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Food, Drug, and Cosmetic Law (1958)

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FOOD, DRUG, AND COSMETIC LAW

FREDERICK M. HART

I

LEGISLATION¹

Seized Imports.—The legislative history of the Federal Food, Drug, and Cosmetic Act² is replete with instances of long and intense controversy. It is refreshing that in 1957 the Dollinger Amendment³ was passed with the support of both the Food and Drug Administration and the affected industries. Under the amendment two avenues are open to the importer whose goods are seized and condemned. If he can show that the violation did not occur after the article was imported and that he had no reason to believe that it was violative before it was released from customs, he may elect either to return it immediately to the original foreign supplier, or to label it for export and send it to a purchaser in any foreign country where it meets local standards. The amendment does not apply to articles containing natural or added poisonous or deleterious substances, or to drugs which would be dangerous when used as recommended on the label. This qualification is designed to eliminate potential harm to foreign consumers.⁴

Chemical Additives.—The unanimity of support which characterized the passage of the aforementioned Dollinger Amendment affords sharp contrast to the fight being waged over a proposal providing for governmental control of chemical food additives. Areas of disagreement include the scope of judicial review to be afforded agency decisions, and the question whether the Government should have the authority to reject an additive, admittedly shown to be safe, on the grounds that no beneficial use⁵ to the consumer has been found by the agency. Industry argues, as to this latter point, that governmental action should be confined to the question of safety, and that the func-

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¹ For another recent enactment not discussed in the text, see 71 Stat. 441, 21 U.S.C.A. §§ 451-69 (Supp. 1957), providing for compulsory inspection of poultry by the Federal Government.

² 52 Stat. 1040 (1938), 21 U.S.C. §§ 301-92 (1952).

³ 71 Stat. 567, 21 U.S.C.A. § 334(d) (Supp. 1957).

⁴ 1957 U.S. Code Cong. & Ad. News, vol. 14, p. 3147.

⁵ That is, unless it "benefits . . . [the consumer] directly, in terms of product improvement or food convenience, or indirectly, in terms of improvement in food processing, storage, packing, or other steps in moving the food from its raw state to the dinner table." Goodrich, *The Rational Use of Chemicals in Food*, 12 *Food Drug Cosm. L.J.* 535, 540 (1957).

tional value of an additive should properly be tested in the market place.

Although Congress presently has before it a number of bills,⁶ it appears that two of these will receive special attention. They are the Williams Bill,⁷ supported by the industry, and the Administration Bill,⁸ supported by the FDA. Five years of legislative consideration have narrowed the points of disagreement, and it seems probable that 1958 will see an amendment to the act in this important field.

II

CASES⁹

Coal-Tar Colors.—An immediate result of the removal of FD & C Red No. 32 from the approved list¹⁰ of coal-tar colors was the institution of three suits asking for a stay of the delisting order. Two of the cases¹¹ have reached opposite results in construing the federal statute which states that "the Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use"¹² In *Certified Color Industry Comm. v. Folsom*¹³ the

⁶ Congress is still considering twelve separate bills concerning food additives: H.R. 366, H.R. 4014, H.R. 4432, H.R. 6747, H.R. 7700, H.R. 7798, H.R. 7938, H.R. 8112, H.R. 8390, H.R. 8629, H.R. 8945, all 85th Cong., 1st Sess. (1957), and H.R. 10404, 85th Cong., 2d Sess. (1958).

⁷ H.R. 10404, 85th Cong., 2d Sess. (1958).

⁸ H.R. 6747, 85th Cong., 1st Sess. (1957).

⁹ Other cases decided since the 1956 Survey but not discussed in the text include: *United States v. 353 Cases * * * Mountain Valley Mineral Water * * **, 247 F.2d 473, 2 CCH Food Drug Cosm. L. Rep. ¶ 7407 (8th Cir. 1957) (mineral water advertised as dietetic, held misbranded where labels lacked information as to proper use); *Lelles v. United States*, 241 F.2d 21, 2 CCH Food Drug Cosm. L. Rep. ¶ 7389 (9th Cir.), cert. denied, 353 U.S. 974 (1957) (president held guilty of causing introduction of adulterated food into interstate commerce but his corporation acquitted); *United States v. Parkinson*, 240 F.2d 918, 2 CCH Food Drug Cosm. L. Rep. ¶ 7377 (9th Cir. 1956) (remedy of restitution unavailable under Food, Drug, and Cosmetic Act); *United States v. Continental Baking Co.*, 2 CCH Food Drug Cosm. L. Rep. ¶ 7411 (D.D.C. 1957) ("buttermilk" and "buttermilk enriched" bread condemned as failing to conform to standard); *Columbia Research Corp. v. Schaeffer*, 152 F. Supp. 515, 2 CCH Food Drug Cosm. L. Rep. ¶ 7403 (S.D.N.Y. 1957) (Postmaster General not competent to decide validity of claims for weight-reducing pills); *United States v. 10 Cartons, Etc.*, 152 F. Supp. 360, 2 CCH Food Drug Cosm. L. Rep. ¶ 7402 (W.D. Pa. 1957) (representations in advertising literature held "labeling"); *United States v. 39 Bags, Etc.*, 150 F. Supp. 648, 2 CCH Food Drug Cosm. L. Rep. ¶ 7394 (E.D.N.Y. 1957) (palliative for rectal discomfort misbranded in failing to contain adequate warnings).

¹⁰ 20 Fed. Reg. 8492 (1955). For the present approved list, see 21 C.F.R. § 9.3 (1955).

¹¹ The third, brought by Eli Lilly in the seventh circuit, was dismissed at the request of the petitioner. Before the decisions in these cases, Congress approved for a limited period the use of Red 32 for coloring oranges not intended for processing. 70 Stat. 512 (1956), 21 U.S.C. § 342(c) (Supp. IV, 1957).

¹² 52 Stat. 1049 (1938), as amended, 21 U.S.C. § 346(b) (1952).

¹³ 236 F.2d 866, 2 CCH Food Drug Cosm. L. Rep. ¶ 7367 (2d Cir. 1956).

second circuit held that a color is not "harmless" if its use in food may render the food injurious to health. The court refused to set aside the Secretary's order, pointing out that it would be difficult, if not impossible, for the Secretary to set tolerances on the use of the color. In the second case, *Florida Citrus Exchange v. Folsom*,¹⁴ the Secretary's delisting order was attacked only insofar as it forbade the use of Red 32 on the skins of oranges. The fifth circuit thought that the act was not intended to prohibit absolutely the use of coal-tar colors necessary in good production practice. The court held that the Secretary should first determine whether the color was necessary for production and if it were, should set tolerances for its use. According to this court, "harmless," as used in the act, is a relative term and a coal-tar color, admittedly toxic, is not per se forbidden under the statute.

The clear language of the statute contradicts the fifth circuit's interpretation. The section directs that the *color* must be safe, not the use to which it might be put. No authority is provided to limit the use of a color to any particular food. There is no basis for distinguishing the two cases. The identical issue of construction was presented in each and was correctly decided by the second circuit.

Oral Misrepresentations.—In *United States v. Hohensee*¹⁵ a series of lectures was given to promote the sale of a line of food products. At the lectures oral representations were made as to the therapeutic effect of the products on a variety of diseases. The court held the oral statements relevant to determine for what purposes the products were being sold and found that the seller intended to sell his products as drugs. This principle has been extended in *V. E. Irons, Inc. v. United States*¹⁶ to include less formal oral representations made by a salesman.

Section 402(a)(3)—Contamination.—Turkeys were shipped from Maine to New York with waste material still in their intestines. On arrival the contamination had spread to edible parts. The court held, in *Penobscot Poultry Co. v. United States*,¹⁷ that section 402(a)(3),¹⁸ which defines adulteration under section 301(a),¹⁹ looks only to the state of the food at the time of introduction into interstate commerce, and not to future conditions which might be expected to arise during transportation. The court noted that the Government might

¹⁴ 246 F.2d 850, 2 CCH Food Drug Cosm. L. Rep. ¶ 7404 (5th Cir. 1957).

¹⁵ 243 F.2d 367, 2 CCH Food Drug Cosm. L. Rep. ¶ 7386 (3d Cir.), cert. denied, 353 U.S. 976 (1957).

¹⁶ 244 F.2d 34, 2 CCH Food Drug Cosm. L. Rep. ¶ 7396 (1st Cir.), cert. denied, 354 U.S. 923 (1957).

¹⁷ 244 F.2d 94 (1st Cir. 1957).

¹⁸ 52 Stat. 1046 (1938), 21 U.S.C. § 342(a)(3) (1952): "A food shall be deemed to be adulterated . . . if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food . . ."

¹⁹ 52 Stat. 1042 (1938), 21 U.S.C. § 331(a) (1952).

have fared better had it relied on section 402(a)(4),²⁰ suggesting that this section makes "it a criminal offense for a person to prepare, pack or hold food under [such] insanitary conditions that it may become contaminated."²¹ A close reading of the statute, however, discloses that Congress used the words "whereby it may *have* become contaminated,"²² indicating, even more forcefully than does section 402(a)(3), that the reference is to a possibility occurring prior to the time of shipment. If the indictment was defective, as the court held, it should have been corrected by charging an offense under section 301(b).²³

Constitutionality of FDA Public Warnings.—The action of the FDA in sending posters to post offices warning the public against the Hoxsey Cancer Clinic²⁴ was held not to be a deprivation of due process,²⁵ though there was neither notice nor hearing. There seems to be little reason to argue with the result reached by the court, but its treatment of the issues involved has far-reaching implications. A publicly disseminated warning that governmental investigation has found a product or practice to be ineffective could cause irreparable and unwarranted harm to an innocent party, yet no opportunity need be given him under this precedent to contest the Government's allegations.

²⁰ 52 Stat. 1046 (1938), 21 U.S.C. § 342(a)(4) (1952): "A food shall be deemed adulterated . . . if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health"

²¹ 244 F.2d at 97-98.

²² Emphasis supplied.

²³ 52 Stat. 1042 (1938), 21 U.S.C. § 331(b) (1952). This section prohibits "the adulteration or misbranding of any food, drug, device or cosmetic in interstate commerce." It would therefore appear that defendant would have violated this section if the adulteration occurred during shipment.

²⁴ Food and Drug Administrative Release, 2 CCH Food Drug Cosm. L. Rep. ¶¶ 7351, 7376.

²⁵ *Hoxsey Cancer Clinic, Inc. v. Folsom*, 155 F. Supp. 376, 2 CCH Food Drug Cosm. L. Rep. ¶ 7417 (D.D.C. 1957).