

1978

## Drugs--Federal Drug Administration Ban on Laetrile Treatments for Terminally Ill Cancer Patients is Arbitrary and Capricious

Terry Horwath Bitting

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### Recommended Citation

Terry H. Bitting, *Drugs--Federal Drug Administration Ban on Laetrile Treatments for Terminally Ill Cancer Patients is Arbitrary and Capricious*, 14 Tulsa L. J. 222 (1978).

Available at: <https://digitalcommons.law.utulsa.edu/tlr/vol14/iss1/9>

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## RECENT DEVELOPMENT

DRUGS—FEDERAL DRUG ADMINISTRATION BAN ON LAETRILE TREATMENTS FOR TERMINALLY ILL CANCER PATIENTS IS ARBITRARY AND CAPRICIOUS. *Rutherford v. United States*, 582 F.2d 1234 (10th Cir. 1978).

In *Rutherford v. United States*,<sup>1</sup> the Court of Appeals from the Tenth Circuit held that terminally ill cancer patients may receive treatments of laetrile despite the prohibition of the drug by the Food and Drug Administration (FDA). This decision overturned an earlier ruling by the FDA Commissioner that laetrile<sup>2</sup> was a new drug<sup>3</sup> within the meaning of the Federal Food, Drug and Cosmetic Act (FFDC Act).<sup>4</sup> As a new drug, laetrile had not been determined by the FDA to be generally recognized by qualified experts as safe and effective.<sup>5</sup> Therefore, its distribution had been banned by the agency.<sup>6</sup>

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1. 582 F.2d 1234 (10th Cir. 1978), *aff'g* 399 F. Supp. 1208 (W.D. Okla. 1975), *cert. granted* 47 U.S.L.W. 3492 (U.S. Jan. 23, 1979)(No. 78-605).

2. "Laetrile is the name of a product whose major component or ingredient is the chemical amygdalin, a substance that occurs naturally in the pits of apricots, peaches, bitter almonds, and in other plant material." 42 Fed. Reg. 10,066 (1977).

3. The Federal, Food, Drug and Cosmetic (FFDC) Act of 1928, 21 U.S.C. §§ 301-392 (1976), defines a new drug as:

(1) Any drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, . . . or (2) any drug . . . the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

21 U.S.C. §321(p) (1976) (1962 amendments in italics). The 1962 amendments added the additional requirement that a new drug be effective as well as safe.

A drug could avoid a new drug classification under the grandfather clause of the FFDC Act, if on October 9, 1962: (1) the drug was commercially used or sold in the United States; (2) it was not a new drug pursuant to 21 U.S.C. §321(p) of the Food and Drugs Act then in force, which required that only the safe test be met; and (3) it was not covered by an effective new drug application; and (4) its labeling contained the same representations concerning the conditions of its use.

4. 21 U.S.C. §§301-392 (1976).

5. 42 Fed. Reg. 39,768 (1977). Moreover, the Commissioner concluded that laetrile was not exempt under the grandfather provisions of the FFDC Act. *Id.* at 39,787-91.

6. The FDA derives its authority to regulate drugs in interstate commerce pursuant to 21 U.S.C. §244(a) (1972) which states that "no person shall introduce or deliver for introduction into

In 1975, a class action was brought on behalf of cancer patients and their spouses to enjoin the FDA from interfering with the distribution of laetrile.<sup>7</sup> The trial court reviewed the administrative record and concluded that the FDA's classification of laetrile as a new drug<sup>8</sup> was unsupported by substantial evidence.<sup>9</sup> On this finding, the court ruled that the agency's action was arbitrary and capricious.<sup>10</sup> Further, it held that the provisions of the FFDC Act were violative of a cancer patient's constitutionally protected right of privacy, here the right to use a non-toxic substance.<sup>11</sup> The district court enjoined the FDA from preventing the plaintiffs' importation and interstate transportation of laetrile for their own consumption, until there was substantial evidence to support the FDA's determination.<sup>12</sup>

On appeal, the Tenth Circuit affirmed the lower court's decision.<sup>13</sup> It found that the FDA had not advanced any standard against which the safety and effectiveness of laetrile as a treatment for terminally ill cancer patients could be judged.<sup>14</sup> Absent such a standard, the court of appeals held that the safety and effectiveness requirements of the FFDC Act had no reasonable application.<sup>15</sup> The court, however, qualified its holding by stating that it was not concluding that all substances were beyond the agency's reach in relation to the terminally ill.<sup>16</sup> Rather, it was ruling that at present there exists no applicable measure by which laetrile could be banned.<sup>17</sup>

The Tenth Circuit's conclusion raises the issue of whether the safe

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interstate commerce any new drug, unless an approval of an application is effective with respect to such drug."

7. 399 F. Supp. 1208 (W.D. Okla. 1975). Although the action was brought as a class action, it was not until 1977 that it was certified as one. 424 F. Supp. 105, 108 (W.D. Okla. 1977).

8. The district court remanded to the FDA the issue of whether laetrile fell within the grandfather provisions of the FFDC Act. 424 F. Supp. at 107.

9. *Id.* at 106-07.

10. *Id.* at 107.

11. 399 F. Supp. at 1213-14. The Tenth Circuit declined to consider this issue in its decision. 582 F.2d at 1237.

Although the Tenth Circuit did not directly reach the constitutional issue, perhaps the court did so by implication. By sufficiently narrowing the class, and by showing that there was no known cure, the court recognized the *right* of cancer patients to procure laetrile. It appears that the court engaged in a balancing of the cancer patients' interest in using laetrile with the FDA's interest in prohibiting its use.

12. 424 F. Supp. at 107.

13. 582 F.2d at 1237.

14. *Id.* at 1237.

15. *Id.* The court of appeals, however, put several limitations on a cancer patient's access to laetrile. First, the cancer patient must be certified by a licensed medical practitioner to be terminally ill of cancer. Second, the cancer patient may only procure intravenous injections of laetrile administered by a licensed medical practitioner. *Id.* at 1237.

16. *Id.*

17. *Id.*

and effective test of the FFDC Act is applicable to any unapproved new drug when its use is sought by a terminally ill cancer patient. Although the court of appeals recognized that there is no known cure for cancer,<sup>18</sup> the decision does not appear to give a cancer patient carte blanche access to any unapproved new drug. At a minimum, the decision implies that the drug must be generally recognized by experts as nontoxic.<sup>19</sup>

If the substance's nontoxicity is the standard of access, what measures exist to protect the unsuspecting and vulnerable cancer patient from being victimized by persons claiming to have some miracle cure? The Tenth Circuit stated that the matter was a regulatory one for the FDA.<sup>20</sup>

In 1973, the United States Court of Appeals for the Seventh Circuit dealt with a case similar to *Rutherford*. In that case, *Durovic v. Richardson*,<sup>21</sup> plaintiffs sought court approval of a new drug, krebiozen, for the management and treatment of malignant tumors.<sup>22</sup> The FDA had earlier denied the plaintiffs' new drug application because its evidence had failed to establish that krebiozen was both safe and effective under the requirements of the FFDC Act.<sup>23</sup> In upholding the district court and the FDA, the court of appeals found that krebiozen was not sufficiently known to be recognized as safe even in the narrow sense of being nontoxic.<sup>24</sup> Moreover, the court concluded that the drug did not come within the purview of the grandfather clause of the FFDC Act.<sup>25</sup>

In light of *Durovic*, there is an apparent split between the Seventh and Tenth Circuits. From the cancer patient's point of view, this dichotomy may create inequitable results. A cancer patient living in the Tenth Circuit's jurisdiction could escape the FDA's prohibition against laetrile. In contrast, those living in the Seventh Circuit's jurisdiction would be denied access to a drug which they believe is effective in the treatment of cancer.

This difference, however, may be reconciled by a closer examination of the facts affecting the respective decisions. In *Durovic*, the court

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18. *Id.*

19. The Tenth Circuit did not overturn the district court's finding that laetrile is a nontoxic substance if used in proper dosage. 399 F. Supp. at 1214.

20. 582 F.2d at 1237.

21. 479 F.2d 242 (7th Cir. 1973).

22. 327 F. Supp. 386, 387 (N.D. Ill. 1971), *aff'd*, 479 F.2d 242 (7th Cir. 1973).

23. *Id.*

24. 479 F.2d at 250-251.

25. *Id.* at 247-49.

upheld the FDA denial of the plaintiff's new drug application because there was not sufficient evidence to conclude that krebiozen was nontoxic.<sup>26</sup> In contrast, the plaintiffs in *Rutherford* did not file a new drug application with the FDA.<sup>27</sup> Rather, they sought to enjoin the agency from enforcing its interstate ban on the drug.<sup>28</sup> Moreover, the court found laetrile to be nontoxic.<sup>29</sup> Finally, the class of plaintiffs was narrowed to those cancer patients certified to be terminally ill.<sup>30</sup> Given the factual setting of *Rutherford*, the Seventh Circuit might reach a similar result on laetrile without overruling *Durovic*.

Today, many people are questioning orthodox approaches to the treatment of cancer. Cancer patients, however, should be able to take advantage of a drug which has been found to be nontoxic.<sup>31</sup> Personal convictions of a terminally ill cancer patient may not be easily changed by contrary evidence. These convictions have developed in light of conventional methods of treatment. Often orthodox methods and treatments are painful, disfiguring, unpleasant, and involve some risk. Understandably, cancer patients are frustrated and angered when denied the right to choose a potential treatment related to their own healths. These are persons who are terminally ill. Further treatment of these persons should not be precluded by the FFDC Act or FDA action, absent a sufficiently compelling basis.

*Terry Horwath Bitting*

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26. *Id.* at 250-51.

27. 399 F. Supp. at 1212.

28. *Id.* at 1210.

29. *Id.* at 1214.

30. 582 F.2d at 1237.

31. Laetrile was established to be nontoxic in the FDA's records. "Laetrile—Notice of Administrative Rule Making Hearing," 42 Fed. Reg. 10,066, 10,068 (1977).

