UNITED STATES of America, Libelant,v.An Article of Consisting of 4 Devices, More or Less, and Component Parts for 6 Additional Devices, LABELED in part: (Device) "CAMERON SPITLER AMBLYO-SYNTONIZER * * * CAMERON SPECIALTY CO. CHICAGO SERIAL NO. * * *" (Serial numbers 933, 1008, 1042, and 320), Claimant

MEMORANDUM AND ORDER

Not overruled or negatively treated on appeal
United States District Court, D. NebraskaJan 13, 1966
261 F. Supp. 243 (D. Neb. 1966)

VAN PELT, District Judge.

This in rem civil proceeding was instituted by the United States pursuant to the Federal Food, Drug, and Cosmetic Act, Title 21 U.S.C.A. § 301 et seq. The government seeks a decree condemning as misbranded certain devices known as Cameron Spitler Amblyo-Syntonizers. More specifically, the action is based upon Title 21 U.S.C.A. § 352(f)(1) which provides that a drug or device shall be deemed to be misbranded

> "(f) Unless its labeling bears (1) adequate directions for use; * * * *Provided,* That where any requirement of clause (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement."

The libel charges that the seized devices were misbranded when introduced into and/or while in interstate commerce, and/or while for sale within the meaning of the Act.

J.O. Jenkins, an optometrist licensed in Nebraska and from whom the devices were seized, has filed a claim seeking the return of the devices. One of the devices was purchased by the claimant from a Pennsylvania optometrist who shipped the device to North Platte, Nebraska, where it has been used in Mr. Jenkins' optometry business. The other devices are the property of the College of Syntonic Optometry, a non-profit Ohio corporation of which the claimant is a Vice-President and a Director. In 1963 the claimant agreed to store the devices as the corporation disposed of its physical assets. The college, however, still operates by giving lectures to optometrists and by selling the devices to only those optometrists who take courses concerning the purpose and use of the device. The device is composed of a metal tube 1 and 1/2 feet long. Within the tube are a 50 watt bulb and three round metal discs; two discs with seven colored glass filters and one open space and the third disc having three colored glass filters, four targets and an open space. The claimant admits using the device in the treatment of various eye malfunctions and diseases.

The device has admittedly been used for the purpose of aiding in cases of amblyopia, asthenopia, phorias, strabismus, cross eyed condition, wall eyed condition, myopia, opacities of eye, senile cataract, migrain and ocular headaches, and low reserves.

On the basis of the pleadings and claimant's answers to the interrogatories, the government now moves for summary judgment pursuant to Rule 56. It is well established that such a motion is appropriate in libel actions brought pursuant to the Federal Food, Drug and Cosmetic Act. Alberty Food Products Co. v. United States, 185 F.2d 321 (9th Cir. 1950); United States v. One Device * * * The Ellis Micro-Dynameter, 224 F. Supp. 265 (E.D.Pa. 1963); United States v. 4 Cans etc. Master Liquid, 127 F. Supp. 243 (N.D.Iowa 1955). Not every issue of fact, however genuine, precludes entry of summary judgment. It is only genuine issues of material fact which have that effect.

While claimant contends that the machines have not been represented as a cure for any particular eye malfunction, he admits the use of them in the treatment of certain eye maladies. Clearly, the seized machines are each a device within the meaning of § 321(h).

Sec. 321(h) provides: "The term `device' * * * means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, *mitigation, treatment,* or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals." (Emphasis added)

Section 352(f)(1), upon which the action is based, requires that the labeling bear "adequate directions for use." This section has been construed to mean that the labeling must include a statement of every purpose for which a drug or device is intended to be used. V.E. Irons, Inc. v. United States, 244 F.2d 34 (1st Cir. 1957) cert. denied, 354 U.S. 923, 77 S.Ct. 1383, 1 L.Ed.2d 1437; United States v. Hohensee, 243 F.2d 367 (3rd Cir. 1957), cert. denied, 353 U.S. 976, 77 S.Ct. 1058, 1 L.Ed.2d 1136. In Alberty Food Products v. United States, 194 F.2d 463 (9th Cir. 1952), the court required the labeling to also state sufficient information to enable a layman to intelligently and safely attempt self-medication. Failure of the labeling to list the diseased conditions for which the drug should be used has been held to be misbranding. United States v. El-O-Pathic Pharmacy, 192 F.2d 62 (9th Cir. 1951); United States v. Grayce, Inc., 126 F. Supp. 6 (N.D.Ind. 1954).

The claimant admits that the seized devices, when introduced into and while in interstate commerce, were not labeled and had no written, printed, or graphic matter attached to or accompanying the devices. See Kordel v. United States, 335 U.S. 345, 69 S.Ct. 106, 93 L.Ed. 52 (1948).

Claimant, however, directs the court's attention to the provision in 21 U.S.C.A. § 352(f) which reads:

> "Provided, That where any requirement of Clause (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement."

Such regulations are found in 21 C.F.R. § 1.106(d), a portion of which reads:

> "A device which, because of its potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which `adequate directions for use' cannot be prepared, shall be exempt from section 502(f)(1) of the act if all the following conditions are met:" — Conditions applicable here are:
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> "(2) The label of the device (other than surgical instruments) bears:
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> (i) The statement `Caution: Federal law restricts this device to sale by or on the order of a . . .," the blank to be filled with the word `physician', `dentist', `veterinarian', or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device; and

(ii) The method of its application or use."

Claimant contends that the government has the burden of proving the devices to be not safe to the public, either by potential harmful effects, by methods of its use, or by collateral measures necessary for its use. To answer this contention, the court believes Circuit Judge McAllister's explanation of the regulation's effect is appropriate.

> "[W]here no adequate directions for use of specified dangerous drugs can be written for purposes of self-medication by a layman, and they can be safely taken only upon the advice and under the supervision of a physician, it is within the statutory power conferred upon the Administrator to require, by regulation, that the label set forth that they be taken only upon prescription of a physician. * * * [A]side from the regulation, the only adequate direction for use of the drug in question would be a requirement that it be taken only on the prescription of a physician and that, in default of a label embodying such direction, the drug would be misbranded under the statute." United States v. El-O-Pathic Pharmacy, 192 F.2d 62, 75 (9th Cir. 1951). See also United States v. Sullivan, 332 U.S. 689, 68 S.Ct. 331, 92 L.Ed. 297 (1947).

The claimant in his answers to certain interrogatories admits that requirements expressed in 21 C.F.R. § 1.106(d) (2) (i) and (ii) [see above] were not fulfilled. Thus, even assuming the government has the burden and does prove the devices to be within the scope of the exemption, the devices would be misbranded as the conditions to obtain an exemption have not been fulfilled. United States v. El-O-Pathic Pharmacy, supra. Further, if the devices do not fall within the scope of the exemption, they are not exempt from the labeling requirements of § 352(f)(1). United States v. Ellis Research Laboratories, Inc., 300 F.2d 550 (7th Cir. 1962), cert. denied, 370 U.S. 918, 82 S.Ct. 1558, 8 L.Ed.2d 499. The government may condemn a device even though not inherently dangerous and not presently in interstate commerce. United States v. Olson, 161 F.2d 669 (9th Cir. 1947), cert. denied, 332 U.S. 768, 68 S.Ct. 79, 92 L.Ed. 353. Once an article is misbranded, it has violated the law and is subject to seizure at any time thereafter and no subsequent action can purge it from the violation. United States v. 1800.2625 Wine Gallons, 121 F. Supp. 735 (W.D.Mo. 1954).

The fact that the seized devices may be only sold to or used by licensed optometrists is not in itself a sufficient basis for an exemption. United States v. Ellis Research Laboratories, supra; United States v. 22 Devices, More or Less, Halox Therapeutic Generator, 98 F. Supp. 914 (S.D.Cal. 1951).

> "Licensed practitioners are not exempt from the terms of the Act, and we see no reason why a device used solely by licensed practitioners should, for that reason alone, be exempt from that portion of the Act requiring the labeling to bear `adequate directions for use.'" United States v. Ellis Research Laboratories, supra, 300 F.2d at 552-553 .

The court is also of the opinion that the devices were misbranded while being held for sale. Although the claimant never sold the devices in the commercial sense, the device was used in the claimant's treatment of patients. In United States v. 10 Cartons of Black Tablets, 152 F. Supp. 360 (W.D.Pa. 1957), the articles were not sold to patients but used as part of the treatment in the cancer clinic. The court held that such a use was within the scope of the "holding for sale." See also Kordel v. United States, 335 U.S. 345, 69 S.Ct. 106, 93 L.Ed. 52 (1948); United States v. Kocmond, 200 F.2d 370 (7th Cir. 1953), cert. denied, 345 U.S. 924, 73 S.Ct. 782, 97 L.Ed. 1355.

The court concludes that there is no genuine issue as to any material fact and that the United States is entitled to summary judgment.

It is therefore ordered by the court that Libelant's motion for summary judgment, the same being filing number 13, be granted.

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