

**DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED
ACCORDING TO DIRECTIONS**

2931. Misbranding of male sex hormone tablets and female sex hormone tablets.
U. S. v. Allen H. Parkinson (Hudson Products Co.). Plea of not guilty.
Tried to the court; verdict of guilty. Fine, \$400. (F. D. C. No. 26686.
Sample Nos. 6134-K, 14917-K, 37357-K, 37358-K.)

INFORMATION FILED: April 8, 1949, Southern District of California, against
Allen H. Parkinson, trading as the Hudson Products Co., Long Beach, Calif.

ALLEGED SHIPMENT: On or about February 27, June 15, and August 3, 1948,
from the State of California into the States of Pennsylvania, Illinois, and
Washington.

LABEL, IN PART: "Male Sex Hormones 10 Mg. Methyl-Testosterone Tablets" and
"Female Hormones 0.1 Mg. Cryst. a-Estradiol."

NATURE OF CHARGE: Male sex hormone tablets. Misbranding, Section 502 (a),
certain statements in accompanying leaflets entitled "The Male Hormone"
and "The Story of Hormones" were false and misleading. These statements
represented and suggested that the article was the true male sex hormone;
that in the average man in his late forties, it would stimulate growth and de-
velopment of the sex organs and the male sex characteristics, such as dis-
tribution of hair, muscular development, and depth of voice; that the article
would correct lack of sexual power and impotence; that it would relieve and
postpone the many conditions associated with middle age and would improve
the sense of well-being; that it would be efficacious in the treatment of flushes,
sweats, and chills, impaired memory, inability to concentrate on activities and
tendency to evade them, nervousness, depression, general weakness, and lack
of physical strength; that use of the article would result in improved physical
and mental work and would exert a tonic action resulting in renewed vigor;
that the article would impart a better attitude toward social life and would
cause nervousness, exhaustion, and melancholy to disappear; that in the aver-
age man, the article would relieve and postpone the many conditions formerly
thought to be inevitable with middle age; that it would be efficacious in the
treatment of nervous tension and intense subjective nervousness and irrita-
bility; that it would be efficacious in the treatment of numbness in the extreni-
ties, and itching, prickling, and tingling of the skin on waking up at night;
that it would be efficacious in the treatment of headaches; that it would
prevent a decrease in the ability to concentrate and would remedy faulty
memory; that it would be efficacious in the treatment of depression and
melancholia; that it would correct a lack of interest in social and business
life, lack of mental concentration, and lack of energy; that it would correct
a feeling of inadequacy and impotency; that it would be efficacious in the treat-
ment of hot flashes, feelings of smothering and sweating, and chilly, creepy
sensations; that it would prevent the user from tiring easily and gaining
excessive weight; that it would be efficacious in the treatment of constipation,
vague digestive complaints, and precordial angina pectoris-like pains; that it
would be efficacious in the treatment of urinary symptoms, such as frequency,
nocturia, dribbling, and inability to start urinary stream; that it would restore
confidence in mental reactions and decisions; that it would notably increase
the user's capacity for mental and physical work and that it would increase

potency and libido. The article was not the true male sex hormone, and it would not fulfill the promises of benefit stated and implied. Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the following directions on the labeling of different portions of the article were not adequate directions for use: "Dosage: 1 tablet daily Important: In case of pronounced male sex hormone deficiency take 3 tablets daily for ten days. After 10 day period take 1 tablet daily" and "Dosage: 1 tablet daily Important: In case of pronounced male sex hormone deficiency take 3 tablets daily before eating for 10 days. After the 10 day period take 1 tablet daily before meals or as directed by your physician."

Female sex hormone tablets. Misbranding, Section 502 (a), certain statements in accompanying leaflets of the same titles as those referred to above were false and misleading. These statements represented and suggested that the article would relieve and postpone the conditions associated with middle age; that the article would bring prompt relief from hot flashes, emotional disturbances, and other manifestations associated with the menopause; and that it would be efficacious to bring about a steady readjustment and to help overcome most menopausal conditions in women approaching or passing through the menopause. The article would not be efficacious for the purposes represented. Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the directions for use "Just One Tablet A Day" and "In case of pronounced female sex hormone deficiency take 3 tablets daily before meals for 10 days. After the 10 day period take 1 tablet daily or as directed by your physician," borne on the labeling of the article, were not adequate directions for use. Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings against unsafe dosage and duration of administration, in such manner and form as are necessary for the protection of users, since each tablet of the article contained .1 milligram of crystalline alpha estradiol; and the labeling of the article failed to warn that use of the article in the dosage and with the duration of administration recommended on its labeling may result in uterine bleeding and damage to the ovaries. Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency prescribed, recommended, and suggested in its labeling since each tablet contained .1 milligram of crystalline alpha estradiol, and the use of a drug containing .1 milligram of crystalline alpha estradiol with the frequency prescribed, recommended, and suggested in its labeling, namely, "3 tablets daily before meals for 10 days. After the 10-day period take 1 tablet daily," would be dangerous to health since use of the article may result in uterine bleeding and damage to the ovaries.

DISPOSITION: July 13, 1949. A plea of not guilty having been entered, the case came on for trial before the court without a jury. At the conclusion of the trial, the court returned a verdict of guilty and fined the defendant \$400.

2932. Misbranding of Male Hormone tablets, Menformon Dosules, Female tablets, and Metandren Linguets. U. S. v. El-O-Pathic Pharmacy, Inc., and Martin A. Clemens (as manager and director of the corporation and as an individual trading as M. A. Clemens Pharmacy). Pleas of not guilty. Tried to the court; verdict of guilty. Fine of \$700 against corporation and \$700 against Martin A. Clemens. (F. D. C. No. 25607. Sample Nos. 30046-K, 30047-K, 30068-K, 30919-K, 31204-K, 31208-K, 31217-K to 31220-K, incl., 31610-K.)