fact that it contained cinchophen, was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling, i. e., "One every 3 hours, follow with glass of water."

DISPOSITION: April 7, 1947. A plea of nolo contendere having been entered, the court imposed a fine of $200 on count 3 of the information. With respect to counts 1 and 2 of the information, the court suspended the imposition of sentence and placed the defendant on probation for 1 year, conditioned that he do nothing in conflict with the Federal Food, Drug, and Cosmetic Act, and that he stop the use of cinchophen, unless it appears in a prescription of a duly authorized physician.

2253. Misbranding of devices known as Anatatherm. U. S. v. 5 Devices * * *. (F. D. C. No. 23194. Sample No. 22246–H.)

LIBEL FILED: June 17, 1947, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about May 31, 1946, by the Miller Electro Research Laboratories, from Milwaukee, Wis.

PRODUCT: 5 devices known as *Anatatherm* at St. Louis, Mo., together with 12 circulars entitled "How the Anatatherm SW 150 Short Wave internal heat treatment relieves, corrects, stimulates" and 6 circulars entitled "The New Anatatherm Short Wave Internal Heat Treatment for Health." Examination showed that *Anatatherm* was a device to apply short radio waves to the body.

NATURE OF CHARGE: Misbranding, Section 502 (j), the article was dangerous to health when used with the frequency or duration prescribed, recommended, and suggested in its labeling, i. e., "Treatment Duration: Apply average power of Anatatherm for a period not to exceed one half hour. Three to four treatments per day are generally permissible."

Further misbranding, Section 502 (a), certain statements on the direction cards packed with the article and in the above-mentioned circulars accompanying the article were false and misleading. These statements represented and suggested that the article may be safely and efficaciously used in the treatment of impaired health, sluggish bowels, biliousness, gas pains, intestinal flu, colitis, painful hemorrhoids, prostatitis, colds, painful breathing, catarrhal congestion, asthmatic conditions, localized inflammation, neuralgia myalgia, chronic localized arthritis, arthritis deformans, tired, aching joints, neuritis, sluggish kidneys, grippe, contusions, muscle strains, myositis ossificans, sprains and dislocations, traumatic tenosynovitis, chronic arthritis, myositis and myofascitis (lumbago), fractures, genito-urinary conditions, pelvic infections, respiratory diseases, gastrointestinal diseases, acute and chronic sinusitis, diabetes, paralysis, abscesses, articular rheumatism, asthma, backache, bladder disorders, blood clot, boils, Bright's disease, bronchitis, bursitis, catarrh, carbuncle, colic, congestion, constipation, convulsions, cough, cystitis, deafness, discharge, dropsy, ear disorders, felon, fever, fistula, fracture, furuncles, gall bladder inflammation, gas pressure, headaches, hepatic disorders, hemorrhoids, indigestion, influenza, jaundice, kidney inflammation, laryngitis, lesions, lumbago, mastoiditis, muscular tension, nausea, nephritis, osteitis, ovaritis, peritonitis, pharyngitis, phlebitis, pleurisy, pneumonia, quinsy, rheumatism, salpingitis, sciatica, silicosis, stiff neck, synovitis, teeth abscess, thrombosis, tonsillitis, tooth extractions, ulcers, and whooping cough. The article may not be safely used and was not efficacious in the treatment of such diseases, conditions, and symptoms.

DISPOSITION: December 3, 1947. The Miller Electro Research Laboratories, claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond to be brought into compliance with the law, under the supervision of the Federal Security Agency.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

2254. Misbranding of sulfathiazole tablets. U. S. v. Jordan James Sullivan (Sullivan's Pharmacy). Tried to the court. Judgment for the Government. Defendant fined $200 and placed on two years' probation. Appealed to the Circuit Court of Appeals; judgment of District Court reversed. Certiorari to Supreme Court; judgment of District Court affirmed. (F. D. C. No. 16600. Sample Nos. 64091–F, 64236–F.)

INFORMATION FILED: January 2, 1946, Middle District of Georgia, against Jordan James Sullivan, trading as Sullivan's Pharmacy, at Columbus, Ga.

*See also Nos. 2251, 2255.

ALLEGED SHIPMENT: Between the approximate dates of November 25, 1943, to March 15, 1944, from the State of Illinois into the State of Georgia.

LABEL, IN PART: (When shipped) "1000 Tablets (Bisected) SULFATHIAZOLE (2-sulfanilamidothiazole) 0.5 gm. (7.7 grs.) Abbott-List No. 3430 Caution—To be used only by or on the prescription of a physician * * * Abbott Laboratories North Chicago, Ill., U. S. A."

ALLEGED VIOLATION: On or about September 29 and December 13, 1944, while the drug was being held for sale after shipment in interstate commerce, the defendant caused a number of tablets to be removed from the bottles in which they had been shipped in interstate commerce and caused them to be repacked in boxes bearing no other label than the statement "Sulfothiazal" or "Sulfathiazole," which acts caused the article to be misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling on the box failed to bear adequate directions for use; and, Section 502 (f) (2), it failed to bear such adequate warnings against use in those pathological conditions where the use of the article may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: On September 2, 1946, the case was tried to the court and the defendant was convicted. The sentence of the court was that the defendant pay a fine of $200, and that he be placed on probation for 2 years. On May 12, 1947, the case having been appealed to the Circuit Court of Appeals for the Fifth Circuit, the judgment of the District Court was reversed. The Government petitioned the Supreme Court for a writ of certiorari, which was granted; and on January 19, 1948, the following opinion was delivered by the Supreme Court, reversing the Circuit Court of Appeals and sustaining the judgment of the District Court, with Justices Frankfurter, Reed, and Jackson dissenting:

JUSTICE BLACK: "Respondent, a retail druggist in Columbus, Georgia, was charged in two counts of an information with a violation of § 301 (k) of the Federal Food, Drug, and Cosmetics Act of 1938. That section prohibits 'the doing of any . . . act with respect to, a . . . drug . . . if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded.'[1] Section 502 (f) of the Act declares a drug 'to be misbranded . . . unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use . . . dangerous to health, or against unsafe dosage . . . as are necessary for the protection of users.' The information charged specifically that the respondent had performed certain acts which resulted in sulfathiazole being 'misbranded' while 'held for sale after shipment in interstate commerce.'

"The facts alleged were these: A laboratory had shipped in interstate commerce from Chicago, Illinois, to a consignee at Atlanta, Georgia, a number of bottles, each containing 1,000 sulfathiazole tablets. These bottles had labels affixed to them, which, as required by § 502 (f) (1) and (2) of the Act, set out adequate directions for the use of the tablets and adequate warnings to protect ultimate consumers from dangers incident to this use.[2] Respondent bought one of these properly labeled bottles of sulfathiazole tablets from the Atlanta

---

[1] "Sec. 301. The following acts and the causing thereof are hereby prohibited:

* * * * *

"(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded." 52 Stat. 1042, 21 U. S. C. § 331 (k).

[2] The following inscription appeared on the bottle labels as a compliance with § 502 (f) (1) which requires directions as to use: "Caution.—To be used only by or on the prescription of a physician." This would appear to constitute adequate directions since it is required by regulation issued by the Administrator pursuant to authority of the Act. 21 C. F. R. Cum. Supp. § 2.106 (b) (3). The following appeared on the label of the bottles as a compliance with § 502 (f) (2) which requires warnings of danger: "Warning.—In some individuals Sulfathiazole may cause severe toxic reactions. Daily blood counts for evidence of anemia or leukopenia and urine examinations for hematuria are recommended.

"Physicians should familiarize themselves with the use of this product before it is administered. A circular giving full directions and contraindications will be furnished upon request."

consignee, transferred it to his Columbus, Georgia, drugstore, and there held the tablets for resale. On two separate occasions twelve tablets were removed from the properly labeled and branded bottle, placed in pill boxes, and sold to customers. These boxes were labeled 'sulfathiazole.' They did not contain the statutorily required adequate directions for use or warnings of danger.

"Respondent's motion to dismiss the information was overruled, a jury was waived, evidence was heard, and respondent was convicted under both counts.

"The Circuit Court of Appeals reversed. 161 F. 2d 629. The court thought that as a result of respondent's action the sulfathiazole became 'misbranded' within the meaning of the Federal Act, and that in its 'broadest possible sense' the Act's language 'may include what happened.' However, it was also of the opinion that the Act ought not to be taken so broadly but held to apply only to the holding for the first sale by the importer after interstate shipment.' Thus the Circuit Court of Appeals interpreted the statutory language of § 301 (k) 'while such article is held for sale after shipment in interstate commerce' as though Congress had said 'while such article is held for sale by a person who had himself received it by way of a shipment in interstate commerce.' We granted certiorari to review this important question concerning the Act's coverage.

"*First.* The narrow construction given § 301 (k) rested not so much upon its language as upon the Circuit Court's view of the consequences that might result from the broader interpretation urged by the Government. The court pointed out that the retail sales here involved were made in Columbus nine months after this sulfathiazole had been shipped from Chicago to Atlanta. It was impressed by the fact that, if the statutory language 'while such article is held for sale after shipment in interstate commerce' should be given its literal meaning, the criminal provisions relied on would 'apply to all intrastate sales of imported drugs after any number of intermediate sales within the State and after any lapse of time; and not only to such sales of drugs, but also to similar retail sales of food, devices and cosmetics, for all these are equally covered by these provisions of the Act.' The court emphasized that such consequences would result in far-reaching inroads upon customary control by local authorities of traditionally local activities, and that a purpose to afford local retail purchasers federal protection from harmful foods, drugs and cosmetics should not be ascribed to Congress in the absence of an exceptionally clear mandate, citing *Federal Trade Commission* v. *Bunte Bros.*, 312 U. S. 349. Another reason of the court for refraining from construing the Act as applicable to articles misbranded while held for retail sale, even though the articles had previously been shipped in interstate commerce, was its opinion that such a construction would raise grave doubts as to the Act's constitutionality. In support of this position the court cited *Labor Board* v. *Jones & Laughlin Steel Corp.*, 301 U. S. 1, 30, and *Schechter Poultry Corp.* v. *United States*, 295 U. S. 495.

"A restrictive interpretation should not be given a statute merely because Congress has chosen to depart from custom or because giving effect to the express language employed by Congress might require a court to face a constitutional question. And none of the foregoing cases, nor any other on which they relied, authorizes a court in interpreting a statute to depart from its clear meaning. When it is reasonably plain that Congress meant its Act to prohibit certain conduct, no one of the above references justifies a distortion of the congressional purpose, not even if the clearly correct purpose makes marked deviations from custom or leads inevitably to a holding of constitutional invalidity. Although criminal statutes must be so precise and unambiguous that the ordinary person can know how to avoid unlawful conduct, see *Krauss & Bros., Inc.* v. *United States*, 327 U. S. 614, 621–622, even in determining whether such statutes meet that test, they should be given their fair meaning in accord with the evident intent of Congress. *United States* v. *Raynor*, 302 U. S. 540, 552.

"*Second.* Another consideration that moved the Circuit Court of Appeals to give the statute a narrow construction was its belief that the holding in this case with reference to misbranding of drugs by a retail druggist would necessarily apply also to 'similar retail sales of food, devices and cosmetics, for all of these,' the court said, 'are equally covered by the same provisions of the Act.' And in this Court the effect of such a possible coverage of the Act is graphically magnified. We are told that its application to these local

sales of sulfathiazole would logically require all retail grocers and beauty parlor operators to reproduce the bulk container labels on each individual item when it is taken from the container to sell to a purchaser. It is even prophesied that, if § 301 (k) is given the interpretation urged by the Government, it will later be applied so as to require retail merchants to label sticks of candy and sardines when removed from their containers for sale.

"The scope of the offense which Congress defined is not to be judicially narrowed as applied to drugs by envisioning extreme possible applications of its different misbranding provisions which relate to food, cosmetics, and the like. There will be opportunity enough to consider such contingencies should they ever arise. It may now be noted, however, that the Administrator of the Act is given rather broad discretion—broad enough undoubtedly to enable him to perform his duties fairly without wasting his efforts on what may be no more than technical infractions of law. As an illustration of the Administrator's discretion, § 306 permits him to excuse minor violations with a warning if he believes that the public interest will thereby be adequately served. And the Administrator is given extensive authority under §§ 405, 503 and 603 to issue regulations exempting from the labeling requirements many articles that otherwise would fall within this portion of the Act. The provisions of § 405 with regard to food apparently are broad enough to permit the relaxation of some of the labeling requirements which might otherwise impose a burden on retailers out of proportion to their value to the consumer.

"*Third.* When we seek the meaning of § 301 (k) from its language we find that the offense it creates and which is here charged requires the doing of some act with respect to a drug (1) which results in its being misbranded, (2) while the article is held for sale 'after shipment in interstate commerce.' Respondent has not seriously contended that the 'misbranded' portion of § 301 (k) is ambiguous. Section 502 (f), as has been seen, provides that a drug is misbranded unless the labeling contains adquate directions and adequate warnings. The labeling here did not contain the information which § 502 (f) requires. There is a suggestion here that, although alteration, mutilation, destruction, or obliteration of the bottle label would have been a 'misbranding,' transferring the pills to non-branded boxes would not have been, so long as the labeling on the empty bottle was not disturbed. Such an argument cannot be sustained. For the chief purpose of forbidding the destruction of the label is to keep it intact for the information and protection of the consumer. That purpose would be frustrated when the pills the consumer buys are not labeled as required, whether the label has been torn from the original container or the pills have been transferred from it to a non-labeled one. We find no ambiguity in the misbranding language of the Act.

"Furthermore, it would require great ingenuity to discover ambiguity in the additional requirement of § 301 (k) that the misbranding occur 'while such article is held for sale after shipment in interstate commerce.' The words accurately describe respondent's conduct here. He held the drugs for sale after they had been shipped in interstate commerce from Chicago to Atlanta. It is true that respondent bought them nine months after the interstate shipment had been completed by their delivery to another consignee. But the language used by Congress broadly and unqualifiedly prohibits misbranding articles held for sale after shipment in interstate commerce, without regard to how long after the shipment the misbranding occurred, how many intrastate sales had intervened, or who had received the articles at the end of the interstate shipment. Accordingly we find that the conduct of the respondent falls within the literal language of § 301 (k).

"*Fourth.* Given the meaning that we have found the literal language of § 301 (k) to have, it is thoroughly consistent with the general aims and purposes of the Act. For the Act as a whole was designed primarily to protect consumers from dangerous products. This Court so recognized in *United States* v. *Dotterweich*, 320 U. S. 277, 282, after reviewing the House and Senate Committee Reports on the bill that became law. Its purpose was to safeguard the consumer by applying the Act to articles from the moment of their introduction into interstate commerce all the way to the moment of their delivery to the ultimate consumer. Section 301 (a) forbids the 'introduction or delivery for introduction into interstate commerce' of misbranded or adulterated drugs; § 301 (b) forbids the misbranding or adulteration of drugs while 'in interstate commerce'; and § 301 (c) prohibits the

'receipt in interstate commerce' of any misbranded or adulterated drug, and 'the delivery or proferred delivery thereof for pay or otherwise.' But these three paragraphs alone would not supply protection all the way to the consumer. The words of paragraph (k) 'while such article is held for sale after shipment in interstate commerce' apparently were designed to fill this gap and to extend the Act's coverage to every article that had gone through interstate commerce until it finally reached the ultimate consumer. Doubtless it was this purpose to insure federal protection until the very moment the articles passed into the hands of the consumer by way of an intrastate transaction that moved the House Committee on Interstate and Foreign Commerce to report on this section of the Act as follows: 'In order to extend the protection of consumers contemplated by the law to the full extent constitutionally possible, paragraph (k) has been inserted prohibiting the changing of labels so as to misbrand articles held for sale after interstate shipment.'[3] We hold that § 301 (k) prohibits the misbranding charged in the information.

"*Fifth.* It is contended that the Act as we have construed it is beyond any authority granted Congress by the Constitution and that it invades the power of the States. A similar challenge was made against the Pure Food and Drug Act of 1906, 34 Stat. 768, and rejected, in *McDermott* v. *Wisconsin*, 228 U. S. 115. That Act did not contain § 301 (k), but it did prohibit misbranding and authorized seizure of misbranded articles after they were shipped from one State to another, so long as they remained 'unsold.' The authority of Congress to make this requirement was upheld as a proper exercise of its powers under the commerce clause. There are two variants between the circumstances of that case and this one. In the *McDermott* case the labels involved were on the original containers; here the labels are required to be put on other than the original containers—the boxes to which the tablets were transferred. Also, in the *McDermott* case the possessor of the labeled cans held for sale had himself received them by way of an interstate sale and shipment; here, while the petitioner had received the sulfathiazole by way of an intrastate sale and shipment, he bought it from a wholesaler who had received it as the direct consignee of an interstate shipment. These variants are not sufficient we think to detract from the applicability of the *McDermott* holding to the present decision. In both cases alike the question relates to the constitutional power of Congress under the commerce clause to regulate the branding of articles that have completed an interstate shipment and are being held for future sales in purely local or intrastate commerce. The reasons given for the *McDermott* holding therefore are equally applicable and persuasive here. And many cases decided since the *McDermott* decision lend support to the validity of § 301 (k). See, *e. g.*, *United States* v. *Walsh*, 331 U. S. 432; *Wickard* v. *Filburn*, 317 U. S. 111; *United States* v. *Wrightwood Dairy Co.*, 315 U. S. 110; *United States* v. *Darby*, 312 U. S. 100; see *United States* v. *Olsen*, 161 F. 2d 669. *Reversed.*"

JUSTICE RUTLEDGE, *concurring:* "This case has been presented as if the Federal Food, Drug, and Cosmetics Act of 1938 had posed an inescapable dilemma. It is said that we must either (1) ignore Congress' obvious intention to protect ultimate consumers of drugs through labeling requirements literally and plainly made applicable to the sales in this case or (2) make criminal every corner grocer who takes a stick of candy from a properly labeled container and sells it to a child without wrapping it in a similar label.

"The trouble-making factor is not found in the statute's provisions relating specifically to drugs. Those provisions taken by themselves are clear and unequivocal in the expressed purpose to protect the ultimate consumer by the labeling requirements. So is the legislative history. Standing alone, therefore, the drug provisions would cover this case without room for serious question.

"However, those provisions do not stand entirely separate and independent in the Act's structure. In some respects, particularly in § 301 (k), they are interlaced with provisions affecting food and cosmetics. And from this fact is drawn the conclusion that this decision necessarily will control future decisions concerning those very different commodities.

---

[3] H. Rep. 2139, 75th Cong., 3d Sess., 3.