1975 WL 29070 (S.C.A.G.)

Office of the Attorney General

State of South Carolina
August 13, 1975

***1** THE SUBSTITUTION OF ALTERNATIVE BRANDS OF THE SAME GENERIC DRUG, IN AND OF ITSELF, DOES NOT CONSTITUTE MISBRANDING SO AS TO VIOLATE SECTION 32-1510.104(a) and (i) OR SECTION 32-1510.105(b) OF THE 1962 CODE, AS AMENDED.

TO: Thomas D. Wyatt, Jr., R.Ph.
Director
Narcotic and Drug Control Division

QUESTION PRESENTED:

Whether the substitution by a pharmacist of alternative brands of the same generic drug, without more, violates the provisions of Sections 32-1510.104(a) and (i) and Section 32-1510.105(b) of the 1962 Code, as amended, prohibiting the misbranding of drugs?

STATUTES, CASES, ETC., INVOLVED:

Statutes: The South Carolina Drug Act, as presently amended (Section 32-1510.101 et seq. of the 1962 Code, as amended); The South Carolina statutes governing Narcotics and Controlled Substances, as presently amended (Section 32-1510.21 of the 1962 Code, as amended); The Federal Food, Drug and Cosmetic Act, as presently amended (21 U.S.C. § 301 et seq., as amended).

Cases: Abbott Laboratories v. Celebrezze, 352 F.2d 286 (1965); De Freeze v. United States of America, 270 F.2d 730 (1959); U.S. v. Articles of Drug, etc., 263 F.Supp. 212 (DC Neb. 1967); U.S. v. Carlisle, 234 F.2d 196 (1956); U.S. v. Hoxsey Cancer Clinic, 94 F.Supp. 464 (DC Tex. 1950); U.S. v. One Device, More or Less, Ellis Micro-Dynameter, 224 F.Supp. 265 (DC Pa. 1963); U.S. v. 2000 Plastic Tubular Cases, More or Less, Toothbrushes, 231 F.Supp. 236 (DC Pa. 1964); U.S. v. 39 Bags, More or Less, 'Elip Tablets,' 150 F.Supp. 648 (DC N.Y. 1957).

Position Papers: Various Position Papers of the Federal Food and Drug Administration.

DISCUSSION OF ISSUES:

The South Carolina Drug Act was enacted in 1972 by the South Carolina General Assembly. The language of the Drug Act, in substance, parallels that of the related sections in the Federal Food, Drug and Cosmetic Act. More precisely, with a few minor exceptions, the language of Sections 502 and 503 of the Federal Act (21 U.S.C. §§ 352-353) is identical to the language of Sections 32-1510.104 and 32-1510.105 of the 1962 Code, as amended. Consequently, the Federal cases relating to the misbranding of drugs serve as appropriate guides in the discussion of the issue presented.

At the outset, attention should be given to the differentiation between different drugs and different brands of the same drug. The South Carolina Drug Act defines 'drug' as follows:
(A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and,

(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and,

(C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and,

(D) articles intended for use as a component of any articles specified in clause (A), (B), or (C); but does not include devices or their components, parts, or accessories.

***2** Section 32-1510.102(b) of the 1962 Code, as amended.

The definition of 'drug' in the Narcotics and Controlled Substances Law, at Section 32-1510.27 of the 1962 Code, as amended, is worded substantially similar to the language of the Drug Act set forth above.

In the Narcotics and Controlled Substances Law, the various controlled drug substances are classified into several schedules, depending on the need for management of the handling of the substances. Within the given schedules, the drugs are referred to by their 'generic' names. The drug's 'generic' name may be either the chemical name, the common name, or the official name used in official compendiums. Abbott Laboratories v. Celebrezze 352 F.2d 286 (1965), rev'd on other grounds at 87 S.Ct. 1507, 387 U.S. 136 (1967). Also see, U.S. v. Article Consisting of 36 Boxes, etc., 286 F.Supp. 107, 111 (1968). The generic name, then, is that name which is common to all drug substances having the same chemical composition.

Substitution of drugs involves the replacement of one brand of a given generic drug with another brand of that same drug. It does not involve the substitution of one generic drug for another generic drug.

I. Misbranding under Section 32-1510.104(a) and (i) of the 1962 Code, as amended.

To analyze the permissibility of the substitution of drugs under the S.C. Drug Act, it is appropriate to discuss the specifics of the applicable statutory provisions. Section 32-1510.108 of the 1962 Code, as amended, makes unlawful the following: (1) the introduction or delivery for introduction of misbranded drugs into commerce within the State;

(2) the misbranding of drugs in intrastate commerce;

(3) the receipt in intrastate commerce of misbranded drugs when coupled with attempts to deliver the drugs for pay; and,

(4) the manufacture of misbranded drugs within the State.

The penalties for violation of these restrictions are set forth in Section 32-1510.109 of the 1962 Code, as amended.

The circumstances which the General Assembly considered to create 'misbranding' are set forth in Section 32-1510.104 of the 1962 Code, as amended. Basically, misbranding occurs in eleven situations. For the purposes of this discussion, however, only two situations appear relevant. Those criteria are set forth in Section 32-1510.104(a) and Section 32-1510.104(i) of the 1962 Code, as amended.

Section 32-1510.104(a) directs that a drug is misbranded when its 'label' is either false or misleading in any particular. 'Label' is defined at Section 32-1510.102(e) of the 1962 Code, as amended, in language identical to that of the Food, Drug, and Cosmetics Act at 21 U.S.C. § 321(k). At least one Federal District Court has held that allegedly false material relating to a drug need not be on the container in order to constitute misbranding. The information may in fact reach the user either by accompanying the drug or by some other manner. U.S. v. Hoxsey Cancer Clinic, 94 F.Supp. 464 (DC

Tex. 1950), rev'd on other grounds at 198 F.2d 273 (1952). As to misleading material, several cases have held that it is sufficient to constitute misleading material if any one claim in the labeling was misleading. Consider: U.S. v. 2000 Plastic Tubular Cases, More or Less, Toothbrushes, 231 F.Supp. 236 (DC Pa. 1964), aff'd at 352 F.2d 344 (1965), and U.S. v. One Device, More or Less, Ellis Micro-Dynameter, 224 F. Supp. 265 (DC Pa. 1963).

***3** The Federal District Court in Nebraska issued some guidelines for establishing information as misleading in U.S. v. Articles of Drug, etc., 263 F.Supp. 212 (DC Neb. 1967). The determinative factors included the effect that the label and labeling will have on prospective purchasers. In 1957, the District Court of New York indicated that a drug was misbranded for purposes of the Federal Act if the labeling were false or misleading or if the labeling failed to provide adequate warnings as to the use of the drug. U.S. v. 39 Bags, More or Less, 'Elip Tablets,' 150 F.Supp. 648 (DC N.Y. 1957).

As relates to misbranding within Section 32-1510.104(a) of the 1962 Code, as amended, the law suggests that so long as the brand of a generic drug to be substituted for another brand of the same generic drug is not mislabeled or labeled in a false or misleading fashion, the substitution does not constitute misbranding.

It should be noted that the related Federal section, 21 U.S.C. § 352, also known as the Durham-Humphrey Amendment of 1951, has consistently been interpreted by the Food and Drug Administration as not comprising a Federal anti-substitution law. The interest of consistency in construction of the similar statutory language in the Federal and the State law adds another argument against viewing Section 32-1510.104(a) and (i) of the 1962 Code, as amended, as a State anti-substitution statute.

Section 32-1510.104(i) provides that a drug is deemed misbranded—
(1) If it is a drug and its container is so made, formed, or filled as to be misleading; or,

(2) If it is an imitation of another drug; or,

(3) If it is offered for sale under the name of another drug.

Assuming that the drug and its container are properly formed and filled, the question under this section then becomes whether substitution of one brand of a generic drug for another brand of the same generic drug constitutes either 1) the imitation of another drug, or 2) the offer for sale under the name of another drug. So stated, the question suggests the answer. Both brands are of the same generic drug, so that substitution, alone, does not amount to imitation of another drug or to an offer for sale under the name of another drug. If the second brand was not, in fact, of the same generic drug as the first, then a different result would presumably follow.

II. Misbranding under Section 32-1510.105(b) of the 1962 Code, as amended.

The South Carolina Drug Act also provides that the dispensation of a drug without a necessary prescription constitutes misbranding of the drug while held for sale. See Section 32-1510.105(b) of the 1962 Code, as amended. The circumstances where the prescription of a practitioner is requisite are set forth in Section 32-1510.105(b)(1). That sub-section also sets the conditions for the dispensation of a prescription drug.

In addition, Section 32-1510.105(b)(4) directs that a prescription drug is deemed misbranded if, at any time prior to dispensing, its label does not include the language 'Caution: Federal law prohibits dispensing without prescription.' Similarly, a non-prescription drug is misbranded if its label does contain this language.

***4** As was true in relation to Section 32-1510.104(a) and (i), the language of Section 32-1510.105(b) is substantially similar to the comparable section of the Federal Act, Section 503(b) or 21 U.S.C. 353(b). For Federal court cases enforcing the provisions of 21 U.S.C. 353(b), see U.S. v. Carlisle, 234 F.2d 196 (1956), cert. den'd, 77 S.Ct. 63, 352 U.S. 841 (1956) and De Freeze v. U.S.A., 270 F.2d 730 (1959).

As relates to the South Carolina version of that section, specifically Section 32-1510.105(b), the language does not prevent the substitution of one brand of a generic prescription drug for another brand of the same generic prescription drug. Presumably, if the provisions of the section are otherwise complied with by the pharmacist, the simple act of such substitution alone would not constitute misbranding within the S.C. Drug Act.

III. Food and Drug Administration—Statement of Position relating to construction of the Food, Drug and Cosmetics Act in light of the substitution of drugs.

By letter dated June 16, 1975, Richard A. Merrill, Chief Counsel of the Food and Drug Administration, forwarded copies of letters relating to this matter which were initially issued by his predecessor as Chief Counsel, Peter Barton Hutt. This information was forwarded to Thomas D. Wyatt, Jr., Director of the Narcotic and Drug Control Division of the South Carolina Department of Health and Environmental Control.

The first correspondence, dated April 15, 1975, is between Mr. Hutt and Mr. William E. Woods, Washington Representative and Associate General Counsel of the National Association of Retail Druggists. The gist of the letter is that, while section 503(b) of the Food, Drug and Cosmetic Act provides that a drug containing the required prescription legend may be dispensed only by prescription, that Section does not deal with the question of substitution of one brand of a generic prescription drug for another brand of the same generic prescription drug presented with the necessary prescription.

The second correspondence, dated May 12, 1975, is between Mr. Hutt and Professor Sidney H. Willig of the Temple University School of Law. This letter restates the position adopted in the April 15 correspondence and also discusses Section 502 of the Food, Drug and Cosmetic Act. In summary, the May 12 letter opines that, so long as the label attached to the substituted brand accurately describes the drug, Section 502(a) is not violated. Section 502(i)(1) is not violated by mere substitution of different brands of the same generic drug, providing that the containers are properly made, formed or filled. Similarly, Section 502(i)(2) is not violated because both brands represent the same generic drug. Finally, Mr. Hutt concludes that, so long as the drugs are only offered for sale under the name of the proper generic drug, Section 502(i)(3) is not violated.

These letters, taken together and as official position expressions of the Food and Drug Administration, offer substantial support for the conclusion that the similar language in the South Carolina Drug Act does not create a State anti-substitution law.

CONCLUSION:

***5** Thus, the question of the permissible substitution of drugs narrows itself into one of whether one brand of a given generic drug may be substituted for another brand of the same generic drug. If the substitution does not otherwise violate Section 32-1510.104 or Section 32-1510.105(b), then substitution alone would not contravene Sections 32-1510.104(a) and (i) and 32-1510.105(b). Consequently, substitution in those circumstances would not amount to 'misbranding' within the meaning of the South Carolina Drug Act.

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