

graphed sheets entitled "No. 1. Here Is An Important New Product," 4 mimeographed sheets entitled "No. 2. Here Is A New Discovery," 4 mimeographed sheets entitled "No. 3. Now . . . At Last!" 4 mimeographed sheets entitled "No. 4. One of the Loveliest," 3 mimeographed sheets entitled "No. 5. Thousands and Thousands," 1 mimeographed sheet entitled "No. 7. Immediate Release," 1 mimeographed sheet entitled "No. 8. Immediate Release," 4 letters dated August 14 and 19 and September 10 and 18, 1952, 1 copy of a newspaper mat entitled "New Desert Springs Home Restorative Mineral Baths," and 2 business reply cards entitled "Dear Editor."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), certain statements in the labeling of the article, namely, the above-described cartons, sheets, pamphlets, letters, mimeographed sheets, newspaper mat, placards, and business reply cards accompanying the article, were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for arthritis, rheumatism, neuritis, overwork, tired, aching back, stiff joints, nervous strain, aftermath of old injuries, tensions that prevent sound sleep, a worn-out condition, sleeplessness, all kinds of ailments, and for providing in one's home restorative benefits and curative effects equal to those derived by visiting world-famous mineral spring health resorts. The article was not an adequate and effective treatment for such conditions or purposes.

**DISPOSITION:** May 18, 1953. Default decree of condemnation and destruction.

**4100. Misbranding of phonograph records. U. S. v. 23 Records, etc. Tried to the court. Judgment for the claimant. Judgment reversed upon appeal. Decree of condemnation and destruction. (F. D. C. No. 20564. Sample No. 8839-H.)**

**LIBEL FILED:** July 25, 1946, Eastern District of New York.

**ALLEGED SHIPMENT:** On or about May 31, 1946, by DeLuxe Record Co., Inc., from Linden, N. J.

**PRODUCT:** 23 *phonograph records* at Brooklyn, N. Y., together with a number of accompanying display cards entitled "DeLuxe Records Presents Time to Sleep A Tested Method of Inducing Sleep Conceived and Transcribed by Ralph Slater" and a number of accompanying posters headed "A 'Dream Girl' Shows a New Way to Dreamland."

Each record was contained in an album which bore a picture of the head and shoulders of a young woman in deep slumber and which contained a leaflet reading, in part, "Sleep with this amazing record 'Time to Sleep'" and a certificate entitled "Sleep Guaranteed."

**LABEL, IN PART:** (Record) "Time to Sleep A Tested method to induce sleep Prepared and transcribed by Ralph Slater."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), certain statements and designs in the labeling of the article were false and misleading. The statements and designs represented and suggested that the article when used as directed would induce sleep, whereas the article was not capable of affecting that function of the body.

**DISPOSITION:** Ralph Slater, claimant, filed an answer denying (1) that the records were a device within the meaning of the law and (2) that the records were misbranded. The case came on for trial before the court without a jury on January 4, 1950, and, at its conclusion, the case was taken under advisement by the court. On March 9, 1950, the following opinion was handed down:

RAYFIEL, *District Judge*: "Under the libel of information filed herein the government seeks the seizure and condemnation of certain phonograph records, together with the albums in which they were contained, as well as a quantity of leaflets, guarantees and display cards, all in said libel identified and described, on the ground (1) that the said records are devices, and, with their accompanying graphic and printed matter, are misbranded within the meaning of the Federal Food, Drug and Cosmetic Act, and, (2) that the same were shipped in interstate commerce in violation of the said Act, and are therefore illegally within the jurisdiction of this Court.

"Ralph Slater, the claimant herein, answering the said libel, denies that the aforementioned records are devices within the meaning of the said Act, and, further, denies that the said records, albums and their accompanying leaflets, guarantees and display cards were misbranded, as alleged in the libel.

"A pre-trial conference was held and the resultant order, dated May 7th, 1948, provided that one of each of the items involved, to wit: a record, album, guarantee, leaflet, poster and display card, be received in evidence as exhibits without objection, and that it be stipulated and conceded by the defendant that duplicates thereof were shipped in interstate commerce from a point in New Jersey to a point in Brooklyn, within the Eastern District of New York.

"The defendant has not disputed the fact that the printed and graphic matter appearing on the record, album, guarantee, poster and display card constitute 'labeling' within the meaning of subdivision 'm' of section 321 [201] of the Act. Hence, two questions remain to be answered.

(1) Is the phonograph record hereinabove referred to a device, as defined by subdivision 'h' of section 321 [201] of the Act?

(2) Is the said record misbranded, in violation of subdivision 'a' of section 352 [502] of the Act, in that the labeling is false or misleading in any manner?

"As to the first question: *Is the record a device?*—For the purpose of the Food, Drug and Cosmetic Act the word 'device' (with certain exceptions not here pertinent) is defined as an instrument, apparatus or contrivance including its components, parts or 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.

"Funk and Wagnalls New Standard Dictionary defines 'apparatus' as 'any complex device or machine designed or prepared for the accomplishment of a special purpose; also a collection of tools, appliances, materials, etc.' . . . . The same authority defines 'contrivance' as '... a project or artifice; an apparatus or invention . . . . especially . . . . for scientific or professional purposes . . . .' Clearly the record comes within none of those definitions, nor does it, or its accompanying printed matter purport that it may be effectively used (1) for the *diagnosis, cure, mitigation, treatment or prevention of disease* or (2) *to affect the structure of or any function of the body*. In my opinion the word 'function' in subdivision 'h' of section 321 [201] of the Act is limited in meaning to the specific power of action and operation of an organ of the body, such as the brain, heart or liver. Funk and Wagnalls gives as a definition of 'function' the following: 'Physiol. A special office in the animal economy that has as its agent or instrument a specific organ or system of organs; the normal action of any organ or set of organs.'

"It is this Court's opinion that the 'devices' contemplated by the statute is such a machine or apparatus which is applied to or injected into the body or some organ thereof or whose current or rays enter the body.

"As to the second question: *Is the record misbranded in that the labeling is false and misleading?*—I find nothing in the record, or in the printed matter hereinabove referred to, which constitutes misbranding within the meaning of the statute herein involved. It appears that there is more than a modicum of self-opinion in the claimant's references to his own talents and experience, but those probably extravagant statements do not extend to the record, except possibly in some detail which I do not think was a persuasive factor in the sale of the record.

"Bernard Locke, a clinical psychologist associated with the Veterans Administration, and Dr. Wilbur, a psychiatrist, testifying in behalf of the government, stated that they had tested the record on a number of patients and

nad found it to be ineffective. Those tests, however, were made under most unfavorable conditions. All of the subjects were psychoneurotic war veterans who suffered from insomnia as one of a number of prevailing symptoms. They could hardly be expected to co-operate and respond to suggestion as the record indicates is a necessary prerequisite. Mr. Locke testified that he performed the test because he was interested in seeing whether it (the record) would *cure even* psychoneurotic cases. Slater made no such claim.

"Dr. Hoffman, a well-known psychiatrist, testified in behalf of the claimant. He stated that treatment of the type indicated by the record had been employed by the medical profession; further, that while the record would have little beneficial effect in cases of persons suffering from organic diseases or defects, it could be successfully used in other cases. Music and suggestion are frequently used to mitigate and relieve insomniac conditions.

"Accordingly, I find for the claimant, who is entitled to the return of the articles seized by the government.

"Submit decree in conformity herewith."

In accordance with the above opinion, the court, on April 13, 1950, entered judgment in favor of the claimant and ordered that the records and accompanying literature be returned to the claimant.

An appeal was taken by the Government to the United States Court of Appeals for the Second Circuit, and on November 7, 1951, the following opinion was handed down:

WOODBURY, *Circuit Judge*: "The United States of America filed a libel of information in the court below under Sec. 304 (a) of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1044; 21 U. S. C. Sec. 334 (a)) seeking the seizure and condemnation of certain phonograph records, and various accompanying items of printed and graphic matter, all of which were moving or had moved in interstate commerce. The phonograph records are entitled in part 'Time To Sleep,' and their accompanying literature consists of (1) an album in part entitled, 'De Luxe Records Presents Time to Sleep A Tested Method of Inducing Sleep Conceived and Transcribed by Ralph Slater,' (2) a leaflet in part reading: 'Sleep With This Amazing Record "Time To Sleep,"' (3) a certificate entitled 'Sleep Guaranteed,' (4) display cards entitled 'De Luxe Records Presents Time To Sleep,' and (5) a poster headed 'A "Dream Girl" Shows a New Way to Dreamland.' The court below after full hearing without a jury filed a memorandum opinion in accordance with which it entered a final decree ordering the libel dismissed and the libeled property returned to Ralph Slater, the claimant. The United States thereupon took this appeal.

"Two questions are presented. The first is whether a phonograph record is a 'device' within the meaning of Sec. 201 (h) of the Act. 21 U. S. C. Sec. 321 (h). The second question, which arises only if the first is answered in the affirmative, is whether the records in question are misbranded within the meaning of Sec. 502 (a) id. 21 U. S. C. Sec. 352 (a).

"Section 201 (h) of the Act under consideration provides in material part that '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.'

"Certainly a phonograph record, if not itself an instrument or an apparatus, is a contrivance. And moreover, it is without a question a component, part or accessory of a phonograph, or like record playing machine, which in its turn is without any doubt at all an instrument, apparatus or contrivance. The real question therefore is whether the libeled records were intended for either of the uses described in (1) or (2) of Sec. 201 (h), *supra*. Obviously the records were intended for use in the cure, mitigation, treatment or perhaps prevention of insomnia. But the medical experts who testified at the trial were agreed that insomnia is not a disease, but is a symptom of a disease, usually although not necessarily a neurological one, or of an emotional disturbance of some kind. Thus it may be argued that the records do not fall within the coverage of (1) above.

"However, all the expert witnesses who testified on the point were unanimous that sleep is a function of the body, or body and mind, of man and other animals, and this testimony brings the records within the terms of (2), supra, for their intended use was to affect that function, i. e., to induce sleep in those who needed it but had difficulty in obtaining enough. Without further laboring the point it will suffice to say that the records involved are 'devices' within the meaning of Sec. 201 (h) (2) of the Act.

"The question therefore arises whether the records are misbranded within the meaning of Sec. 502 (a) of the Act in that their labeling (which term includes not only the actual labels on the records and their containers or wrappers, but also any other written, printed, or graphic matter accompanying them (Sec. 201 (m) id.), 'is false or misleading in any particular.'

"The sounds produced by the record when played upon any standard phonograph or record player are the voice of Ralph Slater, the claimant, superimposed upon faint background music. On the side of the record intended to be played first the claimant explains how the record is to be used, in the course of which he says: 'You may not be able to teach yourself to sleep, yet listening to me and believing as you must believe, that I can help you, makes insomnia a thing of the past.'

"The statements on the album stress Slater's 'uncanny' and 'phenomenal' power to induce sleep by suggestion, even though not personally present, his long and arduous training, and the fact that his method is well tested and efficacious 'in the treatment of unusual, difficult psychoneurotic cases.' In the leaflet it is stated, among other things, that 'Mr. Slater, who has put people to sleep on the stage, and by various powers of remote contact, has translated his power into this record which will be invaluable to everyone who suffers from insomnia.' The certificate guarantees that the record 'will induce blissful sleep in the most delightful manner,' and the display card and poster, although they seem innocuous enough considered separately and apart from their context, convey the same impression.

"Reading the foregoing labeling together, in the way it would be read by persons who might be sufficiently interested to read it at all, conveys the impression that the record is a cure-all for insomnia from whatever cause, or at least is an adequate substitute for medication.<sup>1</sup> This is not only misleading but also false, for the evidence clearly establishes that the record can not possibly do as much. Indeed the expert witnesses called by the Government who had made actual tests of the record on persons suffering from insomnia, testified unanimously that it proved wholly ineffectual, and one of them went even further and said that it might in some cases be actually harmful in that a person might resort to it for trial and in so doing postpone medical care and treatment for the cause of the insomnia from which he suffered. And the medical experts called by the claimant did not flatly contradict the Government's evidence. Although they said that in their opinion based upon hearing the record a few times (they had not conducted actual tests) it might prove helpful in certain cases of insomnia, they freely admitted on cross-examination that some of the statements in the labeling were 'extravagant.' For instance they would by no means go so far as to say, indeed they denied, that the record 'makes insomnia a thing of the past,' or that it would be 'invaluable to everyone who suffers from insomnia.' Thus it cannot be said that the labeling of the record is not 'false or misleading in any particular' and from this it follows that the record is misbranded within the meaning of Sec. 502 (a) of the Act.

"The decree of the District Court is vacated and set aside and the case is remanded to that Court for further proceedings consistent with this opinion."

On December 15, 1953, following the remanding of the case to the United States District Court, an order was entered vacating the judgment of April 13, 1950, and providing for the condemnation and destruction of the records and accompanying literature under seizure.

<sup>1</sup> Indeed on the inside of the front cover of the album the statement is made in a testimonial that Slater's "aim is to discourage the fad for sleeping pills."

# U. S. Department of Health, Education, and Welfare

## FOOD AND DRUG ADMINISTRATION

### NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

4101-4120

### DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare, and include, where indicated, the results of investigations by the Department, prior to the institution of the proceedings. Published by direction of the Secretary of Health, Education, and Welfare:

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs*.

WASHINGTON, D. C., April 27, 1954.

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\*For presence of a habit-forming narcotic without warning statement, see No. 4111; omission of or unsatisfactory ingredients statements, No. 4110; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 4110, 4111; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 4110, 4116.