Waving: 12 units at Stamford and 60 units at Norwich, Conn., alleging that the article had been shipped in interstate commerce on or about November 20, 1940, and February 6 and 24 and April 4, 1941, by Heatless Permanent Wave Co. and Ashford Distributing Co. from San Francisco, Calif., and Jackson Heights, N. Y.; and charging that it was adulterated in that it contained a poisonous or deleterious substance, ammonium hydrogen sulfide, which might have rendered it injurious to users under such conditions of use as are customary or usual. The curling solution contained in each unit was labeled in part: (Bottles) "Willat [or "Willat Wave"] De Luxe Curling Solution."

On September 20, 1941, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

75. Adulteration of heatless method of permanent waving. U. S. v. 12 Units, 12 Units, and 12 Units of Willat Method of Heatless Permanent Waving. Default decrees of condemnation and destruction. (F. D. C. Nos. 4562, 4565, 4566. Sample Nos. 56631-E, 56634-E, 56635-E.)

On May 3, 1941, the United States attorney for the District of Connecticut filed libels against the following quantities of Willat Method of Heatless Permanent Waving: 12 units at Waterbury and 24 units at Hartford, Conn., alleging that the article had been shipped in interstate commerce on or about November 25, 1940, and February 8, 1941, by Ashford Distributing Co. from Jackson Heights, N. Y.; and charging that it was adulterated in that it contained a poisonous or deleterious substance, ammonium hydrogen sulfide, which might have rendered it injurious to users under such conditions of use as are customary or usual. The curling solution contained in each unit was labeled in part: (Bottles) "Willat [or "Willat Wave"] De Luxe Curling Solution."

On September 20, 1941, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

76. Alleged adulteration of Roux Lash and Brow Tint. U. S. v. 8 Packages, 12 Packages, and 26 Packages of Roux Lash and Brow Tint. Cases ordered removed to the District of New Jersey for consolidation and trial. Tried to the court and jury. Disagreement of jury and mistrial declared. Case retried before the court and a jury verdict for claimant. Judgment dismissing libel and ordering product returned to claimant. (F. D. C. Nos. 56, 62, 63. Sample Nos. 25976-D, 33229-D, 33230-D.)

This product consisted of three preparations, "No. 1," "No. 2" (Black and Brown), and "Stain Remover," respectively. "No. 1" consisted of about 2 percent of pyrogallol, with a little sodium lauryl sulfate and about 16 percent isopropyl alcohol; the "No. 2 Black" consisted of about 9 percent ammoniacal silver sulfate, about 5 percent ammoniacal silver nitrate, and 1/10 of 1 percent free ammonia in water; and "No. 2 Brown" was half the strength of "No. 2 Black." The stain remover consisted of ½ percent solution of sodium hypochlorite.

On August 13 and 24, 1938, the United States attorneys for the District of New Jersey and the Northern District of Illinois filed libels against 8 packages of Roux Lash and Brow Tint (Black) at Newark, N. J., 12 packages of Roux Lash and Brow Tint (Brown), and 26 packages of Roux Lash and Brow Tint (Black) at Chicago, Ill., alleging that the article had been shipped in interstate commerce on or about July 14 and 23, 1938, from New York, N. Y., by the Roux Distributing Co.; and charging that it was adulterated.

The article was alleged to be adulterated in that it contained poisonous and deleterious substances, namely, pyrogallol, ammoniacal silver sulfate, and silver nitrate, which might have rendered it injurious to users under the conditions of use prescribed in the following labeling and under such conditions of use as are customary or usual: (Carton) "Caution This product contains a metallic salt. It is for external use only and must be used with care"; (circular) "10 Rules For Applying Roux Lash And Brow Tint The observance of the ten simple rules set forth here below will produce the best results with the greatest degree of efficiency. Read these rules carefully. * * * Rule No. 1—Sit patron in upright position. Rule No. 2—Instruct patron to keep eyes closed during entire treatment. Rule No. 3—Wash the brows and lashes thoroughly with a good neutral soap, and dry by padding with soft absorbent cotton. Rule No. 4—Place a layer of vaseline on one side of the eyeshield and place this shield under the lower lashes with the vaseline side against the lower lid. Rule No. 5—Now cover all skin adjacent to brows and lashes with vaseline. Do Not Get Any Vaseline On The Hair Structures. Any Part Of The Brows Or Lashes That Becomes Covered With Vaseline Or Other Oily Substance Will Not Take Coloring. Rule No. 6—Wind a piece of absorbent cotton around the end of a

toothpick. Saturate this applicator with Solution No. 1, and impregnate the brows and lashes with the preparation. Rule No. 7—Allow Solution No. 1 to dry, taking about three minutes. Rule No. 8—Now impregnate a new cotton-tipped toothpick with Solution No. 2 and thoroughly treat the eyebrows first, and then the eyelashes with Solution No. 2. Use Solution No. 2 freely, but not so excessively as to permit any running. Rule No. 9—After thirty seconds, wash the brows with absorbent cotton saturated with a warm soap solution. After one minute wash the eyelashes with absorbent cotton saturated with cold water. Rule No. 10—If deeper shades are desired, repeat the process. * * * This product contains a metallic salt. It is for external use only and must be used with care."

On October 7, 1938, the Roux Distributing Co., claimant, filed a petition in the District Court for the District of New Jersey, praying removal of the cases to the Eastern District of New York for consolidation and trial. On October 20, 1938, an order was entered granting the petition of the claimant and ordering that the clerks in the respective courts forward all papers to the Eastern District of New York, also that any further actions that might be instituted against the product be consolidated with the instant cases.

On November 4, 1938, the claimant filed answers admitting the interstate shipment but denying that the product was adulterated as alleged in the libels and praying dismissal of the libels and delivery of the goods.

The case came on for trial before a jury on March 27, 1939. The hearing of the evidence and arguments of counsel were concluded on April 14 and the case was submitted to the jury, which, after lengthy deliberation, announced that it could not agree on a verdict. The court thereupon declared a mistrial and discharged the jury. The case was set for trial finally on March 16, 1942, before a jury and was concluded on April 1, 1942. The following charge to the jury was delivered by the court.

INCH, *Judge*. "Members of the jury, at last this case comes to you for your verdict. It has been an interesting case, mostly expert testimony, and you are the sole judges of the fact. Nothing said by the court or by the lawyers is to be taken in place of your recollection of the testimony. You and you alone decide what the truth is, what the facts are. You must take the law from the court and apply it to the facts which you and you alone find to be facts. The law is very simple in this case. There is no necessity for a long charge, but it is an important law, and therefore I want you to pay a little attention to it as we go along—more so than ordinarily. Before we come to that I will explain the nature of this action. Perhaps you know it already from the summation. This action is an action in rem, as we call it. It is not against the Roux Co. It is against certain packages of cosmetics which the Government claims violated the law. The Roux Co. comes in as the claimant of those packages. It is not a criminal case at all; it is a civil case. In other words, the United States of America has seized eight packages more or less of an article labeled in part 'Roux Lash and Brow Tint Black,' that was shipped from New York to Newark, N. J. It has also seized 12 packages more or less of an article labeled in part 'Roux Lash and Brow Tint Brown,' and 25 packages more or less of the said article Roux Lash and Brow Tint Black shipped from New York to Chicago, Ill. The case has been brought against these packages. It is not against Roux Laboratories, Inc., which has appeared in this court to claim them, but, of course, Roux Laboratories, Inc. is vitally interested in this action because it is their preparation. The packages in question were seized after the Government had brought charges against them under the Federal Food, Drug, and Cosmetic Act. That statute was passed by Congress and approved by the President, and was effective insofar as this case is concerned on June 25, 1938.

"Now, as I have already mentioned, I want to call particular attention to this law, more so than ordinarily, for the reason that it is a new law comparatively speaking. It is known as the Federal Food, Drug, and Cosmetic Act of June 1938. Prior to 1938 there was the well known Food and Drugs Act, but this was not deemed to be sufficient to cover the field of cosmetics; hence Congress passed this law which now governs us in this action. Primarily the purpose of the law is the same as that of the former law, that is, to prevent injury to the public health by the sale and transportation in interstate commerce of adulterated cosmetics, and this laudable purpose naturally requires that such a law be given a fair and reasonable construction to attain its aim. Now, the law is found in Title 21, United States Code, Section 301. First we come to section 321 which covers definitions, and there we find this definition: 'The term cosmetic means, first, articles in-

tended to be rubbed, poured, sprinkled or sprayed on, introduced into or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and second, articles intended for use as a component of any such article, except that such term shall not include soap. So, while it is a fact for you to find, I think there is no dispute but that these articles which we have before us here and which have been seized by the Government are cosmetics under this definition. I do not think that is disputed. If that is so, and if you find that is so, then, of course, cosmetics as a rule are not subject to seizure; it is, as I have stated, adulterated cosmetics that are to be taken off the market; so we come to section 361 of the law, which is as follows—and this is the important law governing your verdict—'A cosmetic shall be deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual.' I think I can read it to you again without any harm: 'A cosmetic shall be deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual.' I shall refer to this, of course, a little later, but I think now you have the law under which we are proceeding. That being so, the Government claims that these articles that have been mentioned are adulterated cosmetics under this definition. Now, the burden of proving this by a preponderance of evidence rests upon the Government. You must be satisfied by a preponderance of evidence that these articles are adulterated cosmetics. The claimant, Roux Laboratories, Inc., denies any such adulteration and asserts that the Government therefore has no right to seize and condemn the cosmetics for that reason. By preponderance of evidence is meant not necessarily the greater number of witnesses but that amount of evidence which taken on the whole produces the stronger impression upon your minds and satisfies you of its truth when weighed against evidence in opposition thereto. You are the sole judges of the weight of the evidence and the credibility of the witnesses. You are entitled to take into consideration, therefore, the demeanor of the witnesses, their apparent intelligence, their opportunity of knowing or seeing the facts about which they testified, their interest, if any, and the probability of their testimony. All these things, or the lack of them, are to be considered by you in weighing the evidence. You will find therefore when you have followed my charge up to this point and return to consider the law again that the first thing is that a cosmetic shall be deemed to be adulterated if it bears or contains any poisonous or deleterious substance. Well, of course, you will want to know at once, 'What do you mean exactly by poisonous or deleterious substance?' I think that I can best charge you in the language of the request of counsel for the claimant as to that. The terms 'poisonous or deleterious' or 'injurious to users' must be given their natural and ordinary meaning. Poison has been defined as, first, a potion containing a noxious or deadly ingredient, any agent which introduced especially in small amounts into an organism may chemically produce an injurious or deadly effect. That is poison. A deleterious substance has been defined as a harmful or destructive article. The common and generally accepted meaning of the word is having the power of destroying or extinguishing life, that is, that which is destructive, poisonous, pernicious. They are in about the same category, but those definitions are in order for you to take them into the jury room. Now, a cosmetic shall be deemed to be adulterated if it bears or contains any poisonous or deleterious substance,—now comes a very important part of the law—'which may render it injurious to users under such conditions of use as are prescribed in the labeling thereof or under such conditions of use as are customary or usual.' The term 'may' is here used in its ordinary and usual signification; it is an auxiliary verb qualifying the meaning of another verb by expressing ability, contingency, or liability, or possibility or probability, and you are instructed that, if you find from the evidence that the cosmetics involved in this case or either of them contain the substances referred to in the Government's libels and that such substances are poisonous or deleterious and are likely to result or may result in injury to users under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual, then such articles are adulterated and you should render a verdict for the Government. The burden of proof is on the Government to satisfy you that that is so.

"Now, it is the general public health that is to be protected by this law, not that of any one particular individual.

"These cosmetics came in cartons, and on each carton are printed directions for their use with other articles to be used in the application of the liquid, with which you are familiar, and the cosmetic itself is contained in little bottles. There is no necessity whatever in my opinion for me to go into the details of the chemistry. You have had the witnesses for both parties testify before you and you have had the summations by the able lawyer for the claimant and by the equally able Assistant United States Attorney. There is no necessity in my opinion for me to dwell on that. But I call your attention to the fact that the Government claims that it has proved that these cosmetics are adulterated cosmetics, in that they contain pyrogallol, ammoniacal silver sulfate, and ammoniacal silver nitrate which may render them injurious to users under the conditions for use prescribed in their labeling or under such conditions of use as are customary or usual. This therefore is the issue which you must decide by a preponderance of evidence: do the cosmetics in question contain poisonous or deleterious substances which may render them injurious to users under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual?

"Now, there is one more important thing for you to consider under this law. The extent of injury is not important: whether it is temporary or permanent is not important in this case. However important it is to the victim, Congress was protecting the public against any injury. Now, of course, that does not mean that a mere inconvenience can be considered an injury, because you must follow the definition of what is meant under the law as an injury—a harm, a damage to the human being using these preparations—but a person doesn't have to go blind to come under the law. A person must, however, at least be harmed, injured by the use of this preparation.

"Now, if you find that the Government by a preponderance of evidence has proved to you that these cosmetics were so adulterated your verdict should be for the Government. If, on the other hand, you find that the cosmetics were not so adulterated, your verdict should be for the claimant. As I say, I see no reason, nor shall I attempt, to discuss the details of the medical proof, for you are well aware of it. The Government has alleged in its libels that these articles or cosmetics are adulterated under the provisions of this act, that is, that they may render it injurious to users under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual. I therefore charge you that, if you find from the evidence that either or both of these articles or cosmetics, namely, the packages of Roux Lash and Brow Tint Black and Roux Lash and Brow Tint Brown contain any of the substances specified in the libels, and that any of such substances are poisonous or deleterious substances, and you find that any such poisonous or deleterious substances may render these cosmetics injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual, then the cosmetics are adulterated and your verdict should be for the Government. On the other hand, if you find from the evidence that the substances mentioned in the libels are not sufficiently poisonous or deleterious so that they may render these cosmetics injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual, then the cosmetics are not adulterated and your verdict should be for the claimant.

"The intent of the claimant, that is, the Roux Laboratories, Inc., has no bearing in this case on the facts. It is not a question of intention, good or bad intention. The only question that you are to determine is whether or not these two articles of cosmetics fall under the ban of the statute. Therefore you will come to this finally: is there actual danger of injury to users when the contents are applied in the manner recited in the directions which are present in the packages. You will have to take all of the evidence in that regard and consider it in coming to the conclusion whether the directions are sufficient. There is testimony by witnesses for the Government, which is for you to consider, that a liquid such as this cosmetic if freely applied to an eyelash may be drawn by capillary attraction to the root of the eyelash which is at the margin of the eyelid and that the margin of the eyelid is likely then to come in contact with the surface of the eyeball, and that even if that does not happen there is a possibility that some of this liquid will reach the inside of the eye by reason of an involuntary opening of the eye and thus cause the product to be injurious to such user. That is testimony for you to consider. But you must also consider the fact that there is no claim by the Government, and certainly no assertion by the claimant, that this is to be inserted into the eye. It is a dye for an eyelash or an eyebrow.

It is not intended to go into the eye. The directions are supposed to be sufficient to keep it out of the eye. On the other hand, there is testimony by the claimant, which is for you to weigh and consider, that these cosmetics contain no such poisonous or deleterious substance which can injure the eye of the user, even if it got in there, but that if the directions are reasonably followed none of the substances should touch the eyelid or reach the eyeball. Those are facts for you to find based on the evidence one way or the other, and in doing that you will have to consider all the expert testimony, of which there has been a great deal. Whether or not there was such adulteration, of course, is a question of fact for you to determine.

"I have already called your attention to the fact that the statute uses the word 'may,'—not 'will' or 'must,' but 'may' render the substance injurious to the person using it.

"Now, ordinarily in the trial of cases in this court witnesses are confined to testifying to facts within their personal knowledge and are not permitted to draw conclusions or express opinions. This is a general rule, but where the points in issue arise out of a particular trial concerning which there are trained minds who have special knowledge, learning, or schooling in that particular field such persons are called experts and in their case they are entitled to express opinions concerning the matter in issue. I therefore charge you that you must weigh and value the testimony of the expert chemists, pharmacologists, physicians, opthalmologists, and dermatologists who have testified in this case precisely as you weigh the testimony of other witnesses, taking into account the probability of such expert testimony, the reasonableness of it, the schooling of the person giving it, the learning he has in his profession, the breadth of his experience, all of those things which go to give weight to or detract from the value of the testimony of an expert.

"Now, I think that I have covered the whole field. You know exactly what you have to do when you retire to the jury room. You have got to consider all the testimony, all the expert opinions, weigh the testimony, bearing in mind that the burden of proof is on the Government to satisfy you by a preponderance of evidence, first, that these articles that they have seized are cosmetics that have been adulterated, and that as such they contain poisonous or deleterious substances which may render them injurious to users under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

"Now, of course, it doesn't mean that some person that is allergic to something can be considered protected by this law, because he is an exceptional individual. It doesn't mean, as I have already said, possible inconvenience without any harm to the eye, but it does mean that the general public, the general users must be protected against cosmetics that are adulterated and which may in spite of the instructions, in spite of the ordinary and customary use injure in some way—to a small or to a great extent is immaterial.

"When you retire you will consider, of course, and it needs no proof, that the eyes of a human being are shown by the evidence to be delicate and that they are vastly important to our lives, and that the eyelashes are in close proximity to the eye. If this thing that is before you now results in some hardship to the claimant, the importance of the health of the public outweighs any such consideration. If, on the other hand, the claimant has an article, a cosmetic that is not adulterated and that the law does not condemn, why, then of course in the absence of proof to the contrary by a preponderance of evidence your verdict should be promptly for it. There is no difficulty about that. The only difficulty is when you retire that some of you may consider that you have got your own opinions and will not be changed by anyone on the jury. Now, the duty of a juror is individual, of course. That doesn't mean that you are to put yourself in one corner and say, 'I won't listen to argument: I won't listen to anything at all. I am satisfied just where I am.' That leads to disagreement. That leads to expense for the claimant and for the Government. It means more trouble and more time. There should be no difficulty about a sensible common sense consideration of this case. That is your duty. Don't leave your common sense behind. When you go into the jury room sit down and say, 'Now, the Judge has told us that the Government must prove by a preponderance of evidence, which he has defined, that these cosmetics are adulterated in that they contain a poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual. Do they contain such a substance? If so, may such substances render it

injurious to any extent within the definition of an injury—harm, damage to users generally under the conditions of use prescribed in the labeling thereof, or are the directions so excellent and so positive, that no one could do damage to their eye by following the directions?' If the Government has failed to satisfy you to that extent, bring in a verdict for the claimant. If on the other hand, you are satisfied that the Government has carried the burden and that here is an adulterated cosmetic that should be taken off the market under the law, then it is you duty to bring in a verdict for the Government. Your duty is plain. We are not concerned with anything else except this particular issue. We are protecting the people of the country against adulterated cosmetics where the labeling is not sufficient or the customary use is not sufficient, and at the same time we want every manufacturer to feel he has had a fair trial and that unless the Government proves its case by a preponderance of evidence it can go on manufacturing by reason of the verdict of the jury. Any exceptions or requests?"

Mr. PARKER. "Perfectly satisfactory, your honor."

Mr. HAYES. "I want to take exception to that part of your honor's charge to the effect that the Government's case is made out when it proves its case by a preponderance of evidence."

THE COURT. "Yes. All right."

Mr. HAYES. "And I want to take exception to all those parts of your honor's charge as to the extent of injury which may allow condemnation of the product."

THE COURT. "All right. Overruled."

Mr. HAYES. "With reference to the requests to charge, I don't want to take up the time of your honor before the jury here."

THE COURT. "Come on. Let us get along with it. I don't want to get into any argument."

Mr. HAYES. "I ask your honor to charge the jury that any use of this product under conditions and for purposes not reasonably prescribed in the directions cannot be considered."

THE COURT. "I shall not charge anything more than I have already charged. Your requests were all handed up before the summations in accordance with our rules and have been considered. I give you an exception for the failure to charge any of those I haven't charged."

Mr. HAYES. "Very well."

THE COURT. "You may retire and we will excuse our additional juror with thanks.

"You, Mr. Foreman, can have any of the exhibits. You can take them all with you if you want them or you can leave them here. Just suit yourselves. You had better consult with your fellow jurors and if you want them all the exhibits will go right with you."

On the same day, April 14, 1942, the jury returned a verdict for the claimant, and judgment was entered ordering the consolidated case dismissed and the product returned to the claimant.

77. Adulteration and misbranding of Louise Norris Lash & Brow Coloring. U. S. v. (Mrs.) Louise Norris (Louise Norris Co.). Plea of nolo contendere. Fine of $650 and jail sentence of 1 year. Jail sentence suspended and defendant placed on probation for 3 years. (F. D. C. No. 5494. Sample Nos. 4570–E to 4574–E, incl., 11108–E, 15901–E, 16329–E, 26808–E to 26811–E, incl., 32037–E, 32038–E, 44931–E to 44933–E, incl.)

Examination of this product showed that it contained 2,5 toluylenediamine, or salts of 2,5 toluylenediamine, an uncertified coal-tar color.

On November 21, 1941, the United States attorney for the Western District of Missouri filed an information against (Mrs.) Louise Norris, trading as Louise Norris Co. at Kansas City, Mo., alleging shipment from on or about October 27, 1939, to on or about August 23, 1940, from the State of Missouri into the States of Arkansas, California, Colorado, Illinois, Kansas, Texas, and Washington of quantities of Louise Norris Lash & Brow Coloring that was adulterated and a portion of which was also misbranded.

The article was alleged to be adulterated (1) in that it contained a poisonous or deleterious substance, namely, 2,5 toluylenediamine, or salts of 2,5 toluylenediamine, which might have rendered it injurious to users under the conditions of use prescribed in the labeling and under such conditions of use as are customary or usual; and (2) in that it was not a hair dye and it contained a coal-tar color, namely, 2,5 toluylenediamine, or salts of 2,5 toluylenediamine, which said coal-tar color was other than one from a batch that had been certified in accordance with regulations as provided by law.