- Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of the diseases and conditions for which the article was intended, namely, for all forms of rheumatics, tuberculosis, blood disorders, kidney and liver afflictions, syphilis, and tumors.
- DISPOSITION: January 18, 1954. The individual defendants having entered pleas of guilty, the court imposed a fine of \$100 against each individual, but imposed no sentence against the partnership.
- 4314. Misbranding of rubber diaphragms. U. S. v. 166 Devices \* \* \*, (F. D. C. No. 35680. Sample No. 55178-L.)
- Libel Filed: October 1, 1953, Eastern District of Wisconsin.
- ALLEGED SHIPMENT: On or about August 25, 1953, by Hychex Products, from Chicago, Ill.
- PRODUCT: 166 devices, consisting of *rubber diaphragms*, contraceptive type, each of which was contained in a cardboard box, at Milwaukee, Wis.
- RESULTS OF INVESTIGATION: The device was a prescription device, and its label did not bear the legend "Caution Federal Law Restricts This Device To Sale By or On The Order of a Physician." Further, the device was not restricted by the dealer to sale by or on the order of a physician.
- LABEL, IN PART: (Box Cover) "PreCare Mensinga Diaphragm."
- NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the device failed to bear adequate directions for use.
- Disposition: January 27, 1954. Default decree of condemnation and destruction.

## DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

- 4315. Adulteration and misbranding of testosterone, Lynntestro, and estrone. U. S. v. Milton A. Calesnick (Addison Laboratories). Plea of guilty. Defendant fined \$300 and placed on probation for 2 years. (F. D. C. No. 33794. Sample Nos. 22330-L, 41516-L, 56320-L.)
- Information Filed: September 29, 1953, Eastern District of Pennsylvania, against Milton A. Calesnick, trading as Addison Laboratories, Philadelphia, Pa.
- ALLEGED SHIPMENT: On or about April 30, June 30, and July 8, 1952, from the State of Pennsylvania into the States of New Jersey, Ohio, and Texas.
- Label, In Part: (Vials) "10 cc. Multiple-Dose Vial Testosterone Aqueous Macrosuspension Crystalline 100 mg./cc. Sterile—Intramuscular Distributed by Leon Rosengarten Dallas, Texas," "10 cc. Multiple-Dose Vial Lynntestro Aq Aqueous Macrosuspension Crystalline 100 mg./cc. Sterile—Intramuscular Distributed By Lynn Pharmacal Co. Camden, N. J.," and "10 cc. Multiple-Dose Vial List No. 1015 Estrone U. S. P. (2.0 mg. per cc.) \* \* Mfg'd for The Caldwell & Bloor Co. Mansfield, Ohio."