

Analysis of the Nulfey Tablets disclosed that they consisted essentially of sodium salicylate, sodium biphosphate, methenamine and plant drugs including a laxative plant drug. The article was alleged to be misbranded because of false and misleading statements in the labeling which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of rheumatism, arthritis, neuritis, sciatica and kidney dysfunction; and that diuretics and analgesics are efficacious in the cure, mitigation, treatment, or prevention of kidney dysfunction.

Analysis of the O. B. C. Capsules disclosed that they consisted essentially of phenolphthalein, caffeine, and clay. The article was alleged to be misbranded because of false and misleading statements in the labeling which represented and suggested that it would be efficacious in the treatment of obesity.

Analysis disclosed that the Medrex Ointment consisted essentially of zinc oxide and petrolatum with small amounts of acetanilid, starch, methyl salicylate, benzoic acid, carbolic acid, and salicylic acid. The article was alleged to be misbranded because of false and misleading statements in the labeling which represented and suggested that it would be efficacious in the cure, mitigation, treatment, or prevention of the itching and irritation accompanying eczema; and that, when used alone or in conjunction with Medrex Soap, it would be efficacious in the cure, mitigation, treatment, or prevention of eczema, pimples, skin blotches, and surface skin conditions.

Analysis of the Medrex Soap disclosed that it was a soap containing small amounts of a zinc compound, starch, and salicylic acid. The article was alleged to be misbranded because of false and misleading statements in the labeling which represented and suggested that, when used alone or in conjunction with the Medrex Ointment, it would be efficacious in the cure, mitigation, treatment, or prevention of eczema, pimples, skin blotches, and surface skin conditions.

On May 23, 1944, a plea of nolo contendere having been entered by the defendant, the court imposed a fine of \$100 on each of 5 counts, a total fine of \$500.

1231. Misbranding of "666." U. S. v. 70½ Dozen Bottles and 76½ Dozen Bottles of "666." Tried to a jury. Verdict for the Government. Decree of condemnation and destruction. (F. D. C. Nos. 10914 to 10916, incl., 11043 to 11045, incl. Sample Nos. 35187-F, 35189-F, 35623-F, 35851 to 35853-F, incl.)

On October 12 and November 3, 1943, the United States attorney for the Middle District of Georgia filed libels against a total of 147 dozen bottles of "666" at Valdosta, Ga., alleging that the article had been shipped between the approximate dates of March 31 and October 21, 1943, from Jacksonville, Fla., by the Monticello Drug Co.; and charging that it was misbranded. On February 22 and March 20, 1944, the libels were amended.

Examination of samples disclosed that the article contained as medicinal ingredients antipyrine (an analgesic drug), ammonium chloride, and Epsom salt; and that it contained no quinine or other ingredient useful in the treatment of malaria. The article was colored yellow with a coal-tar dye, in simulation of a drug of similar appearance and packaging which contained quinine sulfate and which was previously marketed by the Monticello Drug Company for the treatment of malaria.

The article was alleged to be misbranded (1) in that the bottle, the bottle top, the color and appearance of the article, the price, and the labels and cartons with the numerals "666" printed in red color on the yellow background, and with the other portions of the label and carton in yellow, red, and black, were misleading since in combination they constituted a statement and device which created in the minds of purchasers the impression and belief that the article was the product which had been formerly for many years advertised and sold as a treatment for malaria; (2) in that the article was an imitation of the former product; and (3) in that it was offered for sale under the name of another drug, the former product.

On March 20, 1944, the Monticello Drug Co., claimant, filed exceptions to the amended libels on the ground that there was no authority for the seizure of the product since its label clearly stated the active ingredients and did not mention that it was an antimalarial preparation. The claimant's motion to sustain those exceptions was denied by the court. On March 27, 1944, the claimant having filed answers to the libels, denying that the product was misbranded, and the libels having been consolidated, the case came on for trial before a jury. The taking of testimony was concluded on March 29, 1944, on which date the court delivered the following instructions to the jury:

DEAVER, *District Judge*: "Gentlemen of the jury, an act of Congress known to some of us as the Pure Food and Drug Act, prohibits the shipment in interstate commerce of any drug—of course, there are a great many other things in the Act

but I am confining it here to drugs because that is all we are interested in here—which is misbranded; and then the Act goes on to define the meaning of mis-brand and it says that a drug is misbranded if the label is misleading. That is one instance in which it is misbranded. Then, it is misbranded if the container of the drug is so made or filled as to be misleading. Then, another instance of misbranding is if a drug is an imitation of another drug. And another is, that if a drug is offered for sale under the name of another drug. The whole act is designed to protect the public, so that the public will not be buying one thing, thinking that they are buying another thing.

“Now here the libel, as it is called—the paper filed by the government as a suit—alleges that this product which you have heard about here, the new product, is a misbranded drug; that there is and has been, the Government contends through a long number of years a product known and advertised to the public and well known to the public as three sixes or six hundred and sixty six or 666, and that the general buying public have become acquainted with that product, whatever it is. They contend, as a matter of fact, that it contained quinine and iron and that the new product does not contain either; but the government contends that inasmuch as the old product of 666 containing iron and quinine was well known to the public and had been for years and years, that this product, this new product which does not contain iron or quinine, would under the circumstances which you have heard outlined in the evidence, the government contends, cause the general public to buy this new product, thinking they were obtaining the old product. In general, that is the contention.

“The Monticello Drug Company comes into the case—of course, this case originated by the seizure of certain bottles of this product by the government and then this paper that I referred to, called a libel, which is a paper asking the court to condemn the seized product, it is really a proceeding against the product itself, but under the law the interested party, that is the Monticello Drug Company, has a right to come into the case and defend. The papers, if you want to look at them, denominate the Monticello Drug Company as the intervenor and in some cases as the claimant, that is the claimant of the product seized—But in any event, the Monticello Drug Company came into the case, as it had a right to do, and defends against the condemnation of this seized product, and that is the issue. The issue is between the government and the Monticello Drug Company as to whether this product is under the circumstances misbranded or not in any of the respects which I mentioned.

“Now, the question is to be decided by this jury and you are to decide the case from a preponderance of the evidence in the case. A preponderance of the evidence is just that greater weight of the evidence which inclines the mind of a reasonable man to one side of an issue rather than to the other side. The burden is on the government to show that this new product, which has been seized, is misbranded in at least some one of these respects which I have mentioned. You will apply the evidence to the law, as I have stated it in these various respects, and say whether, in your opinion, the evidence does show that the product was misbranded in any one of these different ways.

“Now, the first way I mentioned to you is that it is misbranded if the label is misleading. Well, I want to make that division of the suit clear to you. I may state to you, I think, that if a purchaser or anybody else of average intelligence should actually take the label on the new product and read it, that the label in and of itself and without more would not be misleading because the label itself does state what the drug contains. But the government goes further on other grounds and says that the drug is misbranded in that the method in which it is dressed up, the container, the box or paper carton, whatever you want to call it, is so colored and so designed with the figures 666, and the color of the product and the well known former product of 666, that all of those things taken together would mislead the average member of the public who calls for 666 in any store where it is available.

“Now, before I elaborate at all on these, I think that inasmuch as the evidence has taken a very wide latitude and certainly the arguments of counsel on both sides have taken a very wide latitude, I conceive it to be my duty under those circumstances to try to put before this jury exactly what it is you are to pass on.

“A great many things have been argued here in this case on both sides that haven't really got anything to do with the question that you are to decide. Of course, it is properly a matter of the history of the case here to show that when the war came along and quinine had to be restricted for military use, except in malaria, and that a certificate had to be had before it could be sold for malaria, that is all properly before you, but that is not the question that you are to decide:

and the question moreover is not whether the wholesale druggist and retail druggist were advised that a change had been made. That is not the point in the case either. There is evidence here that the Monticello Drug Company did inform certainly a large part, if not all, of the wholesale druggists and the retail druggists that a change had been made in this product and specifically called their attention to it. But that is not the question that you are to decide, whether a wholesale druggist or the retail druggist knew about it. If they didn't, they might be innocent of selling something that was not what they thought it was, of if they did know the difference and sold it nevertheless without complying with the law, why some of the druggists might be guilty, but that is not the question for you to decide here. We are dealing here with the question of, not whether the wholesale druggist was misled, not whether the retail druggist was misled, we are dealing here with whether under all the facts and circumstances an average member of the buying public who was not informed would be misled by the way this product is gotten up and handled.

"Something was said too here in argument—and that is the only reason that I mention it—that if you were to find in favor of the government and against the Monticello Drug Company, that would prevent the Monticello Drug Company from using their trade name, 666. Well, I didn't stop counsel in the argument because I intended at least to try to make it clear to the jury. Your finding, no matter which way it is, will not prevent the Monticello Drug Company from using its trade name 666. No attack is made in this case on that trade-mark and certainly the old product of 666, when the war is over and the ingredients can be obtained for that product, can be manufactured and again put on the market for people with malaria or anything else as for that matter they want to buy it for. There is no reason, so far as your verdict is concerned, why they can't continue to do that right on. The effect of an adverse verdict against the Monticello Drug Company, so far as this suit is concerned would be that it would prevent the Monticello Drug Company from putting out and selling to the public this new product under the name, if you find that is true, 666, which would mislead the buying public into thinking they were buying the old product. If you found a verdict against the Monticello Drug Company, then they could not keep on putting up this new product in the same form and with the same lettering and with the same figures and under the same circumstances that we have heard about in this case. They could not keep on doing that but the government contends that that is the very thing that they ought not to do, is to put this product on the public under circumstances which would lead the public to believe that it is the old 666.

"And then too, if I am wrong the Food and Drug agents here can correct me, but if you find a verdict against this product or against the claimant to it, then, as has been done in numerous other cases where the product itself is not in and of itself objectionable, it would not necessarily have to be destroyed or withdrawn and not used or lost utterly. I know that in a great many food cases and drug cases this is the result, that if you have a food case and the food is rotten or poison or unfit for use for any purpose, then, of course, it is destroyed, where it is condemned. It is destroyed because it is not fit for use and can't be used for any purpose; but if some food product is shipped in violation of the Food and Drug Act, but nevertheless may be properly used for some purpose in some other way, then by an arrangement and under the supervision of the Food and Drug people, the owner or the claimant of such food as that would be permitted to rework it, so to speak, under the supervision of the Food and Drug Agency; and if it could be used for some proper purpose, than the Food and Drug agent would cooperate in reworking or supervising the reworking just to see that it is properly used.

"So, in this case, so far as this suit is concerned, no attack has been made on this new product itself as a cold remedy or for any purpose as for that matter. No attack has been made on the drug itself. It may or may not have proper uses; we just don't know anything about that and not particularly concerned with it. It may be a product that could be used and it might be a good product, but the question here is not whether it is a good product or not. That is not the question at all. But if it is a good product, then the effect of your verdict would be to prohibit the sale of it in this present form. If you think it would mislead the public, then your verdict against the Monticello Drug Company would prevent them from selling this package that you have seen here in its present form and with its present coloring just as it stands now, would prevent them from selling that under this name 666 because your verdict would mean that you think that the sale of it with its present get-up, dressing, boxing and present coloring in connection with the previous reputation of the old product and all the other facts and circumstances in this case, your verdict would mean that you think that to

sell that product now under that name and style and get-up would mislead members of the buying public; and if you found such a verdict, it would prevent the Monticello Drug Company from continuing to sell it in that present form, and so far as I know, that is the only effect your verdict would have, except of course to destroy these bottles that have been seized, if the Monticello Drug Company did not ask to have them returned and re-worked and sold in some way or other that would not be misleading. But I know of no reason why they could not take all of this product that is bottled at present in that form, why they couldn't take that back and put the same product out under some form or other that would not be misleading.

"Now, gentlemen, the question is for you to decide and you are to decide it from what you have heard in the evidence itself. You are the sole judges of what the evidence shows. I could review the testimony on both sides and I could even tell you what I think about it; I could express an opinion about what I think about it under the practice in this court but I doubt if that would be helpful because, after all, even if I did, you would not be bound by any opinion that I might have about the evidence. The law provides that you should accept without question the law that I give you, that whatever I tell you is the law, you are supposed to take that; but so far as the facts are concerned, you are not bound by anybody's opinion, including my own. If I should express one—as a matter of fact, I am not going to express one, I don't think it would be helpful at all—but you are to decide whether this product here, this new product is misbranded in any of the respects contended by the government.

"Now, if you think, under the second section that I stated to you in the beginning, if you think that the container of this new product is so made in size and color, lettering and figures, that it is so made and the container so filled and colored, in connection with whatever reputation you may think the old product previously had, if you think that because of the container fixed up as it is and the product colored as it is, in view of the impression which the public has heretofore had of the original 666, if you think under all the circumstances that this product, if put out to the public, would be misleading, then you would find in favor of the government, because that would mean that this product here, under the definition which I have given you and which is in the statute itself, would be misleading.

"Or, if you think that this new product, because of the way it is handled and bottled and dressed up and colored, if you think that the new product is being offered for sale or sold to the public in imitation, as just a drug in imitation of the old original 666, but is not the old 666; in other words, if you think that the new drug is just an imitation of the old 666 and under all the facts and circumstances that it is not the old 666 but is an imitation of the old 666, then it would be misbranded under this act.

"Or, somewhat similarly, that if it is offered for sale under the name of another drug. You see the second thing that I mentioned to you there was if it is an imitation of another drug. Now, this one is slightly different. It says that if it is offered for sale in the name or under the name of another drug. Now, that would mean that if you think that this product, this new product, is not the same as the old original 666, but that it is being offered for sale to the public under the name of the old original 666, then it would be offered for sale, one drug would be offered for sale under the name of another drug, and if that is in your mind, under all the circumstances, likely to mislead the average member of the buying general public who buy this medicine, if you think from all the circumstances you have heard in this case, that the average member of the buying public who go to stores and call for this medicine 666 would likely be misled into accepting the new product under the impression that they were obtaining the old product, that would amount to misbranding and you would find then in favor of the government.

Now, of course, the question here is not a question of whether it would be harmful financially to the Monticello Drug Company. Whether it would entail a loss, of course, I do not know about that and I do not suppose you do. What loss would be entailed if they had to take this product back and rework it or even if it was destroyed, I do not know. But that is not the question that you are to pass on. It might, even if it did entail a loss to the Monticello Drug Company, and regardless of what that loss might be, still if they are as a matter of fact putting out a misbranded product, why you would not be concerned with whether they lost or whether they didn't. Your only question, that is what I am trying to say, your only question is whether the Monticello Drug Company is putting out an article, this new 666, whether they are putting out an article that is misbranded

and by that I mean misbranded or handled in the ways that I have mentioned here that would mislead members, average members of the buying public. If they are doing that, then you ought to find that and if they are doing it, then you ought to find against them.

"If, in your opinion, on the other hand, under all the evidence in this case the get-up, color, lettering, container and everything that you have heard about in this case would not be misleading to the average member of the public who buys 666, not misleading, why then, of course, there is no reason for stopping the Monticello Drug Company from putting it out in this form; and if you think that is true, you ought to find in favor of the Monticello Drug Company, which would mean that this product may be handled in the same way that it is being handled up to the time of filing this suit. That would mean that, in your opinion, under the evidence that there is no real danger or likelihood that members of the public would be misled by it, and that if they bought it, they would know what they were getting and would not be misled; and if that is what you think about it under this evidence you ought to find in favor of the Monticello Drug Company.

"So, that is your question. I state it finally that your only question is this: Is this new product under all the facts and circumstances that you have heard about in this case and under the definition which I have given you from the law, is this product a misbranded product? If it is, you ought to find in favor of the government. If it is not, you ought to find in favor of the Monticello Drug Company.

"Now, if you find in favor of the government, just write somewhere on the papers which you will have out, 'We the jury find—if you think it is a misbranded article—we the jury find in favor of the United States.' I believe that is the way the plaintiff is designated. On the other hand, if you think that this article is not misbranded in any of the ways which I have discussed with you and not misleading, then you ought to find in favor of the Monticello Drug Company, and the form of that verdict would be, 'We the jury find in favor of the Monticello Drug Company,' then date your verdict and let your foreman sign it."

"Mr. Davis. 'Your Honor please, in your recapitulation there, you probably inadvertently overlooked that if it was sold under the name of another drug, it was misbranded. It would not have to be misleading but if it is actually sold under the name of another drug, it would be misbranded.'

"The Court. 'Very well. I will see counsel in the office before the jury retires.'

[In the court's chambers]

"The Court. 'All right, any exceptions you want to get in the record?'

"Mr. Ashby. 'Doesn't the government proceed first?'

"The Court. 'Well, doesn't make any difference to me?'

"Mr. Walker. 'I think in the last two sub-divisions, under sub-section 'i' that if it is offered for sale under the name of another drug, then it doesn't have to be misleading.'

"The Court. 'It technically might not but the whole object of that part of the statute would be to keep from misleading anybody, I think.'

"Mr. Davis. 'Well, you may be right about that.'

"Mr. Ashby. 'Your Honor, the Intervenor takes exception to so much of the court's charge as submits to the jury any issue of whether the product here involved, the drug here involved, is in imitation of another drug; and likewise takes exception to such portion of the charge as submits to the jury the question of whether or not the drug here involved is offered for sale under the name of another drug. I have already argued that, Your Honor. I just make the point again.'

"The Court. 'All right.'

[Returning to the Court-room]

"Gentlemen of the jury, you may retire to the juryroom the Marshal will show you."

The jury, after deliberation, returned a verdict for the Government. On April 1, 1944, judgment was entered condemning the product and ordering that it be destroyed.