

down and down; to reveal a whole new world of buoyant energy, vitality, and strength when the signs of advancing age are due to lack of thiamine, riboflavin, niacinamide, and vitamin C; to build new, red blood; to attack the true, basic causes of the tired feeling, poor appetite, loss of weight and strength, insomnia or sleeplessness, and other conditions of deficiencies in one's nutritional intake that may be responsible for one's condition; and to enable one to really begin to enjoy life again and to know the joy of feeling one's level best.

LABEL, IN PART: (Bottles) "Super Lipitrons Improved B Complex Vitamin C Iron Vitamin Industries Incorporated 1511 Davenport St., Omaha 2, Nebr. * * * Each Capsule Contains: Vitamin B₁---- 15 mgm. Vitamin B₂---- 6 mgm. Vitamin C---- 50 mgm. Niacinamide---- 30 mgm. Calcium Pantothenate---- 3 mgm. Vitamin B₆---- 0.5 mgm. Liver Concentrate---- 30 mgm. Choline Dihydrogen Citrate---- 20 mgm. Inositol---- 20 mgm. Iron as Ferrous Gluconate---- 30 mgm. Folic Acid---- 0.1 mgm. Vitamin B₁₂ USP (Crystalline)---- 3 mcg. and dl-Methionine---- 20 mgm."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article in bulk and in the bottles failed to bear adequate directions for use for which it was intended. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: September 17, 1952. Vitamin Industries, Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond to be brought into compliance with the law, under the supervision of the Federal Security Agency. The product was relabeled.

4029. Misbranding of Drown Radio Therapeutic Instrument. U. S. v. Ruth B. Drown (Drown Laboratories). Motion for dismissal of information denied. Plea of not guilty. Tried to court and jury. Verdict of guilty. Fine, \$1,000. Judgment affirmed on appeal to Court of Appeals for Ninth Circuit. Petition for certiorari denied by Supreme Court. (F. D. C. No. 29440. Sample No. 60624-K.)

INFORMATION FILED: January 29, 1951, Southern District of California, against Ruth B. Drown, trading as Drown Laboratories, Los Angeles, Calif.

ALLEGED SHIPMENT: On or about October 28, 1948, from the State of California into the State of Illinois, of 1 *Drown Radio Therapeutic Instrument*.

The device was accompanied by certain labeling consisting of circulars entitled "The Drown Radio Diagnostic Therapeutic Photographic Instruments"; leaflets entitled "Drown Atlas"; a chart dated March 7, 1949, and entitled "The Drown Radio Therapy . . . Home Vibra Ray Diagnosis"; a chart dated February 7, 1949, and entitled "Drown Laboratory of Radio Therapy . . . Treatment Rates"; a letter signed "Dr. R. B. Drown" replying to a letter dated March 9, 1949, from Mr. Rice to Dr. Drown; a chart dated July 15, 1949, and entitled "Drown Laboratory of Radio Therapy . . . Treatment Rates"; and a letter dated August 3, 1949, from Dr. Ruth B. Drown to Mr. E. C. Rice. The device was accompanied also by 6 ampuls of drugs to be used unopened in conjunction with the operation of the device.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying labeling of the device were false and misleading since the device, when used with or without the unopened ampuls of drugs accompanying it, would not provide the therapeutic benefits stated and implied. The

statements suggested that the device would eliminate a lump or lumps in the breast and prevent cancer therefrom; that it would treat disease; that it would direct the body energy to the diseased area, resulting in the formation of healthy cells; that it would step up the vibrations in the area of the diseased organ, bringing in new cells and causing the diseased cells, which cannot live in the higher rate of vibration, to fall away; that it would bring about cell division; that it would be efficacious in treating any part of the body and in treating, selectively, the area into which it was "tuned"; that it surpassed any other known method of therapy; that it would be efficacious in the treatment of kidney and bladder complications, adhesions, tipped uterus, extra kidney, painful urination, calcium deposit in the ureter and urethra, inflammation and streptococcus in the urethra and in the pyloric end of the stomach, and bladder; that it would be efficacious in the treatment of cirrhosis and carcinoma of the right kidney and interstitial tissue; that it would be efficacious in the treatment of low function of the left suprarenal gland, pancreas, prostate, and testicles of a six-year-old boy; that it would be efficacious in the treatment of fibrous adhesions in the brain and meningeal tissue, affecting the eleventh dorsal; that it would be efficacious in the treatment of contracted brain sinus, cystic fluid in the brain and madulla, heart trouble of many years' standing, head pains and noises, "explosions" in right ear when falling asleep, constipation, pains in the lower back, and enlargement and trauma of left ventricle of the heart; that it would be efficacious in the treatment of calcium deposit in the right kidney, cystic fluid in the right kidney and ureter, aftereffects of scarlet fever, septicemia in the left mastoid, headaches, streptococcus, abscesses, loss of speech and memory, inability to digest food, vomiting of bile, frequent passing into coma, abscesses draining in an arm, an elbow, and the back of a hand, inability to lift the arm, and abscesses in the brain, left medulla, and left ear; that it would be efficacious in the treatment of low functioning of most of the glands, affections of the glands, female organs, male organs, and blood, head colds, sore throat, cold in the lungs, and affections of the left and right bronchials and lungs; that it would be efficacious in the treatment of worry, fear, and nervousness; and that it would be efficacious in the treatment of cold with an achy feeling, cold with a hot and cold feeling, affections of the lymphatics of the right breast, and affections of the kidney, gallbladder, colon, liver, ovary, small intestine, bile duct, uterus, and rectum.

Further misbranding, Section 502 (a), the labeling of the device suggested that another Drown device, a diagnostic instrument, would tune into the body and its various organs, glands, systems, and parts so as to measure their function and detect the presence of disease, record "impinged" nerves, count the cells in the blood, analyze urine, and ascertain blood pressure and body temperature; that the diagnostic device would furnish a complete and scientifically accurate blueprint of the body and uncover many obscure conditions; and that it would employ the body's energy (that is, the electromagnetic force generated by the combination of minerals and fluids in the body and the total life force—an invisible light ray) in the diagnosis of disease and in the selection of remedies for disease. The diagnostic device was incapable of accomplishing such results.

Further misbranding, Section 502 (f) (1), the labeling of the device failed to bear adequate directions for use in the treatment of any of the conditions for which it was suggested in its labeling since the labeling failed to specify the frequency, duration, time, method, or manner of application or usage of the device or drugs in the treatment of such conditions.

DISPOSITION: On April 2, 1951, the defendant filed a motion to dismiss the information, and on April 27, 1951, the court denied this motion. On September 11, 1951, the case came on for trial upon the defendant's plea of not guilty. The trial was had before a jury and was concluded with a verdict of guilty on September 24, 1951. On October 22, 1951, the court fined the defendant \$1,000.

An appeal was taken by the defendant to the United States Court of Appeals for the Ninth Circuit, and on September 10, 1952, the following opinion was handed down by that court:

ORR, *Circuit Judge*: "The appellant, Dr. Drown, is a chiropractor who does business in Hollywood, California, under the name of Drown Laboratories. Appellant manufactures certain photographic, therapeutic and diagnostic instruments of her own design which she uses in her practice. She sold one of these instruments to a Mr. Rice, resident of Blue Island, Illinois, for which she was charged with selling a device that was misbranded, in violation of the Federal Food, Drug and Cosmetic Act, 21 U. S. C. A. § 301 et seq., by reason of claims in its labeling which were allegedly false and misleading both with respect to the particular instrument sold to Rice and with respect to another instrument also designed by the appellant.¹

"Fantastic therapeutic and diagnostic qualities are claimed by appellant for her instruments in their labeling. The Drown Radio Therapeutic Instrument, the device whose sale resulted in her arrest, is represented as capable of eliminating a lump in the breast and preventing cancer therefrom; as efficacious in treating kidney and bladder complications, tipped uterus, extra kidney, painful urination, streptococcus in the urethra and the pyloric end of the stomach, and bladder, cirrhosis and carcinoma of the right kidney, low function of the left suprarenal gland, pancreas, fibrous adhesions in the brain and meningeal tissue, brain sinus, cystic fluid in the brain and medulla, heart trouble, head pains and noises, explosions in right ear while falling asleep, constipation, pains in the lower back, abscesses, loss of speech and memory, worry, fear and nervousness, conditions of the colon and liver. The device is further represented as effective in the treatment of many other ailments; and it is asserted that the contraption 'far surpasses any other known method of . . . therapy.'² Another larger instrument advertised for sale by appellant is represented as having not only the therapeutic qualities attributed to the smaller instrument but also extraordinary diagnostic properties.³

"Appellant's instruments employ no commercial electricity; they are represented as employing the patient's own body energy in diagnosis, remedy selection and treatment.⁴ The instruments are based upon appellant's theory of vibration: ' . . . under the laws of vibration, each individual has a rate of vibration peculiar to himself. In addition, each organ, gland, etc., in the body has its own rate of vibration. Likewise various diseases all vibrate to specific rates (slower or coarser than the normal body rates and more akin to earth vibrations).'⁵ Appellant asserts that this body energy may be directed through her instrument back to the diseased part of the body at the same vibration rate previously found in diagnosis to be appropriate for the treatment of that particular area. 'This steps up the vibrations in that particular area . . . and the diseased cells will automatically fall away, since disease cannot live in the higher rate of vibration.'⁶ Both diagnosis and treatment, the

¹ The one count information was based upon 21 U. S. C. §§ 321 (h), 331 (a), 333 (a), 352 (a), and 352 (f) (1).

² Most of these claims are made in the circular entitled "The Drown Radio Therapeutic Photographic Instruments."

³ This instrument is represented as capable of measuring the function of the various parts of the body, detecting the presence of disease, and taking blood count, urinalysis, blood pressure and temperature; all accomplished merely by tuning in on the vibrations of the body.

⁴ "By body energy we mean that electro-magnetic force which is generated by the combination of the minerals and the fluids of the body, as well as the total life force, which is an invisible light ray just past the white light in the spectrum"

⁵ See footnote 2.

⁶ See footnote 2.

appellant claims, can be accomplished either directly or with the patient absent entirely from the physical proximity of the instrument. When the patient is present, two pieces of metal attached by wires to the instrument are placed upon the body, a drop of the patient's blood is placed in the device, and unopened ampuls of chemicals are sometimes placed on the face of the instrument. When the patient is not present, diagnosis and treatment may still take place, a piece of blotting paper with a second drop of the patient's blood being clamped between the two pieces of metal.

"Two of the Government's witnesses, one a physicist and the other a radio engineer, testified that they had taken the instruments apart and found that the devices consist of a wire with two dissimilar metals as electrodes on either end; that in effect they operate in a manner similar to a chemical battery; that when the circuit is completed by placing the electrodes in contact with the human body or any other conductor of electricity a minute flow of current is generated and may be measured by the micrometer in the device; that the devices are incapable of measuring, detecting, or transmitting electromagnetic energy of any kind.

"Six eminent medical witnesses testified for the Government. Each is an authority in a specialized area of medicine. These expert witnesses expressed the unanimous belief that appellant's instruments are useless for diagnosis or treatment of any human ailment. Dr. Carpender testified concerning actual tests conducted by the appellant at the University of Chicago, which tended to support the conclusions of the Government's medical witnesses.⁷

I. THE INTERSTATE TRANSACTION

"Rice, concerned about a lump in his wife's breast, had been advised by a business friend, while temporarily in Los Angeles, to contact appellant. On phoning appellant's place of business in Hollywood, Rice was informed that she was then in Chicago. When Rice returned to his home in a suburb of Chicago he made an appointment with appellant for an examination of his wife. Mrs. Rice had been previously examined by her family doctor who had suspected a possible cancer and suggested an immediate biopsy. Appellant concluded from her examination of Mrs. Rice on April 23, 1948, by means of one of her instruments that the lump was not a cancer but was caused by a fungus that had spread through her digestive system into the liver.⁸ Appellant at that time gave Mr. and Mrs. Rice a copy of a pamphlet describing the alleged qualities of her devices⁹ and recommended treatments with the Drown Radio Therapeutic Instrument by a Dr. John, who practiced in Chicago. Mrs. Rice commenced taking the treatments and appellant advised their continuation upon re-examination of Mrs. Rice in September, 1948. The treatments continued until, on October 28, 1948, Rice went to the Drown Laboratories in Hollywood and personally purchased the device in question. Rice returned to Blue Island, Illinois, and his wife used the instrument to treat the lump in her breast.

"Appellant first contends that the purchase of the Drown Radio Therapeutic Instrument by Rice at the Drown Laboratories in Hollywood was a wholly intrastate transaction and, therefore, not within the scope of the Federal Food, Drug, and Cosmetic Act. It is alleged that transportation in interstate commerce or an obligation to so transport on the part of the appellant is an essential element of the offense; that since any transportation in interstate commerce was brought about by the purchaser, the seller, Dr. Drown, was not criminally responsible.

⁷ Dr. Carpender was present at tests carried on by the appellant at the University of Chicago on December 31, 1949. The appellant attempted to diagnose the physical condition of three persons from samples of their blood which had been obtained by the University and dried on small pieces of filter paper identified only by number. The diagnoses of Dr. Drown, obtained by means of one of her instruments, differed radically from the actual physical condition of the persons in question as it appeared in the records obtained by the University in preparation for the tests.

⁸ Testimony was to the effect that at the time of the trial Mrs. Rice's condition was malignant, and she was physically unable to make the trip to Los Angeles for the purpose of testifying.

⁹ See footnote 2.

"Appellant relies upon a number of cases dealing with the power of a state to tax goods moving in interstate commerce.¹⁰ They are not in point since the question in such cases does not concern the power of Congress to regulate, but whether a particular exercise of state power in view of its nature and operation must be deemed in conflict with the federal power. The power of a state to tax is not necessarily inconsistent with the power of Congress to regulate under the Commerce Clause.¹¹ *Minnesota v. Blasius*, 290 U. S. 1 (1933); *Stafford v. Wallace*, 258 U. S. 495 (1922); *Bacon v. Illinois*, 227 U. S. 504 (1913); *Swift & Co. v. United States*, 196 U. S. 375 (1905).

"Appellant argues that federal power over interstate commerce is limited to transportation. We do not agree. The power of Congress to regulate interstate commerce may be exercised to the utmost extent, and acknowledges no limitations other than those that are prescribed by the Constitution. *Gibbons v. Ogden*, 9 Wheat. 1 (1824). Where goods are purchased in one state for transportation to another, the commerce includes the purchase quite as much as it does the transportation. *Currin v. Wallace*, 306 U. S. 1 (1939); *Lemke v. Farmers Grain Co.*, 258 U. S. 50 (1922); *Dahnke-Walker Milling Co. v. Bondurant*, 257 U. S. 282 (1921). The place where title technically passes is not significant. *Santa Cruz Fruit Packing Co. v. N. L. R. B.*, 303 U. S. 453 (1938); *N. L. R. B. v. Lavaur*, 115 F. 2d 105 (1st Cir. 1940), cert. denied, 312 U. S. 682. Even if the sale to Rice with knowledge that he intended to take the device to Illinois be not considered part of the stream or flow of commerce, a 'flow of commerce' is not essential to the federal power to regulate. The instances in which the metaphor 'stream of commerce' has been used are but particular, and not exclusive, illustrations of the protective power which Congress may exercise. *Santa Cruz Fruit Packing Co. v. N. L. R. B.*, *supra*; *N. L. R. B. v. Jones & Laughlin Steel Corp.*, 301 U. S. 1 (1937). The power to regulate wholly intrastate activities because of their relation to or effect upon interstate commerce is now established. *Mandeville Island Farms, Inc. v. American Crystal Sugar Co.*, 334 U. S. 219 (1948); *Wickard v. Filburn*, 317 U. S. 111 (1942); *United States v. Wrightwood Dairy Co.*, 315 U. S. 110 (1942); *United States v. Darby*, 312 U. S. 100 (1941); *N. L. R. B. v. Jones & Laughlin Steel Corp.*, *supra*; *Stafford v. Wallace*, *supra*. The power of Congress to regulate the sale of a drug within one state where transportation to another state by either the purchaser or seller is contemplated by the parties therefore cannot be successfully disputed.

"Having determined that Congress had the power to regulate the sale in question, we next consider whether Congress intended to exercise that power. Appellant asserts that transportation in interstate commerce or an obligation to so transport on the part of the seller is an essential element to criminal responsibility. The statute prohibits 'The introduction or *delivery for introduction into interstate commerce* of any food, drug, or cosmetic that is adulterated or misbranded.' 21 U. S. C. A. § 331 (a) (Our emphasis). Appellant's interpretation fails to give meaning to the entire wording of the statute. Referring to this Act, the Supreme Court of the United States has said: 'The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words.' *United States v. Dotterweich*, 320 U. S. 277, 280 (1943). See *United States v. Walsh*, 331 U. S. 432, 434 (1947). Having in mind the broad purpose of the Act, protection of the public health, we believe that Congress intended to prohibit the delivery of a misbranded device by a seller to the purchaser where the seller has knowledge that the purchaser intends to introduce the device into interstate commerce by taking it into another state. The Tenth Circuit adopted this interpretation of the statute in a recent case, *United States v. Sanders*, . . . F. 2d . . . (May 7, 1952), where a seller was held to have violated an injunction by selling misbranded drugs intrastate knowing that the purchasers

¹⁰ For example: *Superior Oil Co. v. Mississippi*, 280 U. S. 390 (1930); *United Fuel Gas Co. v. Hallanan*, 257 U. S. 277 (1921); *McCluskey v. Marysville & Northern Railway Co.*, 243 U. S. 36 (1917); *Ware & Leland v. Mobile County*, 209 U. S. 405 (1908); *New York, ex rel. Hatch v. Reardon*, 204 U. S. 152 (1907); *Coe v. Errol*, 116 U. S. 517 (1886); *Utah Power & Light v. Frost*, 52 F. 2d 226 (Idaho 1931).

¹¹ *United States Constitution*, Art. I, § 8.

intended to take the drugs out of the state. Such an interpretation gives reasonable meaning to each word of the statutory prohibition. A comparable interpretation has been given to similar language in the Fair Labor Standards Act. See *Tobin v. Grant*, 79 F. Supp. 975 (N. D. Cal. 1948).

"The appellant endeavors to distinguish the Sanders case by pointing out that the defendant there was engaged regularly in an interstate business of selling. The Sanders case, however, does not turn on the nature of the seller's business, but rather upon whether the seller had knowledge that the misbranded drugs would be taken out of the state. The Act does not require a business; it prohibits *each* sale in violation of the statutory prohibition. 21 U. S. C. A. § 331 (a).

"The evidence was sufficient to support a finding that the sale to Rice constituted 'delivery for introduction into interstate commerce.' Both by recommending that Mrs. Rice receive treatments by the Drown Radio Therapeutic Instrument and through the descriptive circular that was given to Mr. and Mrs. Rice in Chicago, the appellant stimulated interest in her device and led Mr. Rice to believe that her instrument 'far surpasses any other known method of diagnosis or therapy.' The appellant knew the device was to be used to treat a lump in Mrs. Rice's breast, and it is obvious that she contemplated that Mr. Rice would take the device back to his Illinois home. The invoice of sale states that the instrument was sold to 'Mr. Edgar Rice, 13005 Greenwood Ave., Blue Island, Illinois.'

II. THE INFORMATION

"Appellant asserts that the information upon which she was convicted is defective in a number of ways.

"First, it is said that the information fails to allege a crime. The cases which the appellant cites¹² merely set forth various applications of the general rule in testing the sufficiency of an indictment or information. As this court stated in *Woolley v. United States*, 97 F. 2d 258, 261 (9th Cir. 1938), cert. denied, 305 U. S. 614: 'It is not necessary that an indictment set forth a myriad of detail, or that it satisfy every objection which human ingenuity can devise. It is enough if it charges every essential element of the offense and at the same time apprises the accused of the charge against him in such a manner that he can prepare his defense without being taken by surprise, and that he have the assurance that he will be protected against another prosecution for the same offense.' See *Hagner v. United States*, 285 U. S. 427, 431 (1932). Appellant contends that the Government failed to plead sufficient facts as to the nature of the device and the method and manner of interstate shipment to inform her sufficiently of the nature of the charge and protect her from subsequent prosecution for the same offense. The appellant was apprised of the nature of the charge to the extent that she entered into a stipulation as to facts. The information described the alleged offense in considerably greater detail than the form of indictment appearing in the Appendix of Forms following the Federal Rules of Criminal Procedure, 18 U. S. C. A. See Form 11. The information specifies the name, model number and serial number of the particular device sold to Rice, thereby precluding a second prosecution for its sale.¹³ The test of an information is not whether it could have been made more definite and certain in any way. *Hagner v. United States*, *supra*. Appellant could have sought a bill of particulars to clarify any uncertainty. Fed. R. Crim. P. 7 (f).

¹² For example:

United States v. Simmons, 96 U. S. 306 (1878);
Fontana v. United States, 262 F. 283 (8th Cir. 1919);
United States v. Albert Steinfeld & Co., 209 F. 904 (Ariz. 1913);
United States v. Burns, 54 F. 351 (C. C. D. W. V. 1893);
United States v. Nelson, 52 F. 646 (Minn. 1892).

¹³ The information alleges:

"That displayed upon said device was certain labeling which consisted of the following printed and graphic matter:

DROWN RADIO THERAPEUTIC INSTRUMENT

Patent Applied For

Manufactured by

DROWN LABORATORIES

LOS ANGELES

Model No. 98M

Serial No. 10264817"

"Appellant next asserts, with respect to violation of the requirement of a label containing adequate instructions for use imposed by 21 U. S. C. A. § 352(f) (1), that she should have been exempted under the terms of the proviso granting exemption for any drug or device where the Administrator finds that directions for use are not necessary for the protection of public health.¹⁴ She argues that the use of her instruments 'could not possibly harm any human being.' While the instruments may be harmless in themselves, their danger lies in the possibility that 'ignorant and gullible persons are likely to rely upon them instead of seeking professional advice for conditions they are represented to relieve or prevent.' *United States v. Kordel*, 164 F. 2d 913, 916 (7th Cir. 1948), affirmed, 335 U. S. 345; see *Ewing v. Mytinger & Casselberry, Inc.*, 339 U. S. 594, 600 (1950). In this broader sense appellant's instruments cannot be considered harmless. Thus, even if the proviso were to be considered mandatory in certain situations, see Justice Rutledge concurring, *United States v. Sullivan*, 332 U. S. 689, 704 (1948), the appellant has not made a sufficient showing that the requirements of 21 U. S. C. A. § 351 (f) (1) are 'not necessary for the protection of the public health' as regards her instruments.

"Complaint is made that the information is based upon irrelevant and immaterial matter insofar as it charges that certain circulars and letters not in existence at the time of the sale in question constitute part of the instrument's labeling.¹⁵ Most of the claims concerning the qualities of appellant's instruments are made in the circular actually given to Rice at the time of the sale. It was stipulated that all of the circulars and letters were part of the labeling of the device. Further, the Supreme Court of the United States has held that 'labeling' in the statutory sense is not confined to materials given simultaneously to the purchaser with the product, but rather that materials sent to the purchaser subsequent to the sale may constitute part of the 'labeling' where one integrated transaction is involved.¹⁶ *Kordel v. United States*, 335 U. S. 345 (1948). In the present case the subsequent materials gave instructions as to use of the instrument and contained diagnoses of Mrs. Rice's condition. In the light of the integrated nature of the whole transaction these subsequent materials constituted part of the whole transaction.

"It is further asserted that reference in the information to a second instrument which was not sold to Rice was prejudicial. Appellant claims she cannot determine whether she is charged with misbranding the instrument sold to Rice, another instrument, or both instruments. We find that the information clearly alleges that *the device sold to Rice was misbranded* in that its labeling contained false and misleading therapeutic claims about that device and false and misleading diagnostic claims about a second device. The applicable statute states that a drug or device shall be deemed misbranded 'if its labeling is false or misleading *in any particular*.' 21 U. S. C. A. § 352 (a) (our emphasis). The statute thus does not confine the definition of misbranding to statements concerning the labeled device itself. We believe that the interpretive regulation of the Federal Security Administrator construing this

¹⁴ "§ 352. Misbranded drugs and devices. A drug or device shall be deemed to be misbranded—

"(f) Directions for use and warnings on label. Unless its labeling bears (1) adequate directions for use; Provided, that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the administrator shall promulgate regulations exempting such drug or device from such requirement."

¹⁵ The information described the device's labeling as follows:

"That accompanying said device was certain additional labeling relating to said device namely, circulars entitled 'The Drown Radio Diagnostic Therapeutic Photographic Instruments'; leaflets entitled 'Drown Atlas'; a chart dated March 7, 1949, and entitled 'The Drown Radio Therapy Home Vibra Ray Diagnosis'; a chart dated 2/7/49 and entitled 'Drown Laboratory of Radio Therapy Treatment Rates'; a letter signed Dr. R. B. Drown replying to a letter dated March 9, 1949, from Mr. Rice to Dr. Drown; a chart dated 7/15/49 and entitled 'Drown Laboratory of Radio Therapy Treatment Rates'; and a letter dated August 3, 1949, from Dr. Ruth B. Drown to Mr. E. C. Rice: [Our emphasis.]

¹⁶ "§ 321. Definitions; generally. For the purposes of this chapter—

"(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

language to include representations on the labeling of one device with respect to another device constitutes a reasonable construction of the statute.¹⁷

III. OTHER CONTENTIONS

"A motion for an instructed verdict filed by the appellant at the close of the Government's case was denied by the district court. No similar motion was made at the close of all the evidence. Appellant now seeks to assert that the denial of her motion for an instructed verdict constituted error. However, appellant by offering evidence after her motion was denied and not subsequently renewing that motion, waived the motion so that it need not be considered on appeal. *Mosca v. United States*, 174 F. 2d 448 (9th Cir. 1949) and cases cited at 451; see *Gaunt v. United States*, 184 F. 2d 284, 290 (1st Cir. 1950), cert. denied, 340 U. S. 917.

"On October 22, 1951, 28 days after the verdict had been returned by the jury, appellant moved for permission to file motions for a new trial and in arrest of judgment. She contends that denial of these motions by the district court constituted error because she had substituted counsel and he was unable to familiarize himself with the trial record at an earlier date. A motion for a new trial based on any grounds other than newly discovered evidence, as well as a motion in arrest of judgment, must be filed within five days after verdict or within such further time as the court may fix during that five day period. Fed. R. Crim. P. 33 and 34. Grounds for extending this five day period are expressly limited. Fed. R. Crim. P. 45 (b). The district court therefore lacked jurisdiction to grant the appellant's motions. *Marion v. United States*, 171 F. 2d 185 (9th Cir. 1948), cert. denied, 337 U. S. 944; see *United States v. Smith*, 331 U. S. 469, 473-475 (1947). The dictum in *Abbot v. Brown*, 241 U. S. 606, 609 (1916), relied upon by the appellant, is not in point since it involves a situation where a motion for new trial was granted in violation of a mere regulation of practice followed by a particular district court prior to the adoption of the Federal Rules of Criminal Procedure, 18 U. S. C. A.

"A number of other contentions are made by the appellant in her brief. However, we do not find them sufficiently substantial to warrant discussion. "Judgment affirmed."

A petition for a writ of certiorari subsequently was filed with the United States Supreme Court, and on January 19, 1953, this petition was denied.

¹⁷ 21 C. F. R. (1949 Ed.) Sec. 1.101 (p. 12): "Drugs and devices; labeling misbranding—

(a) Among representations in the labeling of a drug or device which render such drug or device misbranded is a false or misleading representation with respect to another drug or device or a food or cosmetic." [Our emphasis.]

4030. Misbranding of Le Joi device. U. S. v. 160 Devices, etc. (F. D. C. No. 33126. Sample No. 17220-L.)

LIBEL FILED: May 15, 1952, Southern District of California.

ALLEGED SHIPMENT: On or about April 15, 1952, by the Propenex Co., from Minneapolis, Minn.

PRODUCT: 160 *Le Joi devices* at Hollywood, Calif., each of which was packed in a plastic case containing a leaflet entitled "Instructions Le Joi." Additional leaflets entitled "New Horizons," which were used by the consignee in promoting the sale of the device, were caused to be printed by the consignee in Los Angeles, Calif., from copies of a similar leaflet originally obtained from the Propenex Co.

Examination showed that the device consisted of a thin rubber tube with a locking attachment at each end.

NATURE OF CHARGE: The libel alleged that the device was misbranded while held for sale after shipment in interstate commerce within the meaning of