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Food, Drug, and Cosmetic Law (1959)

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FOOD, DRUG, AND COSMETIC LAW

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LEGISLATIVE and administrative activities, rather than judicial developments, have taken the forefront of progress in Food and Drug law for 1959. New color additive legislation appears imminent and necessary because of the strict regulatory actions instituted pursuant to the Supreme Court's pronouncements in the *Florida Citrus* case. An administrative press release concerning contaminated cranberries precipitated a major industry crisis as well as questions of unique legal significance. Implementation of the 1958 Food Additives Amendment continued its pioneering course, especially in its application to packaging.

Color Additives.—Under the existing coal-tar color provisions of the Federal Food, Drug and Cosmetic Act as interpreted by the Supreme Court in *Flemming v. Florida Citrus Exchange*,¹ the Food and Drug Administration is without power to set safe limits of use for colors found not to be harmless for unrestricted uses. Consequently, a substantial number of commercial colors are being delisted and, with the use of newer scientific procedures in re-examining previously certified colors, further delistings may be expected.² The administration cannot certify the absolute safety of a color while there is even a remote degree of toxicity in any quantity of use.

Intended in part to remedy this stunted application of the law, a new color additive bill has been passed by the Senate and is awaiting action in the House.³ The House bill contains the controversial "De-

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¹ 358 U.S. 153, 2 CCH Food Drug Cosm. L. Rep. ¶ 7468 (1958).

² Four yellow coal-tar colors were delisted for unrestricted use on Feb. 6, 1959, although their external use in drugs and cosmetics may be authorized. 24 Fed. Reg. 883 (1959). The use of Citrus Red No. 2 to color the skins of oranges has been authorized from May 1, 1959 to Sept. 1, 1961. 73 Stat. 3, amending 21 U.S.C. § 342(c) (1958). On April 15, 1959, a proposal was made to remove seventeen colors used principally in lipsticks from the approved unrestricted cosmetic list. 24 Fed. Reg. 2873 (1959). The most recent proposal, 24 Fed. Reg. 8503 (1959), would delist F.D. & C. Orange Nos. 3 and 4.

³ S. 2197, 86th Cong., 1st Sess. (1959), was passed on August 24, 1959, 105 Cong. Rec. 15394 (daily ed. Aug. 24, 1959); H.R. 7624, 86th Cong., 1st Sess. (1959), was referred to the House Committee on Interstate & Foreign Commerce, 105 Cong. Rec. 15558 (daily ed. Aug. 25, 1959).

laney Cancer-Clause,"⁴ but in other respects is the same as the Senate's. If enacted, the bills will provide generally for: (1) extension of the current act's provisions (including certification procedures) to noncoal-tar as well as coal-tar colors, (2) the setting of safe tolerance levels and uses, (3) pretesting and safety clearance requirements.⁵

Informational Releases.—In a statement by the Secretary of Health, Education and Welfare released at a pre-Thanksgiving Day news conference, a warning was issued concerning the contamination of cranberries by the possibly carcinogenic weed-killer, Aminotriazole.⁶ This action, authorized by the statute⁷ and established in past practice, had far-reaching effect upon the public and the subject industry, and has drawn considerable attention toward this formidable power of "regulation by press release." Such news releases can have the substantial effect of a multiple seizure. Questions have been raised as to the practical limits of this administrative sanction and the availability of legal redress should such discretionary power be ever abused.⁸

Another aspect of the cranberry episode was the refusal of the administration to establish a tolerance for any amount of the carcinogene, even though the Pesticides Amendment⁹ (which, unlike the Food Additives Amendment, contains no "cancer-clause") was applicable to the cranberries. The Secretary explained the refusal by stating that "while in theory there may be a minute quantity of a carcinogene which is safe in foods, in actuality our scientists do not

⁴ The cancer provision inserted in the 1958 Food Additives Amendment, 72 Stat. 1785, 21 U.S.C. § 348(c)(3)(A) (1958), through the efforts of Congressman James J. Delaney, reads in part that no additive shall be deemed safe, "if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal"

⁵ See S. Rep. No. 795, 86th Cong., 1st Sess. (1959).

⁶ Statement by Arthur S. Flemming, Secretary of Health, Education and Welfare, at a news conference, Washington, D.C., Nov. 9, 1959, 2 CCH Food Drug Cosm. L. Rep. ¶ 7532 (1959).

⁷ "The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health or gross deception of the consumer." 52 Stat. 1058 (1938), 21 U.S.C. § 375(b) (1958).

⁸ In *Hoxsey Cancer Clinic v. Folsom*, 155 F. Supp. 376, 2 CCH Food Drug Cosm. L. Rep. ¶ 7417 (D.D.C. 1957), plaintiff argued that public warnings against use of his cancer treatment, issued pursuant to the act, were unconstitutional because the act did not provide him with a hearing prior to the issuance of the warnings. The court upheld the act and held the Secretary had inherent power to warn the public even without the act. In dicta the court suggested plaintiff's only remedy would be an action for damages for libel.

The recent decisions of *Barr v. Matteo*, 360 U.S. 564 (1959), and *Howard v. Lyons*, 360 U.S. 593 (1959), according absolute privilege even to lower executive officers for defamation, cast serious doubt on the availability of any remedy at all. See Oberst, 35 N.Y.U.L. Rev. 502 (1959).

⁹ 68 Stat. 511 (1954), 21 U.S.C. § 346(a) (1958).

know whether this is true or how to establish a safe tolerance.”¹⁰ The Secretary indicated further that he would “oppose any attempt to take the cancer clause out of the Food Additives Amendment, and . . . [would] support the inclusion of such a clause in the color bill which is now before the Congress.”¹¹

At this writing, the cranberry situation has been resolved by announcement of a “Cranberry Certification Plan” whereby Government approved safety testing procedures are being carried out by industry, and cleared lots will be authorized to bear official safety certification statements on their containers.¹²

Food Additives.—Definitions and Procedural and Interpretive Regulations which implement the requirements of the Food Additives Amendment were issued this year.¹³ Included therein is the list of additives which are exempted from tolerances because of the general recognition of their safety (“GRAS”) for their specified uses. “GRAS” is crucial because it is the starting point¹⁴ to whether a substance shall be subjected to the act. Who shall be the “experts qualified by scientific training and experience to evaluate” safety and what shall be the criteria whereby their opinions of safety become a “general recognition” poses the initial issue for determination.

For additives in use prior to 1958, “experience in common use in food” may be considered as well as “scientific procedures”; but new additives must be pretested for safety before use. In evaluating the safety tests the administration will consider again the opinions of experts, cumulative effects in the diet, and the probable consumption of the additive. No safety tolerance will issue where the cancer-clause applies¹⁵ or where the proposed use will “promote deception of the consumer”; nor where the data does not “establish that such use would accomplish the intended physical or other technical effect.” Litigation will probably settle the interpretation of the quoted phrases although the amendment is clearly concerned with safety rather than functional values. The Secretary should not pass on the benefits of

¹⁰ 2 CCH Food Drug Cosm. L. Rep. ¶ 7532 (1959).

¹¹ *Ibid.*

¹² Statement by Secretary Flemming, Nov. 19, 1959, 2 CCH Food Drug Cosm. L. Rep. ¶ 7534 (1959).

¹³ 24 Fed. Reg. 2434 (1959).

¹⁴ See Goodrich, *The Beginning Point Under the Food-Additives Amendment—What Substances Do Qualified Experts Generally Recognize as Safe?*, 14 Food Drug Cosm. L.J. 584 (1959).

¹⁵ In tests of twenty-four waxes used for milk cartons, it has been shown that one wax contained a known carcinogene which produces cancer in laboratory animals. The studies are not final and no action has yet been taken. Statement by Secretary Flemming, Nov. 10, 1959, 2 CCH Food Drug Cosm. L. Rep. ¶ 7532 (1959).

an additive, but merely determine whether it will do what the petitioner proposes it to do.¹⁶

Chemicals used in the production of containers and packages are subject to the testing and other requirements of the act if they may reasonably be expected to become a component, or to affect the characteristics of food, as by "migration" of the substance from the package to the food. The scientific problems here are vast and complicated. Migrations will vary as to the types and state (frozen, liquid, etc.) of food, the types of packages, storage conditions and other factors. Safety tests for each condition will present a time-consuming task entailing high costs which surely are quite beyond the range of smaller businesses.¹⁷

State Legislation.—Four states this year enacted basic Food and Drug legislation patterned in whole or in part on the 1938 Federal Food, Drug and Cosmetic Act.¹⁸ In addition, the proclamation of the statehood of Alaska added another Copeland-type statute¹⁹ to the final total of thirty-one states.

Interrogatories in Seizure Actions.—Under the Federal Food, Drug and Cosmetic Act the Government may institute both an in rem action against adulterated or misbranded goods and criminal proceedings against anyone who shares in the responsibility for the distribution of the violative product. *United States v. 49 Jars . . . Tranquilease*²⁰ considered whether a corporation could escape answering written interrogatories under Federal Rule of Civil Procedure 33 because the individual chosen to answer elected to protect himself through the fifth amendment, since the act of answering might tend to make him a "responsible person"²¹ and amenable to the criminal sanctions of the act. The court held, in an equitable solution, that the corporation must answer, but that it should select someone to answer

¹⁶ See Oser, Recent Developments on the Food Additives Front, 14 Food Drug Cosm. L.J. 254 (1959).

¹⁷ See Kaufman, Food Packaging and the 1958 Food Additives Amendment, 14 Food Drug Cosm. L.J. 649 (1959).

¹⁸ Idaho Sess. Laws Reg. Sess. 1959, ch. 153; Ill. Ann. Stat. ch. 56½, § 40 (Smith-Hurd Supp. 1959); R.I. Pub. Laws 1959, ch. 56; Vt. Stat. Ann. tit. 18, §§ 4051-71 (Supp. 1959).

¹⁹ Alaska Comp. Laws Ann. § 40-5A-1 (Supp. 1958).

²⁰ 23 F.R.D. 192, 2 CCH Food Drug Cosm. L. Rep. ¶ 7463 (D.D.C. 1958). Two other cases adopted the same approach. *United States v. 42 Jars . . . "Bee Royale Capsules"*, 264 F.2d 666, 2 CCH Food Drug Cosm. L. Rep. ¶ 7478 (3d Cir. 1959); *United States v. 3963 Bottles . . . Enerjol*, 265 F.2d 332, 2 CCH Food Drug Cosm. L. Rep. ¶ 7489 (7th Cir.), cert. denied, 360 U.S. 931 (1959).

²¹ See *United States v. Dotterweich*, 320 U.S. 277 (1943). See also *United States v. Parfait Powder Puff Co.*, 163 F.2d 1008 (7th Cir. 1947), cert. denied, 332 U.S. 851 (1948).

who had in no way participated in the questionable transaction.²²

Prosecution of Physicians.—In *Brown v. United States*,²³ reported herein last year, the prosecution of a licensed physician for selling prescription drugs without a prescription was upheld by the Fifth Circuit. A similar case arose before it again this year. In *De Freese v. United States*²⁴ the defendant physician sold barbituates in lots of between five and twenty thousand pills to an FDA inspector posing as a truck driver. The defendant contended on appeal from his conviction that section 503(b)(1) applied only to the retail sale of drugs. De Freese maintained that he was operating as a wholesaler and, since the statute provides that barbituates “shall be dispensed” only upon prescription, his operations were outside the prohibition.

The court held, however, that the act covered both the retail and wholesale levels. It answered the charge that such a holding would require prosecution of all wholesale distributors by reference to section 353(b)(3) which authorizes the Secretary to issue regulations dispensing with the requirements of these provisions when such requirements are not necessary for the public health.

In a companion case²⁵ bearing the same name the court held that the Government’s burden of proving an interstate shipment was satisfied by the testimony of an expert witness that the drug was produced in a jurisdiction different from that in which the prohibited sale took place. This fact was demonstrated by identification of microscopic markings on the tablets which exhibit, in effect, the “fingerprints” of each company’s stamping machine.

Administrative Res Judicata.—Since jurisdiction over foods, drugs, and cosmetics is divided among several federal agencies, it is natural to expect the question of res judicata to be raised. During the past year two cases, *United States v. 42 Jars . . . “Bee Royale Capsules”*²⁶ and *United States v. 3963 Bottles . . . Enerjol*,²⁷ were decided in which action by the Post Office Department was held not to foreclose subsequent proceedings by the Food and Drug Administration involving the same product. But, in *United States v. One Carton, More or*

²² This solution poses no particular difficulty, since Rule 33 does not require the answerer to have personal knowledge of the facts. 4 Moore, Federal Practice ¶ 33.07, at 2277 (2d ed. 1950).

²³ 250 F.2d 745, 2 CCH Food Drug Cosm. L. Rep. ¶ 7426 (5th Cir.), cert. denied, 356 U.S. 938 (1958), 34 N.Y.U.L. Rev. 244, in 1958 Ann. Survey Am. L. 211 (1959).

²⁴ 270 F.2d 730, 2 CCH Food Drug Cosm. L. Rep. ¶ 7517 (5th Cir. 1959).

²⁵ *De Freese v. United States*, 270 F.2d 732, 2 CCH Food Drug Cosm. L. Rep. ¶ 7518 (5th Cir. 1959).

²⁶ 264 F.2d 666, 2 CCH Food Drug Cosm. L. Rep. ¶ 7478 (3d Cir. 1959).

²⁷ 265 F.2d 332, 2 CCH Food Drug Cosm. L. Rep. ¶ 7489 (7th Cir.), cert. denied, 360 U.S. 931 (1959).

Less,²⁸ where the Government contended that a judgment in a criminal action should be res judicata in a subsequent seizure action against the product upon which the criminal prosecution had been based, the Government prevailed.

Claimant's position was weak in both the *Bee Royale* and *Enerjol* cases. As a result of proceedings by the Post Office Department, agreements had been signed whereby certain claims were no longer to be made for the product. It was noted in the *Bee Royale* case that the claimant in the seizure action was not the same party who entered into the Post Office settlement and that no privity between the two had been shown. This, in addition to the reluctance of the court to consider the two governmental agencies in privity, constituted the rationale of the opinion. In the *Enerjol* case the court referred to a clause in the prior settlement which stated that "its filing will not act as a defense or relieve the undersigned [claimant's president] of responsibility for violation of any other statute." This provision, in conjunction with the fact that the issues to be determined under the two statutes were different, led the court to distinguish the cases of *United States v. Willard Tablet Co.*²⁹ and *George H. Lee Co. v. FTC*,³⁰ and to find that there was no bar to the FDA action.

²⁸ 2 CCH Food Drug Cosm. L. Rep. ¶ 7492 (N.D. Ill. 1959).

²⁹ 141 F.2d 141 (7th Cir. 1944).

³⁰ 113 F.2d 583 (8th Cir. 1940).