DRUGS AND DEVICES ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

3661. Misbranding of male and female hormones. U. S. v. 628 Linguets, etc. (F. D. C. No. 31936. Sample Nos. 1039–L, 1040–L, 1062–L.)

LIBEL FILED: November 2, 1951, Southern District of Florida.

ALLEGED SHIPMENT: On or about June 25, 1951, and within the past 18 months from the date on which the libel was filed, from Cedar Rapids, Iowa.

PRODUCT: 628 5-milligram and 1,835 10-milligram *oral androgen male sex hormone linguets* and 887 *Vitro No. 318 oral estrogen female sex hormone linguets* at Jacksonville, Fla., in possession of the Vitro Co., together with a number of leaflets entitled "Oral Androgen Male Sex Hormones."

LABEL, IN PART: (Bottle) "Oral Androgen Male Sex Hormone Linguets for absorption through the oral mucous membranes 5 mg. [or "10 mg."]. Each linguet contains 5 mg. [or "10 mg."] of the pure methyl ester of testosterone, with more marked androgenic properties than testosterone when taken by mouth. Use as Directed by Your Physician. Distributed by the Vitro Company" and "Linguets Vitro No. 318 Oral Estrogen Female Sex Hormone Linguets for absorption through the oral mucous membranes. Each linguet contains naturally occurring estrogens, with estrons as the chief active principle, biologically standardized to the equivalent of 0.5 mg. estrogen=5000 I. U."

NATURE OF CHARGE: 5 and 10 milligram *oral androgen male sex hormone linguets.* Misbranding, Section 502 (j), the articles were dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling, namely, in the leaflet entitled "Oral Androgen Male Sex Hormone," as follows: "5 mg. to 40 mg. 3 times or more weekly before meals and preferentially in divided doses. Dosage should be lowered as improvement occurs to minimum maintenance levels." Further misbranding, Section 502 (f) (2), the labeling of the articles failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users.

Vitro No. 318 oral estrogen female sex hormone linguets. Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; and, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions where the use of the article may be dangerous to health, and against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users.

The articles were misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: December 3, 1951. Default decree of condemnation and destruction.

3662. Misbranding of Detoxacolon (Hydr-Oxy-Colon) device. U. S. v. 1 Device * * * (F. D. C. 31715. Sample No. 30862–L.)

LIBEL FILED: June 19, 1951, Southern District of Illinois.

ALLEGED SHIPMENT: The product was ordered from, and invoiced by, the United X-Ray & Equipment Co., Los Angeles, Calif.; and various parts were shipped from Dallas, Tex., on or about June 23, 1950, and from Hollywood,

Calif., on or about June 22 and 29, 1950. There were also in possession of the consignee a copy of a booklet entitled "DeWelles Detoxacolon Oxygen Therapy" which had been received from a representative of the United X-Ray & Equipment Co. and a copy of a booklet entitled "Here's How Oxygen Can Put New Life Into Your Practice" which was received either directly or indirectly from a representative of the company.

PRODUCT: 1 *Detoxacolon (Hydr-Oxy-Colon) device* at Quincy, Ill., together with the 2 booklets referred to above.

LABEL, IN PART: (When shipped in interstate commerce) "Detoxacolon"; (after shipment in interstate commerce) "Hydr-Oxy-Colon Therapy Model 6 960 Serial Licensed under U. S. Patent No. 2420586."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the booklet entitled "DeWelles Detoxacolon Oxygen Therapy" were false and misleading. These statements represented and suggested that the device was an adequate and effective treatment for spasticity of the rectum, extreme ulceration of the lower bowel, common cold, sinusitis, dysentery, flaccid condition of the sphincters, ulcerative colitis, prolapse of the rectum and sigmoid, asthma, hay fever, acute coryza, ptosis of the colon, high blood pressure, low blood pressure, anemia, amebic dysentery, heart conditions, epilepsy, toxemias of pregnancy, and infections and inflammations of the female reproductive organs; that the device was an excellent treatment following childbirth to return muscle tone; and that it would correct any abnormal condition. The device was not an adequate and effective treatment for such disease conditions, and it was not capable of fulfilling such promises of benefit made for it.

Further misbranding, Section 502 (j), the device was dangerous to health when used with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, in the booklet entitled "DeWelles Detoxacolon Oxygen Therapy," since in the post partum period and in the acute stages of vaginal infections, treatment as directed would force infective material into or through the cervical canal, resulting in ascending infection with probable serious consequences to the health of the patient.

Further misbranding, Section 502 (a), certain statements in the booklet entitled "Here's How Oxygen Can Put New Life Into Your Practice" were false and misleading. These statements represented and suggested that the device was an adequate and effective treatment for many allergies, asthma, sinusitis, hay fever, arthritis, epilepsy, diabetes, neuritis, rheumatism, high and low blood pressure, pernicious and secondary anemias, certain varicoses, functional heart conditions, skin disorders, stomach ulcers, kidney conditions, parasites, rectal disorders, sluggish colon, infectious and inflammatory diseases of the female pelvis, colitis, and ulcerated colon; that it would kill certain infections and decay-producing causes; that it would control and regulate the activities of the brain, heart, circulation, and breathing; that it would aid digestion, assimilation, elimination, metabolism, gland functions, and acid-alkaline balance of the blood; that it would give a normal effect to the body in general; and that it would rebuild the bowels. The device was not an adequate and effective treatment for such diseases and conditions, and it was not capable of fulfilling the promises of benefit made for it.

The device was misbranded in the above respects when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: January 5, 1952. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

3663. Action to enjoin and restrain the interstate shipment of various Alberty products. U. S. v. Alberty Food Products, et al. Tried to the court. Decree for injunction entered in district court. Judgment of district court affirmed on appeal to United States Court of Appeals. (Inj. No. 206.)

COMPLAINT FILED: September 16, 1949, Southern District of California, against Alberty Food Products, a partnership at Hollywood, Calif., also doing business under the name of Cheno Products, and against Ada J. Alberty and Kenneth Hackworth.

On October 7, 1949, an order was entered dismissing Kenneth Hackworth as a defendant; and, at the same time, an amended complaint was filed against Alberty Food Products, Ada J. Alberty, Harry Alberty, Florence Alberty, Margaret Quinn, and Helen Hackworth, as the individuals primarily responsible for the policies and activities of the partnership.

ALLEGED VIOLATION: The complaint alleged that the defendants were the manufacturers, packers, and distributors of certain drugs, namely, *Alberty's Vegetable Compound capsules, Alberty's Oxorin tablets, Alberty's Food Regular, Instant Alberty Food, Alberty Garlic perles (Alberty Garlic and Vegetable Oil perles), Alberty's Sabinol, Alberty Phloxo B tablets, Alberty's Phosphate pellets, Alberty's Riol tablets, Alberty's Rico tablets, Alberty Special Formula tablets, Alberty's vitamin A (high potency) shark liver oil, Alberty's Vi-C, wheat germ oil, Alberty's vitamin B complex tablets with high-potency* B_1, *Alberty's vitamin* B_1 *with supplementary amounts of other B complex factors, Alberty's Lebara pellets, plain, Alberty's Lebara pellets No. 2, Cheno herb tea, Cheno Phytolacca Berry Juice Extract tablets, Cheno combination tablets, Pandora tablets, Recal tablets, Alberty's Vio-Min vitamin-mineral tablets, Alberty's R-Gon tablets, Alberty's Laxative Blend Tea, Alberty's Ca-Mo pellets, Alberty's vitamin A and G perles,* and *Alberty's Rego.*

The drugs consisted for the most part of dried vegetables, cereals, vitamins, and minerals, in various combinations.

The complaint alleged further that the defendants had been and were continuing to introduce into interstate commerce the above-named drugs which were misbranded under Sections 502 (a) and 502 (f) (1); that the defendants had caused and were continuing to cause certain printed matter to accompany the drugs while held for sale after shipment in interstate commerce, which acts resulted in the drugs being misbranded under Section 502 (a); and that the defendants had caused and were continuing to cause certain oral representations to be made by demonstrators regarding the therapeutic effect of the drugs while held for sale after interstate shipment, which acts resulted in the drugs being misbranded under Section 502 (f) (1).

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying printed matter relating to the drugs were false and misleading since the drugs were not effective for the prevention, treatment, or cure of the diseases or conditions represented; and, Section 502 (f) (1), the labeling of the drugs failed to bear adequate directions for use for the purposes and conditions for which they were intended and for the purposes for which they were recommended by oral representations sponsored by the defendant.

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*See also No. 3661.