Notices of Judgment—

Nos. 1001 to 5000

By JAMES C. MUNCH and JAMES C. MUNCH, JR.

This Record of Food-Drug-Cosmetic Actions Immediately Before and After Passage of the Sherley Amendment Follows "Notices of Judgment—The First Thousand" (April, 1955 *Journal*). The Authors State That They Will Gladly Answer Inquiries on Specific Points Not Covered in the Current Article

THE PREVIOUS REPORT of this series dealt with Notices of Judgment (N. J.'s) 1 through 1000, published in accordance with the provisions of Section 4 of the 1906 Federal Food and Drugs Act. This report extends discussion of the next 4,000 notices. Every effort has been made to maintain consistency in classifying products as "foods," "drugs," "drug products and preparations," or "cosmetics."

In this group of 4,000 notices, there were 205 dealing with foods, 275 dealing with drugs, 505 dealing with drug products and preparations, and 24 dealing with cosmetics. This represents a total of 1,009, or slightly more than one fourth of the total. A total of 55 contests were undertaken, of which the government won 28.

Foods

In considering the 205 notices in this group, the same general types of products were involved as in the previous report. Attention was directed in several cases to wording in Section 7:

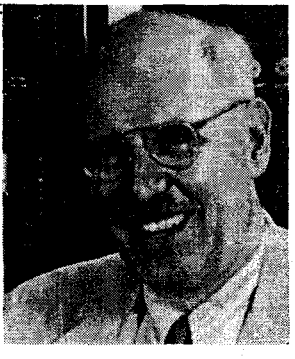
> If it contain any added poisonous or other added deleterious ingredient which may render such article injurious to health: *Provided,* That when in the preparation of food products for shipment they are preserved by any external application applied in such manner that the preservative is necessarily removed mechanically, or by maceration in water, or otherwise, and directions for the removal of said preservative shall be printed on the covering or the package,

the provisions of this act shall be construed as applying only when said products are ready for consumption.

Action was brought because of the presence of arsenic, boric acid, caffeine, cocaine, poisonous coal-tar colors, formaldehyde, lead, copper, zinc or talc. A number of actions included the charge that the presence of harmful, poisonous and deleterious bacteria and spores rendered such foods unfit for consumption and, therefore, injurious to health. However, these charges were dropped by the Department of Agriculture in presenting many of these cases to the courts.

It is noted that there were ten cases in which pleas of not guilty or of *nolo contendere* were offered. In six of these cases, the finding of the court, with or without a jury, was against the government. In one instance (N. J. 4099), a seizure of meat products was ordered to be returned to the owner.

Actions against Coca-Cola, as recorded in N. J.'s 1455, 4032 and 4801, trace the early history of this product. Seizure was made under Section 10, on the basis that the product contained an added ingredient, caffeine—a poisonous and deleterious ingredient—which might render Coca-Cola injurious to health. The company was given a trial by jury. Evidence was offered that the caffeine content was about 1.2 grains to each fluid ounce of the syrup. The conflict in testimony dealt with the deleterious effect on health of such a quantity. It was shown that an average cup of coffee contains more caffeine than an ordinary drink of Coca-Cola. Judicial attention was directed to the interpretation of the term "added." The judge ruled that the public obtained the article desired and that the product was neither adulterated nor mis-



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branded, and directed a verdict in favor of the Coca-Cola Company (N. J. 1455).

The government appealed this decision to the Circuit Court of Appeals for the Sixth Circuit, which affirmed the finding of the district court in N. J. 4032. The point on which the holding in the case turned was whether or not evidence that caffeine is a poisonous or deleterious ingredient should be submitted to the jury for consideration as an "added" ingredient. The court was persuaded that since a glass of Coca-Cola as consumed contained 1.2 grains of caffeine, whereas an average cup of tea contained 1.5 grains and an average cup of coffee more than two grains, and since the chemical and physiological properties of the caffeine content were identical, such an element would not be within the meaning of Congress as an "added deleterious ingredient."

The government then appealed to the Supreme Court of the United States, which reversed the findings of the lower courts and returned the case for further proceedings (N. J. 4801). Evidence was presented in this hearing that:

> . . . the standard by which the combination in such a case is to be judged is not necessarily the combination itself; that a poisonous or deleterious ingredient with the stated injurious effect may still be an added ingredient in the statutory sense, although it is covered by the formula and made a constituent of the article sold.

Reasoning from decisions in the *Lexington Mills* (N. J. 3898), the *Antikamnia* (N. J. 3868), and the *443 Cans of Egg Product* (N. J. 2437) decisions, it was concluded as a matter of law that the name was not

primarily descriptive nor had it attained a secondary meaning. Apparently, the injury to health was not a moving feature to the Supreme Court in reaching its decision, except to state that:

. . . the question was plainly one of fact which was for the consideration of the jury.

A series of cases was brought against various types of confectionery under Section 7:

In the case of confectionery:

If it contain terra alba, . . . talc, . . . or other mineral substance or poisonous color or flavor, or other ingredient deleterious or detrimental to health . . . .

In N. J. 1642, candy eggs were seized because talc was present. The district judge, in his charge to the jury, stated:

In considering the quantity of a substance like this, not claimed to be poisonous, it seems to me that of a quantity so small as not to be appreciable for any practical purpose whatever, the law does not take account. Things which are entirely trifling, insignificant, unsubstantial, of no consequence for any practical purpose, as a general rule the law does not take account of. . . . If you have been satisfied by a fair preponderance of the evidence that there is talc in these candies, I instruct you that you should also be satisfied, in order to find for the Government, by a fair preponderance of the evidence, that there is in the candies a quantity of talc sufficiently appreciable to enable you, as reasonable men, to regard it as significant or important for some practical purpose . . . that it is not merely a quantity so small that all the difference it could possibly make for any purpose whatever would be only imaginary or theoretical. . . . it is not necessary that you should find that there was enough talc to injure or hurt any consumer of those candies.

This decision was appealed by the government to Circuit Court of Appeals for the First Circuit, which reversed the decision in the lower court (N. J. 3871). It was conceded that the candy contained 0.01 to 0.1 per cent of talc.

In declaring that confectionery containing this pigment or any of the liquors named should be deemed adulterated, Congress likewise refrained from making the question of adulteration depend upon the quantity which the confectionery contained, and plainly manifested an intention that confectionery containing any of these things should be deemed to be adulterated. The language of the statute being unambiguous, so far as it relates to the particular adulterants mentioned, its words must be given their ordinary meaning. When so construed, confectionery which contains any of the specific substances or liquors named is adulterated, without regard to the question whether in the particular case the amount of added adulterant indicates an intention to deceive, or is liable to injure health or morals.

A test case of some significance was brought against some wintergreen confectionery which was found to contain 5.5 per cent of talc, alleged to be a deleterious and detrimental ingredient (N. J. 3440).

There was some discussion whether this product was a drug because of the trace of wintergreen present, or whether it was a confection; the jury decided it to be confectionery. Under this decision it was not material whether or not the talc might be injurious to health, since the Act forbade the presence of any talc in confectionery. Under the circumstances the jury upheld the government seizure of this article.

Action was brought against grain alcohol varnish which contained about 35 parts per million of arsenic as As_2O_3 and which was used to coat fudge, on the basis that arsenic is an added poisonous and deleterious ingredient. Witnesses for the government claimed that the amount of arsenic left on the fudge would tend to injure the health of persons who ate it. Experts on behalf of the defense testified that the amount of arsenic taken could not have any injurious effect upon either a child or an adult consuming it from day to day. The question whether the added ingredient might injure health was a question of fact which had to be decided by the jury. After due deliberation the jury returned a verdict of guilty (N. J. 3332).

This was appealed to the Circuit Court of Appeals for the Second Circuit on the basis that all shellac imported into this country contains arsenic to brighten its natural orange color, added in India or Southern Asia at the time of manufacture. Recognizing that eating candy glazed with this varnish would contribute only minute amounts, this court stated that the only question was:

> Was there sufficient arsenic in the varnish to make it an article which "may be injurious to health"?

It was proper to submit this question to the jury for decision, and the court upheld the verdict of the lower court (N. J. 4055).

A decision (N. J. 508) against certain preserved whole eggs containing 2 per cent of boric acid added as a preservative was appealed to the United States Supreme Court (N. J. 1043). In upholding the condemnation by the lower court, the Supreme Court stated that the Act did apply to such material, shipped in interstate commerce to be used in making cakes or for other baking purposes, and set forth its policy:

> The object of the law is to keep adulterated articles out of the channels of interstate commerce or, if they enter such commerce, to condemn them while being transported or when they have reached their destination, provided they remain unloaded, unsold, or in original unbroken packages, . . . transportation in interstate commerce is forbidden to them, and, in a sense, they are made culpable as well as their shipper. It is clearly the purpose of the statute that they shall not be stealthily put into interstate commerce and be stealthily taken

out again upon arriving at their destination and be given asylum in the mass of property of the State. Certainly not, when they are yet in the condition in which they were transported to the State, or, to use the words of the statute, while they remain "in the original unbroken packages." . . . Whether they might be pursued beyond the original package we are not called upon to say.

A suit was brought by the government against 443 cans of frozen egg product which was decomposed and contained added sugar (N. J. 1027). The decision by the court was that the government had not sustained the burden of proof that the eggs were decomposed. This decision was appealed by the government to the Circuit Court of Appeals for the Third Circuit (N. J. 1576), which gave further consideration to the bacteriological and baking experiments in ruling that the product was decomposed. In this connection, consideration was given to evidence that this liquefied product, when hypodermically injected into guinea pigs and other animals, produced sickness and death, whereas similar administration of fresh egg product had no harmful effects. The case was then appealed to the Supreme Court (N. J. 3437), which overruled the decision in the circuit court for jurisdictional reasons.

The presence of 1.8 p. p. m. nitrites in flour shipped by the Lexington Mill and Elevator Company led to the seizure of 625 bags of flour; after very extensive testimony, the jury sustained the government charges (N. J. 722) that nitrites formed in flour are poisonous and deleterious substances, and that Congress intended to prohibit adding any quantity of nitrites to flour. Flour is used in making other articles of food such as:

. . . biscuits, dumplings, pastry, cake, crackers, gravy, and perhaps other articles of food—which may be consumed by all classes of persons—the young, the old, the sick, the well, the weak, the strong . . . .

This decision was appealed to the Circuit Court of Appeals for the Eighth Circuit, which reversed the decision in the lower court (N. J. 2549). Among other reasons, the court stated:

The trial judge decided that if the added substance was qualitatively poisonous, although in fact added in such minute quantity as to be noninjurious to health, that it still fell under the ban of the statute; and the distinction is sought to be drawn between substances admittedly poisonous when administered in considerable quantities but which serve some beneficial purpose when administered in small amounts, and those substances which it is claimed never can benefit and which in large doses must injure. The distinction is refined. To apply it must presuppose that science has exhausted the entire field of investigation as to the effect upon the human body of these various substances;

that nothing remains to be learned. . . . There is no warrant in the statute for such a strained construction. . . . the statute only prohibits it if it may render such article—the article of food—injurious to health.

The case was then appealed to the United States Supreme Court, which affirmed the findings of the circuit court (N. J. 3398), and interpreted Section 7, regarding adulteration of food, by stressing the italicized portion:

If it contain any added poisonous or other added deleterious ingredient *which may render such article injurious to health.*

In reaching its conclusion, the Supreme Court referred to the statement of Senator Hepburn upon the floor of the Senate:

As to the use of the term "poisonous," let me state that everything which contains poison is not poison. It depends on the quantity and the combination. A very large majority of the things consumed by the human family contain, under analysis, some kind of poison, but it depends upon the combination, the chemical relation which it bears to the body in which it exists, as to whether or not it is dangerous to take into the human system.

A difference in opinion may be noted in these decisions, which distinguish between flour and other foods, on one hand, and the absolute prohibitions of the Act in the case of confectionery, on the other.

Drugs

Two hundred and seventy-five N. J.'s dealt with drugs. Many of the drugs differed from the official standards chemically or showed significant shortages from official requirements of potency. There were eight cases in which pleas of not guilty were entered. In five, verdicts of guilty were reached by the juries.

A product labeled "Tragacanth Gum USP" was shipped from Brooklyn, New York, to Norfolk, Virginia, induced by the government. Upon examination it was found to be so-called "Indian gum," not meeting the *United States Pharmacopoeia* standards. The imported material had been cleared through United States Customs after inspection; testimony was offered that all vegetable gums having similar properties were known as "tragacanth." Apparently the charges were brought in the wrong district; charges were dropped (N. J. 1881). A further indictment was obtained in another district; the jury returned a verdict of guilty (N. J. 2436). In the judge's charge to the jury re misbranding:

. . . you are to take the United States Pharmacopoeia—not only the text, but the preface, with such limitation and explanation as it contains, and in the

light of that, and all the other evidence, you are to find whether this article was misbranded as specified in the act.

The judge was favorably impressed with the testimony of Mr. Hopkins, so he suspended sentence.

A product was shipped from New York to California, labeled "Alex. Senna Broken U. S. P." which contained 20 per cent of stalks. The *United States Pharmacopoeia* requirement for senna specified that it should be free from stalks. Evidence was offered that all senna contained stalks. In his charge, the judge stated:

. . . was there any senna ever brought into the United States which was free from stalk? The proof shows contradiction. Therefore, in considering this clause of the Pharmacopoeia it is quite clear that you cannot construe it literally or absolutely; . . . the Pharmacopoeia is a book put in the hands of druggists all over the country, men of no great learning, for practical use, and this surely must be intended to bear upon the commercial usages of the country and to have some reference to the raw materials which the chemists actually use, else it is a merely delusive, arbitrary, and scholastic publication which it certainly is not. Therefore, you can not consider the word as meaning it should be wholly free from stalks.

Since the product in question did not appear to differ from the requirements of the *United States Pharmacopoeia,* the judge directed a verdict of acquittal upon the charge of adulteration. The case was tried before a jury with respect to misbranding. The judge stated that the product was going to people familiar with the trade, and that the label was intended to be read by men in the drug business. Dr. H. H. Rusby testified that he coined the term "broken" for one type of senna sifting, and that it was generally understood in the trade. The verdict was "not guilty" (N. J. 1881).

In testimony on adulteration and misbranding of oil of cassia (N. J. 2841), testimony dealt with the difference between "resin" distilled with oil of cassia, and "rosin" from a species of pine tree, which is not permitted in oil of cassia. After a verdict of guilty, the case involving a second offense, a fine of $150 was imposed. The judge charged that when a man gets an article from the end of the earth and puts it out in the United States, with a label stating that it conforms to the law of the United States, it is his business to see that it does correspond.

Assays of a lot of FE Cinchona showed the ether-soluble alkaloids to average somewhat below 3 per cent, as compared with the *United States Pharmacopoeia* standard of 4 per cent. It was developed that the product as manufactured assayed understrength, and so was fortified by addition of quinine and cinchonidine, which was improper. Assays must be made by the tests in the current *United States Pharma-*

copoeia, and the use of methods of analysis other than the *United States Pharmacopoeia* method would constitute no defense. The judge's charge also stated:

> When an article of this kind, like fluid extract of cinchona, is purchased in the market, having been shipped in interstate commerce, with this law in force the purchaser has the right to assume that he is receiving a preparation of a certain well-defined strength, quality, or purity, as the case may be, and neither he as a user, nor the physician, nor the druggist who gives it to others is under any obligation to make tests for themselves but may rely to an extent at least upon the article being of the strength, quality, or purity fixed by this standard. . . . The manufacturer who compounds them and puts them on the market in interstate commerce is bound at his or its peril to see to it that they are up to the standard fixed by law not only when made and shipped but are so compounded and put up for sale that they will be of the required standard when shipped [in] interstate commerce for sale to the consumer or user.

The jury returned a verdict of guilty, and a fine of $200 was imposed (N. J. 4980).

Drug Products and Preparations

Under this classification, there was a total of 505 N. J.'s. This was the transition period for passage and beginning enforcement of the Sherley Amendment with respect to therapeutic claims. Of a total of 33 pleas of not guilty, findings in 14 cases supported that claim, including four under the *Johnson* decision which led to that amendment of the Act.

According to the label and circular, "Eckman's Alterative" was useful in all throat and lung diseases, also effective as a preventative and cure for tuberculosis. Seizure was made in Nebraska (N. J. 2995), to which the company demurred, leading to review by the United States Supreme Court (N. J. 4816). The validity of the Sherley Amendment was challenged, and upheld by the Supreme Court. It was also held that this Amendment included circulars or printed matter placed inside the package transported in interstate commerce. In discussing false and fraudulent claims, it was stated:

> That false and fraudulent representations may be made with respect to the curative effect of substances is obvious . . . persons who make or deal in substances, or compositions, alleged to be curative, are in a position to have superior knowledge and may be held to good faith in their statements . . . . Congress recognized that there was a wide field in which assertions as to curative effect are in no sense honest expressions of opinion but constitute absolute falsehoods and in the nature of the case can be deemed to have been made only with fraudulent purpose. The amendment of 1912 applies to this field and we have no doubt of its validity.

In connection with a shipment of Dr. Tucker's Specific for asthma, *hay fever* and all catarrhal diseases of the respiratory organs, the jury returned a finding of guilty on the charge of misbranding by failure to declare the presence and amount of cocaine present. In overruling a motion for a new trial, the judge stated that depositing such medicine in the mails for delivery outside the State of Ohio constituted interstate shipment (N. J. 1077).

A wide variety of products was involved, making broad claims for curing or relieving rheumatism, along with a host of complaints, associated or widely diverse from that condition. Interesting comments were noted in the decisions in two such products. In N. J. 1049, action was brought against the products Radio-Sulpho (a remedy for rheumatism, diseases of the skin, etc.) and Radio-Sulpho Brew (blood purifier and tonic for indigestion, laxative, claimed to prevent appendicitis). After a number of witnesses testified that the products had cured their eczema, rheumatism and cancer, the judge charged the jury that they should weigh the correctness of lay diagnoses of these serious diseases against the testimony of men schooled in the professions of medicine and chemistry who testified that neither of these products would cure, relieve or be of any help in the treatment of these diseases. The chemists reported the contents to be simple; the defendant stated that there were other ingredients present, which he refused to disclose since that was a "great secret" that belonged to the company. He also claimed that 30 to 40 days were required to make these remedies. In discussing the status of the induced shipments under a false name, the court stated:

> Congress passed this law and it is the duty of the officers in every capacity, who have anything to do with the prosecution of crime or with the enforcement of the different acts of Congress, to use whatever means they think may be most successful in enforcing the act and suppressing what Congress intended to be suppressed; therefore the fact that Dr. Morgan wrote under an assumed name, the fact that he stated in his letters things that perhaps were not true, is not to be considered by the jury at all in arriving at a verdict.

Another rheumatism remedy contained 23 per cent of alcohol and 5 grains of KI per fluid dram; a number of testimonials were included in the booklet accompanying the product (N. J. 4842). In the judge's charge to the jury, he pointed out that laymen, such as blacksmiths, barbers, farmers or lawyers, are not able to diagnose rheumatism and other diseases accurately, and their testimony or testimonials should be weighed carefully when contradicted by testimony of medical witnesses:

Expert evidence is often spoken of as opinion evidence, and it is opinion evidence. When a man has devoted years of study to a science or branch of learning, and has become proficient in that branch, it is of assistance to juries and to average men to have their opinions upon certain questions of fact about which the witness is informed and about which the jurors ordinarily are not informed.

The jury returned a verdict of guilty (upheld on appeal to the Circuit Court of Appeals for the Seventh Circuit, N. J. 5588).

There was much overlapping of claims for these antirheumatics, the so-called blood purifiers, the female-complaint remedies, and the preparations for kidney, liver and nervous diseases; some products might have been classified in several groups. Efforts have been made to list them in accordance with the chief claims offered.

The proceeding against Johnson for selling a combination of six products for the treatment and cure of cancer (N. J. 266) was ordered to be dropped by the district court. This decision was appealed to the United States Supreme Court. The decision of the majority of the Supreme Court affirmed that decision in N. J. 1058:

Congress . . . was much more likely to regulate commerce in food and drugs with reference to plain matter of fact, so that food and drugs should be what they professed to be when the kind was stated, than to distort the uses of its constitutional power to establish criteria in regions where opinions are far apart. See *School of Magnetic Healing v. McAnnulty,* 187 U. S. 94. . . . the reference of the question of misbranding to the Bureau of Chemistry for determination confirms what would have been our expectation and what is our understanding of the words immediately in point. . . . we are of opinion that the phrase is aimed not at all possible false statements, but only at such as determine the identity of the article, possibly including its strength, quality and purity, dealt with in section 7.

A dissenting opinion was filed by Justices Hughes, Harlan and Day, claiming that the Act did intend to cover false and misleading claims on medicinal products. It admits that the curative properties of some medicinal products are matters of opinion, but insists that there still remains a field covered by the statute in which statements as to curative properties are downright falsehoods. This situation was corrected by Congress, by passing the Sherley Amendment, which added a third paragraph to Section 8, stating:

If its package or label shall bear or contain any statement, design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein, which is false and fraudulent.

This amendment was approved August 23, 1912.

A variety of cough and cold cures received attention; many carried sweeping claims of value in all lung conditions, including consumption. In N. J. 1912, action was brought since the product as analyzed was deficient 84 per cent in chloroform content as declared on the label. The act was passed, for example, to prevent people taking cocaine when they did not know it to be present. The volatility of chloroform was stressed to the jury. The judge then charged:

> It might take a chemist to make a proper compound, but we think anyone with a formula can mix the ingredients in a mixture unless there are to be peculiar things done to the different parts before they go into the mixture. It does not require a chemist to make a mixture.

Two shipments were induced from Dr. Stephens for the treatment of alleged drug addiction in two government employees, after each had submitted data, by mail, on physical condition. One set of 18 bottles contained morphine sulfate in quantities gradually decreasing from 3.91 grains per fluid ounce to none, the other from 3.25 to none. Even though it was recognized that proper treatment of morphine addicts should be by gradual decreases in dose, without the knowledge of the addict, the court ruled that there was no provision in the law to permit physicians to ship such prescriptions interstate without proper label declaration of the morphine and alcohol content of each bottle. The court directed a jury verdict of guilty (N. J. 1891), which was affirmed on appeal to the Circuit Court of Appeals for the Sixth Circuit (N. J. 2511).

The label on a headache remedy, "Antikamnia," stated that it contained a specified quantity of acetphenetidin, and no acetanilide was present. The shipment of the product was seized, since the label did not state that, under Regulation 28 of the Bureau of Chemistry, acetphenetidin was considered to be a "derivative" of acetanilide (N. J. 1056). The court stated that people generally are no more familiar with one of these terms than with the other, that such labeling does not add anything to the safety of the product and that this regulation exceeded the authority given under the Act. On appeal to the Supreme Court of the District of Columbia, that decision was affirmed:

> The regulation having named acetphenetidin as a derivative of acetanilide, the manufacturer complied therewith to the extent of naming the proportion of said derivative contained in antikamnia tablets, but did not comply with the requirement of the same that it should also recite that it was, in fact, a derivative of acetanilide. The last requirement was, in our opinion, an amendment of, or an addition to the act itself, and therefore beyond the powers of the executive authority.

This decision was then appealed to the United States Supreme Court (N. J. 3868), which reversed these decisions and remanded the case to the lower court. It concluded that:

. . . the composition of drugs is a matter of technical skill, their denomination often by words of scholastic origin, conveying no meaning to the uninformed.

Therefore, naming a drug as a derivative of another may help prevent surreptitious sale of noxious drugs or their derivatives. The Court apparently ignored the opinion that the action of derivative may differ from that of the parent substance.

A number of cases were brought against so-called "mineral waters," which carried exaggerated claims for therapeutic value, as violating the Sherley Amendment. A shipment of "Buffalo Lithia Water" was seized (N. J. 3869) for being sold with the suggestion that it contained a significant quantity of lithium, which was supposed to treat gout, rheumatism, stone in the kidney and similar conditions. Testimony was offered, regarding the composition of the product, that the common understanding was that a lithium water should contain enough lithium to produce a therapeutic effect when consumed. The opinion of the court stated that:

. . . a chemical analysis showed absolutely no appreciable amount of lithium in the bottle of water of the size usually sold. By the use of the spectroscope, however, it was found that there was two thousandths of a milligram in a liter; that is, about one ten-thousandth of a grain per gallon of water, or 1 grain in 10,000 gallons of water. To further illustrate the infinitesimal quantity of lithium in this water, it was testified that the average dose of lithium as a uric acid solvent was from 5 to 7½ grains three times a day. So that, for a person to obtain a therapeutic dose of lithium by drinking Buffalo Lithia Water he would have to drink from 150,000 to 225,000 gallons of water per day . . . the Potomac River water contains five times as much lithium per gallon as the water in controversy.

The court entered judgment for the government. This was appealed to the Appellate Court of the District of Columbia, which affirmed the decision (N. J. 4310).

In an effort to develop the belief in the therapeutic value of mineral waters further, a concentrated *Salz* was prepared, to be dissolved in tap water in order to bring sufferers the value of such waters in their own homes. The product was claimed by the physician who operated the company to be able to prevent and to dissolve away gallstones, even though this theory was opposed by many other physicians. The jury convicted the physician under the Sherley Amendment (N. J. 3962).

A number of "tonics" were involved, usually under the Sherley Amendment. Particular attention is directed to the action against "Pink Pills for Pale People" (N. J. 4849) as typical of the presentation of evidence, court considerations and decisions. The product was recommended as a safe and effective tonic for the blood and nerves, and useful in anemia, locomotor ataxia, etc. Analysis indicated it to be substantially the usual Blaud's Pill. Testimony of laymen claimed value for the product; testimony by chemists and physicians pointed out that there was no ingredient present capable of producing the stated effects in these diseases. The object of this Act is to prevent credulous and ignorant people and the public generally from being deceived in purchasing medicines such as this. Every man is presumed to intend the natural and probable consequences of his act; distribution of this product for the treatment and cure of these conditions is a natural consequence of the use of the language used. The jury returned a verdict of guilty, and the district judge overruled a motion for a new trial. Upon appeal to the Circuit Court of Appeals for the Third Circuit, the decision in the lower court was affirmed.

It was noted that a number of products and preparations intended for use by sufferers from pulmonary diseases, including involvements of the lungs and throat, contained morphine, iodides and chloroform. Several preparations for the treatment of skin diseases claimed they were "absolutely harmless"; analysis revealed the presence of substantial quantities of strychnine, which would render them dangerous to children, if not to adults. The same claim of safety was made for teething syrups, which were found, on analysis, to contain appreciable amounts of morphine or codeine. Finally, many preparations for the treatment of tuberculosis contained large amounts of iodides, opium or morphine, and alcohol.

The passage of the Sherley Amendment appears to be responsible for the marked increase in the number of actions against drug products and preparations in this series of N. J.'s.

Cosmetics

A total of 24 N. J.'s were issued against products which may now be considered cosmetics. It may be noted that methyl alcohol was present in one product (N. J. 2321), and a substantial amount of arsenic in another (N. J. 3331). Other products contained lead acetate or ammoniated mercury. The charges made by the government with respect

to these products were that they were not harmless, since such materials contained these poisonous and dangerous ingredients.

In all four contested cases, the courts decided against the government. Action was brought against a product labeled "Peroxide Cream" (N. J. 1194), which was represented as a harmless whitening agent for the skin. The government charged that the title suggested the presence of peroxide as an important ingredient, whereas there was only a very small quantity present. The court ruled:

> If the label on a drug is not false or misleading in any of the particulars enjoined or prohibited by section 8, no offense is committed under that section. By no possible construction can the terms of the act be extended to such a boundless field of inquiry as that involved in the accuracy of the remedial effects claimed for a drug. Such an inquiry could be pursued only through the opinions of contending experts and the experience of those who had used the article, and a conclusive determination could seldom, if ever be reached.

Relying on the *Johnson* decision, the court stated that the original Act did not hold manufacturers or vendors to criminal responsibilty for misstatements of curative effects. Also, this court offered the opinion that:

> An advertising circular inclosed with an article inside the carton in which it is offered for sale, does not induce the sale or deceive the intending purchaser, and is not within the purview of the act.

These opinions have been modified by subsequent court decisions, as well as changes in the law. **[The End]**

N. J.'s CITED

N. J. No. 1043: *Hipolite Egg Company v. U. S.*
N. J. No. 1049: *U. S. v. Schuch.*
N. J. No. 1056: *U. S. v. 100 Packages Antikamnia Tablets.*
N. J. No. 1058: *U. S. v. Johnson.*
N. J. No. 1194: *U. S. v. American Druggists' Syndicate.*
N. J. No. 1642: *U. S. v. 307 Cases Confectionery.*
N. J. No. 1881: *U. S. v. J. L. Hopkins & Company.*
N. J. No. 1912: *U. S. v. Piso Company.*
N. J. No. 2436: *U. S. v. J. L. Hopkins & Company.*
N. J. No. 2549: *Lexington Mill & Elevator Company v. U. S.*
N. J. No. 3398: *U. S. v. Lexington Mill & Elevator Company.*
N. J. No. 3868: *U. S. v. Antikamnia Chemical Company.*
N. J. No. 3869: *U. S. v. Seven Cases of Buffalo Lithia Water.*
N. J. No. 3871: *U. S. v. R. C. Boeckel & Company et al.*
N. J. No. 4032: *U. S. v. 40 Barrels and 20 Kegs of Coca-Cola.*
N. J. No. 4055: *Weeks v. U. S.*
N. J. No. 4801: *U. S. v. Coca-Cola Company.*
N. J. No. 4816: *Seven Cases of Eckman's Alterative v. U. S*
N. J. No. 4842: *U. S. v. Abbott Brothers Company.*
N. J. No. 4980: *U. S. v. G. F. Harvey Company.*

Outcome of Court Contests: N. J.'s 1001-5000

(1) Foods (205)

NJ	*Product*	*Plea*	*Decision*		*Discussion*
			g.	*n. g.*	
1031	Soda Syrup	*Nolo*		Jury	Cocaine present by accident.
1265	Crackers	Demur.		Jury Sust.	No added poisons.
1455	Coca-Cola	n. g.		Court acquitted	Caffeine harmful health?
1507	Diabetic Flour	n. g.	Jury		Gluten chief ingredient.
1642	Confectionery	n. g.		Jury	Trace talc won't matter.
2943	Kafeka	n. g.		Jury	Decaffeinated coffee.
3332	Varnish, grain	n. g.	Jury		Amount As_2O_3 added harmful?
3334	Cherry Comp.	n. g.	Jury		Benzaldehyde present.
4099	Meats	S.; demur.		Court returned	BAI inspection O. K.
4330	Cider	n. g.	Jury		Saccharin harmful 140 p. p. m.?
	Total	10	4	6	

(2) Drugs (275)

1796	Nitroglycerine	n. g.	Jury		
1881	Senna "broken"	n. g.		Jury	Meaning of term to man in trade.
1881	Tragacanth	n. g.		Jury	Adulteration Indian gum, guilty on retrial (N. J. 2436)
2090	Stramonium lf.	n. g.	Jury		
2091	Belladonna lf.	n. g.		Jury	
2841	Cassia Oil	n. g.	Jury		Resold as import from China.
3359	Birch Oil	n. g.	Jury		Adulterated Me salicylate.
4980	FE Cinchona	n. g.	Jury		Must follow *United States Pharmacopoeia* methods.
	Total	8	5	3	

1035	Oxidine	n. g.		Court	Result *Johnson* decision.
1049	Radio-Sulpho	n. g.	Jury		Testimonials v. medical opinion.
1056	Antikamnia	S.; Contest		Court	Deriv. acetanilide (United States Supreme Court g. N. J. 3868).
1058	Johnson Cancer	n. g.		Court	United States Supreme Court, therapeutic claims not covered by original Act.
1077	Dr. Tucker Asthma	n. g.	Jury		Cocaine undeclared.
1182	Hall Catarrh	Demur.		Court	Result *Johnson* decision.
1197	Williams Cough	n. g.		Court	Result *Johnson* decision.
1392	Mineral Water	Demur.		Court	Only trace Lithium present.
1507	Ralston Tonic	n. g.	Jury		
1891	Dr. Stephens Drug	n. g.	Jury		
1912	Piso Cough	n. g.		Jury	
1939	Pepsin Gum	n. g.	Jury		Label must be correct when sold.
2550	Freeman Headache	*Nolo*		*Nolle Prosse*	
2834	Fernet Bascal	Demur.		Court	
2995	Eckman's Alterative	S.; Contest	Court		United States Supreme Court affirmed N. J. 4816.
3004	Radam Microbe	n. g.	Jury		
3494	Dodsen Headache	n. g.		Jury	Caffeine, acetanilide habit forming?
3869	Buffalo Lithium Water	S.; demur.	Court		Very slight traces Lithium.
3962	Bad-Em Salz	n. g.	Jury		
3973	Rheumaside	S.; Contest	Jury		
4133	Rheuma	S.; Contest	Jury		
4134	Jackson Balm	S.; Contest	Jury		
4190	Matusow	n. g.	Jury		
4367	Tu-Ber-Ku	S.; Contest	Jury		
4521	Sil-Ferro-Sal	S.; Contest		Court	
4834	Athlophoros	n. g.	Jury		
4839	Pect. Plaster	n. g.		Jury	
4840	Texas Wonder	n. g.		Court	Guilty in later cases.
4842	Abbott Rheum.	n. g.	Jury		

Outcome of Court Contests: N. J.'s 1001-5000—Continued

(3) Drug Products and Preparations (505)—Continued

NJ	*Product*	*Plea*	*Decision*		*Discussion*
			g.	*n. g.*	
4846	Dr. Kellett's Oil	n. g.	Jury		
4849	Williams Pills	S.; Contest	Jury		
4862	Caly Rheum.	n. g.		Jury	
4988	Benne Catechu	n. g.	Jury		Claimed harmless; contained morphine.
	Total	33	19	14	

(4) Cosmetics (24)

1194	Peroxide Cream	Demur.		Court	Result *Johnson* decision.
1677	Walnut Oil	*Nolo*		Court	
1691	Cuticura Ointment	Demur.		Court	
4317	Oriental Cream	S.; Contest		Court	
	Total	4	0	4	

Summary

Class	*Total Number*	*Contested*	*Verdict*	
			Government	*Defendant*
(1) Foods	205	10	4	6
(2) Drugs	275	8	5	3
(3) Drug Products and Preparations	505	33	19	14
(4) Cosmetics	24	4	0	4
Total	1009	55	28	27

Abbreviations:
Nolo—nolo contendere
g.—gullty
n. g.—not guilty
S.—seizure
Demur.—demurrer