The Laetrile Controversy: Background and Issues

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Cancer is a disease that afflicts thousands of Americans each year.[1] Because scientists have been unsuccessful in their search for an absolute cure for the disease[2] and because the conventional methods of treatment—surgery, chemotherapy, and radiation—frequently cause traumatic side effects,[3] thousands stricken with cancer have turned for help to an unproven remedy—laetrile.[4] Although proponents of laetrile swear that it has cured cancer, put cancer in a state of remission, or produced some other beneficial result,[5] the Food and Drug Administration [FDA] prohibits the interstate shipment of laetrile because its distributors have not complied with laws requiring proof that the drug is safe and effective for its intended use.[6]

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1. Clark, *Laetrile: Should It Be Banned?*, NEWSWEEK, June 27, 1977, at 49. In 1976, over 370,000 Americans died of cancer and another 675,000 were told for the first time they had cancer. *Preface* to L. AGRAN, THE CANCER CONNECTION at xv (1977) (citing AMERICAN CANCER SOCIETY, CANCER FACTS AND FIGURES (1976)).

2. Despite intensive research on cures for the more than 100 forms of cancer, the survival rates for the most common types of cancers—lung cancer, breast cancer, and cancer of the colon—have remained almost unchanged for the past 25 years. *Preface* to L. AGRAN, *supra* note 1, at xiii. Between 1950-59, only 8 of every 100 victims of lung cancer survived 5 years after diagnosis. In 1975, the 5 year survivial rate was 9 out of 100. *Id.* The 5 year year survival rate was 64% for the 89,000 women suffering from breast cancer in 1975, as compared with 60% 20 years ago. *Id.* For the 100,000 new cases of colon cancer each year, the 5 year survival rate in 1975 was about 44%, which was the rate between 1950-59. *Id.* (citing AMERICAN CANCER SOCIETY, CANCER FACTS AND FIGURES (1975)).

3. Clark, *supra* note 1, at 49. Surgery involves severe scarring and mutilation. *Id.* Chemotherapy not only destroys cancer cells but also may destroy other rapidly dividing normal body cells such as hair follicles, cells lining the gastrointestinal tract, and bone marrow cells involved in the immune defense system. This results in the common side effects of nausea, vomiting, hair loss, and increased susceptibility to infection. Buchenal, *Chemotherapy of Cancer*, CHEMISTRY, June 1977, at 12. Radiation is used to treat localized tumors. It not only destroys the tumor but also damages surrounding normal tissue, and it cannot be used over the whole body to destroy disseminating cancer cells without seriously harming the patient. Nelson, *Radiation Therapy*, CHEMISTRY, June 1977, at 7.

4. *See* Clark, *supra* note 1, at 48.

5. *See* M. CULBERT, VITAMIN B-17 at 35-46 (1974) [hereinafter cited as VITAMIN B-17]; J. RICHARDSON & P. GRIFFIN, LAETRILE CASE HISTORIES 115-233 (1977). The effects of laetrile treatment have been described as an increase in well-being, a general cessation of pain, regaining of normal color, appetite, and weight, and actual remission of all symptoms. M. CULBERT, FREEDOM FROM CANCER 148 (1977) [hereinafter cited as FREEDOM FROM CANCER].

6. "The affidavit . . . of the Bureau of Drugs establishes that no new drug application for laetrile . . . has ever been on file at the FDA. Any distribution of laetrile . . . in interstate com-

The federal ban has made it exceedingly difficult for those cancer victims who, in a desperate search for a cure from this devasting malady, have sought relief in laetrile. As a result, individual cancer sufferers have brought suit to enjoin the FDA from interfering with their interstate transportation of the drug.[7] Furthermore, several states, including Arizona, reacted to public demand and legalized the manufacture and/or sale of laetrile within their state.[8] These lawsuits and state

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merce is therefore a violation of 21 U.S.C. § 355(a)." Hanson v. United States, 417 F. Supp. 30, 36-37 (D. Minn.), *aff'd*, 540 F.2d 947 (8th Cir. 1976).

The particular law that justifies the FDA prohibition on interstate transportation of certain drugs is 21 U.S.C. § 355 (1966). "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." *Id.* § 355 (a). Subsection (b) provides:

> [a]ny person may file with the Secretary [of HEW] an application with respect 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; (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 . . . 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.

Id. § 355(b).

7. *See, e.g.*, Gadler v. United States, 425 F. Supp. 244, 245 (D. Minn. 1977); Rutherford v. United States, 399 F. Supp. 1208, 1210 (W.D. Okla. 1975). See text & notes 64-121 *infra*.

8. Fifteen states have legalized the use of laetrile within their boundaries. Alaska, *see* Ariz. Daily Star, June 10, 1978, § A, at 7, col. 1; Arizona, ARIZ. REV. STAT. ANN. § 32-1962 (Supp. 1977-78); Delaware, DEL. CODE tit. 16, §§ 4901-4905 (Supp. 1977); Florida, FLA. STAT. ANN. §§ 395.066, 458.24, 459.24 (West Supp. 1979); Illinois, ILL. ANN. STAT. ch. 56½, §§ 1801-1804 (Smith-Hurd Supp. 1978); Indiana, IND. CODE ANN. §§ 16-8-8-1 to -6 (Burns 1977); Kansas, *see* Ariz. Daily Star, *supra*; Louisiana, LA. REV. STAT. ANN. § 40:676 (West 1977); Nevada, NEV. REV. STAT. §§ 585.495, 630.303, 633.521, 639.2804, 639.2805 (1977); New Hampshire, N.H. REV. STAT. ANN. § 329:30 (Supp. 1977); New Jersey, N.J. STAT. ANN. § 24:6F-1 to -5 (West Supp. 1978); Oklahoma, OKLA. STAT. ANN. tit. 63, §§ 2-311.1 to .6 (West 1977); Oregon, ch. 611, 1977 Or. Laws 533; Texas, TEX. REV. CIV. STAT. ANN. art. 4476-5a (Vernon Supp. 1978-79); Washington, WASH. REV. CODE ANN. § 70.54.130 to .150 (Supp. 1977).

The state laws differ in one significant respect. Some states passed laws to regulate the manufacture, distribution, and sale of laetrile, *e.g.*, ARIZ. REV. STAT. ANN. §§ 32-1962 to -1981 (Supp. 1977-78), 36-2451 to -2453 (Supp. 1978-79); IND. CODE ANN. §§ 16-8-8-1 to -6 (Burns 1977), while others provided only for regulation of the distribution and sale of laetrile, *e.g.*, OKLA. STAT. ANN. tit. 63, §§ 2-311.1 to .6 (West 1977).

The Arizona legislation, as originally passed, exempted laetrile from the Arizona law requiring new drugs to comply with the provisions of the federal act (the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301-392 (1976)). "No person shall manufacture, sell, offer or hold for sale or give away any new drug or device unless it fully complies with the provisions of the federal act." ARIZ. REV. STAT. ANN. § 32-1962(A) (Supp. 1977). "This section shall not apply to amygdalin, a cyanogenetic glycoside, also known as laetrile, which is processed from the seeds of certain fruits including apricots, peaches, and plums." *Id.* § 32-1962(B). At the same time, the Arizona legislature passed a section of the same bill, House Bill 2059, giving the Department of Health Services the responsibility of establishing standards for the manufacture of laetrile and adopting rules and regulations for its production, processing, labeling, storing, handling, and administering. *Id.* § 32-1981.

However, after a year of delays in adopting standards for the manufacture and sale of laetrile within Arizona, the legislature amended the statute and defined laetrile as a nutritional supplement rather than a drug, thereby eliminating the need to adopt special standards for its manufacture. Ariz. Daily Star, May 9, 1978, § A, at 4, col. 1. The amendment provided: "This section shall not apply to the nutritional supplement amygdalin, a cyano-genetic glycoside, also known as laetrile and vitamin B-17, which is processed from the seeds of certain fruits including apricots, peaches and plums." ARIZ. REV. STAT. ANN. § 32-1962(B) (Supp. 1977-78). The new statute also defines nutritional supplement as "any vitamin essential to, important in, or claimed to have value

statutes have added fuel to the growing controversy surrounding laetrile—a controversy steeped in politics, emotionalism, and frustration—pitting the FDA and the American medical establishment against thousands of laetrile proponents.[9]

This Note will explore laetrile's popularity in the face of scientific evidence showing its ineffectiveness. Background history on the drug will be presented in conjunction with information on research performed with the drug. Then, the sections of the Food, Drug, and Cosmetic Act, which lie at the center of the controversy,[10] and the arguments that have been advanced in several court cases concerning laetrile will be discussed. Constitutional issues that surround the debate will then be examined with particular attention given to the issues of whether the laetrile legislation is a valid exercise of the states' police powers, whether Congress, in its attempt to protect citizens from unsafe and ineffective drugs, has exceeded its constitutional power to control interstate commerce, and, finally, whether federal law has preempted state laws governing the distribution of laetrile.

LAETRILE

Laetrile is a substance made from the pits of apricots, peaches, and bitter almonds. The chemical amygdalin, occurring naturally in those pits, is the major component of laetrile.[11] Although laetrile is regarded as an effective cancer treatment by many who have used it,[12] the FDA

in human nutrition, which shall include laetrile or amygdalin, also known as vitamin B-17." *Id.* § 36-2452. The amendment also provided that laetrile could be distributed or sold by any person within the state, and no special license or prescription would be required. *Id.* § 36-2452(A). The label must clearly identify the substance and include a statement that laetrile is not approved as a cancer treatment by the FDA. *Id.* § 36-2452(B). The Department of Health Services was given authority only to inspect laetrile manufacturing plants to ensure that it is produced in compliance with sanitary standards. *Id.* § 36-2453.

9. Laetrile is taken as a cancer treatment by an estimated 50,000 Americans, some of whom offer themselves as living proof if its effectiveness. Clark, *supra* note 1, at 48. *See* FREEDOM FROM CANCER, *supra* note 5, at 57-88; J. RICHARDSON & P. GRIFFIN, *supra* note 5, at 115-233. *See generally* Culliton, *Sloan-Kettering: The Trials of an Apricot Pit,* 182 SCI. 1000, 1001-03 (1973); *Laetrile: The Political Success of a Scientific Failure*, CONSUMER REP., Aug. 1977, at 444-45 [hereinafter cited as *Political Success*]. In addition, the Committee for Freedom of Choice in Cancer Therapy was organized to promote the cause of laetrile, and it has grown to 500 chapters nationwide, with 30,000 members. FREEDOM FROM CANCER, *supra* note 5, at 10. Included in its membership are 1,200 medical doctors and 800 "medical professionals of various kinds." *Id.* At least 100 physicians have reportedly used laetrile in their practices. *Id.*

10. Section 102 of the Drug Amendments of 1962, 21 U.S.C. § 355 (1976), requiring drugs to be proven effective for their intended use, is a major part of the current controversy. Also at issue is whether laetrile comes within the FD&C Act definition of "new drug." *See* 21 U.S.C. § 321(p) (1976).

11. 42 Fed. Reg. 10,066, 10,067 (1977); 42 Fed. Reg. 39,767, 39,770 (1977). For an interesting discussion that highlights the confusion, even among laetrile proponents, as to exactly what laetrile is, see *Banning of the Drug Laetrile from Interstate Commerce by FDA: Hearing Before the Subcomm. on Health and Scientific Research of the Comm. on Human Resources*, 95th Cong., 1st Sess. 249-52, 258-60 (1977) [hereinafter cited as *Banning Laetrile*].

12. *See* text & notes 5, 9 *supra*.

and major cancer research centers throughout the United States assert that it is worthless as a cancer remedy.[13] Opponents of the drug also argue that laetrile is indirectly harmful because hundreds of people will forego proven methods of cancer therapy and rely instead solely on laetrile until it is too late for the cancer to be treated effectively.[14]

The scientific theory espoused by laetrile promoters to explain its effect upon cancer cells is not complex. The theory is that the chemical amygdalin acts with a cancer cell enzyme called beta-glucosidase to release hydrogen cyanide. The hydrogen cyanide, in turn, attacks the malignant growth. Normal cells contain a different enzyme, rhodanese, which detoxifies the cyanide and prevents destruction of the normal cells.[15] The theory is appealing, but reasearch has not supported it.[16]

13. The FDA has compiled a comprehensive record of expert testimony and experimental results to back up its conclusion that laetrile is ineffective against cancer. *See* 42 Fed. Reg. 39,767, 39,767-806 (1977).

Several experiments testing laetrile's effect on cancer in animals have been performed under contract with the National Cancer Institute. *See* Arehart-Treichel, *Laetrile: The Science Behind the Controversy*, 112 SCI. NEWS 92, 94 (1977). Where laetrile was injected into mice that had cancer tumors transplanted into them, laetrile produced no significant anticancer activity. *Id.* When laetrile was tested alone and in combination with an enzyme that helps break it down in the body, it was found ineffective in mice with leukemia. *Id.* Laetrile, alone and in combination with an enzyme, was likewise ineffective against tumors transplanted in mice. Laster & Schabel, *Experimental Studies of the Antitumor Activity of Amygdalin MF (NSC-15780) Alone and in Combination With Beta-Glucosidase (NSC-128056)*, 50 CANCER CHEMOTHERAPY REP. 951 (1975); *see* Hill *et al.*, *Failure of Amygdalin to Arrest B16 Melanoma and BW5147 AKR Leukemia*, 36 CANCER RESEARCH 2102, 2102 (1976); Levi *et al.*, *Laetrile: A Study of Its Physiocochemical and Biochemical Properties*, 92 CANADIAN MED. A.J. 1057, 1060 (1965) (finding, in addition to laetrile's ineffectiveness, that the Canadian and American products are different pharmaceutical formulations with different chemical properties).

Extensive tests on laetrile have also been conducted at New York's Memorial Sloan-Kettering Cancer Center. Preliminary results of tests conducted in 1972 suggested that laetrile might have some anticancer activity. *See* Arehart-Treichel, *supra*, at 94; Culliton, *supra* note 9, at 1001. At Sloan-Kettering, Kanematsu Sugiura gave laetrile to 60 mice and saline injections to 60 control mice. He found 90% of the control mice experienced lung metastases due to spreading breast tumors; however, only 21% of the laetrile-treated mice showed spreading of the breast tumors. *Id.* Sugiura was able to confirm these results in subsequent experiments, but other investigators were not able to produce similar results in their experiments. *Id.* The discrepancies in the results have been explained to be a result of the different method of evaluation used. *Id.* at 94-95. Sugiura's tests were not blind, that is, he knew which mice received laetrile injections and which received the control substance. Therefore, bias may have influenced his conclusions. Furthermore, the results favorable to laetrile were evaluated mostly from Sugiura's visual observation. Those most unfavorable to laetrile came from bioassay, where lungs from the tested animals were shredded and injected into other mice. If the lung tissue injections cause tumors to form, it may be concluded that the lungs contained metastases. Researchers do not feel that the favorable visual observations are credible when compared to the negative results produced by bioassay. *Id.* at 95.

14. *See* 42 Fed. Reg. 10,066, 10,066 (1977); *Political Success, supra* note 9, at 446. Proponents argue that laetrile is nontoxic and harmless and should, therefore, be legally available. However, death has resulted from an overdose of laetrile. Clark, *supra* note 1, at 48. In July 1977, two cancer patients were treated at Georgetown University Medical Center from serious adverse reactions to laetrile. Arehart-Treichel, *supra* note 13, at 92. Laetrile proponents argued that these cases are similar to intermittent allergic reactions which a small percentage of people experience with numerous other approved drugs. However, neither the safety of laetrile nor the specific danger from its toxicity has been established, 42 Fed. Reg. 39,767, 39,806 (1977), and the FDA feels there is sufficient documentation indicating the consumption of apricot pits can be hazardous. *Id.* at 39,803.

15. *See* Eyerly, *Laetrile: Focus on the Facts*, 26 CA—A CANCER J. FOR CLINICIANS 50, 52 (1976); Hill *et al.*, *supra* note 13, at 2104; Levi *et al.*, *supra* note 13, at 1059.

16. Studies have shown only traces of beta-glucosidase in experimental tumors and no pro-

After the original theory of laetrile's chemical reactions was discredited, some proponents proffered an alternative hypothesis: laetrile is not a drug but actually a vitamin, vitamin B-17, and cancer is a vitamin deficiency disease that can be prevented by taking vitamin B-17.[17] This hypothesis has also met with much skepticism because laetrile is not a vitamin.[18] Moreover, no disease, including cancer, has been associated with the lack of laetrile in any animal. Laetrile is not an essential nutritional substance, nor does it serve a unique bodily function.[19]

Although the American medical establishment has rejected the theories advanced in support of laetrile's curative powers, laetrile supporters dispute the establishment[20] and contend the FDA has no right to interfere with their choice of medical treatment by banning laetrile from interstate commerce. The FDA's authority to ban the interstate shipment of laetrile stems from a mammoth piece of legislation called the Food, Drug, and Cosmetic Act [FD&C Act][21] and the volumes of regulations adopted to carry out the provisions of that Act.[22] Specifically, the ban on laetrile emerges from the provision of the FD&C Act which requires proof that drugs are effective for their intended use.[23] That provision, and other sections of the FD&C Act, will be discussed next to provide a background for the arguments that highlight the laetrile debate.

The Food, Drug, and Cosmetic Act

The forerunner of the present FD&C Act, the Pure Food and

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nounced differences in the level of rhodanese between normal and cancerous tissue. Eyerly, *supra* note 15, at 50. *See* text & note 13 *supra*. Most reports supporting laetrile appear in foreign medical journals. Hill *et al.*, *supra* note 13, at 2105. The favorable reports do not represent controlled clinical trials from which the true effect of laetrile could be determined. *Id.* at 2105-06.

17. *See Laetrile: When is a Drug Not a Drug?*, 15 AM. FAM. PHYSICIAN 186, 186 (1977); *Political Success, supra* note 9, at 445.

18. *Laetrile: When is a Drug Not a Drug?*, *supra* note 17, at 187.

19. *See* 42 Fed. Reg. 39,802 (1977); *Laetrile: When is a Drug Not a Drug?, supra* note 17, at 186; *Political Success, supra* note 9, at 445. In a further refinement of the claims for laetrile, the most recent theory contends that it is no longer a cancer treatment in itself, but rather only a part of a multi-faceted health program, which includes a diet of special foods and vitamins, aimed at preventing cancer. *See Banning Laetrile, supra* note 11, at 246; FREEDOM FROM CANCER, *supra* note 5, at 26; *Political Success, supra* note 9, at 445.

20. *See generally* VITAMIN B-17, *supra* note 5; FREEDOM FROM CANCER, *supra* note 5; J. RICHARDSON & P. GRIFFIN, *supra* note 5. To support their contentions, the laetrile advocates rely heavily on the favorable test results obtained by Kanematsu Sugiura at Sloan-Kettering. See discussion at note 13 *supra*. Laetrilists also point to a report from a German research institute indicating successful results using amygdalin in the treatment of tumors in mice. *See* FREEDOM FROM CANCER, *supra* note 5, at 52. However, in the opinion of some American scientists, most reports supportive of laetrile do not represent controlled clinical tests. Hill *et al.*, *supra* note 13, at 2105.

21. 21 U.S.C. §§ 301-392 (1976).

22. 21 C.F.R. §§ 300-460.93 (1977) set forth the regulations covering drugs for human use.

23. The efficacy requirements were part of the Drug Amendments of 1962, Pub. L. No. 87-781, § 102, 76 Stat. 780 (codified at 21 U.S.C. § 355).

Drug Act, was passed in 1906[24] by Congress under its authority to exclude from interstate commerce impure and adulterated food and drugs.[25] Congress' authority to regulate the production and distribution of food and drugs is well settled.[26] It is derived from the power to regulate commerce among the states pursuant to the commerce clause of the United States Constitution.[27]

Responsibility for enforcing the original Pure Food and Drug Act and its subsequent amendments has shifted periodically from one agency to another in response to the changing needs of federal law enforcement. The FDA, which is presently charged with the enforcement of these laws, was created in 1931[28] to administer the provisions of the Pure Food and Drug Act.[29] As an aid to the performance of its duties, Congress provided the FDA with the power to make regulations.[30] In the area of human drugs alone, the FDA has amassed seven hundred pages of guidelines for the drug industry to follow.[31]

A major revision of the 1906 Pure Food and Drug Act took place in 1938.[32] One important addition to the Act was a requirement that drugs be proven safe for use.[33] Prior to that revision there was no pro-

24. Food and Drug Act of 1906, ch. 3915, 34 Stat. 768. Two major amendments to the original Food and Drug Act occurred in 1938, Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938), and in 1962, Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780.

25. McDermott v. Wisconsin, 228 U.S. 115, 128 (1913); Savage v. Jones, 225 U.S. 501, 529 (1912).

26. *See* McDermott v. Wisconsin, 228 U.S. 115, 128 (1913); Hipolite Egg Co. v. United States, 220 U.S. 45, 57 (1911). *See generally* Markel, *Federal Preemption*, 17 FOOD DRUG COSM. L.J. 453, 463 (1962).

27. U.S. CONST. art. 1, § 8; *see* McDermott v. Wisconsin, 228 U.S. 115, 128 (1913).

28. *See* Agricultural Appropriations Act, ch. 341, 46 Stat. 392, 422 (1931).

29. The enforcement of the 1906 Act was initially the responsibility of the Department of Agriculture under the Bureau of Chemistry, which later became the Food, Drug and Insecticide Administration. *See* Pure Food and Drug Act, ch. 3915, § 4, 34 Stat. 768, 769 (1906). For a discussion of the early administration of the Food and Drug Act, see 1 H. TOULMIN, THE LAW OF FOODS, DRUGS AND COSMETICS 4, 5 (1942). The FDA became part of the Federal Security Agency in 1940. Reorg. Plan No. 4 of 1940, 5 Fed. Reg. 2421 (1940), *reprinted in* § 12, 54 Stat. 1234, 1237 (1940). In 1953 the Federal Security Agency became the Department of Health, Education, and Welfare, under which the FDA presently functions. Reorg. Plan No. 1 of 1953, 18 Fed. Reg. 2053 (1953), *reprinted in* § 5, 67 Stat. 631, 632 (1953); *see* 3 H. TOULMIN, THE LAW OF FOODS, DRUGS, AND COSMETICS 1289 (2d ed. 1963).

30. Power to prescribe departmental regulations is set forth in 5 U.S.C. § 301 (1976) which states: "The head of an Executive department . . . may prescribe regulations for the goverment of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use and preservation of its records, papers and property." The specific authority for promulgating regulations concerning enforcement of the Food, Drug, and Cosmetic Act appears in 21 U.S.C. § 371(a) (1976) which states: "The authority to promulgate regulations for the efficient enforcement of this chapter . . . is vested in the Secretary [of HEW]." In promulgating these regulations the Secretary has transferred his authority with respect to enforcement and regulation of the Food, Drug, and Cosmetic Act to the Commissioner of the FDA. 21 C.F.R. § 5.1 (1977).

31. *See* 21 C.F.R. §§ 300-460.93 (1977).

32. *See* Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-392 (1976)). For a thorough discussion of food and drug laws at the time of the revisions, see Cavers, *The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions*, 6 L. & CONTEMP. PROB. 2 (1939).

33. Food, Drug, and Cosmetic Act, ch. 675, § 505, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. 355 (1976)).

hibition of interstate transportation of harmful drugs.[34] The FDA could only interfere with the interstate shipment of a product that was adulterated or misbranded,[35] regardless of how harmful it might be.[36] It was not until several people died from taking a drug known as elixir sulfanilamide that Congress passed a bill that required drugs to be generally recognized as proven safe for use before they could be introduced into interstate commerce.[37] The already rapid growth of industrialism had convinced Congress that the public, at an extreme disadvantage in dealing with large pharmaceutical companies, was in need of the protection afforded by these additional regulations.[38]

In 1962, the second part of the present test for drug approval was put into effect.[39] The FD&C Act was amended to prohibit interstate shipment of any drug unless it is first proven both safe *and effective*.[40] The purpose of the Drug Amendments of 1962 was "to strengthen and broaden existing laws in the drug field so as to bring about better, safer medicine . . . and to keep unfit drugs off the market."[41] At the Senate hearings for the new amendment, several physicians testified concerning the need for more stringent drug regulations. They pointed out that since a rapid growth in the drug industry had resulted in over four hundred new drugs being introduced on the market each year, physicians could not possibly be aware of all the medical information available for the new drugs.[42] Thus, they could not always know which drugs had been proven effective. The physicians stressed that the marketing of a safe but ineffective drug could be harmful to the public because a new, ineffective drug is usually used in place of an older but effective drug. Furthermore, a considerable amount of time often elapses before the medical profession discovers that the performance of a newly marketed drug is substandard.[43] In an effort to address these concerns, Congress amended the FD&C Act by adding the efficacy re-

34. Cavers, *supra* note 32, at 39.
35. Act of June 30, 1906, ch. 3915, § 1, 34 Stat. 768.
36. Cavers, *supra* note 32, at 39. *See* Act of June 30, 1906, ch. 3915, §§ 1-2, 34 Stat. 768.
37. Food, Drug, and Cosmetic Act, ch. 675, § 505, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. § 355 (1976)). *See* Cavers, *supra* note 32, at 20. The elixir had been checked by the manufacturer merely for appearance, flavor, and fragrance. There were no tests made on animals and no investigations made of literature that would have apprised the manufacturer of the lethal character of the solvent. The only basis for the FDA's intervention was that the product was not an elixir—it contained no alcohol—so it was, therefore, misbranded. In addition, the presence of diethylene glycol, which was the fatal ingredient, was not mentioned on the label. *Id.*
38. United States v. Dotterweich, 320 U.S. 277, 280 (1943).
39. Drug Amendments of 1962, Pub. L. No. 87-871, § 102, 76 Stat. 780 (codified at 21 U.S.C. § 355 (1976)).
40. *Id.*
41. S. REP. No. 1744, 87th Cong., 2d Sess. 8 (1962), *reprinted in* [1962] U.S. CODE CONG. & AD. NEWS 2884, 2884.
42. *Id.* at 37, [1962] U.S. CODE CONG. & AD NEWS at 2902.
43. *Id.*

quirements.[44]

The application of the efficacy requirements to laetrile is responsible for much of the controversy surrounding the drug, with the debate culminating in litigation and legislation. The following section describes the clash that erupted between the laetrile proponents and the FDA.

Laetrile and the FD&C Act

The FD&C Act prohibits the introduction into interstate commerce of any new drug unless a new drug application has been approved by the FDA.[45] In order to get such approval, an application demonstrating that the drug is safe and effective for use, among other things, must be submitted to the FDA.[46] Despite attempts by proponents of laetrile to obtain approval from the FDA to distribute the drug, the FDA has prohibited the interstate shipment of laetrile because it has not been proven effective against cancer.[47] The laetrilists' lack of success has been due to their inability or refusal to submit adequate information to support an FDA finding that the drug is both safe and effective. The standards that must be met are spelled out at length in the regulations pertaining to drugs intended for human use.[48] Among the regulations is the requirement for adequate and well-controlled investigations of drugs by qualified experts.[49] Adequate and well-controlled clinical investigations require proof of such things as

44. *See id.* The 1962 Amendments were not overwhelmingly popular. After they were introduced as Senate Bill 1552, they were subject to two years of amendments as well as vigorous objection by the drug industry and part of the medical profession. *See* 3 H. TOULMIN, *supra* note 29, at 1361. Early in 1962 the thalidomide scare caused much the same furor as the sulfanilamide disaster which induced the passage of the 1938 amendments. See text & note 37 *supra*. As a result, the public and the press, as well as the executive branch, expressed deep interest in drug regulations. This led to the passage of the 1962 Drug Amendments. *See* 3 H. TOULMIN, *supra* note 29, at 1361.

45. 21 U.S.C. § 355(a) (1976).

46. *Id.* § 355(b). This section of the Act also provides:

> If the Secretary finds, after due notice to the applicant and in accordance with . . . this section . . . that . . . evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, 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 . . . he shall issue an order refusing to approve the application . . . .

Id. § 355(d)(5). This subsection goes on to provide:

> 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 . . . in the labeling . . . thereof.

Id.

47. 42 Fed. Reg. 10,066, 10,067 (1977); 42 Fed. Reg. 38,767, 38,786 (1977).

48. *See* 21 U.S.C. § 355 (1976); 21 C.F.R. § 314 (1977).

49. 21 U.S.C. § 355(d) (1976); 21 C.F.R. § 314.111(a)(5) (1977).

suitable subjects, steps taken to minimize bias on the part of the subject and the observer, comparability in test and control groups of variables such as severity and duration of the disease, and comparison of results of the test drug with those of a placebo.[50] The regulations also specify that isolated case reports, random experience, and reports lacking details that permit scientific evaluation will not be considered in determining effectiveness.[51] Such unreliable evidence, the FDA claims, is the type the laetrile advocates use to support their claims of effectiveness.[52] Although laetrile has received some support from people with very respectable credentials,[53] the FDA claims no one has submitted substantial evidence of adequate and well-controlled investigations from which experts could fairly and responsibly conclude that the drug will be effective against cancer.[54] Accordingly, the FDA has banned the introduction of laetrile into interstate commerce.[55]

Because of the federal ban on laetrile, the drug has been difficult to obtain in the United States. Therefore, in the past few years, thousands have sought treatment in Mexico, where laetrile is readily available, or have smuggled the substance into the United States in defiance of the federal prohibition.[56] In an attempt to avoid some of the expense and

50. 21 C.F.R. § 314.111(a)(5)(ii)(a) (1977).

51. *Id.* § 314.111(a)(5)(c).

52. 42 Fed. Reg. 39,767, 39,777 (1977). One example of the type of information supplied to the FDA is a three-page report from a family physician of a "study" he conducted on over 200 cancer patients to whom he administered laetrile. Almost half of the patients were excluded from the report, however, because of lack of follow-up to determine their condition, because they had been treated by the physician for a period of less than four months, or because they had died within the first three months of treatment. *Id.* In addition to excluding those patients—with the attendant result of biasing the study in favor of laetrile—the physician failed to distinguish between those patients who had also undergone forms of conventional cancer treatment and those who had not. Therefore, no reliable conclusion could be drawn as to whether the favorable results were attributable to laetrile or other treatments. *Id.* Methods such as these lack the details necessary for scientific evaluation by experts in drug research. See 21 C.F.R. § 314.11(a)(5)(ii)(c) (1977).

Another physician submitted a report of case studies compiled in connection with the administrative hearing that resulted from the court order in Rutherford v. United States, 424 F. Supp. 105 (W.D. Okla. 1977). See text & notes 94-98 *infra*. After excluding patients for reasons similar to those stated above, there remained a report on 62 out of 4000 patients treated. The report did not indicate the chemical composition of the laetrile used, and in some cases, there was no information regarding how the diagnosis of cancer was made. 42 Fed. Reg. at 39,778. *But see* J. RICHARDSON & P. GRIFFIN, *supra* note 5, at 115-225 (the authors purport to set forth in detail case histories of cancer patients successfully treated with laetrile).

Another attempt at obtaining FDA approval for laetrile also resulted in failure. In 1970, a California foundation submitted an application to the FDA for approval to test laetrile in humans. The FDA rejected the application, however, because the data supplied in it was inadequate to justify clinical tests of laetrile in humans. 42 Fed. Reg. 10,066, 10,067 (1977).

53. *See* Rutherford v. United States, 438 F. Supp. 1287, 1292 n.9 (W.D. Okla. 1977); 42 Fed. Reg. at 39,785-86 (the proponents include a Ph.D in biochemistry from the University of California, a Ph.D in chemistry and physiology from Cornell, a Ph.D in pharmacology from Wisconsin, and several medical doctors).

54. 42 Fed. Reg. 39,767, 39,786 (1977).

55. See text & note 6 *supra*.

56. *See* VITAMIN B-17, *supra* note 5, at 22; Clark, *supra* note 1, at 48; N.Y. Times, May 26, 1975, at 1, col. 1.

difficulty involved in obtaining laetrile and to legalize interstate shipment of the drug, several people have brought suit to enjoin the FDA from enforcing its ban on laetrile, at least with respect to the shipment of small amounts for personal use.

Several arguments have been advanced in these lawsuits. It has been asserted: (1) that laetrile is not within the purview of the regulations concerning new drugs because it is neither a drug nor a new drug;[57] (2) that even if laetrile is subject to the statutory requirements, such requirements are unconstitutional as a denial of due process;[58] and (3) that government interference with the choice of laetrile as a medical treatment is an invasion of the right to privacy.[59] Proponents of these arguments have succeeded in some jurisdictions and failed in others. The lack of agreement among the courts has fortified the already heated debate.

Probably the most controversial and well-known laetrile case is *Rutherford v. United States*.[60] That class action suit went through a series of appeals and remands, including an order for a FDA hearing.[61] It ended with an injunction prohibiting the FDA from interfering with the interstate shipment of laetrile intended for intravenous injections by persons who are certified by a licensed medical practitioner to have terminal cancer.[62] *Rutherford* opened a path that several other courts have followed.[63] However, as demonstrated by other laetrile cases the decisions by no means unanimously favor the laetrile proponents.

The Laetrile Cases

The United States District Court for Minnesota ruled against pro-laetrile forces in *Hanson v. United States*.[64] This case was brought by vitamin distributors to enjoin the FDA from interfering with their interstate shipment of laetrile.[65] An argument was made in *Hanson* that

57. Rutherford v. United States, 438 F. Supp. 1287, 1290 (W.D. Okla. 1977); Gadler v. United States, 425 F. Supp. 244, 246 (D. Minn. 1977); Hanson v. United States, 417 F. Supp. 30, 33 (D. Minn.), *aff'd*, 540 F.2d 947 (8th Cir. 1976).

58. Rutherford v. United States, 438 F. Supp. 1287, 1290 (W.D. Okla. 1977); Gadler v. United States, 425 F. Supp. 244, 246 (D. Minn. 1977).

59. Rutherford v. United States, 438 F. Supp. 1287, 1299 (W.D. Okla. 1977); Gadler v. United States, 425 F. Supp. 244, 246 (D. Minn. 1977); People v. Privitera, 74 Cal. App. 3d 936, —, 141 Cal. Rptr. 764, 766 (1978).

60. 399 F. Supp. 1208 (W.D. Okla. 1975), *aff'd*, 542 F.2d 1137 (10th Cir. 1976).

61. 424 F. Supp. 105, 107 (W.D. Okla. 1977).

62. 582 F.2d 1234, 1237 (10th Cir. 1978). The FDA petitioned for certiorari and the Supreme Court has decided to hear the case. 47 U.S.L.W. 3492 (1979) (No. 78-605).

63. *See* Rizzo v. United States, 432 F. Supp. 356, 360 (E.D.N.Y. 1977); People v. Privitera, 74 Cal. App. 3d 936, —, 141 Cal. Rptr. 764, 784 (1978); Carnohan v. United States, No. 77-0010-GT, slip op. at 4 (S.D. Cal., Jan. 21, 1977); Suenram v. Society of Valley Hosp., 155 N.J. Super. 593, 603, 383 A.2d 143, 148 (1977).

64. 417 F. Supp. 30 (D. Minn.), *aff'd*, 540 F.2d 947 (8th Cir. 1976).

65. *Id.* at 32.

laetrile is not a drug and, therefore, does not come within section 505 of the FD&C Act, which prohibits interstate transportation of drugs not proven safe and effective.[66] However, "drug" as defined in the FD&C Act includes "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man . . . ."[67] The *Hanson* court reasoned that since laetrile was being promoted and used as a treatment for cancer it came within the FD&C Act definition of drug.[68]

A year later, in *Gadler v. United States*,[69] another Minnesota court heard the case of a cancer patient who sought a preliminary injunction to prevent interference with his importation of laetrile for personal use.[70] Unlike *Hanson, Gadler* involved an individual rather than a business entity, but this did not change the end result; the request for an injunction in *Gadler* was also denied.[71] The arguments advanced in *Gadler* were that laetrile is not a new drug, and if it were, the prohibition of its transportation in interstate commerce is an unconstitutional denial of due process of law and an invasion of the right of privacy.[72] In *Gadler*, the court addressed the question of whether the plaintiff demonstrated a substantial probability that he would succeed at trial.[73] The court found that Gadler failed to substantiate his claim that laetrile is not a new drug and, therefore, not within the purview of the new drug regulations.[74] Gadler had argued that the scheme involved in gaining approval for a new drug application might involve costs so substantial that he could not comply with the statutory requirements.[75] However, that scheme had already been found by the United States Supreme Court to be a valid exercise of Congress' power to set standards in order to protect the public from unsafe drugs.[76] Consequently, the *Gadler* court ruled that the statutory scheme requiring FDA approval for laetrile did not deny the plaintiff life, liberty, or property

66. *Id.* at 34.
67. 21 U.S.C. § 321(g)(1)(B) (1976).
68. 417 F. Supp. at 34. "Countless court decisions emphasize that it is the intended use of an article which determines whether or not it is a 'drug' and that even the most commonly injected foods and liquids are 'drugs' . . . if the intended use . . . falls within the definition of section 321(g)(1)." *Id.*; *accord* Rutherford v. United States, 438 F. Supp. 1287, 1292 & n.8 (W.D. Okla. 1977) (laetrile's well-recognized use in the treatment of cancer renders it a drug within the statutory definition).
69. 425 F. Supp. 244 (D. Minn. 1977).
70. *Id.* at 245. Contrary to some other cases, there was no testimony here that the plaintiff's condition was terminal or that he was not responding to conventional cancer therapy. His physician began chemotherapy treatments, but Gadler discontinued the treatments and sought laetrile treatment in Mexico. *Id.* at 245-46.
71. *Id.* at 249.
72. *Id.* at 246.
73. *Id.*
74. *Id.* at 247.
75. *Id.* at 248.
76. *Id. See* Weinberger v. Hynson, Wescott & Dunning, Inc., 412 U.S. 609, 620-21 (1973).

without due process of law.[77] The court in *Gadler* also rejected the plaintiff's claim that the constitutional right of privacy protected his importation of laetrile solely for personal use.[78] Noting the distinction between the right to import laetrile and the right to possess laetrile,[79] the court stated that the right of privacy does not protect the importation of items whose introduction into interstate commerce is proscribed by law.[80] Therefore, since laetrile is banned from interstate commerce, the right of privacy would not legitimate its interstate shipment.

Even before the Minnesota cases were decided, the court in *Rutherford v. United States*[81] had made the first of several rulings in favor of laetrile proponents.[82] *Rutherford* involved a class action suit brought to enjoin the FDA from interfering with the interstate transportation of laetrile by cancer patients.[83] In granting injunctive relief to the plaintiffs, the court found that the FDA wrongfully denied them the right to choose laetrile as a medical treatment.[84] Also, because the plaintiffs were without the means to comply with the statutory provisions required to legally transport laetrile, the court reasoned that they were denied due process of law.[85] Not surprisingly, the FDA appealed the ruling.[86] On appeal, the Tenth Circuit Court of Appeals did not consider the constitutional issues.[87] Instead, it based the decision on the definition of a "new drug." A new drug is one which is not recognized as safe and effective by qualified experts.[88] However, there is a twofold

77. 425 F. Supp. at 248.

78. *Id.* at 249.

79. *Id.* The distinction here was an analogy to Stanley v. Georgia, 394 U.S. 557 (1969) and Thirty-Seven Photographs, 402 U.S. 363 (1971). *Stanley* held it was unconstitutional to make the mere possession of obscene material a crime. 394 U.S. at 568. However, the Court in *Thirty-Seven Photographs* stated that even though *Stanley* did not prohibit possession of obscenity in one's home, it did not entitle a person to import obscene materials from abroad in defiance of federal regulations aimed at excluding such material from commerce. 402 U.S. at 376.

80. 425 F. Supp. at 249. Several other individual plaintiffs have had motions for a temporary restraining order against the FDA denied. *See, e.g.*, Zavasky v. United States, Civil No. 6-72333 (E.D. Mich. Nov. 16, 1976); Showalter v. United States, Civil No. C76-66A (N.D. Ohio Mar. 8, 1976); Salzman v. United States, Civil No. 75-2150 (S.D. Tex. Jan. 9, 1976); Keyes v. United States, Civil No. C76-630 (W.D. Wash. Sept. 29, 1976). In denying a preliminary injunction to restrain the FDA from interfering with interstate shipment of laetrile, the court in Morgan v. Mathews, No. 76-1637 (D.S.C. Nov. 30, 1976), noted that permitting the distribution of laetrile "would circumvent the laws enacted to assure that drugs be both safe and effective for their intended use and would undermine effective enforcement of those laws in the future." *Id.*; FOOD DRUG COS. L. REP. (CCH), All States, ¶ 38,093.

81. 399 F. Supp. 1208 (W.D. Okla. 1975), *aff'd*, 542 F.2d 1137 (10th Cir. 1976).

82. *See id.* at 1212.

83. *Id.* at 1210.

84. *Id.* at 1212.

85. *Id.* at 1213. *Contra*, Gadler v. United States, 425 F. Supp. 244, 248 (D. Minn. 1977). See text & notes 75-77 *supra*.

86. 542 F.2d 1137 (10th Cir. 1976).

87. *See id.* at 1144.

88. 21 U.S.C. § 321(p)(1) (1976). A new drug is "[a]ny 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 . . . in the labeling thereof . . . ." *Id.*

grandfather clause that may exempt a drug from the new drug regulations.[89] These grandfather exemptions came from the transitional provisions attached to the 1962 Amendments to the FD&C Act and the provisions of the 1938 Act which superseded the original Food and Drug Act of 1906.[90] In an attempt to determine whether laetrile fell within either of the grandfather clause exceptions to the "new drug" status, the Tenth Circuit Court of Appeals in *Rutherford* found that the FDA failed to provide adequate administrative records supporting its conclusion that laetrile is a new drug.[91] Therefore, the case was remanded to determine the following questions material to deciding the applicability of the grandfather exceptions: (1) whether laetrile was marketed before 1962 for the same uses for which it was sold after 1962 and whether it was generally recognized by qualified experts as safe for those uses; and (2) whether it had been subject to the Act of 1906 prior to the 1938 Amendments[92] and whether its labeling at that time contained the same representations concerning the conditions of its use.[93] If either of these sets of questions could be answered affirmatively, laetrile would not be a new drug and would not be subject to the new drug regulations. On remand,[94] the court ordered the FDA to conduct a hearing for the purpose of creating a complete administrative record to support its determination that laetrile is a "new drug."[95] Pending final determination, the plaintiffs were permitted to receive interstate shipments of laetrile for their own personal use.[96]

In compliance with the court order, the FDA conducted an administrative hearing that resulted in the compilation of a comprehensive record on laetrile.[97] The outcome of the hearing was predictable; the offical position of the FDA concerning laetrile remained unchanged. The FDA concluded that laetrile is not generally recognized by qualified experts as a safe and effective drug for the treatment of cancer, and that it is not exempt from the premarket approval requirements for new drugs.[98]

89. Rutherford v. United States, 542 F.2d 1137, 1141 (10th Cir. 1976). A drug not recognized by experts as safe and effective "shall not be deemed to be a 'new drug' if at any time prior to enactment of this chapter it was subject to the Food and Drugs Act of June, 30, 1906, as amended, and if at such times its labeling contained the same representation concerning the conditions of its use . . . ." 21 U.S.C. § 321(p)(1) (1976).

90. Rutherford v. United States, 542 F.2d 1137, 1144 (10th Cir. 1976).

91. *Id.* at 1143.

92. Prior to the 1938 amendments, proof of safety was not even a requirement. *See* text & notes 32-37 *supra*.

93. 542 F.2d at 1142.

94. 424 F. Supp. 105 (W.D. Okla. 1977).

95. *Id.* at 107. *See* 42 Fed. Reg. 10,066, 10,067 (1977).

96. 424 F. Supp. at 107.

97. *See* 42 Fed. Reg. 39,767, 39,767-806 (1977).

98. *Id.* at 39,806. The FDA concluded further: (1) animal studies conducted to date show that laetrile has no anticancer effect in laboratory animals; (2) the history and promotion of lae-

In response, the plaintiffs in *Rutherford* sought and obtained judicial review of the FDA determination.[99] In direct opposition to the conclusion of the FDA, the court decided that laetrile falls within one of the exceptions to the definition of a new drug because it was marketed for the same uses before the 1962 amendment and was generally recognized by qualified experts as safe for those uses at that time.[100] Accordingly, the court reasoned that laetrile is not subject to the new drug regulations and declared the FDA classification of laetrile as a "new drug" arbitrary, capricious, and an abuse of discretion.[101] In addition, this latest *Rutherford* decision held that the FDA action violated the right to personal privacy in denying cancer patients the freedom to choose an unorthodox medical treatment.[102] Although the court did not discuss this issue at length, the thrust of the argument was that the freedom to care for one's health comes within the purview of the right of privacy.[103] Since the right of privacy gives a patient the right to refuse cancer treatment, the court reasoned that a patient has the right to use whatever nontoxic treatments he or she chooses.[104] The interests of the FDA in protecting the public health by prohibiting the use of laetrile were not considered compelling enough to overcome the privacy right.[105]

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trile are characteristic of other unproven cancer remedies because laetrile's popular acceptance by laymen is based on fear of orthodox medical treatment and a false hope that suffering can be avoided by use of laetrile; and (3) laetrile is not in general use as cancer therapy anywhere in the world. *Id.*

99. Rutherford v. United States, 438 F. Supp. 1287, 1289 (W.D. Okla. 1977).

100. *Id.* at 1295. Referring to the record compiled by the FDA and testimony from laetrile proponents at trial, the court concluded that laetrile has been sold and used in the United States for treatment of cancer for over 25 years and during that time was generally recognized as safe. *Id.* at 1298 & n.24. Looking at the same record, the FDA, on the other hand, relied on the testimony of numerous experts and the lack of adequate data with respect to laetrile's safety to conclude laetrile is not generally recognized as safe. 42 Fed. Reg. 39,767, 39,786-90 (1977). In addition to the lack of scientific data concerning laetrile's safety, several experts were of the same opinion as Dr. George J. Hill who testified: "In the absence of scientific evidence of effectiveness, no drug intended for use in treating cancer can be regarded as safe." *Id.* at 39,787. In making its determination, the FDA followed the direction of the court in United States v. An Article of Drug, 469 F.2d 875 (5th Cir. 1972), *cert. denied*, 412 U.S. 938 (1973), which said that a party seeking to show that a drug comes within the grandfather exemptions "must prove every essential fact necessary for invocation of the exemption." *Id.* at 878.

101. 438 F. Supp. at 1295. However, noting the substantial controversy concerning the efficacy of laetrile, the reviewing court found that the FDA was not arbitrary in concluding that laetrile is not generally recognized as safe and effective. *Id.* at 1293. The determination in *Rutherford* that laetrile is not a new drug will hardly put an end to the controversy. Granted, there was some support for the finding that laetrile was in use before 1962 and that it was recognized as safe. However, the conclusion that it was *generally* recognized as safe is debatable in light of the large amount of testimony to the contrary. *See* 42 Fed. Reg. 39,767, 39,786 (1977).

102. 438 F. Supp. at 1299.

103. *Id.* In making this finding, the court relied on the statement by Justice Douglas in Doe v. Bolton, 410 U.S. 179, 213 (1973), that "the freedom to care for one's health and person" comes within the purview of the right to privacy. 438 F. Supp. at 1299.

104. 438 F. Supp. at 1300. By limiting the right of privacy to include choice of nontoxic treatments, the court is again hinging this part of the decision on a finding that laetrile is recognized by experts as safe. That finding is subject to considerable dispute. See discussion notes 89, 90 *supra*.

105. 438 F. Supp. at 1300.

When this decision was appealed, the court again found for the laetrile supporters.[106] However, the holding was limited to a finding that "the 'safety' and 'effectiveness' requirements of the FD&C Act . . . have no application to terminally ill cancer patients who desire to take the drug intravenously."[107] The court reasoned that the terms "safe" and "effective" have no meaning in the context of terminally ill cancer patients, and that the FDA erred in applying its regulations under the circumstances of this case.[108] The right to privacy argument was not addressed in this decision.

Relying on the various decisions of the *Rutherford* case, other courts have granted relief to cancer patients on a limited basis. For example, in *Carnohan v. United States*,[109] a terminal cancer patient, unresponsive to orthodox cancer treatment, was granted injunctive relief and allowed to import laetrile for his personal use.[110] The court recognized, however, that granting a broad injunction could undermine the laws that were adopted to protect people from being victimized by the marketers of unproven and worthless remedies,[111] and that it might further the growing tendency of cancer patients to engage in self-treatment, causing them to delay or forego more conventional forms of treatment.[112]

Another case relied solely on the right of privacy to rule in favor of laetrile proponents. Adopting the freedom of choice argument from *Rutherford*, the court in *People v. Privitera*[113] declared that a California health code prohibiting the administration, prescription, or sale of laetrile unconstitutionally invaded the patient's and the physician's right of privacy.[114] The right of a patient to choose his or her own medical treatment, and the right of a physician to prescribe that treatment, were declared to be of such a fundamental nature that the exercise of that

106. *See* 582 F.2d at 1237.
107. *Id.*
108. *Id.*
109. No. 77-0010-GT (S.D. Cal. Jan. 21, 1977).
110. *Id.*, slip op. at 3.
111. The court in *Carnohan* referred to the decision in Morgan v. Mathews, Civil No. 76-6137 (D.S.C. Nov. 30, 1976), where the requested injunction was denied. See discussion at note 80 *supra*.
112. No. 77-0010-GT, slip op. at 3 (S.D. Cal. Jan. 21, 1977).
113. 74 Cal. App. 3d 936, 141 Cal. Rptr. 764 (1977). *See also* Rizzo v. United States, 432 F. Supp. 356, 360 (E.D.N.Y. 1977) (terminal cancer patient unresponsive to orthodox medical treatment allowed to import laetrile for his personal use); Suenram v. Society of Valley Hosp., 155 N.J. Super. 593, 603, 383 A.2d 143, 148 (1977) (right to privacy was basis for enjoining a hospital from interfering with the administration of laetrile to a terminal cancer patient).
114. 74 Cal. App. 3d at —, 141 Cal. Rptr. at 770-74. The California Health and Safety Code makes it a misdemeanor to "sell, deliver, prescribe or administer any drug or device to be used in the diagnosis, treatment, alleviation or cure of cancer which has not been approved by the designated federal agency or by the state board of health." *Id.* at —, 141 Cal. Rptr. at 765-66. The court did not find the law applied to licensed physicians and their patients. *Id.* at —, 141 Cal. Rptr. at 784.

right could only be impinged upon by a compelling interest.[115] The *Privitera* court recognized that the state had a compelling interest in regulating drugs that are narcotic, habit forming, or toxic, but it found the state's interest in regulating laetrile was substantially less compelling because, in the court's view, laetrile is generally considered harmless.[116] In a lengthy dissent, it was argued that the fundamental right to privacy does not encompass the right to import and distribute drugs that fail to meet established regulatory standards.[117] In criticizing the majority's reliance on the abortion cases, *Roe v. Wade*[118] and *Doe v. Bolton*,[119] the dissent distinguished between the right of choice to have an abortion, which is a medically approved procedure, and the right of choice to use a drug—in this case laetrile—which is not a medically approved treatment.[120] Furthermore, the dissenting justice contended that even if there is such a right, the state's interest in controlling the distribution of ineffective drugs is sufficiently compelling to warrant the ban on laetrile.[121]

It is obvious from the above cases that, as yet, the courts have not settled the battle between the FDA and the laetrile forces.[122] Some arguments have been disposed of, however. The mere contention that laetrile is a vitamin or food supplement, rather than a drug, does not suffice to insulate laetrile from the federal drug regulations.[123] Nor is there a denial of due process of law merely because the high cost of complying with the new drug regulations precludes the ordinary individual from gaining FDA approval of laetrile.[124] Although the *Rutherford* court granted injunctive relief for terminally ill cancer patients within its jurisdiction, that decision exemplifies the difficulty in analyzing the testimony and scientific data that the FDA relied upon to support its position.[125]

Most persuasive is the right of privacy argument, and even that

115. *Id.* at —, 141 Cal. Rptr. at 777.
116. *Id.* at —, 141 Cal. Rptr. at 778. In analyzing the health regulation at issue in *Privitera*, the court found that the purpose of the legislature in adopting the law was to prohibit "false representation with intent to defraud of any device or substance or treatment as an effective cure for cancer." *Id.* at —, 141 Cal. Rptr. at 782. The court concluded that the limitation on the right to prescribe or use laetrile did not bear a logical relationship to the legislative purpose. *Id.*
117. *Id.* at —, 141 Cal. Rptr. at 786 (Cologne, J., dissenting).
118. 410 U.S. 113 (1973).
119. 410 U.S. 179 (1973).
120. 74 Cal. App. 3d at —, 141 Cal. Rptr. at 789.
121. *Id.* at —, 74 Cal. Rptr. at 786.
122. The issue may be settled soon, however, since the Supreme Court has decided to hear the *Rutherford* case. 47 U.S.L.W. 3492 (1979) (No. 78-605).
123. *See* text & notes 65-68 *supra*.
124. *See* text & notes 75-77, 85 *supra*.
125. *Compare* Rutherford v. United States, 438 F. Supp. 1287, 1295 (W.D. Okla. 1977) (finding laetrile generally recognized by qualified experts as safe for treating cancer) *with* 42 Fed. Reg. 39,767, 39,786 (1977) (the FDA concluded that in the absence of scientifically sound information from which scientists can make a determination, laetrile cannot be generally recognized as safe).

point is countered with strong disagreement.[126] If the right to choose an unorthodox medical treatment is within the purview of the constitutionally protected right of privacy, then neither the FDA nor individual states could prohibit the use of such treatment absent a compelling interest.[127] Consequently, it is argued that the interest in protecting the public from purveyors of useless remedies and false hopes is sufficiently compelling.[128]

The disparate views expressed in the foregoing cases emphasize the need for definitive action to be taken on the laetrile controversy. Perhaps it was in response to this confusion that several states decided to legalize the use of laetrile.[129] These states have attempted to design legislation giving their citizens access to laetrile without affecting interstate commerce, thereby avoiding confrontation with the federal government.[130] To determine whether the attempt will prove successful requires an analysis of the legislative powers granted to the states and

126. The dissenting justice in *Privitera* argued that the state's interest in preventing distribution of ineffective drugs, such as laetrile, is a proper exercise of the police power and overrides the individual's choice of unorthodox cancer therapy. 74 Cal. App. 3d at —, 141 Cal. Rptr. at 786. Furthermore, the choice of medical treatment has not been enumerated by the Supreme Court as an activity protected by the fundamental right to privacy. *Id.* at —, 141 Cal. Rptr. at 790. For example, Roe v. Wade, 410 U.S. 113, 116 (1973), dealt with the right to terminate pregnancy; Griswold v. Connecticut, 381 U.S. 479, 485 (1965), dealt with the right of married couples to use contraceptives. *But see* Note, *Constitutional and Legislative Challenges to the Federal Pre-Market Proof of Drug Effectiveness Requirement*, 13 NEW ENG. L. REV. 279, 301 (1977) (arguing that the freedom to choose one's health-care treatment is within the right of privacy).

127. *See* Roe v. Wade, 410 U.S. 113, 154 (1973); People v. Privitera, 74 Cal. App. 3d 936, —, 141 Cal. Rptr. 769, 784 (1977). It is suggested that allowing interstate shipment of laetrile only by terminal cancer patients is a justified middle-ground position for courts to adopt. Comment, *Picking Your Poison: The Drug Efficacy Requirement and the Right of Privacy*, 25 U.C.L.A. L. REV. 577, 608-17 (1978). Another recommendation is to allow the use of safe but ineffective drugs as a supplement to orthodox treatment. *See* Note, *supra* note 126, at 301.

128. *See* 42 Fed. Reg. 39,767, 39,803-06 (1977). The FDA argued that with the passage of the 1962 Amendments "Congress indicated its conclusions that the absolute freedom to choose an ineffective drug was properly surrendered in exchange for the freedom from the danger to each person's health and well-being from the sale and use of worthless drugs." *Id.* at 39,803.

A very similar but less publicized and less controversial situation occurred some years ago with another purported cancer drug, krebiozen. In Rutherford v. American Medical Ass'n, 379 F.2d 641 (7th Cir. 1967), *cert. denied*, 389 U.S. 1043 (1968), an injunction was sought against the AMA, the American Cancer Society, the FDA, and various individuals, requiring them to cease interfering with the national distribution of an alleged cancer drug called krebiozen. *Id.* at 642. Krebiozen was a "new drug," and its distributors had not complied with the procedures set forth by FDA regulations for approval of a new drug. *Id.* at 643. No application with respect to krebiozen was pending before the FDA, and the plaintiffs failed to show that they had in good faith attempted to comply with the procedures required for introduction of the drug into interstate commerce. *Id.* Thus, the petition for an injunction was denied. *Id.* at 645. *See also* Durovic v. Richardson, 479 F.2d 242, 251 (7th Cir. 1973) (krebiozen not generally recognized among qualified experts as safe); Tutoki v. Celebrezze, 375 F.2d 105, 107 (7th Cir. 1967) (the court found that krebiozen had not been approved or exempted by the FDA, noting that the FDA, not the court, was the proper agency to approve new drug applications).

129. *See* text & note 8 *supra*.

130. By regulating use of laetrile solely within their borders, states could conceivably avoid a connection with interstate commerce and thus avoid interference by the federal government. *See* Op. No. 77-66, 1976-77 OP. ARIZ. ATT'Y GEN. 159 (laetrile "produced entirely from ingredients obtained within Arizona and distributed for use solely therein would not fall within the purview of the federal statute."); text & notes 193-210 *infra*.

the federal government and a consideration of the competing interests of the two governmental powers.[131]

DRUG REGULATION: STATE POLICE POWER OR COMMERCE POWER

The police power is one of the powers reserved to the states under the tenth amendment.[132] It is the power vested in the states to protect and promote the health, safety, and general welfare of the states' citizenry.[133] Because it addresses the health needs of the people, the laetrile legislation enacted by several states, which regulates intrastate manufacture and distribution of laetrile, represents an exercise of the police power.[134] However, this exercise of the police power also represents application of much less stringent drug regulations than would be required by the FD&C Act. Federal law requires that drugs be proven effective for their intended use.[135] Nevertheless, several states have enacted laetrile legislation to permit distribution of a substance whose effectiveness against cancer has not been established.[136] A brief look at Arizona's laetrile law partially explains some of the reasons for lenient regulation of laetrile and also suggests problems that could arise in the area of drug regulation because of it.

Arizona Laetrile Legislation

Prior to the passage of Arizona House Bill 2059 in May 1977, Arizona prohibited the manufacture or sale of any new drug unless it com-

131. For purposes of this discussion, it will be assumed that the right to privacy does not extend to the right to choose laetrile as a treatment for cancer. *But see* Note, *supra* note 126, at 301. *See generally* Comment, *Government Regulation of Health-Care Drugs of Questionable Efficacy*, 14 SAN DIEGO L. REV. 378, 390-99 (1977).

132. U.S. CONST. amend. X: "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." The delegated powers of the federal government are actually few in number, *see* U.S. CONST. arts. I-III, leaving the states with a wide range of residual powers. Thus, state police powers have been exercised to determine maturity of avocados that could be sold in the state's markets, Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 133-34 (1963); to require raisin producers to deliver a substantial portion of their crop to a marketing control board, Parker v. Brown, 317 U.S. 341, 346 (1942); to require the disclosure of ingredients in animal feeds, Savage v. Jones, 225 U.S. 501, 522 (1912); and to regulate the navigation of local harbors, Cooley v. Board of Wardens, 53 U.S. (12 How.) 299, 311 (1851).

133. *See* Lochner v. New York, 198 U.S. 45, 54 (1905). A state has unlimited jurisdiction over persons within its boundaries, subject only to restraint by the United States Constitution. Mayor of New York v. Miln, 36 U.S. (11 Pet.) 102, 138 (1837). Therefore, it is the duty of a state to enact whatever legislation is necessary to advance the safety, happiness, and prosperity of its people. *Id.* Legislation concerning the protection of the public health falls within the traditional concept of the police power. Head v. New Mexico Bd. of Examiners, 374 U.S. 424, 428 (1963). It was within the police power to establish and enforce standards of conduct for persons in the medical profession, Barsky v. Board of Regents, 347 U.S. 442, 449 (1953), and to enact a compulsory vaccination law to protect the public health, Jacobson v. Massachusetts, 197 U.S. 11, 25 (1904).

134. *See, e.g.*, ch. 103, 1978 Ariz. Sess. Laws 282 ("An act relating to the public health and safety").

135. *See* text accompanying notes 40-44 *supra*.

136. *See* text & notes 13-16 *supra*.

plied with the provisions of the federal Food, Drug, and Cosmetic Act.[137] Under the old law, Arizona had adopted the federal standards of drug regulation and broadened their effect.[138] Thus, under prior Arizona law, failure to comply with the federal law requiring proof of the effectiveness of laetrile not only prohibited its shipment in interstate commerce but also prohibited its manufacture and sale within the state of Arizona.[139] However, the laetrile bill provided specifically that laetrile would be an exception to that law.[140] This proved to be unsatisfactory. Due to the difficulties Arizona encountered in trying to develop standards for the manufacture and sale of laetrile[141] and the consequent delays in getting laetrile on the market, in 1978 the Arizona legislature repealed the regulations governing the production and sale of laetrile as a drug and passed legislation defining laetrile as a nutritional supplement available for sale without a prescription and without extensive regulation.[142]

The reasons behind the favored status awarded to laetrile are many. State representatives have been pressured for years by both their constituents and laetrile proponents to act on the issue.[143] In addition, despite warnings by the FDA that laetrile is not a proven cancer remedy, people are still spending thousands of dollars for the illegal drug by traveling to Mexico or procuring it through the black market.[144] By regulating the manufacture and distribution of the drug in Arizona, the state could ensure that laetrile would be dispensed at a cheaper price and under regulations that ensure its quality, thereby af-

137. Before it was amended in 1977, ARIZ. REV. STAT. ANN. 32-1962 (1976) provided: "No person shall manufacture, sell, offer or hold for sale or give away any new drug or device unless it fully complies with the provisions of the federal act."

138. The federal drug laws apply to activity which has a connection with interstate commerce. *See* 21 U.S.C. § 331 (1976). By requiring compliance with the federal act, Arizona applied federal standards to activity that was completely intrastate and otherwise not within the purview of federal standards.

139. ARIZ. REV. STAT. ANN. § 32-1962 (1976).

140. The laetrile bill amended ARIZ. REV. STAT. ANN. § 32-1962 (1976) by adding: "this section shall not apply to amygdalin, a cyano-genetic glycoside, also known as laetrile, which is processed from the seeds of certain fruits . . . ." Ch. 65, § 1, 1977 Ariz. Sess. Laws 208 (codified at ARIZ. REV. STAT. ANN. § 32-1962 (Supp. 1977)). See text & note 8 *supra*.

141. *See* Ariz. Daily Star, Apr. 19, 1978, § A, at 1, col. 1; Ariz. Daily Star, May 9, 1978, § A, at 4, col. 1. Some of the delay was a result of lack of information on the substance. At that time no other state had drawn up standards for laetrile so Arizona had no other law to refer to for guidance. Ariz. Daily Star, Jan. 17, 1978, § A, at 2, col. 1. An uncooperative federal government and unwillingness by the State Board of Regents in allowing the University of Arizona College of Pharmacology to help with the study also contributed to the delay. *Id.*

142. Ch. 103, § 6, 1978 Ariz. Sess. Laws 284 (codified at ARIZ. REV. STAT. ANN. § 36-2451 (Supp. 1978-79)). *See* Ariz. Daily Star, May 9, 1978, § A, at 4, col. 1; text & note 8 *supra*. Arizona has not solved the problem of possible federal involvement by defining laetrile as a nutritional supplement because the purpose for which it is intended to be used is the controlling factor in determining whether it may be regulated as a drug. See text & notes 67, 68 *supra*.

143. *See* Ariz. Republic, Feb. 28, 1977, § B, at 1, col. 4.

144. *See* text & note 56 *supra*.

fording protection and benefit to the general health and welfare of the state's citizens.

Although the laetrile legislation is a valid exercise of a state's police power, it may interfere with Congress' regulation of drugs in interstate commerce. This raises doubts as to the validity of the laetrile law because where state legislation impedes the effective implementation of federal laws, the supremacy clause dictates that the state law must yield.[145] Therefore, an examination of how the exercise of the police power has been interpreted in conjunction with Congress' power under the commerce clause is necessary to determine the effect that laetrile laws will have on the implementation, by the FDA, of the FD&C Act, and whether that effect will be sufficient reason to invalidate the state laetrile legislation.

The Role of the Commerce Clause in Limiting the Exercise of the Police Power

One of the most significant congressional powers is found in the commerce clause, which grants Congress the power to regulate commerce among the states.[146] Under the theory that the commerce power has no limitations other than those prescribed by the Constitution,[147] Congress has exercised this power to regulate various state activities that affect interstate commerce.[148] In addition, although Congress has not adopted any formal regulations concerning a specific subject matter, the commerce clause gives Congress authority to keep interstate commerce free from any unreasonable burden or interference by individuals or states.[149]

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145. U.S. CONST. art. 6, § 2; Gibbons v. Ogden, 22 U.S. (9 Wheat.) 1, 210-11 (1824).

146. U.S. CONST. art. 1, § 8, cl. 3: "The Congress shall have power . . . to regulate commerce with foreign nations, and among the several states, and with the Indian tribes." The commerce clause may limit state police power because of the supremacy clause which declares the laws of the United States to be the supreme law of the land. U.S. CONST. art. 6, § 2; Gibbons v. Ogden, 22 U.S. (9 Wheat.) 1, 210-11 (1824). *See* L. TRIBE, AMERICAN CONSTITUTIONAL LAW § 5-4, at 232 (1978).

147. *See* Gibbons v. Ogden, 22 U.S. (9 Wheat.) 1, 196 (1824). Examples of the constitutional limitations are the Bill of Rights and the restraints imposed by the federal governmental structure which provides for a system of checks and balances among the branches of the federal government. *See* L. TRIBE, *supra* note 146, § 5-7, at 240.

148. *See, e.g.*, Fry v. United States, 421 U.S. 542, 545-46 (1975) (Congress could regulate salary increases of state and local government employees); Wickard v. Filburn, 317 U.S. 111, 127-28 (1942) (Congress could regulate the production of home-consumed wheat, a local activity with a minimal effect upon interstate commerce); United States v. Darby, 312 U.S. 100, 121 (1941) (Congress could exclude from interstate commerce products manufactured by business that did not comply with federal labor standards). The *Darby* Court reasoned that states could impose health and sanitary safeguards on milk coming from outside the state, but a state unduly burdens interstate commerce when it regulates prices to be paid to out-of-state producers under the theory that higher prices will promote adherence to sanitation regulations. *Id.* at 24. Since this law unduly burdened commerce, it was held invalid. *Id.*

149. *See* Southern Pacific Co. v. Arizona, 325 U.S. 761, 773 (1945). To reduce the number of train accidents, Arizona passed a law limiting the lengths of trains operating in the state. *Id.* at 763. Evidence showed that the law had no reasonable relation to safety, *id.* at 775, and had no

The Supreme Court has frequently analyzed Congress' power under the commerce clause. One line of cases interpreting the commerce power addresses challenges to state laws that allegedly constitute an interference with interstate commerce. For example, in the well-known case of *Cooley v. Board of Wardens*,[150] the Supreme Court established the principle that the grant of the commerce power to Congress does not necessarily prohibit states from exercising some control over interstate commerce where a problem is particularly local in nature and of the type not requiring exclusive regulation by Congress.[151] However, state laws may not create economic barriers against the introduction into the state of products from another state in an effort to protect local concerns,[152] nor may they impose a substantial burden on interstate commerce or impede its free flow.[153] On the other hand, if a

effect on reducing accidents. *Id.* at 776. Therefore, in balancing Arizona's concern for safety and the interest of the nation in efficient and adequate train service, the Court held the law imposed a serious burden on interstate commerce and that it interfered with the free flow of train traffic passing through the state. *Id.* at 773.

150. 53 U.S. (12 How.) 299 (1851).

151. *Id.* at 319-20. In *Cooley* a state law that required vessels entering or leaving Philadelphia to have a local pilot for navigating the Delaware River was declared a valid exercise of state police power despite a contention that the law interfered with interstate commerce. *Id.* at 321. The Court found that states were not necessarily prohibited from exercising some control of interstate commerce in an effort to regulate a problem particularly local in nature. *Id.* Navigating harbors called for local knowledge and experience and was, therefore, a legitimate subject of local regulation. *See* Great Atlantic & Pacific Tea Co. v. Cottrell, 424 U.S. 366, 371 (1975) (an exercise of state police power is not necessarily invalid if it has an effect on interstate commerce); Huron Portland Cement Co. v. City of Detroit, 362 U.S. 440, 448 (1960) (a state law designed to improve the health and welfare of the community is valid if it does not discriminate against interstate commerce or operate to disrupt its uniformity); Southern Pacific Co. v. Arizona, 325 U.S. 761, 767 (1945) (regulation of local matters that do not affect national commerce or interfere with its operation are within the state police power).

A local problem was also at issue in Parker v. Brown, 317 U.S. 341 (1943), where the Court upheld a California statute regulating the raisin market. *Id.* at 368. "This Court has repeatedly held that the grant of power to Congress by the Commerce Clause did not wholly withdraw from the states the authority to regulate commerce with respect to matters of local concern, on which Congress has not spoken." *Id.* at 360. *See also* Bibb v. Navajo Freight Lines, 359 U.S. 520 (1959). In *Bibb*, the Court recognized the power of the state to regulate highway safety as peculiarly local in nature. The regulation prescribing certain mudguards be used by trucks was applicable alike to interstate and intrastate commerce, *id.* at 522, and did not interfere with the policy of free trade. *Id.* at 529. *But see* Southern Pacific Co. v. Arizona, 325 U.S. 761, 783 (1945) where concern for local safety did not justify a state law limiting the length of trains entering the state. These two cases are distinguishable in that states do not have the same responsibility for building and maintaining railroads and regulating their safety as they do for highways. *Id.*

152. Baldwin v. G.A.F. Seelig, Inc., 294 U.S. 511, 527 (1935). The state law at issue in *Baldwin* set up a system of minimum prices to be paid by dealers to milk producers and prohibited the sale of milk bought from out-of-state producers at a price lower than the established minimum. *Id.* at 519. The law was found to suppress competition and to constitute an impermissible barrier to traffic between states. *Id.* at 521-22. "What is ultimate is the principle that one state in its dealings with another may not place itself in a position of economic isolation." *Id. Accord*, Great Atlantic & Pacific Tea Co. v. Cottrell, 424 U.S. 366, 379 (1976); Polar Ice Cream & Creamery Co. v. Andrews, 375 U.S. 361, 377 (1964); Dean Milk Co. v. Madison, 340 U.S. 349, 354 (1951). *But see* Parker v. Brown, 317 U.S. 341, 368 (1943) (upholding a state law aimed at the economic protection of those engaged in California's raisin industry).

153. *See* Huron Portland Cement Co. v. City of Detroit, 362 U.S. 440, 444 (1960); Bibb v. Navajo Freight Lines, Inc., 359 U.S. 520, 529-30 (1959); Southern Pacific Co. v. Arizona, 325 U.S. 761, 767 (1945).

state legislates for valid health reasons, a law interfering with commerce by prohibiting products deemed unhealthy or unsanitary may be valid.[154]

In *Savage v. Jones*,[155] an Indiana consumer protection statute was challenged because it affected not only intrastate producers but also those who transported products into Indiana from outside the state.[156] The Court upheld the statute, however, stating that although a state cannot regulate interstate commerce or impose a direct burden upon commerce under the justification of exerting its police power,[157] a regulation enacted for the protection of the people of the state, which is not unreasonable in its requirements, is not necessarily invalid.[158] Thus, even though the regulation may have an effect upon interstate commerce, it is valid if it is rationally related to a legitimate state objective[159] and does not conflict with federal law.[160] Under these principles, although the laetrile laws do not address a problem that is unique to a particular locality, they could be deemed valid despite a slight interference with interstate commerce if the states have a legitimate objective in enacting them and if the laws do not conflict with the federal drug regulations. These issues will be considered in more detail below.

The above discussion considered the extent to which a state, in the exercise of its police powers, may interfere with interstate commerce. Conversely, there are also cases interpreting congressional power under the commerce clause that address the question of the extent to which Congress, in the exercise of its commerce power, may impinge on state regulation of local activities. In *McCulloch v. Maryland*,[161] the United States Supreme Court adopted an expansive view of Congress' commerce power and indicated that Congress could use all means "necessary and proper" to carry out its constitutional duties.[162] Subsequently,

154. Mintz v. Baldwin, 289 U.S. 346, 349 (1933). The law in this case required that all cattle shipped into the state be certified free from disease. *Id.*

155. 225 U.S. 501 (1911).

156. *Id.* at 521. The law required the manufacturer of animal feed to disclose the ingredients on a label. *Id.*

157. *Id.* at 524.

158. *Id.* at 525.

159. Legitimate objectives could be public health, Mintz v. Baldwin, 289 U.S. 346, 350 (1933), consumer protection, Savage v. Jones, 225 U.S. 501, 524 (1912), or peculiarly local problems, Cooley v. Board of Wardens, 53 U.S. (12 How.) 299, 314 (1851). *See* Nygh, *The Police Power of the States in the United States and Australia*, 2 FED. L.R. 183 (1966). "The traditional police power concept still exists, for the Court still maintains a theoretically clear category of what are legitimate State objectives. Health, safety and local economic order may suffice . . . [but] local protectionism is outlawed." *Id.* at 199.

160. 225 U.S. at 524-25. In *Savage*, the Court also determined that the state law was not in conflict with the federal food and drug laws even though the statute required disclosure of information which was not required by federal law. *Id.* at 532.

161. 17 U.S. (4 Wheat.) 316 (1819).

162. *Id.* at 411. "Let the end be legitimate, let it be within the scope of the constitution, and all means which are appropriate, which are plainly adapted to that end, which are not prohibited, but consist with the letter and spirit of the constitution, are constitutional." *Id.* at 421.

however, the Court also recognized that states, pursuant to the police power, have exclusive control over certain internal operations.[163] This concept of a strong police power was the basis upon which the Court later decided that Congress could not regulate child labor[164] and various aspects of agricultural[165] and coal[166] production merely because the products were intended to enter interstate commerce.[167]

Out of a fear of limitless federal power arose a distinction between direct and indirect effects of intrastate activities on commerce in *Schechter Poultry Corp. v. United States*.[168] The distinction was a term of art based on the idea that where there is no intent to burden or monopolize any part of interstate commerce and the state's objectives are limited to intrastate activities,[169] an indirect effect on interstate commerce remains within the realm of state power.[170]

Shortly after *Schecter*, however, the distinction between direct and indirect effects on commerce was downplayed, and federal regulatory actions aimed at improving a depressed economy by regulating local activities were upheld. In *NLRB v. Jones & Laughlin Steel Corp.*,[171] the Court upheld Congress' authority to protect interstate commerce

163. *See* Mayor of New York v. Miln, 36 U.S. (11 Pet.) 102, 138 (1837). The Court upheld a state statute imposing criminal fines upon ship masters for failure to make reports of passengers upon arrival in New York. *Id.* at 152. The regulation was considered not one of commerce, but one of internal state affairs aimed at protecting citizens from being oppressed as a result of the influx of poor immigrants. *Id.* at 141. The Court recognized the state's jurisdiction over things within its borders. "[T]hose powers which relate to merely . . . *internal police*, are not surrendered or restrained; and that . . . in relation to these, the authority of a state is complete, unqualified and exclusive." *Id.* at 138 (emphasis in original). *See also* License Cases, 46 U.S. (5 How.) 504, 574 (1847); text & notes 150-60 *supra*.

164. Hammer v. Dagenhart, 247 U.S. 251, 269 (1918). The Court held Congress could not regulate child labor by prohibiting the interstate transportation of products produced in factories that ignored federally prescribed child labor laws. *Id.*

165. United States v. Butler, 297 U.S. 1, 68 (1936). The Agricultural Adjustment Act was held to be invalid as an attempt by Congress to regulate agricultural production, a purely local activity. *Id.*

166. Carter v. Carter Coal Co., 298 U.S. 238, 310 (1936). The commerce clause did not give Congress the power to regulate wages, hours, and working conditions in the coal industry. *Id.* Such things are related to production and "[p]roduction is not commerce; but a step in preparation for commerce." *Id.* at 303.

167. *See id.* at 301.

168. 295 U.S. 495 (1935). In *Schechter*, a poultry business was indicted for not complying with federal regulations concerning slaughtering and selling poultry. *Id.* at 527-28. In denying application of the federal regulations to the local activity, the Court ruled that once the poultry shipped in interstate commerce had reached the slaughterhouse, the interstate commerce had ended, and subsequent transactions, if confined within the state, were solely intrastate commerce. *Id.* at 542-43. Supporting its conclusion to allow indirect effects on commerce, the Court indicated that

> if the commerce clause were construed to reach all enterprises and transactions that could be said to have an indirect effect upon interstate commerce, the federal authority would embrace practically all the activities of the people and the authority of the State over its domestic concerns would exist only by sufferance of the federal government.

Id. at 546.

169. *Id.* at 547.

170. *Id.* at 546.

171. 301 U.S. 1 (1937).

through the National Labor Relations Act—aimed at safeguarding employees' rights to reorganization and collective bargaining.[172] Although case law at that time supported a finding that the interstate commerce connection ended by reason of the steel manufacturing operations,[173] the Court reasoned that strikes by dissatisfied employees would halt steel production, resulting in an indirect but serious impact upon interstate commerce and the national economy.[174] Therefore, Congress could regulate what appeared to be a local activity.

Even before *Jones & Laughlin* was decided, Congress had successfully utilized the commerce clause as a vehicle to enact numerous social welfare programs—one of which was the original Pure Food and Drug Act[175]—that were challenged as infringements upon the states' sovereign power to legislate for the well-being of their citizens.[176] With its decision in *United States v. Darby*,[177] the Court returned completely to the *McCulloch* view of expansive commerce clause powers[178] and stated that Congress "may choose the means reasonably adapted to the attainment of the permitted end, even though they involved control of intrastate activities."[179] Even completely local activities, which individually have only a slight effect on interstate commerce, can be regulated by Congress if the cumulative effect of a number of such activities

172. *Id.* at 45-49.

173. *Id.* at 34. *See, e.g.*, Schechter Poultry Corp. v. United States, 268 U.S. 64, 82 (1925); Oliver Iron Co. v. Lord, 262 U.S. 172, 178 (1923); Kidd v. Pearson, 128 U.S. 1, 20 (1888).

174. 301 U.S. at 41.

175. *See* text & notes 24-27 *supra*.

176. In Champion v. Ames, 188 U.S. 321 (1903), the Court paved the way for a wide range of congressional legislation by upholding the power of Congress to prohibit the interstate transit of articles that were considered harmful. At issue in that case was a federal law prohibiting the interstate transit of lottery tickets. *Id.* at 344. The law was challenged as inconsistent with the tenth amendment. *Id.* at 357. The Court, however, ruled that Congress' power to regulate commerce is subject to no limitations except those found in the Constitution, which did not limit Congress' power to forbid the interstate transportation of something deemed to be harmful to the public morals. *Id.* at 356. In Hipolite Egg Co. v. United States, 220 U.S. 45, 48 (1911), the Court upheld a provision of the Pure Food and Drug Act that prohibited adulterated food from entering interstate commerce. Congress' power was not diminished merely because the product was within the borders of the state, at the place of its destination in the original packages. *Id.* In Hoke v. United States, 227 U.S. 308 (1913), the White Slave Traffic Act was upheld despite protests that it was an attempt to interfere with the police power of the states to regulate the morals of citizens. *Id.* at 321.

177. 312 U.S. 100 (1941).

178. *Id.* at 118-19, 121. In *Darby* the Court upheld the Fair Labor Standards Act as a legitimate scheme for preventing the shipment in interstate commerce of products produced under labor conditions which did not conform to the wage and hour standards set up by the Act. *Id.* at 109. The Act was not affected by the tenth amendment.

> The amendment states but a truism that all is retained which has not been surrendered. There is nothing in the history of its adoption to suggest that it was more than declaratory of the relationship between the national and state governments as it had been established by the Constitution before the amendment or that its purpose was other than to allay fears that the new national government might seek to exercise powers not granted, and that the states might not be able to exercise fully their reserved powers.

Id. at 124.

179. *Id.* at 121.

substantially affects interstate commerce.[180] Since *Darby*, the commerce clause has served as authority for a wide range of legislation, and activities that affect interstate commerce are so numerous that Congress has been given almost limitless legislative authority.[181] Encompassed in this broad authority is the power to adopt pervasive federal drug regulations.[182]

A recent decision by the Supreme Court, however, suggests a reduction in congressional power. In *National League of Cities v. Usery*,[183] the Court limited Congress' power under the commerce clause by holding that Congress could not extend new minimum wage and maximum hour provisions to employees of the states and their political subdivisions.[184] Contrary to prior decisions, the Court emphasized the significance of the tenth amendment,[185] declaring that Congress may not exercise power in a fashion that impairs the states' integrity or their ability to function effectively in a federal system of government.[186] However, the importance of the *Usery* decision in weakening Congress' commerce clause power is mitigated by the closely divided decision[187] and the distinction made between federal regulation of private business and federal regulation of state operated services.[188] Since only the latter point was at issue in *Usery*,[189] the

180. *See* Wickard v. Filburn, 317 U.S. 111, 118 (1942) (extending federal regulation to wheat production which was intended wholly for consumption on the farm); United States v. Wrightwood Dairy Co., 315 U.S. 110, 119 (1942) (applying federal minimum price regulations to local milk producers).

181. *See, e.g.*, Fry v. United States, 421 U.S. 542, 548 (1975) (Congress could limit the wages and salaries of state government employees under the Economic Stabilization Act); Maryland v. Wirtz, 392 U.S. 183, 185-88 (1968) (upholding the application of the Fair Labor Standards Act to state schools and hospitals), *overruled in* National League of Cities v. Usery, 426 U.S. 833, 855 (1976); Heart of Atlanta Motel, Inc. v. United States, 379 U.S. 241, 261 (1964) (Civil Rights Act of 1964 validly prohibited racial discrimination in motels serving out-of-state travelers); Katzenbach v. McClung, 379 U.S. 294, 304 (1964) (Civil Rights Act of 1964 validly prohibited racial discrimination in restaurants which bought products shipped in interstate commerce). *See* text & note 76 *supra*. *See also* Handler, *The Current Attack on the Parker v. Brown State Action Doctrine*, 76 COLUM. L. REV. 1 (1976). "With the broadened conception of interstate commerce which now prevails, virtually every business, no matter how local, spills over, to some extent at least, into activities that can be said to affect commerce." *Id.* at 17.

182. *See* text & notes 24-27 *supra*.

183. 426 U.S. 833 (1976).

184. *Id.* at 838-40.

185. *See* text & notes 177-81 *supra*.

186. 426 U.S. at 843.

187. In the five to four decision, Justice Brennan dissented, strongly criticizing the majority for repudiating an unbroken line of precedents. 426 U.S. at 867. "[T]here is no restraint based on state sovereignty requiring or permitting judicial enforcement anywhere expressed in the Constitution; our decisions over the last century and a half have explicitly rejected the existence of any such restraint on the commerce power." *Id.* at 858.

188. *Id.* at 845. The Court stated that

> [i]t is one thing to recognize the authority of Congress to enact laws regulating individual business necessarily subject to the dual sovereignty of the government of the Nation and State in which they reside. It is quite another to uphold a similar exercise of congressional authority directed not to private citizens, but to States as States.

Id. *See* Matsumoto, *National League of Cities - From Footnote to Holding - State Immunity from Commerce Clause Regulation*, 1977 ARIZ. ST. L.J. 35, 64-68.

189. 426 U.S. at 852. The Court indicated that it was not within the congressional authority to

Court's reasoning does not apply to the problems presented with the state laetrile laws because laetrile production is not a state-operated service; it is a private business under state regulation.[190]

Even though a continued liberal interpretation of the commerce power gives Congress broad control over certain intrastate activities, the states' police power appears to justify state regulation of the totally intrastate manufacture and distribution of laetrile, despite the federal ban on the interstate transportation of the substance.[191] However, whether the commerce clause justifies federal interference in laetrile enterprises must be resolved under the principles set out above relating to state police power and commerce clause power interpretations, and by consideration of the effect the laetrile market might have on interstate commerce and, ultimately, on the enforcement of federal drug regulations.

Is There An Effect on Interstate Commerce?

First, laetrile legislation will be analyzed under principles relating to state laws challenged as an interference with interstate commerce.[192] Where a state has legitimate objectives, which do not conflict with federal law, its exercise of police power is valid.[193] Legislation in the area of health and welfare is traditionally a legitimate exercise of state police power notwithstanding substantial federal involvement in the area of food and drug regulation.[194] The states' objectives in enacting lenient policies concerning laetrile represent an attempt to provide for their citizens' health needs, obviously a legitimate state purpose. Having a legitimate objective suggests that the laetrile legislation is a valid exercise of state police power even though there may be some effect upon interstate commerce.[195] The effect on commerce in this instance is not the type of burden or adverse interference that has been previously prohibited by the Court as an invalid exercise of the police power. For example, the laetrile laws do not prescribe regulations that impede the

enact a regulation which operated directly to displace the states' freedom to carry out traditional governmental functions. *Id.*

190. *See, e.g.*, ARIZ. REV. STAT. ANN. §§ 36-2452 (Supp. 1978-79) (setting up regulations for distribution and sale of laetrile and inspection of laetrile manufacturing plants).

191. *See* Op. No. 77-66, 1976-77 OP. ARIZ. ATT'Y GEN. 159; text & notes 193-95 *infra*.

192. See text & notes 150-60 *supra*.

193. *See id.*

194. *See* text & notes 24-27, 133 *supra*. Even when Congress undertook the adoption of federal food and drug laws, it indicated that it had no intention of usurping the states' power to legislate on the same subject. *See* Pub. L. No. 87-781, § 202, 76 Stat. 780 (1962). In the Drug Amendments of 1962, special mention was made of the effect the amendments would have on state laws. The amendments were not to be construed to invalidate any state laws unless there was a direct and positive conflict between the two regulations. *Id.*

195. The Court has indicated numerous times that state regulations may affect interstate commerce in certain instances. *See* text & notes 150-60 *supra*.

free flow of goods in interstate traffic,[196] nor do they establish regulations which discriminate against or exclude out-of-state products.[197] The laetrile laws merely allow a product to be manufactured and sold within a state and therefore appear to be a valid exercise of the police power when analyzed under this principle alone.

However, when the problem is analyzed under the principles governing the extent to which Congress can regulate arguably local activities, conflicting interests confuse the issue. The extensive drug regulations that Congress has adopted add uncertainty to the validity of the state laetrile laws because of the possibility of inconsistent state and federal regulations. Federal intervention in intrastate laetrile businesses could depend on the extent to which the activity affects commerce because many activities that appear to be local in character have been subjected to federal regulation for even a very slight effect on commerce.[198] Thus, the connection with commerce, in the form of people traveling to various states to obtain laetrile and manufacturers shipping ingredients and other necessary supplies into the state, is the tenuous type of link to interstate commerce that could bring the activities within the reach of congressional control.[199]

Even if the strong state power posture in *National League* were applied to prevent direct FDA interference with a wholly intrastate lae-

196. *E.g.*, Southern Pacific Co. v. Arizona, 325 U.S. 761, 767 (state law limiting train length was an invalid interference with interstate commerce).

197. *E.g.*, Great Atlantic & Pacific Tea Co. v. Cottrell, 424 U.S. 366, 381 (1976) (Mississippi law which allowed out-of-state milk products to be sold only if the other state accepted milk from Mississippi on a reciprocal basis unduly burdened the free flow of interstate commerce and was therefore invalid).

198. In Wickard v. Filburn, 317 U.S. 111 (1942), the federal regulation established production quotas aimed at controlling the volume of wheat moving in interstate commerce in order to avoid abnormal price fluctuations. *Id.* at 115. The Court held that the federal regulation applied as well to wheat produced solely for home consumption, which would never enter interstate commerce, *id.* at 118, because it exerted an economic effect on interstate commerce. *Id.* at 125. Although the impact on commerce by one individual may be very small, it becomes great when multiplied by the effect of others similarly situated. *Id.* at 127-28. In the civil rights case of Katzenbach v. McClung, 379 U.S. 294 (1964), the interstate connection was satisfied where the defendant restaurant bought food that had been shipped in interstate commerce. *Id.* at 304. Therefore, federal regulation in the area of laetrile manufacturing could be justified on the basis that ingredients or supplies are shipped to the producer from outside the state. In *Katzenbach*, the Court said that the activities which are beyond the reach of Congress are those completely within a state which do not affect other states, and those with which it is not necessary to interfere in order to carry out the powers of the federal government. *Id.* at 302.

199. *See* Handler, *supra* note 181, at 17. *But cf.* Kordel v. United States, 335 U.S. 345 (1948). Although the issue in *Kordel* was misbranded drugs, Justice Black, dissenting, addressed the necessity for an interstate commerce connection in order for the FD&C Act to apply: "[I]f a person misbranded a drug which had not been and was not thereafter introduced into interstate commerce, there would be no violation of the federal Act. . . ." *Id.* at 352-53. Arguably, then, if a person manufactured a drug that did not comply with federal efficacy requirements, and there was no interstate commerce connection before or after production, there would be no violation of the federal Act. The FD&C Act efficacy requirements address only the shipment of certain articles in interstate commerce. 21 U.S.C. § 355 (1976). If the activity remains entirely within the state, it appears that federal law does not adversely affect it. *See* Op. No. 77-66, 1976-77 OP. ARIZ. ATT'Y GEN. 159.

trile business, the FDA could indirectly prevent the manufacture of laetrile by seizing the essential ingredient, apricot pits, which must be shipped in interstate commerce if sufficient quantities could not be supplied by intrastate producers.[200] Congress has been given broad powers to keep the channels of commerce free from the transportation of harmful articles[201] and exclude from commerce those products deemed injurious to the public health.[202] As the administrative record compiled for *Rutherford v. United States* indicates,[203] the FDA does consider laetrile to be harmful.[204] The apricot pits destined to be made into laetrile are likewise considered harmful[205] and could be subject to exclusion from interstate commerce on that basis.[206]

If the apricot pits were not seized before being made into laetrile, this major component of laetrile could, nonetheless, provide the interstate connection necessary to justify the seizure of the laetrile by the FDA. The FD&C Act has been applied to products manufactured totally within a state for distribution only in that state where the ingredients comprising the product were shipped in interstate commerce.[207]

200. *See* FREEDOM FROM CANCER, *supra* note 5, at 2; N.Y. Times, June 3, 1977, § A, at 11, col. 1.

201. *See* United States v. Walsh, 331 U.S. 432, 434 (1947). In this case, because a dealer was engaged in the business of making interstate shipments, the prohibition against making false representations for a product was applied to products that were produced and marketed entirely intrastate. *Id. Accord*, United States v. Cardiff, 95 F. Supp. 206, 208 (E.D. Wash. 1951). *See also* Matteoni, *The Interstate Ingredient of Section 304(a)—Federal Food, Drug, Cosmetic Act*, 17 FOOD DRUG COSM. L.J. 380, 397-98 (1962) (the range of the federal food and drug laws is growing because of the very broad interpretation of what constitutes interstate commerce).

202. United States v. Carolene Prods. Co., 304 U.S. 144, 147 (1938). The prohibition of the interstate shipment of filled milk, considered a harmful substance, was a permissible regulation of commerce. *Id.* at 154.

203. See text & notes 81-108 *supra*.

204. *See* text & note 14 *supra*.

205. *See* 42 Fed. Reg. 39,767, 39,803 (1977) (FDA believes consuming apricot pits can be hazardous); *Banning Laetrile, supra* note 11, at 3-6.

206. Although laetrile legislation addresses a public health problem and therefore lies in the area reserved to state police power it is not necessarily a valid exercise of the police power. *See* United States v. Carolene Prods. Co., 304 U.S. 144 (1938) where a federal law was attacked as transcending Congress' power to regulate interstate commerce and as invading powers reserved to the states. *Id.* at 146-47. However, the federal regulation was not invalid because its result was to restrict the use of articles of commerce within the states of destination. *Id.* at 147.

207. In United States v. 39 Cases, More or Less, 192 F. Supp. 51 (E.D. Mich. 1961), the federal misbranding regulations were applied to tablets manufactured within the state for distribution solely within that state, because the ingredients had been shipped in interstate commerce. The court rejected the argument that the misbranding had to be of an article which was itself shipped in interstate commerce and not a product created from ingredients shipped in interstate commerce. *Id.* at 52. *Accord*, Palmer v. United States, 340 F.2d 48, 49 (5th Cir. 1964) (shipment of the active ingredient of a drug is equivalent of shipping the drug); United States v. Dianovin Pharmaceuticals, Inc., 342 F. Supp. 724, 728 (D. P.R. 1972), *aff'd*, 475 F.2d 100 (1st Cir. 1973) (the interstate requirement of the FD&C Act is satisfied where the raw material utilized to produce vitamin K was shipped in interstate commerce). *Compare* United States v. 40 Cases More or Less, 289 F.2d 343, 345-46 (2d Cir. 1961) (the FD&C Act authorized the FDA to seize mislabelled cans of blended vegetable oil mixed entirely within the state from various oils shipped under proper labels from other states) *with* United States v. An Article or Device, 180 F. Supp. 52, 53 (E.D. Mich. 1959) (declining federal regulation of a drug manufactured and distributed within a state where the components shipped interstate comprised only a minor ingredient of the final product).

Although the individual ingredients of a product have complied with the federal regulations at the time of interstate shipment, where federal regulations were violated after the manufacturing process, the end product has been subject to seizure by the FDA.[208] Therefore, even assuming the interstate shipment of apricot pits does not violate federal drug regulations, the end product, laetrile, might still be seized by the FDA for violation of the new drug regulations pertaining to efficacy[209] even though laetrile itself may never be shipped in interstate commerce.

In addition to the interstate nexus found with the transported ingredients, other interstate connections could be contemplated. For instance, given the demand for laetrile by thousands of cancer patients, the transportation of the substance in interstate commerce by individuals traveling to and from states where it is distributed is inevitable. Furthermore, the federal law indicates that "[n]o person shall introduce *or deliver for introduction* into interstate commerce" any ineffective new drug.[210] The FDA, therefore, could seize laetrile from the individuals and, perhaps, from the manufacturer if that manufacturer is the source of the introduction of laetrile into commerce and is aware that it will be taken out of the state.

The application of federal food and drug regulations to activities within the individual states has been challenged frequently.[211] Yet, the

208. *See* United States v. 40 Cases More or Less, 289 F.2d 343, 345-46 (2d Cir. 1961); United States v. 39 Cases More or Less, 192 F. Supp. 51, 52 (E.D. Mich. 1961). Although the federal provisions forbidding misbranding were at issue in these cases, the same argument could be extended to laetrile and distributor's noncompliance with the new drug efficacy requirements.

209. 21 U.S.C. § 355 (1976). *See* text & note 6 *supra*.

210. 21 U.S.C. § 355(a) (1976) (emphasis added). *Cf.* United States v. Millpax, Inc., 313 F.2d 152, 156-57 (7th Cir. 1963) (one who sold misbranded drugs with the knowledge they would be taken out of the state delivered them for introduction into interstate commerce and was within the federal prohibition). An interesting case, which is typical of many brought under the federal drug laws, is Drown v. United States, 198 F.2d 999 (9th Cir. 1952). The FD&C Act prohibited introducing or delivering for introduction into interstate commerce any device which is misbranded. *Id.* at 1004. The misbranded article in this case was the Drown Radio Therapeutic Instrument which was represented to have an extensive list of fantastic therapeutic and diagnostic qualities which included preventing breast cancer and treating kidney and bladder ailments, tipped uterus, cirrhosis and carcenoma of the right kidney, various brain diseases, heart trouble, head pains, constipation, lower back pain, and loss of speech and memory, to name but a few. *Id.* at 1002. The instrument was based on the theory that each person and each body organ, as well as every disease, vibrates at a specific rate. Therefore, the theory went, diseases could be treated by conducting energy from the instrument into the diseased part of the body at a vibration rate higher than that of the disease. The diseased cells would then fall away because they cannot live in the higher rate of vibration. *Id.* Not surprisingly, the therapeutic device was found to be misbranded. *Id.* at 1006. The seller of the device was convicted under federal law of selling a misbranded article despite her contention that the sale was an intrastate transaction. *Id.* at 1003. The court reasoned that the FD&C Act was intended to apply to the seller of a misbranded device who delivered it to a buyer with the knowledge that the buyer intended to take it into another state. *Id.* at 1004. The seller here knew the device would be taken from California to Illinois and was, therefore, guilty of introducing a misbranded article into interstate commerce.

211. *See, e.g.*, McDermott v. Wisconsin, 228 U.S. 115, 134 (1913); Hipolite Egg Co. v. United States, 220 U.S. 45, 52 (1911). The validity of the 1962 amendments and of the regulations

Supreme Court has continually supported Congress' broad enforcement power in this area.[212] Many states have, nonetheless, adopted their own regulations, often with more stringent requirements than the ones set forth in the FD&C Act.[213] But with the laetrile legislation, the states are requiring less than the federal law.[214] Therefore, assuming the state laws legalizing the manufacture and sale of laetrile and the federal provisions banning it from interstate commerce are both legitimate,[215] it must be determined whether these less stringent state laws frustrate the purposes of the federal regulations[216] and will, as a result, be preempted by the federal food and drug laws.

FEDERAL PREEMPTION AND DRUG REGULATION

The doctrine of preemption has its basis in the supremacy clause, which makes federal law the supreme law of the land.[217] The doctrine of preemption is applied to render null any state law that conflicts or interferes with laws enacted by the United States.[218] Clearly, then, where there is a direct conflict between state and federal laws, making

adopted for determining new drug effectiveness was upheld in Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 617-22 (1973).

212. *See* Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609 (1973). "Congress surely has great leeway in setting standards for releasing on the public, drugs which may well be miracles or, on the other hand, merely easy money-making schemes through use of fraudulent articles labelled in mysterious scientific dress." *Id.* at 622.

213. *See, e.g.*, Corn Prods. Refining Co. v. Eddy, 249 U.S. 427, 437-38 (1919) (Supreme Court upheld state law requiring the percentage of each ingredient of certain products to be stated on a label even though the federal food and drug law did not contain that requirement); Weigle v. Curtice Bros. Co., 248 U.S. 285, 288 (1919) (state law prohibiting sale of any food that contains benzoic acid was valid despite the federal law allowing use of the acid); Armour & Co. v. North Dakota, 240 U.S. 510, 517 (1916) (state law requiring lard to be sold in containers displaying the true net weight in even pounds was not repugnant to the Pure Food and Drug Act which did not contain that requirement); Savage v. Jones, 225 U.S. 501, 532 (1912) (state law requiring manufacturer of animal feed to disclose ingredients on a label was valid although federal regulations did not require it).

214. *See* text & note 8 *supra*. The state laws allow distribution of laetrile even though it has not been scientifically proven as an effective cancer remedy.

215. The FDA has determined laetrile to be an unproven new drug. *See* text & notes 45-55 *supra*. The procedures employed by the FDA in determining the safety and effectiveness of new drugs in general have been approved by the Supreme Court. *See* Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 617-19 (1973), and its companion cases, CIBA Corp. v. Weinberger, 412 U.S. 640, 643 (1973); Weinberger v. Bentex Pharmaceutical, Inc., 412 U.S. 645, 648-49 (1973); USV Pharmaceutical Corp. v. Weinberger, 412 U.S. 655, 667-68 (1973). Some lower courts agreed with the FDA determination that laetrile is an unproven new drug. *See* Gadler v. United States, 425 F. Supp. 244, 249 (D. Minn. 1977); Hanson v. United States, 417 F. Supp. 30, 36 (D. Minn.), *aff'd*, 540 F.2d 947 (8th Cir. 1976); Morgan v. Mathews, No. 76-1637 (D.S.C. Nov. 30, 1976). State laetrile laws have not been ruled on, but it can be argued they are a valid exercise of state police power. *See* text & notes 133-34, 193-95 *supra*.

216. *See, e.g.*, Hines v. Davidowitz, 312 U.S. 52, 67 (1941).

217. "This Constitution, and the Laws of the United States which Shall be made in Pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding. U.S. CONST. art. 6, cl. 2.

218. *See* Gibbons v. Ogden, 22 U.S. (9 Wheat.) 1, 210-11 (1824). *See also* Hirsch, *Toward a New View of Federal Preemption*, 1972 U. ILL. L.F. 515, 526-28.

compliance with both impossible, the state laws must give way.[219] However, the preemption doctrine may be applied even where the federal and state laws are apparently compatible, for example, where state and federal laws duplicate each other,[220] where state law imposes more stringent regulations than federal law,[221] or where the state law deals with a specific activity not touched by a federal act.[222] Questions of preemption also arise where there is a clear and manifest intent by Congress to exclude state regulation of a certain subject matter.[223] In all of these examples, if the state law is contrary to the federal law or interferes with the enforcement of the federal law, the state law must yield under the supremacy clause.[224]

Laetrile legislation defies categorization for purposes of applying the preemption doctrine. For example, laetrile is not a matter left untouched by federal regulation.[225] Federal laws provide extensive measures to be followed in the area of drug regulation and specifically address the efficacy standards applicable to laetrile and other new drugs.[226] Thus, state laetrile laws not only fall within the general subject matter, but also encompass a specific activity that has been addressed by federal regulation, a factor weighing in favor of preemption. Furthermore, this is not an area where state and federal laws are entirely compatible.[227] By adopting less stringent drug standards for laetrile than those established by the federal government, and by permitting the use of a drug that the federal government, through enforcement of the new drug regulations, has banned from interstate

219. *See* Gibbons v. Ogden, 22 U.S. (9 Wheat.) 1, 211 (1824).

220. *See* Pennsylvania v. Nelson, 350 U.S. 497, 504 (1956).

221. *See* Huron Portland Cement Co. v. City of Detroit, 362 U.S. 440, 441-42 (1960).

222. *See* Savage v. Jones, 225 U.S. 501, 531-32 (1912).

223. *See* Burbank v. Lockheed Air Terminal, 411 U.S. 624, 633 (1973) (Federal Aviation Act declared to require a uniform and exclusive system of federal regulation to fulfill the congressional objectives); Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947) (federal law gave exclusive authority to the Secretary of Agriculture to regulate licensed warehouses).

224. *See* Gibbons v. Ogden, 22 U.S. (9 Wheat.) 1, 211 (1824).

225. *See* text & notes 45-55 *supra*; Savage v. Jones, 225 U.S. 501, 532 (1912). In *Savage* a state law required manufacturers of animal feeds to disclose the ingredients of the feed on the labels. *Id.* at 521. Such information was not required by the federal food and drug law, but the state law was upheld because it did not interfere with federal provisions related to the same general subject matter. *Id.* at 532. The federal food and drug act was aimed at keeping adulterated and misbranded products out of interstate commerce. *Id.* at 529. Violation of the federal law resulted from false or misleading statements, not from failure to disclose ingredients. *Id.* Therefore, the state requirement of disclosing ingredients did not interfere with the federal prohibition against false and misleading information. *Id.* at 539. The federal law was limited and did not include the specific activity at which the state law was aimed. *Id.* at 532. Again, the situation with respect to laetrile is distinguishable because federal drug laws set up standards to be met before marketing new drugs.

226. *See* 21 U.S.C. §§ 301-392 (1976); 21 C.F.R. §§ 330-460.93 (1977).

227. *See, e.g.*, Huron Portland Cement Co. v. City of Detroit, 362 U.S. 440 (1960). A local smoke abatement code, which applied standards more stringent than those imposed by federal law, was upheld. *Id.* at 442. *See also* Corn Prods. Refining Co. v. Eddy, 249 U.S. 427, 429 (1919) (Court upheld a state law that required manufacturer to state on the products' label the percentage of each ingredient even though the federal law did not contain this additional requirement).

commerce, some states have seemingly undermined the purpose of the federal law which is to prevent the use of drugs of unproven efficacy.[228]

However, the mechanics of the federal and state provisions concerning laetrile are not entirely contradictory and, thus, do not make compliance with both impossible,[229] a factor in favor of the validity of the state laws. Although the FD&C Act prohibits interstate transportation of laetrile, the state legislation is generally designed to avoid interstate transactions and merely permits manufacture and sale of laetrile within the state.[230] Although laetrile legislation seems to present a unique fact situation, analysis under the preemption doctrine might help to determine the validity of this exercise of state police power.

Tests for Preemption

In deciding questions of preemption, no mechanical test has been adopted.[231] Each case is determined on its own facts, taking into consideration the state statute and its operation in contrast to the federal statute and its operation.[232] Two cases have, however, set forth preemption tests that have general applicability to most situations. In *Pennsylvania v. Nelson*,[233] the Court summarized three tests to be applied in a preemption case: (1) whether the scheme of federal regulation is so pervasive as to make reasonable the inference that Congress left no room for the states to supplement it; (2) whether the federal statute touched a field in which the federal interest is so dominant that the federal system must be assumed to preclude enforcement of state laws on the same subject; and (3) whether the enforcement of the state law presents a serious danger or conflict with the administration of the federal program.[234] Another test applied in *Hines v. Davidowitz*,[235] and

228. The ultimate goal of the efficacy requirement is to keep unfit drugs off the market entirely and thereby prevent their use. S. Rep. No. 1744, 87th Cong., 2d Sess. 1, *reprinted in* [1962] U.S. CODE CONG. & AD. NEWS 2884, 2884.

229. *See, e.g.*, Gibbons v. Ogden, 22 U.S. (9 Wheat.) 1, 2-3 (1824). In *Gibbons*, the state granted a steamboat monopoly to one party, while Congress granted Gibbons a federal license to trade on the same waters. *Id.* at 2. Thus, Gibbons could not exercise the right granted by Congress without violating the state provisions. *Id.* at 2-3.

230. See text & note 8 *supra*. *But see* L. TRIBE, *supra* note 148, § 6-24, at 378 (state law may be struck down where it conflicts with the underlying objectives of the federal regulation or its effect is to discourage conduct the federal law attempts to encourage).

231. In referring to the many tests for preemption that have been used, the Court in Hines v. Davidowitz, 312 U.S. 52 (1940), stated that "[n]one of these expressions provides an infallible constitutional test or an exclusive constitutional yardstick. In the final analysis, there can be no one crystal clear distinctly marked formula." *Id.* at 67.

232. *See* Hirsch, *supra* note 218, at 516-19.

233. 350 U.S. 497 (1956).

234. *Id.* at 502-06. In *Pennsylvania v. Nelson* the Court held that, with respect to the state sedition act, Congress had occupied the field to the exclusion of parallel state regulation, that the dominant interest of the federal government precluded state interventions, and that administration of the state law would conflict with the operation of the federal plan. *Id.* at 509.

235. 312 U.S. 52 (1941).

repeatedly thereafter,[236] requires a determination of whether, under the circumstances of the particular case, the state law stood as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.[237]

Applying the preemption tests of *Nelson* does not completely resolve the laetrile issue. Although the scheme of federal regulation in the drug area is pervasive, it cannot be said that Congress left no room for supplemental state regulation in the same area. In fact, Congress has indicated that the FD&C Act shall not invalidate state laws unless there is a direct conflict in the application of the two schemes of regulation.[238] Thus, the mere existence of explicit federal provisions on a matter is not sufficient to work preemption in the absence of exclusionary intent.[239]

The Court does not lightly infer exclusionary intent. Exclusionary intent may be found where federal legislation contains words expressly indicating the act was designed to provide official and uniform standards.[240] Where an intent by Congress to preempt the field is manifested, the Court will infer that Congress has left no room for any supplementary[241] or complementary state regulation.[242] Such an exclusionary intent does not appear in the FD&C Act. Exclusionary intent may also be found by implication if a federal law is pervasive and detailed in its regulations.[243] However, the expressed intent of Congress to allow nonconflicting state drug regulations weakens the argument that exclusionary intent can be inferred from the pervasive federal drug regulations.[244] Therefore, the first test under *Nelson* does not indicate preemption.

236. *See, e.g.*, Jones v. Rath Packing Co., 430 U.S. 519, 526 (1977); Perez v. Campbell, 402 U.S. 637, 649 (1971); Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 141 (1963).

237. 312 U.S. at 67.

238. Pub. L. No. 87-781, § 202, 76 Stat. 780 (1962).

239. The Court will not find preemptive intent unless it was the clear and manifest purpose of Congress. *See* Head v. New Mexico Bd. of Examiners, 374 U.S. 424, 430 (1963); Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 146 (1963); Colorado Anti-Discrimination Comm'n v. Continental Air Lines, 372 U.S. 714, 722 (1963); California v. Zook, 336 U.S. 725, 733 (1949). Exclusionary intent can be inferred from pervasive federal regulations. Even though the FD&C Act is pervasive, Congress indicated that state drug laws would be valid unless there was a direct conflict with federal law. *See* text & notes 243-44 *infra*.

240. *See* Campbell v. Hussey, 368 U.S. 297, 300-01 (1961) (the federal Tobacco Inspection Act referred specifically to uniform and official standards for classifying tobacco).

241. *Id.* at 301.

242. Complementary state regulations will fare no better than conflicting state regulations where the intention to preempt is evident. *Id.* at 302. *See also* Burbank v. Lockheed Air Terminal, 411 U.S. 624, 633 (1973) (Congress' intent to preempt local control appeared in the pervasive power vested in the FAA to achieve a uniform and exclusive system of federal regulation).

243. *See* Warren Trading Post Co. v. Arizona Tax Comm'n, 380 U.S. 685, 690-91 (1965); Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947).

244. *See* text & note 238 *supra*. *But see* Engdahl, *Consolidation By Compact: A Remedy for Preemption of State Food and Drug Laws*, 14 J. PUB. L. 276, 293-99 (1965) (suggesting that the federal drug regulations are so detailed that one could easily infer a congressional intent to preempt the field).

For the same reasons, it is also arguable that the second test under *Nelson* is not met. Since Congress expressed a desire to allow nonconflicting state drug regulations, the FD&C Act cannot be seen as regulating an area where the federal interest is so dominant as to preclude enforcement of state laws on the subject, especially since protecting citizens' health and safety is traditionally left to the states.[245] However, application of the third *Nelson* test poses an argument for preemption because the enforcement of the state laetrile laws may interfere with the administration of the federal program. Whether that interference is serious enough to justify invalidation of the state laws is not certain, but a completely intrastate laetrile business, by marketing a drug which is banned by the FDA, would obviously conflict to some degree with the administration of federal drug laws.

However, a much stronger argument for preemption can be made under the principle set forth in *Hines*, which requires a determination of whether the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.[246] The purposes of the federal food and drug regulations are to protect consumers against health hazards and economic exploitation[247] and to prevent the use of the facilities of interstate commerce for the conveyance of misbranded and adulterated medicine and food.[248] These purposes and objectives are carried over to amendments adding the efficacy requirements for new drugs.[249] The FDA has made a determination that laetrile, because it has not been proven effective, may be harmful to the public and should be kept out of the marketplace.[250] However, the state laetrile laws would circumvent these measures. Clearly, making laetrile available even for local use only is an obstacle to achieving the objective of protecting consumers by keeping such drugs off the market.[251] Moreover, given the demand for laetrile by a growing number

245. *See* Head v. New Mexico Bd. of Examiners, 374 U.S. 424, 428 & n.4 (1963). In *Head* the Court also addressed the issue of state laws affecting interstate commerce and indicated that a state law may not be struck down merely because it affects interstate commerce in some slight way. *Id.* at 429.

246. *See* text & notes 235-37 *supra*.

247. *See* Markel, *Federal Pre-emption*, 17 FOOD DRUG COSM. L.J. 453, 463 (1962).

248. United States v. Sullivan, 332 U.S. 689, 696 (1948); United States v. Walsh, 331 U.S. 432, 434 (1947); United States v. Dotterweich, 320 U.S. 277, 280 (1943); McDermott v. Wisconsin, 228 U.S. 115, 128 (1912). The purpose of requiring drug manufacturers to comply with extensive regulations is to prevent harmful products from reaching the uninformed consumer. Toole v. Richardson-Merrell, Inc., 251 Cal. App. 2d 689, 704, 60 Cal. Rptr. 398, 409 (1967).

249. *See* Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609 (1973), where the Court indicated that Congress has great latitude in setting drug standards to protect people from drugs for which there is no reliable evidence of effectiveness. *Id.* at 622.

250. *See* text & notes 47 *supra*.

251. *See* L. TRIBE, *supra* note 146, § 6-24, at 378 ("State action may also be preempted . . . if it encourages conduct whose absence would aid in the effectuation of the federal scheme") (citing Jones v. Rath Packing Co., 430 U.S. 519 (1977) and City of Burbank v. Lockheed Air Terminal, Inc., 411 U.S. 624 (1973)).

of proponents,[252] total isolation of the substance from interstate transportation seems impossible. Thus, if the state laetrile laws are given effect, the objectives of the federal law—to keep ineffective drug products off the market—will be defeated. Where the state law "frustrates the full effectiveness" of federal regulations, it must yield.[253] Under this test, a strong argument exists that the laetrile legislation is subject to preemption.

CONCLUSION

Amidst the furor that has surrounded laetrile in the past few years, several complex legal issues have emerged. The courts remain divided on how to resolve the numerous challenges to the federal drug regulations. Equally subject to dispute are the issues of whether the right to choose unorthodox medical treatment is within the constitutionally protected right of privacy and whether the state laetrile statutes interfere with federal regulation of the subject to the extent that preemption of the state laws is justified. Although a strong argument exists for preemption, the FDA has not challenged the state laetrile laws—perhaps because the controversy is highly emotional and political. One solution is to allow the use of laetrile only by terminal cancer patients who are unresponsive to orthodox cancer treatment. The harm resulting from foregoing accepted medical treatments to rely on laetrile does not exist for the terminally ill. But to go beyond that and give the general public the freedom to choose laetrile, as well as other unapproved drugs, would be to discard the protection Congress intended to give consumers when the efficacy requirements of the FD&C Act were adopted.

252. *See* text & note 210 *supra*.

253. Perez v. Campbell, 402 U.S. 637, 652 (1973). Added to the arguments on behalf of the FDA is that an agency such as the FDA, entrusted with the administration of federal law, becomes an important factor in determining preemption. San Diego Bldg. Trades Council v. Garmon, 359 U.S. 236, 242 (1959); *see* Burbank v. Lockheed Air Terminal, Inc., 411 U.S. 624, 638-39 (1973); Bethlehem Steel v. New York Labor Relations Bd., 330 U.S. 767, 774 (1947). Because Congress established a single, centralized agency to administer and enforce the applicable laws and regulations, it can be inferred that Congress intended to have the laws uniformly applied and to avoid conflicts and diverse interpretations of the laws that might arise out of local regulation of the same area. San Diego Bldg. Trades Council v. Garmon, 359 U.S. 236, 242-43 (1959); Garner v. Teamsters Local 776, 346 U.S. 485, 490-91 (1953). *See* Engdahl, *supra* note 244, at 296-97. Therefore, since the FDA is given the power to administer federal drug regulations, a stronger argument could be made for more uniformity between state and federal regulations and less acceptance of unproven drugs like laetrile. Because of the rapid growth of the drug industry and the highly technical and complex scientific research that is involved in producing safe and effective drugs, uniform laws have been suggested as a solution to the dilemma of conflicting drug laws. See Christopher, *State Police Power in Health and Fraud Matters*, 8 UTAH L. REV. 289, 297 (1963); Engdahl, *supra* note 244, at 320; Goodrich, *Uniformity in Federal-State Food Regulation*, 17 FOOD DRUG COSM. L.J. 305, 309-10 (1962); Markel, *supra* note 247, at 483. By adopting uniform regulations, all of the resources in the individual states and the federal agencies could be pooled to form a more complete and efficient system for evaluating drugs. In this way, the states could be included in the regulatory process and could devote more of their resources to the enforcement of the drug laws. Goodrich, *supra* at 310.

That would be a step backwards to the philosophy of caveat emptor, a regrettable step if all that it accomplished was to offer desperate people a false sense of hope.[254]

254. "[T]he lesson . . . ought to go out very clearly, that it is unwise, certainly, for any American to be willing to experiment or accept this particular drug and believe they are going to be dealing with the disease of cancer." *Banning Laetrile, supra* note 11, at 272 (statement of Senator Edward Kennedy).