453 F.Supp. 1141

United States District Court, M.D. Alabama, Northern Division.
UNITED STATES of America, Plaintiff,
v.
H. Ray EVERS, M. D., an Individual, doing business as Ra-Mar Clinic, Defendant.

Civ. A. No. 78-93-N.

June 27, 1978.

Action was instituted by United States to enjoin alleged mislabeling of drug by licensed physician. The District Court, Varner, J., held that conduct of licensed physician in promoting and administering chelating drug calcium disodium versenate in treatment for arteriosclerosis after utilizing interstate commerce in obtaining drug did not amount to mislabeling in violation of Federal Food, Drug, and Cosmetic Act and, hence, was not subject to being enjoined where approved package insert was silent as to whether drug was indicated or contraindicated for arteriosclerosis and, while weight of medical opinion in United States was that chelation therapy was of no benefit to treatment of arteriosclerosis, there was a school of thought among medical experts in United States and some foreign countries that arteriosclerosis could be satisfactorily treated with chelation therapy.

Complaint dismissed.

Barry E. Teague, U. S. Atty., Kenneth E. Vines, Asst. U. S. Atty., Montgomery, Ala., Richard M. Cooper, Chief Counsel, Robert A. Dormer, Associate Chief Counsel, for Enforcement, Food & Drug Administration, Rockville, Md., for plaintiff.

J. Paul Lowery, Montgomery, Ala., for Evers.

Clifford W. Cleveland, Prattville, Ala., for defendants-intervenors.

MEMORANDUM OPINION AND FINDINGS OF FACT AND CONCLUSIONS OF LAW

VARNER, District Judge.

This cause is submitted upon the pleadings, the briefs, and evidence for final judgment. The Plaintiff, the United States of America, spear-headed by the Federal Drug Administration, filed this proceeding against Dr. H. Ray Evers, a licensed physician in the State of Alabama, alleging (1) that Defendant has been engaged in promoting and administering calcium disodium versenate in treatment for arteriosclerosis; (2) that the labeling of the drug, commonly called the package insert,[FN1] which is prescribed and approved by the Federal Drug Administration, indicates that the drug is recommended for treatment for heavy metal poisons but not for other things here relevant; (3) that patients being treated by the Defendant are subjected to an unwarranted risk of grave physical injury or death as a result of said treatment; and (4) that the promotion and administering of said drug, after having utilized interstate commerce in obtaining the same, amounts to a mislabeling of the drug under the provisions of Title 21, U.S.C. ss 331(k) and 352(f)(1). The Plaintiff contends that using chelating drugs [FN2] in the treatment of arteriosclerosis and other cardiovascular problems creates a use for the drug for which it is not properly labeled, thereby misbranding or mislabeling the drug within the meaning of 21 U.S.C. s 352(f)(1).

FN1. The package insert for calcium disodium versenate (calcium EDTA) provides in pertinent part the following:
WARNING
Calcium Disodium Edetate is capable of producing toxic and potentially fatal effects. The dosage schedule should be followed and at no time should the recommended daily dose be exceeded. In lead encephalopathy avoid rapid transfusion; intramuscular route is preferred.
Indications: Calcium disodium edetate is indicated for the reduction of blood levels and depot stores of lead in lead poisoning (acute and chronic) and lead encephalopathy. It may be worthy of trial in the treatment of poisoning from other heavy metals having a greater affinity for the chelating agent than does calcium.
Adverse Reactions: The principal toxic effect is renal tubular necrosis.

Intravenous Administration: Dilute the 5 ml. (1 gram, 20% Solution) from an ampule with 250-500 ml. of Solution Isotonic Sodium Chloride, USP or sterile 5% Dextrose solution in water. . . . Such doses may be administered twice daily for periods up to 5 days. The therapy should then be interrupted for 2 days and followed by an additional 5 days of treatment if necessary.

FN2. While the Defendant testified that he now chelates his patients with drugs other than the so-called chelating drugs, the weight of the evidence indicated that it is commonly accepted in the medical field that chelating drugs do not include vitamins and minerals with which the Defendant says that he now chelates his patients.

The defense is that Defendant is not using the drug for other than treatment of metal poisoning, its recommended use, and that, in any event, the Defendant is a licensed physician in the State of Alabama and that licensed physicians have a right and a duty to use drugs in prescribing for their patients' usage in accordance with their best judgment as physicians and that the Federal Food and Drug Act does not prohibit a licensed physician's using a drug for a disease or weakness in a patient in any manner which is not contraindicated on the package insert.[FN3]

FN3. The Pure Food and Drug Act requires that drugs be dispensed in interstate commerce only after being accompanied by a package insert which is a memorandum describing the recommended uses for the drugs (indicated uses), dangers associated with its use, and the purposes for which the drug is contraindicated or for which it may have serious effects. The drug here in question, calcium disodium versenate (better known as Calcium EDTA) is neither indicated nor contraindicated on the package insert for treatment of arteriosclerosis.

It is necessary in considering the issues in this case to have at least a lay conception of what the process of chelation amounts to in treatment of heavy metal poisons [FN4] or for arteriosclerosis. Chelation involves intravenous injections in the patient of chemicals which tend to react chemically with the harmful metals which accumulate in and deter passage of blood within the blood vessels. Upon dissolution of these harmful substances by the chemical reaction to the chelating drug, the harmful metals are dissolved and pass out of the body through the kidneys. The danger involved is that too many of such substances may be passed into the kidneys too rapidly and, on occasion, renal poisoning sets in, and kidney failure results in the death of the patient. The danger associated with the harmful metals remaining in the blood vessels is that the blood vessel may become clogged, disallowing free passage of the blood through the blood vessels and cause stroke, diminished ability to reason or remember (senility) because of inadequate blood supply to the brain, gangrene resulting from failure of sufficient blood in the limbs, and various degrees of numbness, dizziness and pain associated with failure of circulation.

FN4. The so-called heavy metals are lead, cadmium, zinc, mercury and iron and, while aluminum is not a heavy metal, aluminum may be considered as such for the purposes hereinafter mentioned as it tends to some extent to be chelated by the processes concerned. Other trace minerals are necessary for proper maintenance of the body. The Defendant contends that a mineral imbalance in the body fluids is harmful and may cause serious developments and that a part of his process is to properly balance the mineral content within the body.

The Defendant explains that his method of chelation originally involved the intravenous injection of a chelating drug (disodium EDTA, which he no longer uses) mixed with vitamins and minerals designed to maintain the strength of the patient and the proper mineral balance within the patient's body. He insists that each patient who comes into his clinic is given extensive tests to determine the mineral (good and bad) content of the body and that he mixes the injectables to replace the needed trace minerals and to dissolve the harmful mineral content in the fluids of the body.

The alternative treatment for arteriosclerosis is by-pass surgery and one danger associated with Defendant's treatment, according to Plaintiff, is that persons will be delayed beyond the point of no return to surgery by first resorting to Defendant's treatment.

The relief sought by the Plaintiff is that this court grant an injunction restraining (1) The receipt or possession of disodium edetate, calcium disodium edetate, or any other drug possessing chelating action by the Defendant; (2) The continuance of administration of chelating therapy by the Defendant; and (3) The allowance of regular inspection of Defendant's clinic by the Federal Drug Administration.

It must be borne in mind that there are a number of things which this suit is not. This is not a suit for malpractice by the Defendant nor a proceeding to enjoin false advertising. It is not a proceeding to cancel the license to practice medicine of the Defendant nor is this court authorized to invoke such a remedy. It is also not a suit challenging the Defendant for failure to use an obvious cure for a known disease or weakness. This is also not an attempt to enjoin Dr. Evers from administering intravenous injections of vitamins and minerals to his cardiovascular or other patients. While the government suggests that this treatment for cardiovascular patients is without value and could be harmful, these concerns are not within the purview of this lawsuit. This court derives its power from the clause of the Constitution granting the

United States authority over interstate commerce and jurisdiction of this court is so limited.

The legal issues presented by this cause, in the opinion of this court, place squarely before this court the question of whether a licensed physician may be enjoined from prescribing for his patients a drug of which the package insert is silent as to whether the drug is indicated or contraindicated for the patient's illness.

Several recognized factors which the court should keep in mind is that the decision making power of a physician may involve a consideration of the possible curative value of not notifying a patient of all of the risks associated with the use of a drug or indicated on the package insert on the drug prescribed for that patient. In the opinion of this court, that decision must be a professional one made by the physician himself. This court finds from the evidence that Dr. Evers, before using EDTA, did not always inform his patients of the risks shown on the package insert to have been associated with the use of calcium EDTA as a chelating agent. The Court will also keep in mind the well-known medical fact proved by several physicians in testimony in this proceeding that, of all patients treated by physicians, a large majority would recover no matter what treatment is provided therefor. However, this majority is obviously not applicable to those suffering from advanced arteriosclerosis wherein the patient may expect an early disabling resulting from stroke, hypertension, heart failure, or other related diseases or cardiovascular problems.

A part of the defense of Dr. Evers is that no scientific person would attempt to chelate for arteriosclerosis with calcium EDTA. The well-supported theory is that calcium is an element which tends to accumulate in the blood vessels and that the calcium in the calcium EDTA would not tend to chemically react with the calcium in the blood vessels materially so as to achieve dissolution of the deposits within the blood vessels commensurate with action by other chelating agents not having high calcium content. However, Dr. Evers admits that, in treating for a metal toxicity, such as lead, patients who also have arteriosclerosis, he has found that chelation with calcium EDTA has proven effective to aid, not only the heavy metal poison but also, the arteriosclerosis. He explains that the metal content of the blockage in the arteries is neutralized by the chelating agent and passes out of the blood and that the calcium deposit remaining in the blood vessels, having lost its mineral structural balance, tends to disintegrate and pass out through the kidneys along with other undesirable elements. He compares it with the failure of a structural building once the metal supports therein have been removed. It is therefore clear that, while Dr. Evers preferred another chelating agent for arteriosclerosis, he admits a large degree of success in

treating arteriosclerosis victims with calcium EDTA. He is now of the opinion that no chelating agent is necessary for arteriosclerosis as the treatment may be accomplished through intravenous injections of minerals and vitamins without a chelating agent. This suit poses no threat to such treatments for arteriosclerosis or other disease.

It is well-established by the evidence in this case and by the package insert that the danger associated with the use of chelating drugs is kidney failure resulting in death. It is therefore not surprising that no former patient of the subject physician survives to testify against his use of chelating drugs. It is also well-established that there have been no controlled scientific tests in this country which have demonstrated that chelation therapy with calcium EDTA has been successful in treatment of cardiovascular disease. However, the favorable lay support of chelating drugs from former patients relieved by the Evers system of the obvious symptoms of arteriosclerosis, together with testimony from a few doctors and osteopaths who have used the treatment, cannot be ignored. Irrespective of the strong medical school of thought that chelation has not been clinically shown to help arteriosclerosis, the weight of the evidence submitted to this court is to the contrary.

While the primary school of thought in the southeast among reputable medical practitioners is that chelation therapy is not a proper treatment for arteriosclerosis and that use of chelating drugs is a dangerous practice which may cause renal failure and death from kidney poisoning, there is clearly a school of thought to the contrary. Several Western physicians and doctors of osteopathy testified to success in chelation therapy for cardiovascular problems and one doctor indicated it to be the preferred treatment in at least one European country. While the Evers school feels that chelation is a proper treatment for arteriosclerosis, they do not question that a potential danger thereof is kidney poisoning if the drugs are not properly administered. They and Dr. Evers insist, however, that they have administered large quantities of the drugs and that, if regular and proper urine analyses [FN5] are maintained and if the patient is taken off the drug if it appears that excessive minerals are accumulating in the kidneys, there is little danger of kidney failure in an otherwise healthy patient. They, of course, recognize that occasionally arteriosclerosis has progressed to such a stage that the patient is extremely weak, advanced in age, or his kidneys are already weak and in such instances the risk of any treatment may exceed the potential value thereof. The problem for the physician, as in most serious cases, is to weigh the possible benefits of treatment against the possible risks. The Defendant insists that chelation therapy is the best treatment for even the more advanced stages of cardiovascular disease and that the risks and the wear and tear on the patient are less than those associated with by-pass surgery.

FN5. Considerable time in this trial was devoted to the question of whether hair analysis is a proper test for determining mineral content of the body. This court is of the opinion that, while hair analysis is not the most complete or reliable test for mineral content, hair analysis, as well as urine and blood analysis, are tests which may be used to gain information as to the needed or harmful minerals in the body.

The first defense is that the defendant uses calcium EDTA only for treatment of heavy metal poisons and has not used it in treatment of purely arteriosclerosis. This court is of the opinion that the weight of the evidence is to the contrary.

Government agents, examining the files of about 600 of the more recent patients treated by Dr. Evers found that the records of the Ra-Mar Clinic, where Dr. Evers practices, indicated that 72 patients had received chelation therapy involving the use of calcium EDTA. Of this group nearly all had a diagnosis of arteriosclerosis but only 31 had a diagnosis or showing of any lead or heavy metal content whatsoever. While Dr. Evers contends that the presence of any amount of the toxic metals shown by analysis justifies treatment thereof, it appears that over 40 of the patients receiving the chelation treatment showed no heavy metal content in the tests shown on their charts. Additionally, it appears that during the time in question, 2,028 grams of calcium EDTA was received by the Ra-Mar Clinic and that patients were usually treated at 1 gram per person per day for 21 days. At the rate of 21 grams per patient for the 31 lead patients, the lead patients would have received a total of 1611 grams of calcium EDTA. With a showing of little calcium EDTA inventory, a difference of about 1017 grams (2628 minus 1611) of calcium EDTA remains unaccounted for. Assuming that patients receive the usual dose of 21 grams per 3-week period, 1017 grams would provide the routine dose (Evers) for approximately 48 patients (1017 grams divided by 21 grams the average dose per patient) who appear to have been chelated with calcium EDTA but whose records of metal poison are unaccounted for. Since the dose is not always the usual, it is reasonable to assume from either of the above calculations that about 40 patients of the 72 who received calcium EDTA, had absolutely no diagnosis of a heavy lead poison. While this court is aware and judicially knows that some mistakes do occur in most records, Dr. Evers, warned by prior problems associated with his insistence upon the propriety of chelation as treatment for arteriosclerosis, could hardly be expected to not understand the value of his keeping records associated with his establishment of proof that a chelating agent was being properly used. The disparity between the nurses' testimony about the incidence of lead poison among

patients, the statements by a few patients that they received chelation therapy from Dr. Evers, and the advertisement by Evers of chelation therapy, are consistent with the availability at Ra-Mar Clinic of chelation therapy for cardiovascular problems. While the FDA has the burden of proof in these cases, the associated facts convince this court that Dr. Evers has offered chelation therapy associated with use of calcium EDTA to arteriosclerosis patients at Ra-Mar Clinic. The Plaintiff contends, and this court has found, that Dr. Evers has during the past two years offered chelation therapy using calcium EDTA as his chelating agent to arteriosclerosis patients at Ra-Mar Clinic, that he has ordered and received interstate shipments of calcium EDTA for use in said treatments during said period of time, and that he has advertised in interstate commerce his use of chelating agents as treatment for arteriosclerosis. It is agreed that chelation therapy with calcium EDTA is neither indicated nor contraindicated on the package label for said drug. While there have been no controlled clinical tests which indicate either the reliability of chelation therapy in treating arteriosclerosis or the danger thereof while properly supervised, the weight of medical opinion in the United States, and almost the unanimous medical opinion in the Southeast, is that chelation therapy is of no benefit for treatment of arteriosclerosis and that such treatment is dangerous both in the fact that it may result in kidney failure and in the fact that it may cause the patient to delay the alternative treatment of by-pass surgery to the extent that the patient may lose his life when proper action might save it.

The court is of the opinion, however, that there is a school of thought among medical experts in this and some foreign countries that arteriosclerosis may be satisfactorily treated with chelation therapy, that the risks when the therapy is properly administered to selected patients are minimal and that in many cases the probable benefits outweigh the probable risks in such treatment. The Evers proponents take some consolation in the fact that the Plaintiff's experts opposing the Evers method rely upon textbook learning whereas the people who have approved the Evers method are people who have had personal experience with chelation following the Evers school of thought and have found it successful even though they do not profess to have conducted any controlled clinical evaluation thereof such as is ordinarily required by the Federal Drug Administration for approval of a new drug.[FN6]

FN6. A new drug is any drug, no matter how aged, which has not been approved for a particular purpose by the Federal Drug Administration and which may be approved only after careful controlled clinical tests wherein it may be carefully compared in results (pro and con) with a selected group of approximately evenly distributed patients some of whom are taking the controlled drug and some of whom are taking some other

> drug of known capacity with all of the patients being deprived of knowledge of matters which might cause psychological involvement and reaction. One objection to running a controlled clinical test on the effectiveness or dangers of chelation is that the patients receiving the negative treatment for a disease such as arteriosclerosis would be slowly dying while their components taking the chelation would be, according to the Evers school of thought, being cured of their arteriosclerosis. Obviously, it would be difficult to obtain the services of a sufficient number of satisfactory arteriosclerosis patients to conduct a controlled test of sufficient size to give satisfactory clinical evaluation of the effect of chelation therapy thereon. The Tuskegee Syphilis tests resulting in millions of dollars worth of suits is an example of the possible consequences of such tests. See Pollard et al. v. U. S., D.C., 69 F.R.D. 646.

The government contends, and most experts agree, that calcium is not a cause of, nor is it universally associated with, the development of arteriosclerosis and that there is no known method of removing calcium from the arterial wall. The Plaintiff's expert physicians, all of whom are competent and well-recognized in this section of the country, disagree with the Evers theory that arteriosclerosis can be cured by removing excess calcium from the arteries. Even the Defendant's witnesses concur that calcium disodium versenate is not the proper chelating agent to remove calcium from the arteries. However, Dr. Evers contends that, while calcium disodium versenate is not the preferred chelating agent, that the minerals are removed by chemical reaction and the washing of the arteries with the compounds of intravenous injectables which he uses and that once the minerals are removed the calcium tends to be removed with them.

In response to Dr. Evers' contention that the Federal Drug Administration has no power to direct how he shall treat his own patients, the government relies upon United States v. Hoxsey Cancer Clinic, 198 F.2d 273 (5th Cir. 1952), in which a layman, Hoxsey, was advertising and shipping drugs in interstate commerce as a cancer cure and the court found that the literature distributed constituted mislabeling of the drugs within the meaning of the act because it contained misleading statements and therefore the drugs were misbranded and Hoxsey was enjoined from the continuation of such interstate commerce. The Hoxsey case is comparable to the instant case in that the Hoxsey Clinic was staffed by licensed physicians but Hoxsey was shipping the drugs in interstate commerce to other than his patients after having advertised them for unapproved usage while Dr. Evers, after having received a drug in interstate commerce, holds them for prescribed use on his patients. As pointed out in Hoxsey,

"We do not attempt to set ourselves up as arbiters of what method of treatment the Hoxsey Clinic should employ. We are not authorized by law to do so. It is our duty to adjudge the merits of the case in light of the provisions of the Federal Food, Drug, and Cosmetic Act, Supra, which closed the channels of interstate commerce against drugs that are misbranded." (At page 281)

The government also relies on the case of United States of America v. An Article of Drug * * * Diso-Tate, Etc., H. Ray Evers, and Medowbrook Hospital, No. 75-1790 (E.D.La., Sept. 28, 1976), in which Judge Gordon enjoined the Defendant in this case from indulging in chelation therapy with disodium edetate as treatment for arteriosclerosis in Louisiana. In that case, Dr. Evers again was advertising in interstate commerce and receiving shipments of drugs to effect the chelation of patients as a treatment for arteriosclerosis. Two obvious differences appeared in that case as compared with the instant case. The drug used for chelation in Louisiana was contraindicated for arteriosclerosis on the label and Dr. Evers himself was not a licensed physician and was operating as a layman in Louisiana. That case, therefore, has limited authority in the instant case. It is notable, however, that that court expressed its concern about any unwarranted interference with the practice of medicine even though Dr. Evers was not licensed to practice in Louisiana at that time.

The government also relies on the cases of United States v. Collier, 5 Cir., 478 F.2d 268, and United States v. Moore, 423 U.S. 122, 96 S.Ct. 335, 46 L.Ed.2d 333. The Collier case is inapplicable in that the physician was charged with distributing a controlled substance in excess of the moderate amount which he might have prescribed for a patient to treat addiction or to relieve conditions of suffering incident to addiction. The court readily recognized that a physician cannot, under the guise of practicing medicine, sell drugs to a dealer or distribute drugs intended to cater to the cravings of an addict. The case of United States v. Moore, supra, is equally inapposite in that the doctor in that case was distributing a controlled substance, an addictive drug used in the treatment of heroin addicts, that he was prescribing large quantities of methadone for patients without giving them adequate physical examinations or specific instructions for its use and that he charged fees according to the quantity of methadone prescribed rather than fees for medical services rendered. The court concluded that he was using his medical license as an excuse for sale of illicit drugs to addicts and was therefore in violation of the law. The statute under which each of these doctors was tried allowed reasonable dispensation of these drugs in question for normal medical practices.

[1] In the opinion of the court the government's strongest position comes

from the Federal Register. 37 Fed.Reg. 16503-05 provides that a physician is not required to file an investigational new drug plan before prescribing an approved drug for non-approved use but that the Food and Drug Administration does have duties when it appears that the unapproved use of an approved new drug becomes widespread or endangers the public's health. When a manufacturer or anyone in the chain of distribution suggests to a patient that an approved drug may properly be used for unapproved uses for which it is neither labeled nor publicly advertised, that action constitutes a violation of the act and is punishable accordingly as a misbranding of the drug. The government contends that a physician or other person who ships or requests shipment of a prescription new drug in interstate commerce with the intent of applying it to an unapproved use, that person must first file with the Food and Drug Administration an investigational new drug plan as set out in 21 CFR, s 312.1.

Nonetheless, if a new drug has been shipped in interstate commerce intended for its approved use, a physician is not required to file an application for a new drug plan if he prescribes the drug as part of the practice of medicine. A possible violation may arise from the purpose of the person causing the drug to be shipped in interstate commerce. The Plaintiff admits that the government cannot regulate the practice of medicine by any licensed physician but it contends that it can prohibit the use of interstate commerce in transportation of drugs for usages not approved by the Federal Drug Administration.

[2][3] Perhaps the government's position is best exemplified by the explanation of the purposes of the Federal Food and Drug Administration's interest in practices such as those enjoyed by Dr. Evers in the Federal Register for August 15, 1972 (Vol. 37, No. 150, P. 16503). That position is that once a drug is in a local pharmacy, after interstate shipment, a physician may, as part of the practice of medicine, lawfully prescribe a different dosage for his patients or may vary the conditions of use from those approved in the package insert, without informing or obtaining the approval of the Food and Drug Administration. Congress did not intend the Food and Drug Administration to interfere with medical practice as between the physician and the patient. Congress recognized a patient's right to seek civil damages in the courts if there should be evidence of malpractice, and declined to provide any legislative restrictions upon the medical profession. It appears to this Court that such a restriction would exceed the powers of Congress. There is no federal prohibition of transportation of an approved drug in interstate shipment with the approved package insert when neither the shipper nor the recipient intends that it be used for an unapproved purpose. If the illegal purpose is devised after termination of interstate shipment, the matter has passed from federal jurisdiction, but jurisdiction may well apply if the shipper or the recipient intends an illegal use at the time of the deposit of

the shipment in interstate commerce.[FN7] Then the act and the illegal intention may coincide so as to furnish federal jurisdiction over interstate commerce.

FN7. No allegation of such conduct appears in the pleadings in this cause, and this Court does not decide any question arising therefrom.

[4] In the case of F.T.C. v. Simeon Management Corporation, 9 Cir., 532 F.2d 708 (1976), the Court pointed out that, if a drug that has FDA approval for specific uses is used by a treating and prescribing physician for an unapproved use, this is not considered a new drug use that would require the physician to file an investigational new drug plan or to submit a new drug application. The Court pointed out that the physician may, as part of the practice of medicine, lawfully prescribe a different dosage for his patient or may otherwise vary the conditions of use from those approved in the package insert without informing or obtaining the approval of the Food and Drug Administration.

Congressional intent set out in 37 Fed.Reg. 16503 (1972) indicates that Congress did not intend the Food and Drug Administration to interfere with medical practice and that the bill did not purport to regulate the practice of medicine as between the physician and the patient.

[5] It is well-recognized that a package insert may not contain the most up-to-date information about a drug and the physician must be free to use the drug for an indication not in the package insert when such usage is part of the practice of medicine and for the benefit of the patient. Hopefully the physician would welcome a well-documented package insert because he finds it useful because the information in it is supported by substantial documented evidence. However, the physician can ascertain from medical literature and from medical meetings new and interesting proposed uses for drugs marketed under package inserts not including the new proposed usages. The package insert's most important educational value derives from the fact that it is a well-reviewed, authoritative document. New uses for drugs are often discovered, reported in medical journals and at medical meetings, and subsequently may be widely used by the medical profession. But the Federal Drug Administration does not permit the package insert to be amended to include such uses unless the manufacturer submits convincing evidence supporting the change. The manufacturer may not have sufficient commercial interests or financial wherewithal to warrant following the necessary procedures to obtain FDA approval for the additional use of the drug. When physicians go beyond the directions given in the package insert it

does not mean they are acting illegally or unethically and Congress did not intend to empower the FDA to interfere with medical practice by limiting the ability of physicians to prescribe according to their best judgment. See FDA Consumer, November 1975, page 7.

The Supreme Court, in Linder v. U. S., 268 U.S. 5, 45 S.Ct. 446, 69 L.Ed. 819 (1925), stated the following:

"Obviously, direct control of medical practice in the States is beyond the power of the federal government. . . . It (the statute) says nothing of 'addicts' and does not undertake to prescribe methods for their medical treatment. They are diseased and proper subjects for such treatment, and we cannot possibly conclude that a physician acted improperly or unwisely or for other than medical purposes . . . . What constitutes bona fide medical practice must be determined upon consideration of evidence and attending circumstances." 268 U.S. at 18, 45 S.Ct. at 449.

The courts have rather uniformly recognized the patients' rights to receive medical care in accordance with their licensed physician's best judgment and the physician's rights to administer it as it may be derived therefrom. See Doe v. Bolton, 410 U.S. 179, 197, 93 S.Ct. 739, 35 L.Ed.2d 201 (1973); Whalen v. Roe, 429 U.S. 589, 97 S.Ct. 869, 51 L.Ed.2d 64 (1977). The Supreme Court in Doe v. Bolton, supra, observes that if a physician is licensed by the state, he is recognized by the state as capable of expressing acceptable clinical judgment. If he fails in this, professional censure and deprivation of his license are remedies available and reliance must be placed on the assurance given by his license that he possesses the requisite qualifications. Obviously the physician's failures are also subject to the ever increasing possibilities of malpractice suits in current times. In People v. Privitera, Cal.App., 141 Cal.Rptr. 764, 774 (1977), the court in approving the patient's right to an abortion prescribed by her physician stated that,

"To require prior State approval before advising prescribing administering a new treatment modality for an informed consenting patient is to suppress innovation by the person best qualified to make medical progress. The treating doctor, the clinician, is at the cutting edge of medical knowledge. To require the doctor to use only orthodox 'State sanctioned' methods of treatment under threat of criminal penalty for variance is to invite a repetition in California of the Soviet experience with Lysenkoism. The mention of a requirement that licensed doctors must prescribe, treat, 'within State sanctioned alternatives' raises the spector of medical stagnation at the best, statism, paternalistic big brother at worst. It is by the alternatives to orthodoxy that medical progress has been made. A free, progressive society has an enormous stake in recognizing and protecting this right of the physician."

[6] This court is, therefore, of the opinion from the pleadings, the evidence and the authority presented to it that Dr. Evers is not misbranding the drug in question and that the relief prayed by the plaintiff should be denied. Judgment will enter in accordance with this memorandum opinion.