Laetrile, legality

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Subject:

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DRUGS--ACT AUTHORIZING PRESCRIPTION OF LAETRILE--DOES NOT AFFECT DUTIES UNDER CH. 500 TO SAFEGUARD PUBLIC FROM HARMFUL DRUGS

To: William J. Page, Secretary, Department of Health and Rehabilitative Services, Tallahassee

Prepared by: Charles S. Ruberg, Assistant Attorney General

QUESTION:

Does Ch. 77-30, Laws of Florida, supersede the provisions of Ch. 500, F. S., so as to permit the marketing of laetrile, or any new drug, in the State of Florida?

SUMMARY:

Chapter 77-30, Laws of Florida, does not supersede the provisions of Ch. 500, F. S., regarding the marketing of laetrile (amygdalin). The applicable rule of statutory construction requires this conclusion because the two enactments have different fields of operation. In the absence of a specific factual context, opinions or comments as to the application of Florida or federal law to the usage, manufacture, or marketing of laetrile (amygdalin) are unwise.

Chapter 77-30, Laws of Florida, creates ss. 458.24 and 459.24, F. S., within Ch. 458, F. S., relating to the licensing of and practice by medical doctors within this state, and Ch. 459, F. S., relating to the licensing of and practice by osteopathic physicians in this state, to read identically as follows:

"(1) No physician licensed under Chapter 458 or 459, Florida Statutes, shall be subject to disciplinary action by the State Boards of Medical Examiners and Osteopathic Medical Examiners for prescribing or administering amygdalin (laetrile) to a patient under his care who has requested the substance unless the State Boards of Medical Examiners and Osteopathic Medical Examiners, in a hearing conducted under the provisions of the Administrative Procedure Act, chapter 120, Florida Statutes, has made a formal finding that the substance is harmful.

(2) The patient, after being fully informed as to alternative methods of treatment and their potential for cure and upon request for the administration of amygdalin (laetrile) by his physician, shall sign a written release, releasing the physician and, when applicable, the hospital or health facility from any liability therefor.

(3) The physician shall inform the patient in writing that amygdalin (laetrile) has not been

approved as a treatment or cure by the Food and Drug Administration of the United States Department of Health, Education and Welfare."

Chapter 77-30, Laws of Florida, also creates s. 395.066, F. S., within Ch. 395, F. S., relating to hospital licensing and regulation, to read:

"No hospital or health facility shall interfere with the physician-patient relationship by restricting or forbidding the use of amygdalin (laetrile) when prescribed or administered by a physician licensed under chapter 458 or 459, Florida Statutes, and requested by a patient unless the substance as prescribed or administered by the physician is found to be harmful by the State Boards of Medical Examiners and Osteopathic Medical Examiners in a hearing conducted under the provisions of the Administrative Procedure Act, chapter 120, Florida Statutes. Furthermore, no hospital or health facility shall remove the staff privileges of a physician solely because said physician prescribed or administered amygdalin (laetrile) to a patient under the conditions set forth in this act."

It is clear from the language of Ch. 77-30, Laws of Florida, and from its title, *i.e.*,

"An Act relating to *prescription and administration of laetrile*, prohibiting hospitals and health facilities from interfering with the physician-patient relationship by restricting use of amygdalin (laetrile); providing conditions; providing for written release; providing for disclosure by the physician; providing an effective date" (Emphasis supplied.)

that this enactment was intended to have a particular filed of operation. More specifically, it operates within the context of the physician-patient relationship by providing protections for those physicians described within the act who may determine that it is appropriate to administer or prescribe a particular substance, *i.e.*, amygdalin (laetrile), to a patient after otherwise complying with the conditions imposed by the enactment.

On the other hand, Ch. 500, F. S., the Florida Food, Drug and Cosmetic Law, has a much broader field of operation. It is an overall statutory scheme intended, *inter alia*:

"(1) To safeguard the public health and promote the public welfare by protecting the consuming public from injury by product use and the purchasing public from injury by merchandising deceit, flowing from intrastate commerce in food, drugs, devices, and cosmetics" [Section 500.02(1), F. S.]

There is some connection between the two enactments, since laetrile (amygdalin) is a drug which could be marketed through intrastate commerce. Nevertheless, I conclude that the acts cover different fields and, therefore, under a long-established rule of statutory construction, the latter enactment does not repeal the former or supersede its provisions, unless the provisions of the latter act are repugnant to the provisions of the earlier act. *See* Scott v. Stone, 176 So. 852, 853 (Fla. 1937).

There can be no repugnancy between the statutory provisions under examination here, because Ch. 77-30, Laws of Florida, does not in any way address itself to the circumstances under which a physician may lawfully obtain laetrile (amygdalin) for the purpose of administering it to a

patient, nor to the circumstances under which a patient may obtain it, upon its being prescribed by a physician.

Consequently, your inquiry must be answered in the negative. Chapter 77-30, Laws of Florida, does not supersede the provision of Ch. 500, F. S. Therefore, laetrile (amygdalin) may not be marketed in the State of Florida unless there is compliance with all applicable provisions of Ch. 500, F. S. In other words, with respect to the requirements of Ch. 500, F. S., laetrile (amygdalin) is in no different posture than any new drug.

As noted above, your letter presents the apparent position of your department that ss. 500.16 and 500.341(6), F. S., prohibit the marketing of laetrile in the absence of a superseding effect from Ch. 77-30, Laws of Florida. I refrain from commenting upon your construction and interpretation of those statutes, for the following reasons.

It is a well-established legal doctrine that, with respect to statutes administered by a public agency, the views of the administrator merit great weight on the basis of the special expertise of the agency, Brennan v. General Tel. Co. of Florida, 488 F.2d 157 (5th Cir. 1973). In addition, your letter presented no factual circumstances nor description of hypothetical or proposed conduct by any person upon which a legal analysis could be made and an opinion offered with respect to the application of the appropriate provisions of Ch. 500, F. S.

Since there is an ongoing public and scientific debate regarding the usage of laetrile (amygdalin), and pending legal proceedings in regard to various aspects of this debate, I believe it unwise to offer opinions or comments as to the applicability of the Florida Food, Drug, and Cosmetics Laws, or analogous federal legislation in the absence of a specific factual context.