

"The record also includes the affidavit of Dr. Clinton Hobart Thienes, M. D., chairman of the Department of Pharmacology at the University of Southern California Medical School. Dr. Thienes states that the use of chlorine gas in an effective antiseptic concentration would be too irritating to be withstood by the average individual and that concentrations less than this are ineffective for any purpose. He states further that chlorine gas to be safely inhaled for even a short time requires a concentration of less than ten parts per million. The results of Mr. Weiss' test show that a constant output of such a safe amount was obtained at only two dial settings. Yet nowhere in the record is it shown that directions were available suggesting such dial settings. Furthermore, at these settings the chlorine output varied throughout the three hour period. Thus it is clear that adequate directions were not available for the use of the generators.

"Dr. Thienes stated that on the basis of the Weiss affidavit he was of the opinion that it would be extremely difficult to regulate the output of the Halox Therapeutic Generator to consistently elicit a safe output of chlorine. He further stated: 'I would consider the Halox Therapeutic Generator as being incapable of effective operation in the treatment of any disorder *and would consider that it would be impossible to devise for it any adequate directions for use.*'

"It is not necessary to determine whether adequate directions could be devised, although that possibility may be doubted. It is certain, however, that adequate directions were not available to the persons to whom the seized generators were shipped.

"The twenty-two devices, more or less, labeled in part 'Halox Therapeutic Generator' must be condemned and disposed of by destruction in accordance with the provisions of 21 U. S. C. A., Sec. 334 (d). Libelant shall recover its costs.

"Libelant is requested to prepare findings of fact and conclusions of law in conformity with this opinion."

In accordance with the foregoing opinion, findings of fact and conclusions of law were handed down. On September 11, 1951, judgment of condemnation was entered, and the court ordered that 3 of the devices be delivered to the Food and Drug Administration and that the remainder of the devices be destroyed.

#### DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

3568. Adulteration of Fleaseed husks (Plantago). U. S. v. 12 Bags \* \* \*  
(F. D. C. No. 30931. Sample No. 23904-L.)

**LIBEL FILED:** April 17, 1951, Eastern District of New York.

**ALLEGED SHIPMENT:** On or about October 23, 1950, from India.

**PRODUCT:** 12 92-pound bags of *fleeseed husks* at Brooklyn, N. Y. Fleeseed is another name for the drug, Plantago.

**NATURE OF CHARGE:** Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects. The article was adulterated while held for sale after shipment in interstate commerce.

**DISPOSITION:** August 21, 1951. Default decree of condemnation and destruction.

3569. Adulteration of psyllium seed husks. U. S. v. 67 Bags \* \* \* (F. D. C. No. 30933. Sample No. 23917-L.)

**LIBEL FILED:** April 19, 1951, Eastern District of New York.

**ALLEGED SHIPMENT:** From India, arriving on or about November 21, 1950.

**PRODUCT:** 67 92-pound bags of *psyllium seed husks* at Brooklyn, N. Y.

**NATURE OF CHARGE:** Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects. The

article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: August 21, 1951. Default decree of condemnation and destruction.

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

3570. Adulteration and misbranding of Hemoplex and Livofer-B. U. S. v. Bellevue Laboratories, Inc., and Chaim Dick. Pleas of guilty. Fine of \$250 against corporation. Imposition of sentence against individual suspended and individual placed on probation for 1 year. (F. D. C. No. No. 29457. Sample Nos. 73652-K, 73666-K.)

INFORMATION FILED: September 24, 1951, Southern District of New York, against Bellevue Laboratories, Inc., New York, N. Y., and Chaim Dick, president-treasurer of the corporation.

ALLEGED SHIPMENT: On or about January 19, 1950, from the State of New York into the State of New Jersey.

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity of the articles fell below that which they purported and were represented to possess, in that the articles were not sterile and were not suitable for intramuscular injection since they were contaminated with viable sporeforming bacteria.

Misbranding, Section 502 (a), the statement "Sterile \* \* \* For Intramuscular Use" displayed upon the label of the *Hemoplex* and the statement "Sterile \* \* \* Intramuscular" displayed upon the label of the *Livofer-B* were false and misleading. Such statements represented and suggested that the articles were sterile and suitable for intramuscular injection, whereas the articles were not sterile and suitable for intramuscular injection since they were contaminated with viable sporeforming bacteria.

DISPOSITION: November 13, 1951. Pleas of guilty having been entered, the court imposed a fine of \$250 against the corporation and suspended the imposition of sentence against the individual defendant and placed him on probation for 1 year.

3571. Adulteration and misbranding of estrogenic substances. U. S. v. Estro Chemical Co., Inc., and Harold H. London. Pleas of guilty. Fine of \$800 against corporation. Imposition of sentence against individual suspended and individual placed on probation for 1 day. (F. D. C. No. 29430. Sample Nos. 11258-K, 11271-K, 15268-K, 52365-K, 62874-K, 62876-K.)

INFORMATION FILED: September 10, 1951, Southern District of New York, against the Estro Chemical Co., Inc., New York, N. Y., and Harold H. London, president of the corporation.

ALLEGED SHIPMENT: On or about September 10 and November 11 and 24, 1948, and August 15, 1949, from the State of New York into the States of New Jersey, Tennessee, Illinois, and Massachusetts.

LABEL, IN PART: "Aqua-Gyne Aqueous Estrogenic Substance 20,000 I. U. per cc." and "Aqueous Estrogyne 20,000 I. U."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the articles differed from that which they were represented to possess, in the following respects: A number of the vials in two of the shipments of *Aqua-Gyne* con-