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643 F.2d 1043
UNITED STATES of America, Plaintiff-Appellant,
v.
H. Ray EVERS, M. D., an individual, doing business as Ra-Mar Clinic, Defendant-Appellee,
Ann H. Garrett et al., Defendants-Intervenors.
No. 78-2882.
United States Court of Appeals, Fifth Circuit.
April 27, 1981.

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Barry E. Teague, U. S. Atty., Montgomery, Ala., Frederic Freilicher, Robert B. Nicholson, Appellate Sec., Antitrust Div., Dept. of Justice, Washington, D. C., for plaintiff-appellant.

Kirkpatrick W. Dilling, Chicago, Ill., Albert W. Copeland, John A. Henig, Jr., Montgomery, Ala., for defendant-appellee.

Clifford W. Cleveland, Prattville, Ala., for defendants-intervenors.

Appeal from the United States District Court for the Middle District of Alabama.

Before GEE and RANDALL, Circuit Judges, and LYNNE [*], District Judge.

RANDALL, Circuit Judge:

In this action the government charges a licensed Alabama physician with a violation of section 301(k) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 331(k) (1976). That section prohibits, inter alia, the misbranding of a drug which is held for sale after shipment in interstate commerce. The government charges that the drug at issue, which is a prescription drug, was misbranded under section 502(f)(1) of the Act, 21 U.S.C. § 352(f)(1), which deems a drug to be misbranded unless its labeling contains "adequate directions for use." In particular, the government alleges that the physician promoted and administered a drug for a use that is not approved by the Food and Drug Administration (the FDA), without providing adequate directions for such use to his patients. The district court found that the physician had indeed failed to provide adequate directions for the intended use of the drug, but held that the physician's actions were within "the practice of medicine" and therefore beyond the constitutional reach of federal power and beyond the intended reach of the Act. The district court granted a final judgment in favor of the defendant physician in United States v. Evers, 453 F.Supp. 1141 (M.D.Ala.1978).

We do not reach the issue on which the district court's opinion rests, for we find that the government has not established a violation of section 301(k) of the Act. Since prescription drugs are required by regulations promulgated pursuant to section 502(f)(1) of the Act to bear adequate information for use by physicians but not for use by patients, and since the physician charged in this case was administering the drug to his own patients but not distributing it to other physicians, we hold that Dr. Evers has not violated section 301(k) of the Act by his failure to provide such "adequate directions for use" as are required by section 502(f)(1) of the Act. We therefore affirm the judgment of the district court in favor of the defendant.

I. THE FACTS

Dr. H. Ray Evers is the owner and operator of Ra-Mar Clinic, a health facility which opened in 1976 in Montgomery, Alabama. Dr. Evers and his clinic specialize in the treatment of chronic degenerative diseases. Although the clinic is not a hospital, it has a 40-bed capacity and does accept patients for treatment on a resident basis for periods of up to three or four weeks.

A central part of Dr. Evers' approach to the treatment of degenerative diseases is his use of "chemo-endartectomy therapy." Dr. Evers explains this therapy as "a special treatment given

by licensed medical doctors for the relief of poor circulation that has been caused by hardening of the arteries

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(arteriosclerosis, atherosclerosis)." [1] Dr. Evers' approach, which he describes as "holistic" and "preventative," seeks to alleviate circulatory disorders by creating the proper balance of metals, vitamins, enzymes and other substances in the body.

The most important part of Dr. Evers' chemo-endartectomy therapy is his use of "chelation." Chelation is a chemical reaction which occurs between certain drugs and various harmful metals which are in the bloodstream. These drugs, which Dr. Evers injects intravenously, form a bond with heavy metals in a form which allows them to pass out of the body through the kidneys. Chelating drugs are ordinarily used for the treatment of heavy metal poisoning, particularly lead poisoning. [2] According to Dr. Evers, however, this process also removes from blood vessels buildups of calcium which are blocking the vessels and causing hardening of the arteries. Dr. Evers claims that he has used chelation therapy with tremendous success in the treatment of circulatory disorders, and with little danger to his patients. See infra at notes 5-8.

Whether this process actually has this beneficial effect is a serious question. Dr. Evers' claims for his therapy are not generally accepted by the medical profession, and, as discussed below, the FDA has not approved any chelating drug for use in the treatment of circulatory disorders. [3] Moreover, chelating drugs bear a serious danger: if too many heavy metals are passed into the kidneys within too short a period of time, the patient may suffer kidney failure and may die as a result. 453 F.Supp. at 1143, 1145; infra at note 11 (FDA-approved label for the chelating drug used by Dr. Evers). An additional danger, of course, is that patients who could benefit from a more traditional mode of treatment (probably heart by-pass surgery) will be convinced by Dr. Evers' alternative to postpone that treatment until it is too late. 453 F.Supp. at 1144. The value of chemo-endartectomy, and in particular of chelation, was therefore argued at length in the district court, and is discussed in detail in the district court's opinion. 453 F.Supp. at 1143-47. Moreover, Dr. Evers' use of chelation therapy is the subject of an earlier suit brought by the government in the U.S. District Court for the Eastern District of Louisiana. United States v. An Article of Drug ... Diso-tate, 1977 Food Drug Cos.L.Rep. (CCH) P 38,086 (E.D. La.1976). In that suit, in which the government successfully sought an injunction to halt Dr. Evers' promotion and use of a particular chelating drug which he is no longer accused of prescribing, the court also considered the safety and effectiveness of Dr. Evers' practices. Three physicians testified that several deaths had been caused by Dr. Evers' use of chelation therapy, and the court concluded that the doctor's practices were indeed a serious danger.

The focus of the government's case against Dr. Evers is not, however, the potential danger in his use of chelation therapy. [4] Instead, the government challenges

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his vigorous promotion and advertising of chelating drugs for a use which has not been approved by the FDA. As the district court found, Dr. Evers "advertised in interstate commerce his use of chelating agents as treatment for arteriosclerosis." 453 F.Supp. at 1146. Unfortunately, the district court did not discuss this crucial aspect of Dr. Evers' operation in any greater detail. Nevertheless the record clearly indicates the seriousness of Dr. Evers' promotional efforts. When the Ra-Mar Clinic opened in 1976, Dr. Evers placed a full two-page advertisement in the Montgomery Advertiser. Although the ad did not explain Dr. Evers' program in any detail, it specifically listed chemo-endartectomy therapy as one of his chief methods. The more important aspect of Dr. Evers' campaign, however, consists of a booklet describing the Ra-Mar Clinic. The booklet explains chemo-endartectomy and chelation in

lay terms and describes the program employed by the Ra-Mar Clinic. The booklet claims remarkable success for chelation, [5] cites Dr. Evers' extensive experience with the process, [6] urges the reader to try chemo-endartectomy therapy before traditional modes of treatment, [7] and underplays the serious dangers involved in the use of chelating drugs. [8] This booklet was apparently given to patients and prospective patients of the clinic, both in person and through the mail. Although the district court does not appear to have addressed the extent of this distribution, the government did introduce testimony which suggests that as many as 4,000 of these booklets may have been distributed through the mail. Trial Transcript at 218-20. While we cannot trace with precision the particular promotional efforts undertaken by Dr. Evers, it is at least clear from the record that Dr. Evers did, as the government alleges, promote and advertise his use of chelating drugs for the treatment of circulatory disorders. [9]

Although there exists a variety of lawful chelating drugs, the government has charged Dr. Evers in this suit with the misbranding of one particular chelating drug, calcium disodium edetate (Calcium EDTA). [10] Dr. Evers argued in the district court that he did not use this drug for the treatment of arteriosclerosis or other circulatory diseases, but rather only for the treatment of heavy metal poisoning. In fact, Dr. Evers introduced evidence to the effect that Calcium EDTA would be absolutely ineffective in the treatment of circulatory disorders since it could not bind with calcium, which, according to his theory, is the cause of artery obstructions. Trial Transcript at 330-31, 534-35. Accordingly,

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Dr. Evers contended that neither he nor any other proponent of chelation therapy had used Calcium EDTA for the treatment of circulatory disorders. Id. However, an examination of medical records at the Ra-Mar Clinic demonstrated that 72 patients had received chelation therapy with Calcium EDTA; nearly all of this group had a diagnosis of arteriosclerosis but only 31 patients had a diagnosis showing any lead or other heavy metal content whatsoever. 453 F.Supp. at 1146. On this basis the district court concluded that Dr. Evers during the two years before trial had indeed "offered chelation therapy using Calcium EDTA as his chelating agent to arteriosclerosis patients at Ra-Mar Clinic. ..." Id. This finding is not challenged by Dr. Evers on appeal.

The district court also found that the FDA-approved labeling (commonly called the package insert) for Calcium EDTA does not indicate that the drug can be used to treat circulatory diseases and does not include any instructions for the use of the drug for such purposes. Id. In fact, the sole purpose indicated on the label for Calcium EDTA is "the reduction of blood levels and depot stores of lead in lead poisoning (acute and chronic) and lead encephalopathy." [11] The FDA is therefore correct in its assertion that, whether or not chelation is of any beneficial effect to a patient suffering circulatory diseases, the package insert in the Calcium EDTA used by Dr. Evers provided no direction whatsoever for that use of the drug.

II. THE GOVERNMENT'S CASE AGAINST DR. EVERS

The government contends that Dr. Evers violated section 301(k) of the Act, 21 U.S.C. § 331(k), which prohibits any act with respect to a drug which "is done while such (drug) is held for sale (whether or not the first sale) after shipment in interstate commerce and (which) results in such article being ... misbranded." [12] The government must therefore establish two separate elements: (1) that the act in question occurred while the drug was held for sale after shipment in interstate commerce; and (2) that the act resulted in the article being misbranded. See United States v. Sullivan, 332 U.S. 689, 695, 68 S.Ct. 331, 335, 92 L.Ed. 297 (1948). The focus of the government's case, as well as of Dr. Evers' defense and of the district court's opinion, is the second of these elements. In order to establish this element, that is, to demonstrate that Dr. Evers has "misbranded" Calcium EDTA, the government relies solely on section 502(f)(1) of the Act, 21 U.S.C. § 352(f)(1). That section deems a drug to be

misbranded "unless its labeling bears ... adequate directions for use." [13] In brief, the government

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contends that Dr. Evers failed to provide "adequate directions for use" when he promoted and prescribed Calcium EDTA for the treatment of circulatory disorders, a use for which the drug has not been approved by the FDA.

In response to this charge, Dr. Evers (as well as certain of his patients, as intervenors) argues that as a licensed physician he has a right to prescribe any lawful drug for any purpose, whether or not that purpose has been approved by the FDA. The district court agreed with Dr. Evers and held that no misbranding could result from a doctor's prescription of a lawful drug to his own patients. The court relied for this holding on the intent of the statute, which seeks to avoid interference with "the practice of medicine;" on supposed limitations on the powers of Congress; and on the patient's constitutional right to privacy in the context of medical care. 453 F.Supp. at 1147-50.

However, the analysis urged by Dr. Evers and adopted by the district court misapprehends the thrust of the government's case against Dr. Evers, for the FDA has at no point contended, and the government does not argue on appeal, that the misbranding provisions of the Act prohibit a doctor from prescribing a lawful drug for a purpose for which the drug has not been approved by the FDA. To the contrary, the FDA has explicitly informed Dr. Evers that he could legally prescribe chelating drugs for the treatment of circulatory disorders. When Dr. Evers inquired of the FDA in early 1974 whether he could use Calcium EDTA for that purpose, the agency responded by letter that "(u)se of a locally obtained drug for an indication which is not in the package insert is considered 'the practice of medicine,' " and that Dr. Evers therefore need not seek any exception to the regulations. [14] This advice to Dr. Evers rested on a discussion of the Act which appears in a notice of proposed rule making which the FDA issued in 1972 but on which it has never acted. See 37 Fed.Reg. 16503 (1972). As the agency explained in that notice:

Once (an approved) new drug is in a local pharmacy after interstate shipment, the physician may, as part of the practice of medicine, lawfully prescribe a different dosage for his patient, or may otherwise vary the conditions of use from those approved in the package insert, without informing or obtaining the approval of the Food and Drug Administration.

This interpretation of the Act is consistent with Congressional intent as indicated in the legislative history of the 1938 Act and the drug amendments of 1962. Throughout the debate leading to the enactment, there were repeated statements that Congress did not intend the Food and Drug Administration to interfere with medical practice and references to the understanding that the bill did not purport to regulate the practice of medicine as between the physician and the patient. Congress recognized a patient's right to seek civil damages in the courts if there should be evidence of malpractice, and declined to provide any legislative restrictions upon the medical profession.

Id. at 16503.

Of course, while the Act was not intended to regulate the practice of medicine, it was obviously intended to control the availability of drugs for prescribing by physicians. Id. at 16504. In order to extend this control to situations like the one before us, the FDA has proposed regulations and actively has sought legislation which would restrict the availability of lawful drugs for uses for

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which the drugs have not been approved by the FDA. See D. A. Kessler, "Regulating the Prescribing of Human Drugs for Nonapproved Uses Under the Food, Drug, and Cosmetic Act," 15 Harv.J.Legis. 693 (1978); S. A. Shapiro, "Limiting Physician Freedom to Prescribe a Drug for any Purpose: The Need for FDA Regulation," 73 Nw.L.Rev. 801 (1978). Nevertheless the

government agrees with Dr. Evers that the provisions of the Act and the regulations of the FDA that are now in force do not prevent him from prescribing for uses not approved by the FDA drugs which have been approved by the FDA for some other purpose.

The object of the government's case against Dr. Evers is not, therefore, his prescription of Calcium EDTA for use in the treatment of circulatory disorders. Instead, the government seeks to challenge Dr. Evers' promotion and advertising of chelating drugs for that use. According to the government, Dr. Evers "misbranded" Calcium EDTA when he publicly advocated his use of chelating drugs for an unapproved purpose without providing "adequate directions" for such a use:

(T)he district court found, and the record confirms, that Dr. Evers had advertised his EDTA therapy as treatment for arteriosclerosis, and that he administered calcium EDTA to persons with arteriosclerosis. Thus, by his promotion of calcium EDTA for treatment of arteriosclerosis, Dr. Evers created a use for the drug that was different from its previously approved and labeled use in the treatment of lead poisoning. There were, however, no "adequate directions" for that use, as required by Section 502(f)(1).

Government's Brief at 15-16 (citations omitted).

Since the government relies for its case on Dr. Evers' promotion and advertising of chelating drugs for an unapproved use, and since the FDA itself interprets the Act to allow physicians to prescribe (while not promoting or advertising) lawful drugs for unapproved uses, we need not decide whether, as the district court apparently concluded, the Constitution prohibits federal interference with prescriptions by licensed physicians. The question before us is the narrower issue of whether Dr. Evers violated section 301(k) of the Act. In order to establish such a violation, the government must demonstrate the two elements required by that section. In terms of this case, we must find (1) that Dr. Evers held Calcium EDTA for sale after its shipment in interstate commerce, and (2) that Dr. Evers' promotion and advertising of Calcium EDTA without providing any more information than was contained on the drug's label and in the clinic's pamphlets failed to provide "adequate directions for use" and therefore constitutes misbranding under section 502(f)(1) of the Act.

III. THE GOVERNMENT'S APPLICATION OF THE ACT, OR, WHY THE

STATUTE DOES NOT FIT THE FACTS

A. Section 301(k): Extending the Act to Drugs "Held for Sale

after Shipment in Interstate Commerce"

The Act was intended, inter alia, to keep misbranded drugs out of the channels of interstate commerce. The flow of commerce begins with the manufacturer of the drug and ends with the consumer, that is, the patient. Accordingly, section 301 of the Act is designed to prevent misbranding at each stage of the distribution process. Paragraph (k) of section 301 deals with one stage of that process: the period during which a drug is "held for sale after shipment in interstate commerce." As the Supreme court explained in United States v. Sullivan, 332 U.S. 689, 68 S.Ct. 231, 92 L.Ed. 297 (1948):

(The statute's) 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 alteration 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 proffered 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.

332 U.S. at 696-97, 68 S.Ct. at 335-36. See also Kordel v. United States, 335 U.S. 345, 351, 69 S.Ct. 106, 110, 93 L.Ed. 52 (1948).

The gap which section 301(k) was designed to fill arises when a drug which has already been transported in interstate commerce is misbranded by a person who neither shipped nor received the drug in interstate commerce. As the House Committee on Interstate and Foreign Commerce explained in its report on this section of the Act:

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.

H.R.Rep.No. 2139, 75th Cong., 3rd Sess. 3 (1938). Accordingly, the Supreme Court held in United States v. Sullivan, supra, that a retail druggist who had purchased correctly labeled drugs from a wholesaler in the same state and then removed the labels himself had misbranded the drugs under section 301(k), even though the wholesaler who had received the drugs in interstate commerce had not itself misbranded them. Section 301(k) extends the Act's protection to the entire distribution process for drugs moving in interstate commerce by covering what is often the final stage in that process: the distribution by a person not himself a party to the interstate transportation of the drug.

This final stage of the distribution process, where drugs are "held for sale after shipment in interstate commerce," takes on many different forms. The statute has been construed to cover situations in which the drugs are held by a retailer, United States v. Sullivan, supra; a wholesaler, DeFreese v. United States, 270 F.2d 730 (5th Cir. 1959), cert. denied, 362 U.S. 944, 80 S.Ct. 810, 4 L.Ed.2d 772 (1960); and a bailee, United States v. Wiesenfeld Warehouse Co., 376 U.S. 86, 92, 84 S.Ct. 559, 563, 11 L.Ed.2d 536 (1964). A practicing physician may also fall within the bounds of this section. A serious gap would be left in the statute if doctors who had received drugs in an intrastate transaction from a party who had in turn received them from interstate commerce were allowed to misbrand the drugs and then distribute them to their patients. Doctors holding drugs for use in their practice are clearly one part of the distribution process, and doctors may therefore hold drugs for sale within the meaning of section 301(k) of the Act. See United States v. Diapulse Corp. of America, 514 F.2d 1097 (2nd Cir.), cert. denied, 423 U.S. 838, 96 S.Ct. 66, 46 L.Ed.2d 57 (1975); United States v. Ten Cartons, etc., 152 F.Supp. 360, 364-65 (W.D.Pa.1957).

B. Misbranding Under Section 502(f)(1)

We now turn to the second requirement of section 301(k) in the context of this case: the drug at issue must have been misbranded. In order to establish that Dr. Evers misbranded Calcium EDTA, the government relies on section 502(f)(1) of the Act, 21 U.S.C. § 352(f)(1). As discussed above, that section deems a drug to be misbranded "unless its labeling bears ... adequate directions for use." In United States v. Articles of Drug, 625 F.2d 665 (5th Cir. 1980), we considered and upheld the FDA's interpretation of this provision. That interpretation begins with 21 C.F.R. § 201.5 (1980), which defines "adequate directions for use" as "directions under which the layman can use a drug safely and for the purposes for which it is intended." The "intended use" of the drug is the "objective intent of the persons legally responsible for the labeling

of the drug," and may be determined, for example, by "labeling claims, advertising matter, or oral or written statements by such persons or their representatives." 21 C.F.R. § 201.128. Since Dr. Evers clearly intended to use Calcium EDTA for the treatment of arteriosclerosis, these provisions would seem to require him to provide adequate directions in lay terms to his patients for the use of Calcium EDTA in the treatment of arteriosclerosis. However, Calcium EDTA is a prescription drug. [15] The FDA insists that since a prescription drug by definition can be used only under a physician's supervision, see 21 U.S.C. § 353(b)(1), it is impossible to provide "adequate directions for use" to a layman; we accepted this interpretation in Articles of Drug, supra, 625 F.2d at 673. Thus, since Calcium EDTA is a prescription drug, there is no conceivable explanation which Dr. Evers could have given to his patients which would have complied with section 502(f)(1)'s requirement of adequate directions for lay use.

However, this does not mean that drug distributors misbrand each prescription drug which they hold for sale, for the statute provides for two important exceptions to section 502(f)(1) of the Act. In the first place, the section itself authorizes the FDA to create a regulatory exemption. See supra at note 13. The FDA has exercised this authority by creating an exception for prescription drugs. See 21 C.F.R. §§ 201.100, 201.115. In order to qualify for the prescription drug exception under these regulations, the drug's labeling must meet a number of specific full disclosure requirements. The labeling must include, for example: certain information regarding dosage, administration, and the drug's active ingredients; a warning that the drug cannot lawfully be dispensed without a prescription; an identifying number from which one may determine the manufacturing history of the particular package of the drug; a statement directed to the pharmacist specifying the type of container to be used in dispensing the drug; and, if the drug is a "new drug" within the meaning of the Act, a label which has been approved by the FDA pursuant to a new drug application under the Act. If these extensive requirements are met, the drug is completely exempt from the reach of section 502(f)(1) of the Act, and the distributor of the drug therefore need not provide "adequate directions for use" to the layman.

In the second place, the statute itself provides for an exception in section 503(b)(2) of the Act, 21 U.S.C. § 353(b)(2). This section states that if certain basic information is provided on the label a prescription drug shall be exempt from most of the requirements of section 502 of the Act, including that of section 502(f)(1). While the requirements of this section are somewhat more lenient than those of the regulatory exception, it provides a much narrower protection for the distributor of the drug, for it exempts the provisions of section 502 of the Act only at the point at which the drug is actually prescribed and dispensed by a licensed physician. See United States v. Articles of Drug, supra, 625 F.2d at 674; United States v. An Article of Drug ... Amodril Spancap, 1975 Food Drug Cos.L.Rep. P 38,009 at 38,035 (S.D.Fla.1974). The regulatory exemption, on the other hand, protects any person who holds the drug for sale at any point in the distribution process.

A two-fold scheme emerges from section 502(f)(1) when it is read in the context of the FDA's interpretation of the "adequate directions for use" requirement and of the regulatory and statutory exceptions to that requirement. If the drug is a non-prescription drug, the distributor must provide adequate directions in lay terms to the patient himself. But if the drug is a prescription drug, as is Calcium EDTA, the distributor must provide the information which is required by the regulatory or statutory exception to the statute, for it is impossible for the distributor to adequately explain a prescription drug to a layman. Thus, neither prescription nor non-prescription drugs can meet the terms of the statute by providing such "adequate directions for use" as are required for the other type of drug.

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The purpose of this scheme is, in brief, to require that adequate information be provided to

the person who must decide whether and how to administer the drug. Where non-prescription drugs are involved, the "adequate directions for use" requirement insures full disclosure to the layman purchasing the drugs for self-treatment. But prescription drugs depend for their safety and effectiveness on the professional judgment of a licensed physician. Accordingly, the prescription drug exceptions to the "adequate directions for use" requirement contain conditions requiring adequate information for prescribing doctors. As the FDA has itself explained in a notice of proposed rule making:

The primary objective of prescription drug labeling is to provide the essential information the practitioner needs to use the drug safely and effectively in the care of patients.

40 Fed.Reg. 15392 (1975) (emphasis added). The distributor of a non-prescription drug must provide adequate information for use by a layman, for patients are allowed to administer those drugs without the advice of a physician. The distributor of a prescription drug, however, must provide adequate information to the prescribing physician in accordance with the specific conditions of the statutory or regulatory exceptions to section 502(f) (1), for it is the physician who bears the responsibility for dispensing the drug. See D. A. Kessler, supra, at 742, 747; H. A. Toulmin, Jr., A Treatise on the Law of Foods, Drugs & Cosmetics § 24.12 at 576 (2d ed. 1963).

C. Putting Together the Two Elements of Section 301(k)

The government argues that Dr. Evers' prescription and promotion of Calcium EDTA for the treatment of circulatory disorders meets both of the above requirements of section 301(k) of the Act. In the first place, the government contends that Dr. Evers "held (Calcium EDTA) for sale" when he maintained a supply of the drug for use on his own patients at the Ra-Mar Clinic. To support this position, the government relies on cases, cited in part III(A) of this opinion, which did indeed hold that a doctor who had held drugs for use in his practice had held those drugs for sale within the meaning of the Act. In the second place, the government contends that Dr. Evers misbranded Calcium EDTA within the meaning of section 502(f)(1) of the Act by failing to provide "adequate directions for use" either in appropriate lay terms or according to the disclosure requirements of either exemption for prescription drugs. It is undisputed that Dr. Evers did in fact fail to provide adequate directions for either lay or professional use; Dr. Evers does not contend that his booklets contained "adequate directions for lay use" within the meaning of the regulations, and he does not appear to have made any attempt to meet the terms of either the regulatory or the statutory exception for prescription drugs.

When each of the two elements of the offense with which Dr. Evers is charged is examined individually, Dr. Evers does indeed seem to have violated the statute. A different picture emerges, however, when the two elements are considered together. Since Calcium EDTA is a prescription drug, the FDA can establish an act of misbranding under section 502(f)(1) of the Act only by proving that Dr. Evers did not provide adequate information for use by physicians, as is required by the exceptions to that section. The information provided by Dr. Evers to his patients is irrelevant to the question at hand, for according to FDA regulations there is no information which could have been provided about this prescription drug which would have constituted "adequate directions for (lay) use." However, the government argues that Dr. Evers "held (Calcium EDTA) for sale" within the meaning of section 301(k) because he maintained a supply of the drug for use on his own patients ; the government does not contend that Dr. Evers was distributing Calcium EDTA to other licensed physicians. The government therefore must find itself in an awkward position: while the misbranding violation it urges is based on Dr. Evers' failure to provide adequate information to licensed physicians, it seeks to include

his actions within the reach of section 301(k) of the Act by virtue of his distribution to patients.

The requirement which the FDA seeks to impose is nonsensical. Since Calcium EDTA is a prescription drug, the misbranding provision under which Dr. Evers was charged requires him to provide adequate information for use by prescribing physicians. However, Dr. Evers was the only physician who used the Calcium EDTA in question. The government's application of the statute may therefore be reduced to the following proposition: Dr. Evers did not provide adequate information to himself. It is doubtful at best that this interpretation was intended by the drafters of the statute.

In more specific terms, the government's interpretation of the Act breaks down over its use of the phrase "held for sale after shipment in interstate commerce." Although Dr. Evers was holding Calcium EDTA for sale in the sense that he was distributing it to his own patients, he was not holding it for sale to physicians. Section 301(k) of the Act cannot reasonably be read to require a physician who is holding a drug for sale only to patients to provide adequate information to physicians to whom he is not distributing the drug. We think it clear that a single doctor may be holding drugs for sale to one group of purchasers but not to another. If the doctor is not holding the drug for sale to the party to whom he owes a statutory obligation of full disclosure (in this case other prescribing physicians), then it makes no sense to impose the requirements of the statute. No legitimate purpose is served when a statutory provision requiring disclosure to one particular group of purchasers is invoked on the basis of sales made to a different group. Since Dr. Evers was holding Calcium EDTA, a prescription drug, for sale only to his patients, and since section 502(f)(1) of the Act does not require any disclosure to patients regarding prescription drugs, we conclude that Dr. Evers did not violate section 301(k) of the Act. [16]

IV. CONCLUSION

We have not been called upon in this case to consider the safety and effectiveness of Dr. Evers' use of chelation therapy; accordingly, we neither approve nor criticize his medical practices. Nor have we been asked to decide whether Dr. Evers has violated the Federal Food, Drug, and Cosmetic Act on any basis other than that on which the government has built its case. The issue before us is a narrow one: whether Dr. Evers has violated section 301(k) of the Act by his failure to provide such "adequate directions for use" as are required by section 502(f)(1) of the Act. Since Dr. Evers was not holding Calcium EDTA for sale to other prescribing physicians, and since the sole basis of the government's misbranding charge is Dr. Evers' failure to label the

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drug for physicians in accordance with either exception to section 502(f)(1) of the Act, we must conclude that the government has failed in this case to establish a violation of section 301(k) of the Act. We therefore affirm the judgment of the district court in favor of Dr. Evers.

AFFIRMED.

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* Senior Judge of the Northern District of Alabama, sitting by designation.

1 Plaintiff's Exhibit 74, a booklet written by Dr. Evers and entitled "A Successful Therapy for the Relief of Chronic Degenerative Diseases" (hereinafter referred to as the Booklet) at 9.

2 Dorland's Illustrated Medical Dictionary (25th ed. 1974) defines "chelate" as follows:

"chelate": to combine with a metal in complexes in which the metal is part of a ring. By extension, a chemical compound in which a metallic ion is sequestered and firmly bound into a ring within the chelating molecule. Chelates are used in chemo-therapeutic treatments for metal poisoning.

3 Although this case directly involves only one particular chelating drug (Calcium EDTA), evidence taken in the district court indicates that none of the various chelating drugs have been approved by the FDA for use in the treatment of circulatory disorders such as arteriosclerosis.

4 The potential danger of chelation therapy was of course relevant at the initial stage of these proceedings, for the government sought a preliminary injunction and therefore was obligated to establish serious and irreparable harm. But the merits of this action rest on the government's charge of a violation of section 301(k) of the Act. As explained below, the government's case under this section is based on Dr. Evers' promotion of chelating drugs for an unapproved use, not on the danger per se of chelating drugs. The issue before us, therefore, does not rest on the safety and effectiveness of chelating drugs for the treatment of circulatory disorders.

5 "The results often produce significant relief of symptoms, are often life saving, and sometimes miraculous .... In the experience we have, 75% of all diagnoses have achieved almost complete recovery, 15% have had fair to moderate results, and 10% very little or no results at all." Booklet at 10.

6 "In my experience with over 15,000 patients and 300,000 chemo-endartectomy treatments, the end results are almost miraculous." Booklet at 5.

7 "If the medical therapy fails to improve the circulation, then we should by all means go ahead and do surgery, but medical treatment should be tried first." Booklet at 4 (emphasis in original).

8 "This is generally a safe treatment. There have been no reports of significant harmful effects of damage since its first use over 20 years ago .... (I)t is theoretically possible that we could cause damage to the kidneys, but we have never had a case yet where there were any adverse reactions and there have been no deaths from it." Booklet at 19.

9 In this respect Dr. Evers' actions are similar to those challenged in the earlier suit against him, United States v. An Article of Drug ... Diso-tate, supra, at 38,287, in which the court found that Dr. Evers had "held a press conference and distributed promotional literature advocating EDTA therapy for cardiovascular therapy" and had "continued to distribute chelation therapy advertising to prospective patients."

10 The full scientific name of this drug is "calcium disodium enthylenediaminotetraacetate." The trade name of this drug (a trademark of Dow Chemical Co.) is "Calcium Disodium Versenate."

11 The package insert for Calcium EDTA provides in pertinent part the following:

WARNING

Calcium Disodium Edetate is capable of producing toxic and potentially fatal effects. The dosage schedule should be followed and at no time should the recommended daily dose be exceeded. In lead encephalopathy avoid rapid transfusion; intramuscular route is preferred.

Indications: Calcium disodium edetate is indicated for the reduction of blood levels and depot stores of lead in lead poisoning (acute and chronic) and lead encephalopathy. It may be worthy of trial in the treatment of poisoning from other heavy metals having a greater affinity for the chelating agent than does calcium.

Adverse Reactions: The principal toxic effect is renal tubular necrosis. (kidney failure)

12 Section 301(k) of the Act, 21 U.S.C. § 331(k), provides in full as follows:

The following acts and the causing thereof are 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 (whether or not the first sale) after shipment

in interstate commerce and results in such article being adulterated or misbranded.

13 Section 502(f) of the Act, 21 U.S.C. § 352(f), provides in full as follows:

A drug or device shall be deemed to be misbranded

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: Provided, That where any requirement of clause (1) of this subsection, as applied to any drug or device, is not necessary for the protection of the public health, the secretary shall promulgate regulations exempting such drug or device from such requirement.

14 Defendant's Exhibit 73, a letter dated March 7, 1974 and signed by the acting director of the Office of Scientific Evaluation of the Bureau of Drugs.

15 See Physician's Desk Reference (34th ed. 1980) at 1408-09.

16 One might argue that although Dr. Evers did not distribute Calcium EDTA to other physicians, he nevertheless "labeled" the drug to the medical community at large through his public promotional and advertising efforts, and that he therefore caused the drug to be "misbranded" because the drug's label did not meet the full disclosure requirements of the regulatory exception to section 502(f)(1) with respect to the new use advocated for the drug by Dr. Evers. This seems to be the theory on which the District Court for the Eastern District of Louisiana found a misbranding violation in the government's earlier suit against Dr. Evers. See United States v. An Article of Drug ... Diso-tate, supra, at 38,287. This approach relies on the promotion per se of the drug, and seems to ignore altogether the fact that misbranding under section 301(k) of the Act can occur only with respect to particular drugs "held for sale after shipment in interstate commerce." At base, this theory equates promotion with sale, and therefore brings into question the legality of a physician's advocacy of any medical program involving drugs not approved for the advocated use by the FDA, even when the physician does not himself sell or even dispense the drug. But the Act was intended to regulate the distribution of drugs in interstate commerce, not to restrain physicians from public advocacy of medical opinions not shared by the FDA. We believe, therefore, that a doctor who merely advocates to other doctors a lawful prescription drug for a use not approved by the FDA, and does not distribute that drug to other doctors, is not holding that drug for sale within the meaning of the statute and therefore is not in violation of section 301(k) of the Act.