

1976 S.C. Op. Atty. Gen. 358 (S.C.A.G.), 1976 S.C. Op. Atty. Gen. No. 4499, 1976 WL 23116

Office of the Attorney General

State of South Carolina

Opinion No. 4499

OCTOBER 21, 1976

\*1 South Carolina Code §§ 32–1510.83 and 32–1510.84 are not affected by a recent Federal Court decision.

TO: William L. Belvin, Jr.

South Carolina Council for Control of Methadone Programs

QUESTIONS PRESENTED:

1. Does the decision of the United States District Court in American Pharmaceutical Association v. Weinberger, take precedence over South Carolina Code §§ 32–1510.83 and 32–1510.84?
2. Does the phrase ‘other such uses as may be approved’ (S.C. Code § 32–1510.83) imply that dispensing of methadone by a community pharmacy may be an acceptable practice notwithstanding S. C. Code § 32–1510.84?

AUTHORITIES:

South Carolina Code §§ 32–1510.83 and 32–1510.84 (1975 Cumulative Supplement);

[American Pharmaceutical Association v. Weinberger](#), 377 F. Supp. 824 (D.C. 1974); affirmed 530 F.2d 1054 (D.C. Cir. 1976);

21 Code of Federal Regulations, Part 310;

[21 U.S.C. § 301](#), et seq.;

[21 U.S.C. § 801](#), et seq.

DISCUSSION:

The order of the United States District Court for the District of Columbia in the case of American Pharmaceutical Association v. Weinberger, *supra*, invalidated certain regulations of the Food and Drug Administration (FDA). These regulations purported to restrict distribution of methadone to direct shipments from the manufacturer to approved maintenance treatment programs, approved hospital pharmacies, and in cases where hospital pharmacies were unavailable in a particular area, to selected community pharmacies.

Does this decision affect South Carolina Code § 32–1510.84 (1975 Cumulative Supplement)? Section 32–1510.84 provides:

No supplier, distributor or manufacturer shall sell or distribute methadone or its salts to any person other than a hospital licensed by the State Board of Health, the State Department of Mental Health and any facility licensed or approved by the State Department of Mental Health or any facility approved for a methadone program by the Council.

The answer is no.

The Federal Court decision was not based on the reasonableness of such restrictions, but rather on the lack of Congressional authority for the FDA to regulate the distribution of such drugs. The Court found that the FDA under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301, et seq.) has the power to determine which drugs are permitted to enter the flow of commerce. However, once a drug is cleared for marketing by the FDA, the question of permissible distribution of the drug, if it is a controlled substance, is within the jurisdiction of the Justice Department under the Comprehensive Drug Abuse Prevention and Control Act of 1970. (21 U.S.C. § 801, et seq.).

The Comprehensive Drug Abuse Prevention and Control Act of 1970 specifically recognizes the authority of state and local government in the distribution of controlled substances. Persons seeking federal registration as a distributor of Schedule II Controlled Substances (which includes methadone) must comply with applicable State and local law. 21 U.S.C. § 823(b)(2). Therefore, S. C. Code § 32–1510.84 is unaffected.

\*2 The next question involves South Carolina Code § 32–1510.83, which provides:  
Methadone and its salts are hereby restricted:

(a) To use in treatment, maintenance or detoxification programs and facilities approved by the Council;

(b) To use in a hospital for analgesia, pertussis, and detoxification programs as approved by the Council, or other such uses as may be approved by the Food and Drug Administration, United States Department of Health, Education, and Welfare.

Does the phrase ‘other such uses as may be approved by the Food and Drug Administration’ imply that dispensing of methadone by a community pharmacy may be an acceptable practice within the scope of the law? Here again, the answer is no.

In the first place, the FDA has not approved the distribution of methadone to community pharmacies for analgesic use. It simply has withdrawn regulations prohibiting it because of a Federal Court decision. Secondly, statutory construction of Sections 32–1510.83 and 32–1510.84 will not permit this interpretation of the word ‘uses’. Distribution of methadone is addressed directly in Section 32–1510.84.

#### SUMMARY:

In summary the recent changes to the federal regulations affecting methadone (21 CFR §§ 310.304, & 310.505), and the court decision prompting them, do not affect state laws further restricting the distribution of methadone.

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