

present in Asper-Sleep is generally recognized by qualified experts as safe and effective in relieving pain and inducing sleep. No factual question can be said to exist with respect to this ultimate issue, and the court must conclude that Asper-Sleep is a "new drug" within the meaning of 21 U. S. C. § 321(p). *United States v. 7 Cartons . . . "Ferro-Lac Swine Formula Concentrate,"* 293 F. Supp. 660 (S. D. Ill. 1968), *aff'd*, 424 F. 2d 1364 (7th Cir. 1970). The Government is therefore entitled to summary judgment. Rule 56(e), Federal Rules of Civil Procedure.

It is therefore ordered that the seized article, Asper-Sleep, be and it is hereby condemned and forfeited to the United States of America pursuant to 21 U. S. C. § 334. The United States Marshal for the Northern District of Illinois is directed to destroy the condemned article and make due return to this court pursuant to 21 U. S. C. § 334(d).

It is further ordered that the cause be, and it is hereby, dismissed with the claimant, Yonkers Laboratories, Inc., to pay all costs herein.

**UNITED STATES v. AN ARTICLE
OF DEVICE . . . "HUBBARD
ELECTROMETER" OR
"HUBBARD E-METER," ETC.**

**United States District Court for the
District of Columbia. No. D.C. 1-63.
September 29, 1971.**

In a seizure action by the Government against the Hubbard E-Meter, the court ordered, inter alia, condemnation of the seized articles, and release of condemned E-Meters and literature to claimant for the purpose of bringing the devices and literature into compliance with the law. The court further ordered that E-Meters be restricted for use only in bona fide religious counseling.

Sections 304(a), 304(e), 502(a), 502(f)(1),
Federal Food, Drug, and Cosmetic Act.

ORDER

In accordance with the findings of fact and conclusions of law contained in the Memorandum Opinion of this Court dated July 30, 1971, which are incorporated herein and made a part hereof, it is

ORDERED, ADJUDGED, AND DECREED that the article of device under

seizure, known as the Hubbard Electrometer or the Hubbard E-Meter (hereinafter referred to as E-meter) is misbranded within the meaning of 21 U.S.C. 352(a) and (f)(i) and the seized articles, *i.e.*, the E-meters and all writings seized, are condemned pursuant to 21 U.S.C. 334(a); and it is further

ORDERED, ADJUDGED, AND DECREED, pursuant to 21 U.S.C. 334(e), that the United States of America shall have and recover from the claimants herein jointly and severally all court costs and fees (excluding costs and fees relative to the appeal following the first trial), and storage and other proper expenses, to be taxed; and it is further

ORDERED, ADJUDGED, AND DECREED that the United States Marshal for this District shall release such condemned E-meters and literature from his custody to the custody of the claimant, the Founding Church of Scientology of Washington, D.C., Inc., for the purpose of bringing the condemned devices and literature into compliance with the law provided such claimant, within 90 days from the date of this Order so requests and (a) pays in full the aforementioned court costs and fees, and storage and other proper expenses of the proceeding herein, and (b) executes and files with the Clerk of this Court a good and sufficient penal bond with surety, in the sum of \$20,000, payable to the United States of America and conditioned on the claimant's abiding by and performing all the terms and conditions of this Order, and if claimant does not avail itself of the opportunity to repossess the condemned article within the 90 days specified, the United States Marshal for this District shall forthwith destroy all E-meters in his possession and control; and it is further

ORDERED, ADJUDGED, AND DECREED that an E-meter shall be deemed to comply with the law if and only if it is used, sold or distributed in accordance with the following specific conditions:

1. E-meters shall be used or sold or distributed only for use in bona fide religious counseling.

2. No user, purchaser or distributee (other than the Founding Church of Scientology of Washington, D.C., Inc., or an ordained practicing minister of that Church) shall be considered engaged in bona fide religious counseling unless and until such user, purchaser, or distributee files by mail or otherwise (a) an affidavit, under oath, with the

Commissioner, United States Food and Drug Administration, Washington, D.C., setting forth in adequate detail the factual basis on which such user, purchaser or distributee claims he will be engaged in bona fide religious counseling, and (b) a statement, under oath, that he has read and will comply with this Order and the terms and conditions of the warning affixed to the E-meter as required by paragraph 3, immediately below, of this Order.

3. Each E-meter shall bear the following warning, printed in 11-point leaded type, permanently affixed to the front of the E-meter so that it is clearly visible when the E-meter is used, sold, or distributed:

The E-meter is a device which has been condemned by Order of a Federal Court for misrepresentation and misbranding, in violation of the Federal Food, Drug, and Cosmetic Act. Use of the E-meter is permitted only as part of bona-fide religious activity. The E-meter is not medically or scientifically useful for the diagnosis, treatment, or prevention of any disease. It is not medically or scientifically capable of improving the health or bodily functions of anyone. Any person using, selling or distributing the E-meter is forbidden by law to represent, state or imply that the E-meter is useful in the diagnosis, treatment, or prevention of any disease.

4. Every individual who receives auditing or processing or counseling in which an E-meter is used shall be required to sign and date a written statement or contract form which shall also be signed by the person offering such services and indicating the name and address of the organization, if any, with which such person is affiliated. The statement or contract form shall include the following statement in not less than 11-point type:

I understand and have been advised that the device known as a Hubbard Electrometer, or E-meter, has been condemned by Order of a Federal Court on the grounds that the literature referring to Dianetics or Scientology contains false and misleading claims of a medical or scientific nature. I understand it is a violation of law for *anyone* to represent that the E-meter is useful in the diagnosis, treatment, or prevention of any disease, or that it is medically or scientifically capable of improving any bodily function.

The written statements or contract forms referred to in this paragraph shall be retained and preserved, by the person or organization providing the auditing, processing or counseling service for a period of three years. The written statements and contract forms shall be provided for inspection and copying by any duly qualified representative of the United States Food and Drug Administration, upon presentation of appropriate credentials.

5. Any and all items of written, printed, or graphic matter which directly or indirectly refers to the E-meter or to Dianetics and/or Scientology and/or auditing or processing which prior to the date this Order becomes final were distributed directly or indirectly by a seller or distributor of any E-meter, or by any organization or person utilizing or promoting the use of any E-meter, shall not be further used or distributed by any such seller, distributor or organization unless and until the item shall bear the following prominent printed warning permanently affixed to said item on the outside front cover or on the title page in letters no smaller than 11-point leaded type:

WARNING

The device known as a Hubbard Electrometer, or E-meter, used in auditing, a process of Scientology and Dianetics, has been condemned by Order of a Federal Court on the grounds that the literature referring to Dianetics or Scientology contains false and misleading claims of a medical or scientific nature. It is a violation of law for anyone to represent that the E-meter is useful in the diagnosis, treatment, or prevention of any disease, or that it is medically or scientifically capable of improving any bodily function.

6. Any advertisement or other written, printed or graphic material of any kind prepared subsequently to this Order and used directly or indirectly to further the use, sale or distribution of any E-meter shall not represent that the E-meter is useful in the diagnosis, treatment or prevention of any disease and shall not contain any false or misleading claims of a medical or scientific nature concerning the use of the E-meter or benefits derived from such use; and it is further

ORDERED, ADJUDGED, AND DECREED that the bringing of the seized and condemned E-meters and literature into compliance with the provisions of the Federal Food, Drug, and Cosmetic Act, as specified

in this Order, shall be performed under the reasonable supervision of a duly authorized representative of the United States Food and Drug Administration. Claimant, the Founding Church of Scientology of Washington, D.C., Inc., shall compensate the United States of America for costs of reasonable supervision of matters under the direction or control of the Church at the rate of \$8.00 per hour, per representative for each hour or portion thereof actually employed in such supervision under the terms of this Decree as salary or wage; and where subsistence expenses are incurred, at the rate of \$25.00 per day or portion thereof per person for such subsistence expenses. Said claimant shall also compensate the United States of America for necessary traveling expenses and for any other necessary expenses which may be incurred in connection with supervisory responsibilities of the United States Food and Drug Administration, and it is further

ORDERED, ADJUDGED, AND DECREED that within one year from the date this Order becomes final the United States of America shall file with the Clerk of this Court a full statement indicating whether and to what extent the terms and conditions of this Order have been performed, and shall then show cause why the bond given in this proceeding shall not be cancelled and discharged; and it is further

ORDERED, ADJUDGED, AND DECREED that this Court expressly retains jurisdiction for a period of one year from the date this Order becomes final to issue such further orders as may be necessary to the proper disposition of this proceeding.

UNITED STATES v. AN ARTICLE OF FOOD . . . PASTEURIZED WHOLE EGGS . . . FRIGID FOOD PRODUCTS, INC. . . ; UNITED STATES v. ARTICLES OF FOOD CONSISTING OF: 1,250 CANS . . . , ET AL; UNITED STATES v. APPROXIMATELY 26 CANS . . . "SUGAR YOLKS . . . GOLDEN EGG PRODUCTS, INC . . . , ET AL.; UNITED STATES v. ARTICLES OF FOOD . . . "PASTEURIZED FROZEN WHOLE EGGS . . . SUN

CITY DAIRY PRODUCTS, INC. . . .", ET AL.; AND UNITED STATES v. ARTICLES OF FOOD . . . 514 CANS . . . , ET AL.

United States District Court for the Northern District of Georgia, Atlanta Division. Nos. 14782-14784, 14796 and 14821.

**March 8, 1972.
339 F. Supp. 131.**

Frozen whole eggs and sugar yolks were seized because of alleged adulteration. In five consolidated actions to condemn and destroy the eggs, the court found that the eggs had been produced under insanitary conditions in violation of section 402(a)(4) of the Act, that there was evidence of Salmonella poisoning of the eggs in violation of section 402(a)(1), and that they were accordingly subject to seizure and condemnation. As to alleged violations of section 402(a)(3) on decomposed substances, however, the court ruled that the Government had failed to sustain its case. It so held even while adhering to the rule that a food may be condemned under the Act as decomposed, filthy or putrid even if it is not unfit for food.

Sections 201(f), 304, 401, 402(a)(1), 402(a)(3), 402(a)(4), 702, 704, Federal Food, Drug, and Cosmetic Act.

SIDNEY O. SMITH, Jr., Chief Judge.

These five actions were brought in different parts of the United States pursuant to Section 304 of the Federal Food, Drug and Cosmetic Act (21 U. S. C. § 334) to condemn and destroy as adulterated various lots of pasteurized frozen whole eggs and sugar yolks processed and introduced into interstate commerce by the Golden Egg Products, Inc. of Oneonta, Alabama ("Golden Egg"). Proceeding under the statute, the government contends that the lots were "adulterated" in one or more of the definitions prescribed by Congress in 21 U. S. C. § 342, which provides in part:

"A food shall be deemed to be adulterated—

(a)(1) *If it bears or contains any poisonous or deleterious substance which may render it injurious to health;*

* * *

(3) *If it consists in whole or in part of any filthy, putrid, or decomposed substance, or*

Drug, and Cosmetic Act as to safety and have the identity and strength, and meet the quality and purity characteristics which they purport or are represented to possess.

12. Drugs that are not the identical article their labeling indicates them to be are misbranded under Title 21, United States Code, Section 352(a). The seized drugs Neuralvitas 10 cc Lot 70-9 and Neurobexin 10 cc Lot 70-9 are misbranded within the meaning of Title 21, United States Code, Section 352(a) in that their labeling contains false and misleading representations with respect to their strength.

13. Pursuant to Title 21, United States Code, Section 334, plaintiff is entitled to the following relief: a decree condemning all of the seized drugs for violations of the Federal Food, Drug, and Cosmetic Act and ordering their destruction, Title 21, United States Code, Section 334(a) and (d); and an order awarding court costs and fees, and storage and other proper expenses to be paid by claimant, Title 21, United States Code, Section 334(e). Let judgment be entered accordingly.

**UNITED STATES v. AN ARTICLE
OF DEVICE . . . "HUBBARD
ELECTROMETER" OR
"HUBBARD E-METER", INC.,
FOUNDING CHURCH OF
SCIENTOLOGY, ET AL.**

**United States Court of Appeals for the
District of Columbia.**

No. 71-2064.

March 1, 1973.

In a seizure action certain Hubbard E-Meters were condemned and claimant appealed. The Court of Appeals affirmed but modified the order of the lower court so as to avoid excessive entanglement of the Government and courts with religion. The following points in the district court order were modified: The requirement that future users file affidavits with the FDA stating that the device was being used for bona fide religious counseling, and the requirement that all future labeling indicate that the device had been declared misbranded by a United States District Court.

Sections 304(a), 304(e), 502(a), 502(f)(1),
Federal Food, Drug, and Cosmetic Act.

PER CURIAM: This cause came on to be heard on the record on appeal from the United States District Court for the District of Columbia, and was argued by counsel. While the issues presented occasion no need for an opinion, they have been accorded full consideration by the court. See Local Rule 13(c).

On the basis of this record we cannot say that the findings of the District Court are clearly erroneous. The judgment of the District Court, however, would involve the Government and the courts in an excessive entanglement with religion, *Lemon v. Kurtzman*, 402 U. S. 602 (1971), in circumstances in which the legitimate governmental interest in law enforcement can be protected by a narrower remedy. *Sherbert v. Verner*, 374 U. S. 398 (1963). Therefore, it is ORDERED by this court that the order of the District Court is amended to read as follows:

Order

In accordance with the findings of fact and conclusions of law contained in the Memorandum Opinion of this Court dated July 30, 1971, which are incorporated herein and made a part hereof, it is

ORDERED, ADJUDGED, AND DECREED that the article of device under seizure, known as the Hubbard Electrometer or the Hubbard E-Meter (hereafter referred to as E-meter) is misbranded within the meaning of 21 U. S. C. § 352(a) and (f)(1) and the seized articles, *i. e.*, the E-meters and all writings seized, are condemned pursuant to 21 U. S. C. § 334(a); and it is further

ORDERED, ADJUDGED, AND DECREED, pursuant to 21 U. S. C. § 334(e), that the United States of America shall have and recover from the claimants herein jointly and severally all court costs and fees (excluding costs and fees relative to the appeal following the first trial), and storage and other proper expenses, to be taxed; and it is further

ORDERED, ADJUDGED, AND DECREED that the United States Marshal for this District shall release such condemned E-meters and literature from his custody to the custody of the claimant, the Founding Church of Scientology of Washington, D. C., Inc., for the purpose of bringing the condemned devices and literature

into compliance with the law provided such claimant, within 90 days from the date of this Order so requests and (a) pays in full the aforementioned court costs and fees, and storage and other proper expenses of the proceeding herein, and (b) executes and files with the Clerk of this Court a good and sufficient penal bond with surety, in the sum of \$20,000, payable to the United States of America and conditioned on the claimant's abiding by and performing all the terms and conditions of this Order, and if claimant does not avail itself of the opportunity to repossess the condemned article within the 90 days specified, the United States Marshal for this District shall forthwith destroy all E-meters in his possession and control; and it is further

ORDERED, ADJUDGED, AND DECREED that such condemned E-meters and literature shall be deemed to comply with the law if and only if they are used, sold or distributed in accordance with the following specific conditions:

1. E-meters shall be used or sold or distributed only for use in bona fide religious counseling.

2. Each E-meter shall bear the following warning, printed in 11-point leaded type, permanently affixed to the front of the E-meter so that it is clearly visible when the E-meter is used, sold, or distributed:

The E-meter is not medically or scientifically useful for the diagnosis, treatment, or prevention of any disease. It is not medically or scientifically capable of improving the health or bodily functions of anyone.

3. Any and all items of written, printed, or graphic matter which directly or indirectly refers [*sic*] to the E-meter or to Dianetics and/or Scientology and/or auditing or processing shall not be further used or distributed unless and until the item shall bear the following prominent printed warning permanently affixed to said item on the outside front cover or on the title page in letters no smaller than 11-point leaded type:

Warning

The device known as a Hubbard Electrometer, or E-meter, used in auditing, a process of Scientology and Dianetics, is not medically or scientifically useful for

the diagnosis, treatment, or prevention of any disease. It is not medically or scientifically capable of improving the health or bodily functions of anyone.

and it is further

ORDERED, ADJUDGED, AND DECREED that the bringing of the seized and condemned E-meters and literature into compliance with the provisions of the Federal Food, Drug, and Cosmetic Act, as specified in this Order, shall be performed under the reasonable supervision of a duly authorized representative of the United States Food and Drug Administration. Claimant, the Founding Church of Scientology of Washington, D. C., Inc., shall compensate the United States of America for costs of reasonable supervision of matters under the direction or control of the Church at the rate of \$8.00 per hour, per representative for each hour or portion thereof actually employed in such supervision under the terms of this Decree as salary or wage; and where subsistence expenses are incurred, at the rate of \$25.00 per day or portion thereof per person for such subsistence expenses. Said claimant shall also compensate the United States of America for necessary traveling expenses and for any other necessary expenses which may be incurred in connection with supervisory responsibilities of the United States Food and Drug Administration; and it is further

ORDERED, ADJUDGED, AND DECREED that within one year from the date this Order becomes final the United States of America shall file with the Clerk of the District Court a full statement indicating whether and to what extent the terms and conditions of this Order have been performed, and shall then show cause why the bond given in this proceeding shall not be cancelled and discharged; and it is further

ORDERED, ADJUDGED, AND DECREED that the District Court expressly retains jurisdiction for a period of one year from the date this Order becomes final to issue such further orders as may be necessary to the proper disposition of this proceeding.

It is FURTHER ORDERED by this court that the judgment of the District Court, as amended, is hereby affirmed.