . .

To be insensitive to the very fundamental nature of the civil liberties at issue in this case, and the fact that making the choice, regardless of its correctness, is the sole prerogative of the person whose body is being ravaged, is to display slight understanding of the essence of our free society and its constitutional underpinnings. This is notably true where, as here, there are no simple answers or obvious solutions, uncertainty is pervasive, and even the best efforts leave so much to be desired.

When certain 'fundamental rights' are invoked, such as the right of privacy involved herein, regulation may be justified only by a 'compelling state interest,' and legislative enactments 'must be narrowly drawn to express only the legitimate state interests at stake.' Roe v. Wade, supra, 410 U.S. at 155, 93 S. Ct. at 728. By denying the right to use a nontoxic substance in connection with one's own personal health-care, FDA has offended the constitutional right of privacy.

438 F. Supp. at 1300-01 (footnotes omitted).

79. 582 F.2d 1234 (10th Cir. 1978). The court stated:

We are considering only cancer patients who are terminally ill and only their intravenous use of Laetrile. Thus in this context, what can be 'generally recognized' as 'safe' and 'effective' mean as to such persons who are so fatally stricken with a disease for which there is no known cure? What meaning can 'effective' have in the absence of anything which may be used as a standard? Under this record Laetrile is as effective as anything else. What can 'effective' mean if the person, by all prevailing standards, and under the position the Commission takes, is going to die of cancer regardless of what may be done. Thus there has been no standard here advanced by the Commission against which to measure the safeness or effectiveness of the drug as to the plaintiffs. Clearly the terms have no meaning under these circumstances, and certainly not the abstract meaning sought to be applied by the Commission. This was an erroneous application of the Act by the Commission. We do not say that *anything* is safe for the persons here concerned and *nothing* is effective, but it is apparent that no applicable or reasonable measure exists.

tiveness'' have no meaning, the court exempted such patients from the Act and affirmed the district court's decision.[80]

Last term, the United States Supreme Court granted certiorari and reviewed *Rutherford*.[81] Although both the petitioner and respondent argued the constitutional right to privacy and grandfather clause issues, the Supreme Court did not address them.[82] The Court reversed the circuit court's decision that the Federal Food, Drug, and Cosmetic Act did not apply to terminal cancer patients,[83] and held that such patients are subject to the Act to the same extent as other persons. The Court disagreed with the circuit court's decision that ''safety'' and ''effectiveness'' have no meaning when the patient is terminally ill.[84] Because the Tenth Circuit did not deal with the right to privacy or the ''grand-

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Therefore, we hold as a matter of law that the 'safety' and 'effectiveness' requirements of the statute as now written have no application to terminally ill cancer patients who desire to take the drug intravenously.

Id. at 1237.

80. *Id.*

81. 99 S. Ct. 2470 (1979).

82. *Id.*

83. The Supreme Court stated:

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 standard in § 201(p)(1), 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. 7786-87, 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, 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 diseases.'

99 S. Ct. at 2475-76 (footnotes omitted).

84. The Court held:

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.

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. Thus, the Commissioner generally considers a drug safe when the expected therapeutic gain justifies the risk entailed by its use. For 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.

99 S. Ct. at 2477 (footnotes omitted).

father clause," the Supreme Court remanded the case for consideration of those arguments.

The status of laetrile, therefore, remains unsettled.[85] On remand, the circuit court might conceivably dispose of the case by again adopting the distrcit court's finding that the drug is safe and by determining that the 1962 grandfather clause exempts laetrile from the requirement that it be effective. If however, the court finds the exemption inapplicable, it will, in the absence of proof of efficacy necessarily have to resolve the constitutional issue of privacy. In fact, because the Supreme Court directed the circuit court to consider both the exemption and constitutional issues,[86] it is possible the court will rule on each question.

1. Is Laetrile "Safe"?

Even if the circuit court decides that the 1962 grandfather clause applies and exempts laetrile from the efficacy requirement, there is still a question concerning the safety of the drug.[87] Because that court has previously considered the drug's safety, that part of its prior decision can logically be expected to be reiterated on remand.[88]

But in view of the unique procedure followed by the district court, the logical expectation may not occur. Ordinarily, an advocate of a drug must prove its safety and effectiveness in order to obtain an NDA.[89] It seems that a reversal of this burden was effected by the lower court in *Rutherford*. Because the FDA did not "prove" that laetrile was dangerous, the district court concluded it was safe.[90]

Congress established the present NDA procedure, requiring a proponent to prove that a drug is safe and effective, in order to protect the public from drugs such as thalidomide which had caused a great

85. 99 S. Ct. at 2479 n.18.

86. *Id.*

87. A drug which is exempt under the 1962 grandfather clause is only exempt from the effectiveness requirement. *See* note 41 *supra*.

88. Although the appellate court accepted the district court's pronouncement that laetrile was "generally recognized as safe," the circuit court limited the drug's use to intravenous administration. 582 F.2d at 1236-37. The district court's decision regarding safety is found in 438 F. Supp. at 1297-98. To explain the circuit court's limitation, laetrile is more toxic when taken orally, due to the fact that gastric acids release the cyanide in the amygdalin, thus increasing the chance of cyanide poisoning. Smith, Butler, Cohan, & Schein, *Laetrile Toxicity: A Report of Two Patients*, 62 CANCER TREATMENT REP. 169 (1978) [hereinafter cited as *Toxicity*].

89. Edison Pharmaceutical Co. v. FDA, 513 F.2d 1063 (D.C. Cir. 1975) (denial of NDA may be based on failure to submit substantial evidence; uncontrolled studies are not acceptable). *See also* 21 U.S.C. § 355(d) (1976).

90. 438 F. Supp. 1287 (W.D. Okla. 1977). *See* text accompanying notes 59-61 *supra*.

deal of anxiety prior to the enactment of the 1962 amendment.[91] But judicial treatment of laetrile in the context of this procedure has varied. When the government is the plaintiff, seeking an injunction or condemnation of laetrile which has been manufactured, relief has invariably been allowed.[92] When the government is the defendant, however, the response has not been consistent.[93] In *Rutherford*, the district court ordered the FDA Commissioner to develop an administrative record to support his determination that laetrile is a new drug,[94] and then rejected the record as "arbitrary and capricious."[95] Yet another court refused to issue an injunction against the government, stating that the plaintiff had not shown a probability of success on the merits of the case.[96]

Due to the expertise of administrative agencies, it is rare for a court to order an administrative record to be compiled, and then reject it as "capricious and arbitrary," as in *Rutherford*, if the agency attempts to ascertain the truth.[97] The fact that the plaintiffs in *Rutherford* were terminal cancer patients was more than incidental to the circuit court's opinion,[98] and, presumably, affected the district court's decision in a similar manner.

The problem that will emerge from the *Rutherford* case, if the district court's decision on the 1962 grandfather clause exemption is ultimately upheld, is not that terminal cancer patients may be able to obtain unsafe laetrile for their own use, but that once a determination

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91. MASHAW & MERRILL, *supra* note 30, at 462.

92. United States v. Articles of Food & Drug, 444 F. Supp. 266 (E.D. Wis. 1978); Hanson v. United States, 417 F. Supp. 30 (D. Minn. 1976), *aff'd per curiam*, 540 F.2d 947 (8th Cir. 1976).

93. *See* note 57 *supra*.

94. 424 F. Supp. at 107.

95. 438 F. Supp. at 1291.

96. Gadler v. United States, 425 F. Supp. 244, 249 (D. Minn. 1977).

97. *See, e.g.*, Durovic v. Richardson, 479 F.2d 242 (7th Cir. 1973), *cert. denied*, 414 U.S. 944 (1973). The court in *Durovic* was evaluating appellant's claim that Krebiozen, an anti-cancer drug, was "grandfathered" under the Drug Amendments of 1962, Pub. L. No. 87-781, § 107(c)(4), 76 Stat. 781, found in the note following 21 U.S.C. § 321 (1976). The court stated: "In any event a grandfather clause exception is to be construed strictly against one who invokes it." 479 F.2d at 250 n.6. Another indication of the judicial deference to administrative decisions that a drug is a new drug is found in United States v. 41 Cases, More or Less, 420 F.2d 1126 (5th Cir. 1970). The court stated that "the absence of literature establishing safety is proof that a product is not generally recognized." *Id.* at 1130. Yet, in *Rutherford*, the district court took the plaintiffs' word on the 1962 grandfather clause issue, and construed the absence of literature as establishing proof that laetrile was generally recognized as safe. 438 F. Supp. at 1287.

98. 582 F.2d at 1237. This consideration was the focal point of the decision; the court exempted only terminal patients from the requirements of the Act.

is made which takes the drug out of the jurisdiction of the FDA under under the 1962 Act, any attempts to restrict the drug on grounds of ineffectiveness will fail.[99] One of the aspects of "safety" raised by opponents of laetrile, in this regard, does not relate to a property of the drug itself, but rather to the result of allowing the drug to be used if ineffective.[100] The fear is that a patient who has cancer in the early stages will, in order to avoid conventional therapy, consult a doctor who prescribes laetrile, thereby delaying conventional therapy until the disease is too far advanced to respond to such treatment.[101] As the Supreme Court stated in *Rutherford*:

> An otherwise harmless drug can be dangerous to any person if it does not produce its purported therapeutic effect . . . . But if an individual suffering from a potentially dangerous disease rejects conventional therapy in favor of a drug with no demonstrative curative properties, the consequences can be irreversible. 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 to treat terminal illness.[102]

This is essentially an incorporation of the requirements of the 1962 Act into the 1938 Act. By applying this reasoning, even if the court finds that the 1962 Act exemption from effectiveness applies, and the court finds laetrile to be nontoxic in itself, it still may not be safe for its intended use because it is intended to be used to avert terminal illness.

According to medical authorities, there is no proof that laetrile is either safe or effective.[103] Because there have been cases of cyanide

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99. The FDA can only control and ban drugs which have gone on the market prior to 1962 if they are not safe. *See* note 41 *supra*. If laetrile was marketed prior to that time, it will be out of this FDA's jurisdiction unless the Commissioner can prove that laetrile's toxicity makes the drug dangerous enough to warrant strict control.

100. Brief for Petitioner at 33, United States v. Rutherford, 99 S. Ct. 2470 (1979); Amicus Brief in Support of Petitioners at 24-27, United States v. Rutherford, 99 S. Ct. 2470 (1979).

101. *See Vitamin Fraud*, *supra* note 1; *Status*, *supra* note 1.

102. 99 S. Ct. at 2477-78.

103. *See* Ellison, Byar & Newell, *Special Report on Laetrile: The NCI Laetrile Review*, 299 N. ENG. J. OF MED. 549 (1978); *Laetrile at Sloan-Kettering: A Question of Ambiguity*, SCI., Dec. 23, 1977, at 1231 [hereinafter cited as *Sloan-Kettering*]; Jukes, *Laetrile for Cancer*, 236 J.A.M.A. 1284 (1976).

Research was done in two renowned institutes to determine whether laetrile had an effect on cancer. Dr. Sugiura, a scientist at Sloan-Kettering, claimed to have observed reductions in the size of secondary tumors in mice with cancer. These tests, however, were not reproduced by anyone else, and when the same doctor performed autopsies on mice without knowing which mice were given laetrile, he was unable to identify a significant difference in those which had received laetrile and those which did not. *Sloan-Kettering*, *supra* at 1233. Other tests, conducted by the National Cancer In-

poisoning due to ingestion of toxic amounts of laetrile,[104] the potential danger is thought to outweigh the supposed benefit. It is difficult to evaluate the various medical opinions in this area because of a lack of testing in controlled conditions. Until that is done, it would be speculative for a judicial body to declare that the drug is safe or harmless. There are advocates who claim that, even though laetrile does not cure cancer, it slows the progress of the disease and deadens some of the pain.[105] Again, unfortunately, experiments which have been conducted so far have not been able to prove these claims.[106]

Consideration of the grandfather clause issue may not determine the outcome of *Rutherford* or the status of laetrile, because it is possible the court will resolve this in the FDA's favor, agreeing that laetrile does not fall under the exemption and is neither safe nor effective. If that occurs, the court will need to examine the constitutional right of privacy and determine if it is applicable to an individual who is trying to obtain laetrile for his or her own personal use.

2. Right to Privacy: Extension to Unorthodox Treatment?

In *Rutherford v. United States*,[107] *Gadler v. United States*[108] and *Rizzo v. United States*,[109] the plaintiffs raised the constitutional right to privacy[110] as a major part of their argument for obtaining an injunction against the Commissioner of the FDA.

The right to privacy has been extended in state courts to the refusal

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stitute and Sloan-Kettering, did not reveal any appreciable effect of laetrile on cancer. *Status*, *supra* note 1.

The National Cancer Institute has filed an NDA with the FDA for permission to test laetrile clinically, and in press releases, the FDA has indicated that permission will be forthcoming.

104. *Toxicity*, *supra* note 88.

105. Borruso & Moleski, *Laetrile for Cancer*, 12 HOSPITAL PHARMACY 543 (1977).

106. The National Cancer Institute supervised two separate studies, in 1973, on the effects of laetrile on animals. One of the studies was conducted at Sloan-Kettering Institute. Through a leak to the press, it was reported that Dr. Kanematsu Sugiura had found a 17% incidence of lung metastases in mice receiving laetrile, compared to a 78% incidence in the control mice. Sugiura was unable to repeat those results. *Status*, *supra* note 1, at 394. Sugiura, who performed the tests which showed effects on secondary tumors in mice, is standing behind those results, and believes laetrile is valuable for its palliative effects. *Sloan-Kettering*, *supra* note 101. Other cancer researchers have not been able to substantiate Sugiura's claim or reproduce his results. *Id.*

107. 99 S. Ct. 2470 (1979).

108. 425 F. Supp. 244 (D. Minn. 1977) (refusing injunction).

109. 432 F. Supp. 356 (E.D.N.Y. 1977) (granting injunction).

110. The right to privacy has been derived from the first, third, fourth, fifth, ninth, and fourteenth amendments to the U.S. Constitution. *See* notes 111, 124-27, and accompanying text *infra*.

of medical treatment,[111] and the plaintiffs therefore claimed that it should be extended to the right to consent to treatment that is unorthodox or questionably efficacious.[112] A recent state case, *People v. Privitera*,[113] examined this argument. *Privitera* was a criminal prosecution against a physician who had prescribed laetrile in contravention of a state law which prohibited the use or prescription of any drug which was not approved by the FDA.[114] The Supreme Court of California found that the statute was constitutional and did not violate the right to privacy, reversing the lower court's determination.[115]

The circuit court in *Rutherford* did not reach the constitutional question despite the district court's holding that a constitutional right to privacy extended to the use of "nontoxic treatments, however unconventional."[116] In *Rizzo*, the court noted the privacy argument, but did not determine the validity of the contention.[117] The court stated, however, that the plaintiff had raised a serious constitutional question which was "fair grounds for litigation."[118] In *Gadler*,[119] the plaintiff was unable to obtain an injunction because the court was not convinced that the plaintiff had a probability of success on the merits. The constitutional claim raised was not addressed in the opinion.

Two of the major arguments made by the proponents of laetrile are that: (1) the patient has the right to refuse treatments and should, therefore, have the right to submit to harmless treatments; and (2) the Federal Food, Drug, and Cosmetic Act burdens persons who are not wealthy enough to exercise their rights by obtaining the drug outside

111. Rennie v. Klein, 462 F. Supp. 1131 (D.N.J. 1978) (mental patient may refuse medication); *In re* Osborne, 294 A.2d 372 (D.C. Ct. App. 1972) (husband with two children may refuse blood transfusion); Perlmutter v. Florida Med. Center, 47 U.S.L.W. 2069 (Fla. Cir. Ct., July 11, 1978) (right to terminate own life support systems); *In re* Estate of Brooks, 32 Ill. 2d 361, 205 N.E.2d 435 (1975) (it is unconstitutional for someone else to consent to treatment, blood transfusion, in opposition to religious convictions of patient); Erickson v. Dilgard, 44 Misc. 2d 27, 252 N.Y.S.2d 705 (Sup. Ct. 1962) (Jehovah's Witnesses may refuse blood transfusion).

112. Brief for Respondent at 42-52, United States v. Rutherford, 99 S. Ct. 2470 (1979).

113. 23 Cal. 3d 697 (1979), *rev'g* 74 Cal. App. 3d 936, 141 Cal. Rptr. 764 (1977). There is a discussion of the 1977 decision in Note, *People v. Privitera: The Right to Prescribe and Use Laetrile*, 5 W. ST. U.L. REV. 201 (1978).

114. The California statute is found at CAL. HEALTH & SAFETY CODE § 1701.1 (West 1979). That statute prohibits selling, delivering, prescribing, and giving away any drug to be used in cancer treatment or diagnosis unless the drug complies with the Federal Food, Drug, and Cosmetic Act, § 505, 21 U.S.C. § 355 (1976).

115. 23 Cal. 3d 697 (1979), *rev'g* 74 Cal. App. 3d 936, 141 Cal. Rptr. 764 (1977).

116. 438 F. Supp. at 1299-1300.

117. 432 F. Supp. 356 (E.D.N.Y. 1977).

118. *Id.* at 360.

119. 425 F. Supp. 244 (D. Minn. 1977).

the United States.[120] The major difficulty with the first argument is that laetrile has not yet been proven to be safe.[121] Moreover, if the second argument was accepted, it would render the FDA totally ineffective when dealing with any drug distributed in this country which also happens to be available outside the United States.[122]

When determining whether the right to privacy should prevail over the state's right to regulate, a balance must be struck between the state's interest and the individual's right to determine important personal matters.[123] So far, the right to privacy has been extended by federal courts to allow personal decisions concerning contraception,[124] abortion,[125] choice of educational facilities,[126] and marriage.[127] State courts have been recognizing other privacy areas, most notably the right to refuse treatment[128] and the right to die.[129] Often the determination of such rights will rest upon the condition, prognosis, and familial responsibilities of the patient.[130]

In *People v. Privitera*,[131] the California Supreme Court did not agree that the right to privacy encompassed the right to use or prescribe unapproved drugs.[132] The use or prescription of unapproved drugs was, therefore, not considered a "fundamental" right. Thus, the proper test to determine the constitutionality of discriminate regulation of such use or prescription was not strict scrutiny, but rather, the rational relationship test.[133]

120. Brief for Respondent at 42-52, United States v. Rutherford, 99 S. Ct. 2470 (1979).

121. *See* notes 87-106 and accompanying text *supra*.

122. Because of stringent drug laws in the United States, there are often drugs available in other countries before they are permitted on the market in this country. Sometimes such drugs will not qualify for an NDA. Drug testing is expensive, and most individuals can not bear such costs. A detailed account of various restrictions is found in the Amicus Brief in Support of Respondents at 6-9, United States v. Rutherford, 99 S. Ct. 2470 (1979).

123. The state's interest in this case is the health of its citizens.

124. Carey v. Population Serv. Int'l, 431 U.S. 678 (1977); Griswold v. Connecticut, 381 U.S. 479 (1965).

125. Roe v. Wade, 410 U.S. 113 (1973); Doe v. Bolton, 410 U.S. 179 (1973).

126. Pierce v. Society of Sisters, 268 U.S. 510 (1925).

127. Zablocki v. Redhail, 434 U.S. 374 (1978).

128. *See* note 111 *supra*.

129. *In re* Quinlan, 70 N.J. 10, 355 A.2d 647 (1976); *In re* Yetter, 62 Pa. D. & C. 2d 619 (C.P. 1973).

130. *In re* Yetter, 62 Pa. D. & C. 2d 619 (C.P. 1973). The courts will generally allow a person to make choices regarding treatment unless it interferes with a greater state interest, as when young children may be left parentless and wards of the state. Sometimes, even in a situation involving parents, the court will allow the individual to decide. *In re* Osborne, 294 A.2d 372 (D.C. Ct. of App. 1972).

131. 23 Cal. 3d 697 (1979).

132. *Id.*

133. *Id.* at 703. If a right is found to be a fundamental right, such as the right to privacy, the state's ability to regulate discriminately is limited to situations where the

In *Whalen v. Roe*,[134] the Supreme Court upheld a New York statute which required that the government be notified when physicians prescribed certain drugs. In *Whalen*, the Court recognized that the State of New York could entirely prohibit the use of certain dangerous drugs, so the requirement of notification did not infringe on any privacy right.[135] Thus, the right to regulate drugs is recognized as a valid police power of the state. The state's interest is the preservation of human life. Requiring that drugs be tested and approved before being represented as effective is a method of protecting life, and it is rationally related to the state interest. If that is the test that is used on remand, there should be no difficulty in upholding sections 201(p) and 505 of the Act.[136]

If the circuit court determines on remand, however, that the right to obtain unapproved drugs falls within the right to privacy, the result could well be different. The strict scrutiny test would require that the state interest be compelling.[137] Whether in this case the court would determine a compelling state interest exists is speculative, but it may be argued that the state has no compelling interest in a life which has been characterized as terminal.[138]

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state's interest is compelling. This is a strict scrutiny analysis; the individual's rights are weighed more heavily, and the state must justify its interference. Roe v. Wade, 410 U.S. 113 (1973) (abortion); Boddie v. Connecticut, 401 U.S. 371 (1971) (access to divorce court denied to indigents held unconstitutional); Griswold v. Connecticut, 381 U.S. 479 (1965) (birth control). When such a right is involved, the state must show, not only that it has a compelling interest, but also that there are no less intrusive means of protecting that interest. Roe v. Wade, 410 U.S. 113 (1973). If the right is not fundamental, the question is whether the regulation has a rational relationship to its intended purpose.

Proponents of laetrile argue that the right to submit to any unapproved drug which is nontoxic is protected by the constitutional right to privacy because it involves personal integrity, the body. Judge Cardozo in Schloendorff v. Society of N.Y. Hosp., 211 N.Y. 125, 129, 105 N.E. 92, 93 (1914), stated: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body . . . ." Courts have refused to order blood transfusions to be given to Jehovah's Witnesses based on this reasoning. Erickson v. Dilgard, 44 Misc. 2d 27, 252 N.Y.S.2d 705 (Sup. Ct. 1962). "It is the individual alone who is the subject of a medical decision who has the final say." *Id.* at 28, 252 N.Y.S.2d at 706.

134. 429 U.S. 589 (1977).

135. *Id.* at 603. Other cases which have noted the state's interest in regulating dangerous drugs are Robinson v. California, 370 U.S. 660 (1962), and Whipple v. Martinson, 256 U.S. 41 (1921).

136. 21 U.S.C. §§ 321(p), 355 (1976).

137. *See* note 133 *supra*.

138. In two cases in which the courts allowed termination of life support systems, the patients involved were classified as "terminal." Perlmitter v. Florida Med. Center, 47 U.S.L.W. 2069 (Fla. Cir. Ct., July 11, 1978); *In re* Quinlan, 70 N.J. 10, 355 A.2d 647 (1976). In *Quinlan*, the court noted: "We think that the State's interest *contra* weakens and the individual's right to privacy grows as the degree of bodily invasion increases and the prognosis dims. Ultimately, there comes a point at which the individual's rights overcome the State's interest." *Id.* at 41, 355 A.2d at 664.

There is a possibility, of course, that the circuit court would not reach the constitutional issue by holding that laetrile is exempt under the grandfather clause. Because, however, the lower court was directed to consider both issues by the Supreme Court, it may address the constitutional question as well.

The constitutional right to privacy is well established, and has been recognized as a fundamental right. If the right to privacy extends to the right to use an unapproved drug, not only will individual use of laetrile fall outside the scope of the Federal Food, Drug, and Cosmetic Act, but the use of other drugs will as well.[139] While this would not appear to change the FDA's ability to deny a manufacturer's NDA, or institute condemnation proceedings, it would nonetheless have an adverse effect on the FDA's function.[140] But if there is a constitutional right to obtain a drug in interstate commerce in order to use it, it follows that someone must supply the drug or it will not be obtained. Whether the drug is manufactured and shipped within the United States or is imported from another country, the purpose of the Act could be defeated by the necessity of allowing transportation of the drug in interstate commerce without appropriate safeguards. Yet, without a source for the drug, the person claiming and granted the right to privacy would be in the same position as if the right did not exist.

Therefore, in determining whether one's right to privacy extends to the use of unapproved drugs, the court in *Rutherford* should look beyond the concern with laetrile to consider the effect an affirmative finding would have on the objectives of the Federal Food, Drug, and Cosmetic Act. It may be argued that even if a right to privacy exists to obtain unapproved drugs, the state's interest is nonetheless compelling, and there is no effective way to control drugs that would be less intrusive to the individual's right than is presently found in the Federal Food, Drug, and Cosmetic Act.

IV. CONCLUSION

The recent decision in *United States v. Rutherford*[141] raises the question whether laetrile is subject to the Federal Food, Drug, and Cosmetic Act.[142] The Tenth Circuit Court of Appeals had fashioned a

139. It follows that any drug which was not proven to be harmful would be out of the control of the FDA, at least to those patients thought to have the right to obtain the drug under this analysis.

140. *See* note 29 *supra*, for enforcement provisions.

141. 99 S. Ct. 2470 (1979).

142. 21 U.S.C. §§ 301-392 (1976).

decision to allow terminal patients the right to obtain laetrile for their personal use.[143] The holding in the circuit court, that terminal patients were not governed by the Act, was reversed by the Supreme Court, and remanded for consideration of the constitutional and statutory arguments.[144]

If the Tenth Circuit finds applicable either the right to privacy or the grandfather clause exemption, laetrile will probably be out of the hands of the FDA.[145] Following the circuit court's previous decision, it appears that the right to privacy may be limited to terminal patients.[146] Assuming such a right is found to be applicable, there is still a difficulty in determining who is "terminal." Because of the many different types of cancer and the new treatments available, this determination is increasingly difficult. As the Supreme Court recognized, "it is often impossible to identify a patient as terminally ill except in retrospect."[147] Thus, if a doctor simply needs to file a statement that a patient is terminal and that doctor wants the patient to receive laetrile, it would be easy to obtain laetrile regardless of the patient's actual status.[148]

Regardless of the circuit court's decision, it is likely that the losing party will apply to the Supreme Court for certiorari.[149] The issues at stake here are very important to both parties: the plaintiff class is trying to obtain a right to choose a therapy which it believes is beneficial or helpful; the FDA is trying to preserve its ability to regulate an unproven, unapproved drug, which in this case is laetrile. Those issues may need to be determined by the Supreme Court.

There is an additional possible outcome. If the National Cancer Institute is given permission to test laetrile, the question may become moot, because some of the members of the plaintiff class would have access to laetrile. Moreover, the Institute's findings may provide the

143. 582 F.2d 1234 (10th Cir. 1978).

144. 99 S. Ct. at 2478.

145. *See* notes 99 & 139 and accompanying text *supra*. There may be restrictions on its oral use, however. *See* note 88 *supra*.

146. The Tenth Circuit Court of Appeals has said that a doctor would have to certify a patient to be terminally ill in order for that patient to legally obtain laetrile. 582 F.2d 1234 (10th Cir. 1978). The American Cancer Society filed an Amicus Brief in *Rutherford* when the case was before the Supreme Court. It claimed that some doctors stated in affidavits that they would certify a patient to be terminal if that would allow the patient to obtain the drug, even if they knew the patient was not terminal. Amicus Brief for the Petitioner at 29, United States v. Rutherford, 99 S. Ct. 2470 (1979).

147. 99 S. Ct. at 2478.

148. *See* note 146 *supra*.

149. As can be seen from the full citation of this decision, *supra* note 57, *Rutherford* has been heard and reheard for some time. It is doubtful either party would let an unfavorable decision rest without applying for certiorari.

evidence necessary to finally determine the drug's efficacy and safety. The FDA has recently announced that it will approve testing in the near future.

Laetrile has lived a longer life than most purported cancer cures. Because of this, it may be wise to allow it to be tested in order to establish its curative or palliative properties, or put the claims to rest. The decision to grant an NDA is discretionary, however, and is the responsibility of the FDA Commissioner.[150] If it is granted, results of testing may soon be within grasp, and laetrile may no longer be a mystery.

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150. The Commissioner may not act in an "arbitrary or capricious" manner in granting or denying an NDA, but the approval or disapproval will ultimately be based on his or her discretion.