**2275. Adulteration and misbranding of Chexit. U. S. v. 11 Bottles * * * (and 2 other seizure actions).** (F. D. C. Nos. 22692, 22693, 23457. Sample Nos. 67567–H, 67568–H, 86876–H.)

LIBELS FILED: March 12 and 13 and June 24, 1947, District of Kansas and Western District of Wisconsin.

ALLEGED SHIPMENT: On or about March 25 and April 2, 1946, and March 25, 1947, by the United Farmers Exchange, from Council Bluffs, Iowa.

PRODUCT: *Chexit.* 11 3-pound bottles at Baldwin City, Kans., 12 1-pound bottles at Humboldt, Kans., and 61 ½-pound jars and 59 1-pound jars at Madison, Wis. Analyses disclosed that the product consisted chiefly of calcium carbonate, powdered nux vomica, poke root, ginger, fenugreek, and potassium iodide. The amount of potassium iodide in the various lots of the product ranged from 0.17 to 0.27 percent.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, since it contained less than the label declaration of 0.40 percent potassium iodide.

Misbranding, Section 502 (a), the name *Chexit* and the following statements on the label were false and misleading: "Chexit * * * Demulcent Anti-Acid Mixture Suggested as a demulcent anti-acid to the bowels and stomach. May be used when the need of a demulcent anti-acid is indicated. Tonic to the appetite * * * Potassium Iodide .40% * * * For Calves, Lambs, Colts and Kids—Give one (1) tablespoonful Chexit twice daily on their tongue, if suckling, give the dam two tablespoonfuls twice per day over feed for 2 days. May be repeated. For Sows with Suckling Pigs—Give sow one (1) tablespoonful Chexit twice daily in slop or mix in milk or scatter over feed for 2 days. May be repeated. Milch Cows * * * For Steers in the Feed Lot * * *." These statements represented and suggested that the article when used as directed would be effective to check disease conditions of the bowels and stomach of animals and that it was a tonic to the appetite of animals. The article when used as directed would not be effective for such purposes. The representation on the label that the article contained 0.40 percent of potassium iodide was also false and misleading, since it contained a smaller amount.

DISPOSITION: July 24 and 29 and October 28, 1947. Default decrees of condemnation and destruction.

**2276. Adulteration and misbranding of prophylactics. U. S. v. 43½ Gross and 112½ Gross of Prophylactics. Tried to the court. Decree of condemnation. Product ordered released under bond.** (F. D. C. No. 16888. Sample Nos. 18372–H, 18373–H.)

LIBEL FILED: July 21, 1945, District of Minnesota.

ALLEGED SHIPMENT: On or about June 19, 1945, by the Killashun Sales Division, from Akron, Ohio.

PRODUCT: 43½ gross and 112½ gross of *prophylactics* at Minneapolis, Minn. Examination of 108 samples from each of the 2 lots showed that 7.4 percent and 11.1 percent, respectively, were defective in that they contained holes.

LABEL, IN PART: "Xcello's Prophylactics," or "Silver-Tex Prophylactics."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statement "Prophylactics" was false and misleading as applied to an article containing holes.

DISPOSITION: Gellman Brothers, Minneapolis, Minn., appeared as claimant, and on November 27, 1945, the case came on for trial before the court. At the conclusion of the testimony, the case was taken under advisement by the court, and on February 11, 1946, after consideration of the briefs and arguments of counsel, the court handed down the following opinion:

GUNNAR H. NORDBYE, *District Judge:* "The above cause came before this Court on libel proceedings pursuant to 21 U. S. C. A. § 334.

"Mr. Victor E. Anderson, United States Attorney, and Mr. Clifford F. Hansen, Assistant United States Attorney, of St. Paul, Minnesota, appeared in behalf of the United States of America; and Mr. Maurice Weinstein, of Milwaukee, Wisconsin, (Mr. Ralph Stacker, of St. Paul, Minnesota, of counsel) appeared in behalf of the claimant.

"A libel of information was filed against the goods described in the caption on the theory that they were adulterated within the meaning of 21 U. S. C. A. § 351 (c) and that they were misbranded within the meaning of 21 U. S. C. A. 352 (a). The goods were labeled 'Prophylactics' on the carton in which they were contained, and the Government contends that such labeling constitutes misbranding within the meaning of the Act. The articles consist of certain rubber devices sold ostensibly for the purpose of preventing transmission of venereal disease. The government witnesses testified that, of the Xcello brand, 180 were tested and 14 contained holes; that 228 of the Silver-Tex brand were tested and 16 contained holes. Medical witnesses testified that the defective devices would not serve as a means for the successful prevention of the transmission of venereal disease.

"Section 351 provides:

A drug or device shall be deemed to be adulterated—
(c) If * * * its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

"Section 352 provides:

A drug or device shall be deemed to be misbranded—
(a) If its labeling is false or misleading in any particular.

"The government inspection has established that the devices tested were defective in the number indicated, and there can be no serious doubt that the strength and quality of these particular defective articles fell below that which they purported or were represented to possess. Furthermore, it seems clear that, being labeled 'Prophylactics,' there was misbranding within the meaning of the statute. These defective devices are not efficacious in furnishing protection from diseases.

"The problem presented, however, pertains to the right of the Government to condemn the entire shipment. It appears that on or about June 19, 1945, about 43½ gross of the Xcello brand and 112½ gross of the Silver-Tex brand were shipped from the manufacturer in Akron, Ohio, to a concern in Minneapolis. It is from this shipment that the samples were taken and the tests made, as stated above. The Government took two samples—a pre-seizure and a post-seizure. While the method by which the first sample was taken is not entirely clear in the record, it does appear that, in taking the post-seizure samples, the Government took one dozen articles from each of the 36 gross cartons of Xcellos, and from the three gross so selected 72 samples were taken at random. Six, or about 8 per cent of the 72, were found to be defective. In the pre-seizure test of the Xcello brand, 108 were selected and 8 were found to be defective, or about 8 per cent. The post-seizure samples of the Silver-Tex brand were obtained by substantially the same method of selection by which the Xcello post-seizure samples were selected. In the post-seizure test of this brand, 120 samples were taken; four, or 3.33 per cent, were defective. In the pre-seizure test of this brand, 108 were tested and 12 were defective, or approximately 11.11 per cent. The average defects, therefore, of all the tests is approximately 7.37 per cent, but of the entire shipment seized, a fraction of one per cent is definitely shown to be defective, and claimant contends that the Government has failed to sustain the burden of proof which rests on it in these proceedings in its attempt to condemn the entire shipment. It should be pointed out that apparently the only practical tests which the government representatives are able to make with the facilities available to them results in the article's being rendered useless after the test has been made. Concededly, the burden of proof rests upon the Government. United States v. 5 One-Pint Bottles, et al. (D. C. N. Y., 1934) 9 F. Supp. 990; United States v. 11¼ Dozen Packages, (D. C. N. Y., 1941) 40 F. Supp. 208. But it does not follow that each individual article in the shipment must be tested. Inspection and condemnation on the basis of samples tested is clearly contemplated by the Act. In fact, the Act speaks of samples and their availability for testing. 21 U. S. C. A. § 334 (c). And the cases seem to contemplate that testing of samples is sufficient if the samples are representative ones. Andersen & Co. v. United States, (9 C. C. A., 1922) 284 F. 542; United States v. 200 Cases, et al., (D. C. Tex., 1923) 289 F. 157. No serious question is raised in this proceeding as to the samples taken being representative. But claimant contends that the Court cannot order the condemnation of good articles, and concededly some of the remaining articles are in all probability free from defects. However, in urging this contention, claimant fails

to distinguish between condemnation and the confiscation or sale of goods. Condemnation only sustains the Government's position that the goods as they were composed in interstate shipment violate the provision and purpose of the Federal Food and Drug Act. After the decree, the claimant can separate the good from the defective if it posts a bond, and thereby will be able to retain the balance of the goods. 21 U. S. C. A. § 334 (d). The very fact that part of the section of the Food and Drug Act which governs condemnation and confiscation procedure contains a section which permits the separation of the acceptable from the defective goods after condemnation indicates an intent and recognition by Congress that some of the shipment may not violate the Act, but nevertheless would be subject to a decree of condemnation together with the defective merchandise. In view of the fact that the tests which the government representatives have applied render the articles useless, it is highly improbable that the statute intended that only the defective articles are to be condemned. The impracticability of such a libel action is obvious and the impracticability of such a construction also seems clear. In effect, it would prevent application of the Act to many situations to which Congress intended it to be applied. But it is urged that the number of defectives are so low in proportion to the total number of articles involved in this proceeding that a grave injustice would result to the claimant if the entire shipment is condemned. Again, it may be reiterated that condemnation is not necessarily confiscation, and that representative sampling is permitted by the Act. Moreover, the Court is not required or permitted to establish any formula as to what tolerance of defects should be allowed, if any, in every type of libel proceeding before it determines that the Government has sustained the burden of proof as to any particular shipment. Suffice it to say that, on the state of the facts herein, and assuming that the same ratio of defectives would be found in the entire shipment, it would follow that over 1,500 defective articles would be found in this shipment. Such a number, if sold on the market, would constitute a potential menace to public health, and, in view of the claimed purpose and object of the devices, that is, the prevention of disease, are sufficient to sustain the libel proceedings herein.

"The purpose of the Federal Food and Drug Act requires that the Act be interpreted liberally. 'One of the declared purposes of the Federal Food, Drug and Cosmetic Act is to prohibit the movement in interstate commerce of adulterated and misbranded foods, drugs, devices, and cosmetics. United States v. Dotterweich, 320 U. S. 277, 280, 64 S. Ct. 134; * * *' United States v. 1,851 Cartons, etc., (10 C. C. A., 1945) 146 F. 2d 760. Thereby Congress hoped to 'prevent injury to the public health,' United States v. Research Laboratories, (9 C. C. A., 1942) 126 F. 2d 42, by prohibiting the 'sale of inferior for superior articles,' United States v. 200 Cases, etc., (D. C. Tex., 1923) 289 F. 157; and protecting the uninformed from buying an article which was different from what it purported to be. United States v. Lexington Mill & Elevator Co., 232 U. S. 399, 409, 34 S. Ct. 337, 58 L. Ed. 658, L. R. A. 1915B, 774; United States v. 5 One-Pint Bottles, etc., (D. C. N. Y. 1934) 9 F. Supp. 990. If claimant's contention were adopted here, this purpose could not be carried out, for the practical difficulties involved would permit defective articles to move in commerce and to be sold to uninformed persons without affording the protection represented.

"The Circuit Court of Appeals for the Ninth Circuit expressed its views upon a similar problem with reference to food as follows:

> It is further agreed that the court should not destroy 1,600 cases of good salmon because 400 cases of the same lot are found to be adulterated. In answer to this we need only say that destruction does not follow condemnation as a matter of course. Section 10 of the Act provides for the restoration of the goods on payment of the costs and the giving of a sufficient bond to the effect that the articles will not be sold or otherwise disposed of contrary to the provision of the Act. Under this provision the defendant in error may, and will doubtless be permitted to, separate the good from the bad, and the burden of so doing should rest upon it, and not upon the government or the ultimate consumer. If it cannot do this, it is its own misfortune, and it must suffer the consequences. Andersen & Co. v. United States (9 C. C. A., 1922) 284 F. 542, 545.

"United States v. 200 Cases, etc., (D. C. Tex., 1923) 289 F. 157, seems contra to the Anderson case. But it proceeds upon the theory that the shipment cannot be condemned unless every article therein has been shown to be defective. For the reasons noted above in discussing claimant's contention to the same effect, this case seems unsound.

"The claimant herein seems especially concerned, however, because it contends that, upon reinspection pursuant to the bonding procedure provided for in 21 U. S. C. A. § 334 (d), the articles will be rendered useless, or at least their quality and strength impaired by the wear occasioned by any further testing. But the purposes of the Act cannot be relaxed merely because of difficulties which may be encountered upon reinspection. The claimant's own testimony shows that these articles are inspected at the factory before shipment, and it contends that such methods of testing are the most modern known in this particular trade. No good reason is suggested why the same articles cannot be again subjected to the testing to which they were subjected at the factory before they entered the channels of interstate commerce. In any event, these goods are sent into commerce labeled 'Prophylactics.' The Act seeks to prevent the sale of articles labeled as prophylactics when in fact they are not. The burden of separating the good from the bad under these circumstances should rest on the claimant. Certainly, if the manufacturer desires to continue the labeling and representations as to the quality and strength of its products, it will have to contend with whatever hardships or inconveniences the violation of the law may entail.

"It follows from the foregoing that the Government is entitled to findings of fact and conclusions of law in harmony with the foregoing, as prayed for in its libel of information, with the right of the claimant to proceed under Section 334 (d) in accordance with the provisions therein contained.

"An exception is allowed to the claimant."

On April 22, 1946, judgment of condemnation was entered and the product was ordered released under bond to the claimant for the purpose of separating the good portion of the product from the bad, under the supervision of the Federal Security Agency.

The claimant subsequently took an appeal in the case to the United States Circuit Court of Appeals for the 8th Circuit, and on March 4, 1947, the following opinion was handed down by that court, which affirmed the district court's decision:

WOODROUGH, *Circuit Judge:* "This appeal is to reverse a judgment of condemnation entered after trial by the court upon a libel of information by the United States against a shipment of rubber prophylactics transported in interstate commerce from Akron, Ohio, to Minneapolis, Minnesota, and there seized from appellants who are the owners. The articles are sold ostensibly for the purpose of preventing transmission of venereal disease and were labeled in part Xcellos' Prophylactics and in part Silver Tex Prophylactics, and the condemnation was ordered pursuant to the Federal Food, Drug and Cosmetic Act, Sec. 304, 21 U. S. C. A. 334, upon the findings and conclusions of the court that the articles were adulterated within the meaning of 21 U. S. C. A. Sec. 351 (c) and were misbranded within the meaning of 21 U. S. C. A. Sec. 352 (a).

"Before the information of libel was filed, agents of the government purchased some of the articles and subjected them to tests, and after such filing and the seizure of the articles the parties stipulated in writing that the owners 'cannot perfect the evidence required to proceed with said case until furnished with a sample of said seized property,' and that representatives of the parties 'on inspecting said seized property can best determine what sample is necessary to constitute a representative sample thereof' and 'that the court may make the attached order' to permit examination and taking of representative samples of the articles. The court acted in accordance with the stipulation and issued the order agreed upon by the parties. In consequence all of the seized articles were not subjected to testing, and the findings and conclusions of the court in respect to the charges of adulteration and misbranding were drawn from the testimony showing the nature, uses and purposes of the articles, the scale and processes of manufacture, the packing, labelling and shipment, and the results of the tests of the samples taken pursuant to the stipulation and order.

"It appears that the articles are produced in quantities of millions by the manufacturer who has large investment in plant, machinery, material and product, and as the case is said to present the first instance of reported decision in the federal courts upon the application of the Act in interstate shipments of rubber devices of the kind involved through condemnation proceedings, the

grounds relied on to avoid condemnation were fully developed and argued at the trial and on this appeal. The tests of the samples taken from the shipment showed that it included a substantial percentage of 'leakers' having holes in them not discernible to the naked eye but of such size as to permit the passage of disease germs to and fro, which germs in the test carried to that extent remained alive and propagated. But it was also shown that a much larger percentage of the shipment in which the defective devices were indistinguishably commingled were not 'leakers' and were, therefore, disease preventive and prophylactic to the extent limited by the uses for which they are adapted. The tests applied to the samples rendered them unfit for sale in ordinary course and in some instances caused them to burst.

"The judgment of condemnation preserves to the owners the right accorded by Sec. 334 (d) to repossess themselves of the shipment and separate the defective articles therefrom and upon bringing the shipment into compliance with the Act under designated supervision, to sell the same.

"The position taken by the owners is that the Act does not confer the power to order condemnation of the whole shipment of commingled sound and defective articles; that the designation of the articles as Prophylactic was not 'misbranding' even as to the 'leakers' shown to have holes in them, and that the articles with the holes in the rubber of which they are composed, were not adulterated.

"The trial court filed a written opinion with its findings and conclusions, and the same is reported in 65 F. Supp. 534. It presents the issues in the case and contains a fair statement of the evidence and the grounds of decision. It also reflects careful consideration of all matters of defense asserted for the owners and meets all substantial contentions for their position. We think it continues to meet such contentions, notwithstanding additional briefs and arguments submitted to and considered by us on this appeal. The additional contention that the samples were not representative of the shipment is not sustained. Our study of the record has satisfied us that the charges of the libel of information are supported by substantial evidence and that the provisions of the Act relied on authorized the court to enter the judgment of condemnation of the whole shipment subject to the conditions for repossession, separation and restoration of the shipment to compliance contained in the judgment. We think that the judgment in accordance with the opinion of the trial court (and with its separately filed findings and conclusions) was in all respects correct and proper, and although we recognize the importance of the case to the appellants and as a precedent, we think no good purpose would be served by making a re-statement of it from the record before us. We approve the statement of the case, the findings and conclusions, and the reasoning and decision as set forth in the opinion of the trial court, and find no error therein, and therefore affirm the judgment entered in accordance therewith. Affirmed."

**2277. Adulteration and misbranding of prophylactics. U. S. v. 69 Gross * * * (and 1 other seizure action).** (F. D. C. Nos. 23870, 23871. Sample Nos. 12936–K, 12945–K.)

LIBELS FILED: October 27 and 28, 1947, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about July 30, 1947, under the name World Merchandise Exchange & Trading Co., Inc., and on or about September 9, 1947, under the name World Merchandise Exchange, from New York, N. Y.

PRODUCT: 111 gross of *prophylactics* at Philadelphia, Pa. Examination of samples showed that 3.5 percent in one of the shipments and 5 percent in the other shipment were defective in that they contained holes.

LABEL, IN PART: "Lloyd's Prophylactics."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statement "Prophylactics" was false and misleading as applied to an article containing holes.

DISPOSITION: January 7, 1948. Default decrees of condemnation and destruction.

**2278. Adulteration and misbranding of prophylactics. U. S. v. 85 Gross * * *.** (F. D. C. No. 19357. Sample No. 58245–H.)

LIBEL FILED: On or about April 5, 1946, District of Montana.