

## Decision

IN THE MATTER OF  
CARTER PRODUCTS, INC., ET AL.ORDER, ETC., IN REGARD TO THE ALLEGED VIOLATION OF THE  
FEDERAL TRADE COMMISSION ACT

*Docket 4970. Complaint, May 28, 1943—Decision, Oct. 4, 1956*

Order requiring distributors of "Carter's Little Liver Pills" laxative preparation to cease advertising falsely that their said preparation would restore regularity of bowel movement and was a cure and effective treatment for constipation and its symptoms; did not contain strong medicines and was unqualifiedly safe; was an effective treatment for sluggish liver functions; would make bile flow freely; would prevent and overcome discomforts caused by overeating and overindulgence in "good times"; would cause proper flow of the gastric and digestive juices, regulate the digestive system, induce a state of "bounce", vigor, and well-being, and was an effective treatment for "down-and-out" feelings generally; and to cease representing falsely that constipation poisoned the system, and using the word "Liver" in the brand name for said laxative.

Before *Mr. James A. Purcell*, hearing examiner.

*Mr. Fletcher G. Cohn* for the Commission.

*Breed, Abbott & Morgan*, of New York City, for respondents.

## DECISION OF THE COMMISSION

## STATEMENT OF THE CASE

This is a proceeding under the Federal Trade Commission Act wherein the Commission, on May 28, 1943, issued and subsequently served its complaint on the respondents named in the caption hereof, charging them with the dissemination of false advertisements for inducing purchases of a preparation designated as "Carter's Little Liver Pills". After filing by the respondents of their joint answer to the complaint, testimony and other evidence in support of and in opposition to the charges of the complaint were introduced before a hearing examiner of the Commission, theretofore designated by it, and this proceeding came on for final hearing upon the record and the original and supplemental oral arguments of counsel. On March 28, 1951,<sup>1</sup> the Commission made its findings as to the facts and its conclusion drawn therefrom and issued its order directing the respondent, Carter Products, Inc., to cease and desist from the acts and practices found in the Commission's findings as to the facts to have been engaged in unlawfully by that respondent.

<sup>1</sup>See 47 F.T.C. 1137.

ent, and dismissing the complaint without prejudice as to the respondent, Street & Finney.

The respondent, Carter Products, Inc., thereafter filed with the United States Court of Appeals for the Ninth Circuit a petition to review and set aside the Commission's order to cease and desist. Holding that the respondent had been denied a fair hearing in that the hearing examiner had unduly and prejudicially restricted the respondent's right to cross-examine three of the expert witnesses appearing in support of the allegations of the complaint, the Court of Appeals in its opinion rendered January 19, 1953, granted the respondent's petition to review and set aside in its entirety the Commission's order.

A petition for a writ of certiorari was thereupon filed with the Supreme Court of the United States, which petition was on October 12, 1953, granted, and the cause was remanded to the Court of Appeals "with directions to reinstate its prior judgment and order after amending it so that it specifically authorizes the Federal Trade Commission to open this proceeding for further evidence and a new order consistent with the Court of Appeals opinion herein."

Following this action, the Court of Appeals, on November 18, 1953, entered a new order granting the respondent's petition to review and setting aside the Commission's order and remanding the cause to the Commission with authority "to open this proceeding for further evidence and a new order consistent with the opinion of this Court."

The Commission, on December 18, 1953, entered an order reopening the proceeding and remanding the matter to the hearing examiner "for such further proceedings as may be necessary to correct the errors in the original hearings as specified by the Court of Appeals"; and in that order the Commission directed the hearing examiner, upon completion of the hearings, to file a report upon the additional evidence and to state such changes, if any, as he might wish to make in his original recommendations in the light of the additional evidence.

Pursuant to this remand, additional hearings were convened at which the respondent further cross-examined two of the three expert witnesses whose cross-examination had been improperly curtailed. Further cross-examination of the third witness in that category being impossible because of his intervening death, the entire testimony and all exhibits introduced through that witness were, on the respondent's motion, stricken.

The respondent's counsel having announced that he had no further cross-examination of the witnesses tendered for that pur-

pose, the hearing examiner on March 31, 1955, filed his supplemental report. Objections and exceptions to said report were thereafter filed by the respondent, the Commission, on September 20, 1955, having denied the respondent's motion to disqualify the hearing examiner for alleged bias and prejudice, and the matter came on for hearing on the merits before the Commission; and the Commission, having exhaustively considered the entire record, including the evidence adduced after the remand and the briefs and oral arguments of counsel, now finds that this proceeding is in the interest of the public and makes this its modified and supplemental findings as to the facts and its conclusion drawn therefrom, the same to be in lieu of those contained in its decision of March 28, 1951.

#### FINDINGS AS TO THE FACTS

PARAGRAPH 1. The respondent, Carter Products, Inc. (hereinafter referred to as the respondent), is a corporation organized and existing under and by virtue of the laws of the State of Maryland, with its office and principal place of business located at 53 Park Place, New York, New York.

PAR. 2. The respondent, Carter Products, Inc., for many years has been engaged in the sale and distribution through wholesale drug jobbers, chain stores, and department stores, of a medicinal preparation designated "Carter's Little Liver Pills". When sold, the respondent's product is transported from its place of business in the State of New York to purchasers thereof located in various other States of the United States and in the District of Columbia, and the respondent at all times mentioned herein has maintained a course of trade in the aforesaid preparation in commerce between and among the various States of the United States and in the District of Columbia.

PAR. 3. In furtherance of the sale and distribution of the aforesaid medicinal preparation, the respondent has disseminated, and has caused the dissemination of, advertisements concerning said preparation by the United States mails and various means in commerce, as "commerce" is defined in the Federal Trade Commission Act; and the respondent has disseminated, and has caused the dissemination of, advertisements concerning such preparation by various means for the purpose of inducing, and which have been likely to induce, directly or indirectly, the purchase thereof in commerce, as "commerce" is defined in the Federal Trade Commission Act.

PAR. 4. All the representations hereinafter referred to have been made directly or by implication in advertising material which the

respondent has disseminated or caused to be disseminated in the manner noted in the preceding paragraph.

(a) Through use of words, phrases and statements purporting to be descriptive of the therapeutic value, beneficial effects and advantages afforded by use of the preparation "Carter's Little Liver Pills", the respondent has represented, directly and by implication, among other things, that its product represents a fundamental principle of nature in self-treatment, that it is a cure and remedy and constitutes a competent and effective treatment for constipation, and will bring on, help, and restore regularity of bowel movement.

The respondent also has represented that its preparation does not contain any strong medicine, and that it is harmless and safe for use by those individuals who have constipation or are experiencing delay in bowel movement or in whom a failure to digest food has occurred.

(b) The respondent similarly has represented that the preparation is a competent and effective treatment for sluggish liver function, liver ills, and disorders affecting the liver; that its use will "wake up the flow of bile", will make "bile flow freely" by getting the liver back to normal and back to producing; that its use will so influence the production or flow of liver bile that one can overeat and overindulge in "good times" without the ordinary discomforts resulting therefrom; that if one has overeaten and overindulged in "good times" that the preparation "Carter's Little Liver Pills", by its influence on the production or flow of liver bile, will overcome the discomforts that usually and ordinarily follow such indiscretions and will enable the user to wake up "clear-eyed and steady-nerved", "feeling just wonderful", and "alert and ready for work"; that such preparation through its favorable influence on bile flow and in helping to restore regularity provides two-way relief, and that it is not an ordinary laxative but possesses therapeutic properties over and above and in addition to its laxative action.

(c) The respondent's advertising also has contained statements representing that use of its preparation will cause the proper flow of the gastric juices and natural vital digestive juices; that it will lessen food decay and is based on the fundamental principle of the operation of the digestive system; that such preparation will help food digestion, including the stopping of fatty indigestion, and will regulate digestion and the digestive system; and that it so follows nature's own order for regularity and so regulates digestion that it will make the user "fit as a fiddle", and full of "bounce".

The respondent further has represented that constipation poisons the body.

(d) Through the use of colloquial words and phrases, which purport to be descriptive of various physical and mental conditions, the respondent has represented, directly and by implication, among other things, that when caused by constipation or irregularity of bowel movement, the preparation designated "Carter's Little Liver Pills" is a competent and effective treatment for those conditions in which an individual feels:

"Down-and-out", "blue",  
"down-in-the dumps",  
"worn out", "sunk",  
"logy", "depressed",  
"headachy", "sluggish",  
"all-in", "listless",  
"mean", "low", "cross",  
"tired", "stuffy",  
"heavy", "miserable",  
"sour", "grouchy",  
"bilious", "irritable",  
"cranky", "peevish",  
"fagged out", "dull",  
"sullen", "what's-the-use",  
"bogged down", "grumpy",  
"run-down", and "gloomy".

The respondent similarly has represented that its product is a competent and effective treatment for headache, ugly complexion, bad breath, coated tongue, bad taste in the mouth, "lazy digestion", and "indigestion", when caused by constipation.

PAR. 5. The quantitative formula for Carter's Little Liver Pills is as follows:

Podophyllum Resin U.S.P.,  $\frac{1}{16}$  gr.

Po. Purified Aloes,  $\frac{1}{4}$  gr.

Podophyllum Resin, also known as podophyllin, is the resin of the dried root of the Mandrake or Mayapple plant. Aloes is the dried juice of the Aloe plant. Podophyllin is used as a laxative, purgative or drastic cathartic, and aloes is one of the irritant cathartics ranking with senna, rhubarb and cascara sagrada.

PAR. 6. The respondent's product, when used as directed, has laxative properties. Its use serves to increase temporarily the motility of the large bowel by irritation and thus induces partial evacuation of the large intestine. Inasmuch as the laxation afforded by an irritant laxative or cathartic is not a normal physiological method of evacuation and is not based on any principle having relation to natural bowel motility, it is not true as stated in the

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respondent's advertising that the preparation represents a fundamental principle of nature in self-treatment.

PAR. 7. In a scientific sense, constipation is a term used to connote a slower rate of evacuation of the large bowel than the one normal for that individual. Although it has reference to delay in the passage of indigestible residues through the alimentary tract and to infrequency of bowel action, and may be used to describe the condition in which the stools are dry and hard, constipation has been described also as being that condition which causes a person to believe that a cathartic is necessary to cause a bowel movement. Normal frequency in bowel movement varies widely among individuals. Because varied notions obtain with respect to what represents normal frequency, the average layman may not diagnose constipation properly and there is a tendency for self-diagnosis to be made on the basis of symptoms having no relationship to constipation.

In its chronic form, there are two general types of constipation: (1) spastic, and (2) atonic. The state of the musculature of the large bowel differs in the two conditions named. In the spastic variety, the musculature is abnormally contracted and rigid and does not propel the contents thereof forward in a normal manner. In the atonic condition, usually associated with an enlargement of the large bowel due to tremendously increased content, the musculature does not contract and retain its tonus or state of partial contraction. Atonic constipation is attributable to constitutional weakness of the muscles of the colon and is supposed to occur principally in the rectum, while the spastic type is supposed to be due principally to anxiety, worry, or nervous strain. Among the causes of constipation or irregularity of bowel movement are improper diet and stool habits, insufficient intake of fluids and variations or obstructions of the alimentary tract such as fissure, cancer and debilitating conditions. Factors predisposing to chronic constipation are numerous and thorough study by the physician is necessary before comprehensive treatment is undertaken. Its treatment, therefore, varies in individual cases, but is directed to correcting the basic conditions which are responsible. As to the type of constipation known as spastic, Carter's Little Liver Pills will tend to aggravate any state of spasticity which is present. The representations appearing in the advertising that Carter's Little Liver Pills are a cure or remedy for and constitute a competent and effective treatment for constipation accordingly are false and misleading. The habitual use of irritant laxatives and cathartics tends to produce irregularity rather than to restore regularity in cases of chronic

constipation and the use of respondent's preparation will not restore regularity of bowel movement.

PAR. 8. The statements appearing in the advertising to the effect that the respondent's product is composed of two simple vegetable medicines, and containing reference to gentle action purportedly afforded by its use, imply that Carter's Little Liver Pills do not contain strong medicines. Carter's Little Liver Pills, however, do contain strong medicines. Although they are obtained by purification of members of the plant kingdom, the ingredients of respondent's pills are irritant purgatives. Aloes taken in sufficient amounts lead to some hyperemia and increased vascularity. Neither aloes nor podophyllin is absorbed to any great extent, and as long as they remain in the colon may cause local irritation.

Moreover, the product is not safe for and harmless to all individuals who are constipated or suffering from delay or irregularity of bowel movement and symptoms thereof, or from failure of digestion. It is potentially injurious if taken by persons suffering from abdominal pains, nausea, vomiting, or other symptoms of appendicitis. It may cause perforation of the intestine in instances where delay in evacuation is due to obstruction in the tract. In some persons, the use of Carter's Little Liver Pills may be attended with griping and stomach discomfort, and when used in the presence of constipation of the spastic type may serve to increase and aggravate such state of spasticity. The use of a laxative is contraindicated in many conditions.

PAR. 9. A determination of those charges of the complaint as relate to what influence, if any, the use of Carter's Little Liver Pills will have on sluggish liver function and the production and flow of bile and other digestive juices, involves consideration of the testimony and other evidence introduced herein which, among other things, describes the physiology of the alimentary tract, the essential nature of bile, and the pathological conditions impeding the formation and flow of bile.

The alimentary system extends from the mouth to the anus and its primary functions are the taking in of food, digestion thereof, and passage of the indigestible or undigested residues to the outside. From the stomach where ingested food has been changed to a thick liquid and subjected to the action of the gastric juices, food passes into the duodenum, which is the upper extremity of the small intestine. At the time of the food's entry into the duodenum, the pancreatic juice and the bile begin to flow and when the mass passes out of the small intestine into the large intestine more than ninety percent of the proteins, fats, and starches have been digested and

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absorbed into the blood stream. Food residues thereafter are conveyed through the large bowel for evacuation from the body.

The liver is a detoxifying organ and has an important role in the metabolism of proteins, carbohydrates and fats. Formed in the hepatic cells of the liver and secreted by the liver in the bile are the bile salts, which are indispensable in the emulsification and digestion of fats. In addition to bile salts, bile contains pigment or coloring matter which has no function in digestion, fatty acids, and cholesterol, the latter being an excretion. The bile as normally secreted by the liver and as passed through the biliary system into the intestine is not a laxative fluid. However, bile salts when taken by mouth in sufficient quantities will cause laxation.

Bile drains from the hepatic ducts, is propelled into a channel known as the common hepatic duct, and then passes into the gall bladder where it undergoes concentration in a degree depending upon the length of time it is permitted to remain in that muscular sac. When the gall bladder subsequently contracts, the fluid flows into the common bile duct and passes into the intestine when the sphincter of Oddi, certain rings of musculature at the end of the duct, relaxes. When this sphincter is contracted, bile does not flow out of the common duct.

PAR. 10. Among the diseases which may interfere with normal formation or flow of bile are stones in the common bile duct, parasites therein or in the hepatic duct, infections in the bile passages, and cancer or tumor. Other ailments interfering with the flow of bile are spasm of the sphincter of Oddi, and inflammation or cancer of the ampulla of Vater or in tissues of the common bile duct. In the presence of these ailments, increased bile flow would cause pain and distress. Carter's Little Liver Pills will have no therapeutic value whatsoever in the presence of the foregoing diseases affecting the liver or the biliary system.

The various ways in which an increase in the flow of bile into the duodenum could be brought about are the following:

- (1) To stimulate the formation or secretion of bile by the liver.
- (2) To cause the gall bladder to contract.
- (3) To cause the sphincter of Oddi to relax.
- (4) To irritate the intestine in such manner as to eliminate the reflex action which causes contraction of the sphincter of Oddi.
- (5) To milk the bile from the bile ducts or from the ampulla of Vater by increasing the motility of the duodenum.

PAR. 11. Received into the record in this proceeding were testimony and other evidence relating to experiments conducted by various scientists which, together with the opinions expressed in support

of and in criticism of such experiments by other expert witnesses, are of great importance in determining what effects, if any, the ingestion of Carter's Little Liver Pills will have on the biliary system and the liver.

(a) Counsel supporting the complaint introduced into the record testimony and exhibits relating to experiments conducted by Dr. A. C. Ivy, who headed the Division of Physiology, Pharmacology, Materia Medica and Toxicology, of the medical school of a large midwestern university. A member of numerous scientific societies and a past president of the American Gastroenterological Association, Dr. Ivy has for many years engaged in medical research and teaching. At the time he testified in this proceeding, he was assistant and managing editor of the *Journal of Gastroenterology* and a member of the Board of Editors of the *American Journal of Physiology*. His achievements in the field of scientific research include the discovery of the hormone "cholecystokinin", the substance which causes the gall bladder to contract and evacuate upon ingestion of sufficient quantities of certain foods. He has contributed approximately 500 articles or publications to the scientific literature, some 70 of which pertain to the liver and biliary system.

One of the methods adopted for collecting bile from the dogs used in one series of experiments conducted by him and reported in the scientific literature was through a biliary fistula or surgical opening from the outside of the body to the bile duct, and insertion of a catheter. This procedure enabled the scientists to collect biliary fluid itself prior to its entry into the duodenum and before it becomes intermingled with digesting food and other secretions. After a period of measurement and analysis of the bile to establish a standard or control, a mixture of aloes and podophyllin in the ratio contained in Carter's Little Liver Pills was administered and analyses made of the biliary fluids collected. According to the exhibits and testimony relating to those experiments, the results showed no significant increase in bile volume or its content of cholic acid and pigment during the period when the mixture was fed to the dogs. The first group of experiments in this series included 7 experiments conducted with 5 dogs and 4 others using 3 of the same animals. The bile of 1 dog used in 4 of those studies showed marked increases in cholesterol content in several instances. Cholesterol is the chief constituent of gall stones. Cholesterol has no special effect on the digestive process and that pattern of increase was not evident in other experiments. Accordingly, no significance was attached in the report to those increases.

Other studies in this series were designed for comparing the effects on the secretion of biliary fluids as exerted by bile salts alone and the effects of bile salts plus a mixture of aloes and podophyllin. Bile salts in sufficient quantities are a potent choleric and the data also included average outputs for initial periods without active stimulation or medication. The reported results disclose that the ingestion of bile salts ordinarily caused marked increases in bile output, but that the addition of the aloes and podophyllin mixture afforded no significant increases over the level supplied by the bile salts. Generally similar results were reported when Carter's Little Liver Pills instead of the aloes and podophyllin mixture were used as the additive.

In other experiments, bone meal was added to the dogs' standard diet thereby causing hard and scybalous stools which simulated a type of constipation experienced in instances by human beings. Subsequent to measuring the output of bile by the respective dogs, bile output thereupon was measured for each during the period when sufficient Carter's Little Liver Pills were administered to induce catharsis. The measuring procedure was repeated during a period following discontinuance of the pills. The report states that the test results again show that Carter's Little Liver Pills have no effect on the formation of bile. Dr. Ivy additionally testified that the experimental data indicate that the inducing of catharsis does not reflexly change the output of bile and also support conclusions that the form of constipation induced in the experiment does not reflexly decrease the output of bile.

As previously noted, cholecystokinin is the hormone which causes the gall bladder to contract and evacuate bile into the duodenum. Secretin is the hormone which stimulates the secretion of bile by the liver and pancreatic juice. The protocols of another group of comparative studies instituted by Dr. Ivy looked to comparing the effects of these known stimulants with Carter's Little Liver Pills to determine whether or not the latter exerts a similar influence. A clamp on the passage to the gall bladder was made by surgical means on the anesthetized dogs and a tube was inserted in its dome and then connected with a mechanism for registering intra-gall bladder pressure. In some of the experiments, the common bile duct also was cannulated to record bile secretion.

After reaction of the gall bladder of each dog to cholecystokinin had been established, the effect of the respondent's product as variously introduced into the blood streams and into the duodenum of the dogs was observed and recordings made. With respect to one group of 12 intravenous injections of a solution containing two

Carter's Little Liver Pills made on 7 dogs, the tests' report indicates that there was no instance in which the gall bladder ever manifested a contraction or unquestionable change in tone of the type which occurs when cholecystokinin is injected intravenously; and according to the report and testimony substantially similar negative results attended the administration of the ingredients of 4 and 6 pills directly into the duodenum.

The experimenters also compared gall bladder pressure in response to injections of a standard preparation of secretin-cholecystokinin with that resulting when various types of prepared solutions of Carter's Little Liver Pills were injected. It was the conclusion of the report that, while the gall bladder contracted and the formation of bile was increased in response to the secretin-cholecystokinin injections in all 12 experiments of one test group, there were no significant changes in that regard when respondent's preparation was injected either duodenally or intravenously; and generally similar were the results reported when the Carter's Little Liver Pills instead were "hydrolyzed", that is, ground and dissolved in a pancreatic juice and otherwise processed for injection in the duodenum. According to the report summarizing this entire series of comparative studies, "ordinary amounts of aloes and podophyllum cannot act, either by being absorbed into the circulation or by causing secretin and cholecystokinin to be formed by the intestinal mucosa, to promote bile flow into the intestine by causing the gall bladder to contract or the liver to form bile."

The last series of experiments using dogs as subjects, which were performed under Dr. Ivy's supervision, compared volume and biliary content of fluids collected from a surgical opening into the jejunum or middle section of the small intestine during control periods and others following administration of the respondent's preparation through a tube. The experimental data showed an increase in averages for fluid volume during the period following medication, but none with respect to cholic acid or bilirubin contents. According to the witness, because no increase resulted in these two bile constituents, the increase in volume of fluid could not represent an increase in the flow of bile into the duodenum; and he further interpreted these particular test results to signify that the pills do not cause contraction of the gall bladder or bring about relaxation of the sphincter of Oddi or affect motility of the duodenum in manners serving to increase bile flow into the intestine.

Testifying on the basis of his experiments and his general medical knowledge, the witness expressed views that the use of the respondent's preparation will have no effect on the formation or flow of bile.

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(b) The exhibits received in evidence relating to experiments devised by Dr. Case concern cholecystograms or X-Ray studies visualizing the gall bladders of 7 human beings, including himself. When he originally testified, Dr. Case was Professor of Radiology and head of the X-Ray Department of the medical school of the midwest university with which Dr. Ivy is identified. Dr. Case is a former president of the American Roentgen-Ray Society, the American Radium Society and the American College of Radiology, and the various scientific societies of which he is a member includes the American Gastroenterologists Society.

During periods of fasting and generally when the diet is limited to carbohydrates, bile accumulates and undergoes concentration in the gall bladder pending its discharge by an appropriate stimulant. When the particular dye used in his experiments is ingested, the bile concentrated in the gall bladder, and often some of that flowing in the duct as well, can be visualized by X-Ray. The subjects received the dye on the afternoon of the day before the X-Ray examination, and evening meals from which fat and proteins were eliminated. The films serving as basis for these comparative studies were made at three separate stages; first, before eating on the day following ingestion of the dye; again 2 hours up to 5 hours thereafter while still fasting except for 3 or more Carter's Little Liver Pills taken at completion of the first film; and finally, 30 minutes to an hour after a meal containing fat was eaten at the conclusion of the second filming. Fats are known to cause the gall bladder to contract and to stimulate the flow of bile into the intestine. According to Dr. Case's testimony in reference to those exhibits, ingestion of the respondent's preparation did not serve to decrease the size of the gall bladders of the subjects in any way and had no effect thereon, but the subsequently ingested fat meals significantly reduced their size.

(c) Testimony and exhibits were received also concerning studies made by Dr. Jesse L. Bollman, Rochester, Minnesota. Dr. Bollman, prior to his appearance as a witness in this proceeding, had served for 21 years as assistant director of the experimental laboratory of a noted hospital clinic and research foundation. His department's work primarily has involved research on animals and a very substantial portion of those activities has pertained to scientific problems concerning the liver and gastro-intestinal tract. The witness' memberships in various professional societies include membership in the American Society for Experimental Pathology, of which he formerly was president. He has contributed more than 150 articles to the scientific literature.

At a point near the rectum, the colon of each dog was surgically occluded or closed off, thus preventing any passing off of fecal matter and simulating what would be a condition of obstipation in a human being. The various observations conducted on the three dogs included liver function tests and post mortem examinations. He interpreted the results of his experiments to show that obstipation does not prevent the secretion of bile and holds the view that this is indication that constipation, a milder physiological condition, likewise would not impair bile flow. His conclusion that bile continued to flow into the duodenum of the dogs in the experimental period was based in part on the tests for liver function demonstrating that retention of bile constituents in the blood of the dogs had not occurred.

(d) Evidence concerning further experimentation with the respondent's preparation also was presented by counsel supporting the complaint during the case on rebuttal. This included data on duodenal drainage studies made under the supervision of Dr. Ivy with a group of clinically normal subjects. In his view, those experimental results afforded no indications that the introduction of respondent's preparation into the duodenum of the subject caused any essential difference in the flow of bile or bile constituents contained therein.

An additional series of studies used subjects complaining of constipation. In the first phase, control drainages and drainages after the administration of Carter's Little Liver Pills were made and the results tabulated for comparison, and in the second phase, similar drainages following daily use of 4 or 2 pills for a period of a week by the same subjects were made both prior to further medication and with contemporary medication, and the analytical data compared. Dr. Ivy expressed the view that their results likewise failed to show that the taking of Carter's Little Liver Pills increased the flow of bile into the duodenum. This group of studies was limited to analyses of fluids recovered from the duodenum of the subjects. In the opinion of the witness, the results of drainages afforded by duodenal drainage techniques with other than potent stimulants to bile flow are equivocal and largely unreliable.

(e) The evidence presented by the respondent included experiments conducted by Dr. Hazleton in 1941 with anesthetized dogs from which bile fluids were collected through a surgical opening in a common bile duct. Summaries of those experiments were published in the Journal of the American Pharmaceutical Association. At the time when he testified, Dr. Hazleton was serving as Assistant Professor of Pharmacology at an educational institution located in

our Nation's Capital. While not a physician, his qualifications in the conduct of experimental research included specialized work in pharmacology for which his doctorate in philosophy had been conferred, and he was a member of the American Pharmaceutical Association and an associate member of the Society of Experimental Biology. As to the animals to which podophyllin alone or a combination of aloes and podophyllin was administered duodenally, the summary for his work states that the results were too irregular to interpret accurately. On the other hand, intravenous injections of aloes or podophyllin alone were reported to have increased the flow of hepatic bile in the anesthetized dogs. His studies were confined to measuring the volume of biliary fluid and did not include tests or evaluations as to whether any quantitative increases in bile constituents may have occurred.

(f) Also submitted by the respondent were the reports of experiments conducted by a Philadelphia practicing physician. At the time when he appeared as a witness in this proceeding, he also was assistant gastroenterologist and assistant in medicine in the medical school of one of the universities located in that city. In addition to memberships in certain scientific societies, including fellowship in the National Gastroenterology Association which was received in 1940 or 1941, he has contributed approximately 40 articles to the scientific literature. His experiments utilized human subjects, and the fluids which were collected and subjected to analyses were secured by duodenal drainages. In this procedure, a pliable rubber tube is swallowed by the subject on into the stomach and its gastric contents aspirated by a syringe. Another 20-minute period of swallowing usually is necessary for passing the tube into the duodenum, and the secretions there are also aspirated and discarded to begin with a fresh flow of bile.

In the first series of his experiments, the 10 participants were grouped according to whether they were clinically normal or abnormal. The procedure looked to comparing the bile volume and constituents of 3 different types of drainages, namely, a 30-minute control drainage without additive or stimulation, a drainage of one hour after the administration of magnesium sulfate, a recognized stimulant, and then a drainage of one hour after the administration of a mixture of aloes and podophyllin. The results reported by the witness, among others, were that both the magnesium sulfate and the mixture of aloes and podophyllin brought about large increases in duodenal fluid and bile constituents in both the normal and abnormal subjects, and that as between magnesium sulfate and the mixture of aloes and podophyllin greater increases were afforded

by the latter. In the second series, there were variations in procedures but the reported results were substantially similar, and they similarly were interpreted by the witness to indicate that the participants diagnosed as abnormal demonstrated lower biliary values in the control drainages than the normal subjects.

On the basis of the tabulated results for a third series of acute type of experiments, the witness reported that separate administrations of Carter's Little Liver Pills and magnesium sulfate to abnormal subjects resulted in increases in the volume of duodenal fluids and bile constituents in comparison with the values shown for control drainages for corresponding periods of time. Increases in both volume and one bile constituent over the values of the control drainages reportedly occurred also in normal subjects when Carter's Little Liver Pills were used.

The stated purpose of two additional series of studies compared control drainages of subjects suffering from liver disorders or chronic constipation with drainages made after they had taken Carter's Little Liver Pills daily for periods of 2 weeks up to 4 weeks. In addition to the tabulated data pertaining to the drainages, also received were exhibits as to the results of certain liver function tests. The witness interpreted his studies to show, among other things, that liver function in the experimentees became normal or improved and that the capacities of their biliary systems to deliver bile were increased.

(g) The respondent also submitted evidence relating to experiments conducted by Dr. John Killian. A biochemist and director of a research laboratory located in New York City, Dr. Killian prior to the institution of this proceeding had frequently served as a scientific consultant to the respondent. Although not a doctor of medicine, his qualifications for the conduct of investigational work include undergraduate and graduate study in the biological medical sciences for which academic degrees were awarded, including that of doctor of philosophy, and approximately 75 papers prepared by him have been published in scientific literature. He is a member of the American Society of Biological Chemists; the Society of Experimental Biology and Medicine; the American Gastroenterological Society and the American Neurological Society.

His first series of experiments was directed to establishing appropriate procedures for further experiments and also to comparing the results on the control drainages on human subjects without stimulation or medication and drainages after administration by mouth of aloes and podophyllin and others by tube. A second series utilizing 4 subjects undertook comparisons of control drainages with others

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following oral administration of a combination of aloes and podophyllin. While neither series in and of itself was regarded as conclusive by him, his data for these experiments were interpreted by Dr. Killian as giving indications that the administration of a combination of aloes and podophyllin was followed by increased amounts of bile acids and cholesterol in the duodenal fluid.

A third series included persons giving histories of constipation, and were planned for comparing the flow of biliary fluids during periods of constipation both with and without duodenal administration of a known stimulant to bile flow with flow under similar conditions, but during periods of relief from constipation following continued use of the respondent's preparation. They also were undertaken for correlating the responses as between groups of subjects classified on the basis of whether their biliary values appeared as high or low during certain control drainages. In the opinion of the witness, the higher averages in bile constituents which he believed were yielded in the fluid during maximum laxation by certain subjects originally showing low biliary values in control drainages were significant increases. While there were various departures, the plan of Dr. Killian's fourth series was generally similar to that adopted for certain of the groups in the third series. In the opinion of the witness, the latter two series of studies show, among other things, that the continued administration of Carter's Little Liver Pills increased the capacity of the biliary system to respond to the stimulating effect of Peptone, a substance which is a stimulant to bile flow, for subjects whose biliary values had been low in response thereto during control periods.

PAR. 12. Counsel supporting the complaint maintains that the evidence relating to the test studies submitted in support of the complaint conclusively establishes that Carter's Little Liver Pills do not act in any way to increase the secretion or flow of bile. In contending that the greater weight of the evidence fully supports determinations to the contrary, counsel for the respondent asserts that the record shows that a relationship exists between constipation and bile flow in that a large number of people who suffer from constipation also have a subnormal flow of bile; and that, concomitant with the laxation afforded them and the relief of their associated symptoms, the preparation causes significant increases in the levels of biliary constituents for these individuals. Each counsel contends in effect that the scientific evidence presented by his adversary is based on defective experimental procedures and reflects erroneous interpretations of those studies and unsound expressions of medical opinion.

(a) In challenging the evidentiary value of Dr. Ivy's animal experiments, the respondent argues that those comparing drainages following use of known bile stimulants with drainages after use of the same stimulant plus medication with ingredients of respondent's preparation have been invalidated by the witness' admission that they violate his own criteria for authoritative experimental procedures and because it is impossible to determine whether the pills' effects superseded the effects of the stimulants, or vice versa. As to the latter contention, significant increases were absent during medication drainages. The procedures for administering the drugs in some of the experiments included intravenous and intraduodenal injections which afford rapid response to and dissipation of drugs' effects. In the over-all experiments, observation periods ranged from an hour or less up to two days. In all the circumstances, the procedures seem well designed to greatly minimize the possibility of delayed or overlapping effects between periods of control and medication with the pills.

Nor is there force to the respondent's argument that Dr. Ivy in effect condemned his own experiments as violative of criteria for authoritative tests. When commenting on certain experiments utilizing Peptone and Carter's Little Liver Pills, which were presented by the defense, he said he would not test the pharmacological action of an unknown substance by giving it with a potent substance. In his animal experiments, different drainage methods were utilized, and it is clear that his criticism of the other scientist's experiments were based on over-all deficiencies in experimental design.

The briefs in opposition to the complaint also emphasize in these connections the testimony of a scientific witness called by the respondent who characterized certain of the experiments conducted in Dr. Ivy's first group of studies as lacking in scientific significance. His assigned reasons were: (1) that the drainages extended over long periods while the effects of drugs may continue only for short periods, and (2) that inasmuch as the two grams of bile salts administered were commensurate with the total that such animals would secrete in one day, the dosage accordingly was so massive that other medication could not possibly increase the flow of bile. Certain of the experiments looked to evaluating shorter term effects of the drugs and others related to responses occurring over longer terms. Had temporary increases in bile flow actually been afforded by the preparation in the latter, however, the experimental design appears to have been such as to reflect and weigh data in respect thereto. Furthermore, the dogs figuring in those studies were large ones whose daily secretions of the salts would be expected to fluctuate

between 8 to 10 grams daily. Hence, there is no record support for conclusions that the dosages adopted for the stimulant represented a defect in experimental design.

It is urged, too, that scientific articles earlier published by Dr. Ivy indicate that a causal relationship exists between constipation and bile flow and serve to contradict his experimental results and various scientific opinions expressed by him to the effect that such relationship does not exist. Typical of prior statements by him and relied on by the respondent in this connection is one to the effect that, since bile salts are a laxative, a lack thereof would increase the tendency toward constipation, and that any increase in constipation would affect other organs so that the oral administration of bile salts would be an appropriate medical procedure. The context in which the statement appeared in his article is not entirely clear from the examination of the witness. Dr. Ivy affirmed in effect, however, that it was nowise contradictory of his testimony in this proceeding; and that his published views reflected recognition of the fact that an absence of bile in the intestines will reduce the moisture in stools. This constitutes a predisposing factor to constipation, but constipation may or may not develop. In testifying that constipation itself does not act to reduce the flow of bile and that there is no connection between the creation or flow of bile and constipation, he pointed out that bile can be diverted from the intestine in animals or humans without constipation occurring.

Respondent further contends that the results of Dr. Ivy's second group of duodenal drainage experiments with human beings corroborate the experimental evidence introduced by the respondent. Although certain increases in biliary constituents were indicated in the data for those studies, Dr. Ivy evaluated them as failing to show that taking of Carter's Little Liver Pills increased the flow of bile into the duodenum. He further testified that if the differences in output were instead interpreted as significant and thus indicative that the pills afforded increases in biliary values, such a determination would compel evaluations of similar significance respecting differences in output as between first control drainages prior to medication with the pills, and second control drainages following a week of medication. Hence, the lower values evident after a week of medication with the pills in comparison with the original drainages would be deemed to result from a cathartic and irritable gut causing a spasm of the sphincter and decreasing the output of bile pigment. The fact that this particular group of Dr. Ivy's experiments were based on the duodenal drainage method, in and of itself, detracts from their conclusiveness.

The Commission further is of the opinion that there is no merit to the contention that the surgical procedures necessary for collecting biliary fluids from test animals seriously detract from the evidentiary weight of those experiments. That potential effects from the surgical procedures were not ignored in certain of them is evidenced by the fact that the biliary fistula dogs were not used until shown for a period of several days to put out bile which was constant both as to volume and biliary constituents. The dogs regularly ate the standardized diets provided. The responses which occurred in the tests with known stimulants similarly refute conclusions of undue impairment to their biliary systems. As to the cited matters challenging the applicability of the animal experiments to human beings, the evidence shows that the livers of the dog and man are anatomically similar. The only known functional difference between them relates to the metabolism of uric acid which subject is not material here. Probative testimony was received that there is no known stimulant to bile flow for the one that does not stimulate it for the other. The evidence received is clear and convincing that the results of the experiments with dogs which are relied upon by counsel supporting the complaint are transferable to human beings. Nor would it be proper to conclude that the animal experiments conducted by Dr. Ivy were devised for the purpose of proving a negative proposition or that their inconclusiveness is evident from the witness' reference to the results of one series as a negative series of results all around. They were undertaken to evaluate the effects, if any, exerted by the pills on bile flow under the experimental conditions adopted. The experimental methods included correlations of data based on comparative studies and the procedures adopted clearly conformed to recognized criteria for authoritative scientific research. That the studies utilizing dogs attest to an absence of such effects renders them no less impressive and great weight should be accorded them in resolving the issues of this proceeding.

(b) The X-Ray studies devised by Dr. Case compared size and density of outlines of the subjects' gall bladders prior and subsequent to use of the pills and then after ingestion of a fat meal. The respondent's contentions that Dr. Case's interest in and connection with the affairs of Battle Creek Food Company, a manufacturer of foods for the sick, and the fact that he instituted his experiments with the respondent's preparation without being solicited to do so, indicate bias and prejudice against the respondent and preclude conclusions that his testimony is credible, have been noted. Dr. Case's status as an eminent radiologist and his high qualifications to conduct and evaluate scientific research work are apparent from

the record. It is evident, too, that the views expressed by the witness constituted sincere scientific interpretations and opinions reached by him on the basis of his years of medical experience and training.

The evidentiary weight of Dr. Case's experiments is further challenged on the ground that the gall bladders of the subjects may have been emptied by the action of the pills and refilled in interims between their use and times when succeeding films were taken. After it empties, one or two hours are required for that organ to refill in various individuals. The intervals between medication and filming ranged in the experiments from two hours on up. Had contractions resulted therefrom, changes in states of density of the dye and size necessarily would have appeared in one or more of the pictures. They did not, however. It is urged too that the final film for each subject served only to evaluate the combined effects on bile flow of the meals and pills. The film demonstrated that the gall bladders could respond to a stimulant. While a theoretic possibility of combined effects is not excluded, the circumstance that no changes in the gall bladders were apparent in the films made at differing intervals following medication indicates an absence of reasonable probability that the abrupt reductions which invariably succeeded the fat meals were in part due to delayed effects from the pills. Considered by the Commission also have been the additional matters urged by respondent as reasons why Dr. Case's views and experiments should be disregarded. It suffices to say in these connections that the protocols for the experiments to which the documentary evidence relates apparently conform to recognized criteria for scientific research; hence, that evidence and the witness' opinions based both thereon and on other contemporaneous research with which he was familiar should be accorded such evidentiary weight as is its due when appraised against the background of other probative scientific evidence contained in the record.

(c) The respondent contends that the testimony and exhibits relating to the studies conducted by Dr. Bollman with surgically obstipated dogs should be disregarded because the physiological condition created in the test animals did not correspond to constipation, and due to alleged inadequacies in the procedures for determining whether bile was being secreted and an illogical type of diet used for the dogs. The diet selected was nutritious and low in residues and accumulations in the colon were minimized thereby. That it contained a substantial amount of carbohydrates which may have tended to minimize liver damage does not constitute a significant defect in the experimental procedure. Nor does the circumstance that the colonic obstructions did not reproduce the conditions caus-

ing constipation render the evidence irrelevant or inadmissible. Both obstipation and constipation are characterized by abnormal retention of fecal matter. Although the program used in these experiments included no provision for actually collecting or measuring any bile secreted, liver function tests and post mortem visual inspections were made. The witness' view that these latter measures were adequate for informed determinations as to whether bile flow had continued in quantities sufficient for digestive purposes seems entirely reasonable. His testimony in reference to observations made by him in the course of the experiments and the opinions expressed by him in the fields of liver and biliary physiology, among others, likewise appear highly credible in the circumstances here. The Commission is of the view that the matters urged by the respondent in support of its contentions to the contrary are unpersuasive.

PAR. 13. The various matters urged in the briefs of staff counsel in support of his contentions that the experimental evidence introduced by the respondent should be regarded as inconclusive also have been considered, including those challenging the reliability of test procedures and the credibility and objectivity of the testimony presented by the witness who was engaged in medical practice in Philadelphia. It is evident that complete scientific candor was lacking in some phases of the witness' experimental work. For example, his subjects included patients coming to him for treatment of their ailments. They were not informed, however, that they were taking Carter's Little Liver Pills; and he additionally conceded that he charged various of them for the drainages performed with the respondent's preparation and also collected from Carter Products, Inc., for services in those connections. While compensation for other professional services to the company may have been included, his receipts from Carter Products, Inc., approximated between \$17,500 and \$20,000. In certain of the witness' studies furthermore, the control drainages preceding prolonged periods of medication with Carter's Little Liver Pills were made when the patients were not on a diet, whereas the medication ones were made at times when they were on a special nutritious diet. The subjects also received vitamin pills. Hence, proper evaluation of the stated results of those studies also entails due regard to those variations in experimental procedure.

Turning now to the experiments of Dr. Killian, they in no sense support informed determinations that bowel evacuation resulting from casual or prolonged resort to respondent's preparation reflexly increases or otherwise promotes flow of bile for all sufferers from constipation. Instead, he interpreted his studies to indicate that claims that use of the respondent's preparation increases the flow of

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bile are true only under certain conditions: (1) that the preparation be given in sufficient doses over a sufficient period of continuous purgation to produce maximum laxative effects or others conforming to quantitative criteria adopted in the experiments; (2) that the individual show low values for biliary constituents in the duodenal fluid in response to a stimulus introduced into the duodenum when no pills are being taken; and (3), that the individual be one who shows signs when not taking the pills of low or of diminished rates of intestinal motility, as indicated by abnormally small stools, or absence of stools. In other words, only a part of the abnormal participants in his experiments were deemed by him to have experienced increases in biliary values.

The fact that the duodenal drainage method was used for collecting the bile from human subjects in both Dr. Killian's studies and others presented by the respondent greatly detracts from the conclusiveness of the data on which their evaluations were based. This method, of course, is a well recognized procedure for studying the state of biliary function. While widely used for diagnostic purposes, including determinations of whether bile is present qualitatively, it is necessarily less reliable for quantitative determinations. The volume of duodenal fluid recovered in such drainages includes not only the bile but various other digestive fluids and body secretions. Hence, the subsequent assays of bile constituents are limited to revealing those constituents' concentrations in the duodenal fluid rather than the biliary fluid.

In the same individual, the secretion of bile is subject to great variations. Even a small amount of bile flow into the duodenum from the gall bladder will give findings and values identical with much larger amounts of hepatic bile. There is nothing to assure that all hepatic fluids are being collected in the course of a drainage inasmuch as some bile may be absorbed into the walls of the duodenum or escape on into the jejunum of the intestine. The great variations or fluctuations to which the rate of bile flow may be subjected in response to various influences, including the subject's rest and exercise, make interpretations of experimental results obtained from duodenal drainages extremely hazardous. These considerations emphasize the inconclusiveness of data based on comparative duodenal drainages as indices to the relative capacity of an individual's biliary system at different periods.

The record also contains expressions of scientific view by witnesses presented by the respondent to the effect that a favorable influence on bile flow may result from the increased intestinal motility afforded by the irritating action of a laxative of this type. Other

evidence introduced in support of the complaint, particularly when considered in connection with the results afforded by certain of the scientific experiments, constitutes full refutation of those views. Not only is it apparent that the augmented intestinal motility through which this type of laxative affords bowel evacuation does not significantly increase bile flow, but the greater weight of the scientific evidence received shows that there is no casual relationship between constipation and bile flow. Even if increases in the flow of bile into the duodenum were afforded by the respondent's preparation for a person who was constipated, no utilitarian purpose would be served thereby. This conclusion has support in other scientific evidence indicating that constipation will not, under any circumstances, decrease bile in the system to such an extent that there is not sufficient bile to carry on its function in the digestive process.

PAR. 14. The Commission accordingly is of the opinion that the greater weight of the testimony and other evidence introduced into the record supports informed determinations that the preparation Carter's Little Liver Pills will not stimulate the formation of bile by the liver or increase the secretion of bile by the liver. Inasmuch as the evidence further shows that the respondent's product will not cause the gall bladder to contract or cause relaxation of the sphincter of Oddi or prevent its contraction in the first instance or serve in any way to milk bile from the ampula of Vater or the bile duct, the Commission further concludes that the respondent's preparation will not increase the flow of bile or any constituents thereof into the duodenum.

PAR. 15. The preparation "Carter's Little Liver Pills" is not an effective treatment for sluggish liver function and will have no therapeutic action on the liver or diseases thereof. As previously noted, it will not wake up the flow of bile, cause the bile to flow freely or favorably influence the formation or flow of bile either as to quantity or the vital and effective constituents thereof. The use of the respondent's product therefore will not influence the production or flow of bile so that an individual can overeat and over-indulge in "good times" without such discomforts as may normally attend them, nor enable him to wake up "clear-eyed and steady-nerved," "feeling just wonderful," and "alert and ready for work." Diarrhea rather than constipation may result from certain of these excesses. Such laxation as may be induced will not prevent or overcome disturbances caused by overindulgence and may serve to further disturb the digestive process. The respondent's product does not provide two-way relief and has no therapeutic effect beyond that of

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an ordinary laxative, that is to say, of any substance which increases the movements of the large bowel either through irritation, bulk or fluid content.

PAR. 16. Only in the extreme condition where very great quantities of food as such arrive in the large bowel in an undigested state and there remain until bacterial action and putrefaction ensue, can it be said that food decay may be present in the body. In such case, the use of the respondent's product, as is true of any laxative, will only aid in the outward passage of the food. Normally over ninety percent of our food is digested before reaching the large bowel and putrefaction is not a factor in food digestion. The respondent's preparation has no chemical action on food which will prevent decay thereof and the representation that it will lessen food decay is misleading.

Furthermore, the use of such product will not increase the effectiveness of the gastric juices or cause the proper flow of any of the vital digestive juices, and it will not help digestion. The action afforded by the preparation is not based on a fundamental principle of the operation of the digestive system. Its use will not stop fatty indigestion or favorably influence the symptoms thereof, or regulate the digestive system or digestion, or have any salutary effect upon the gastrointestinal tract aside from affording temporary partial evacuation of the colon. In some instances, the use of respondent's preparation may interfere with and disturb digestion. The representations contained in the advertising, as are made directly and by suggestion, to the effect that Carter's Little Liver Pills will cause an individual to feel "fit as a fiddle" and full of "bounce," and have a vigorous state of well-being, by reason of the fact that it follows nature's order for regularity and regulates digestion, are false and misleading. While greater frequency of bowel movement is temporarily afforded, the preparation does not induce natural regularity. Such value as it may have in inducing well-being would be limited to instances in which indispositions impairing such state were due solely to constipation.

PAR. 17. Excluding the conditions of biliousness, "lazy digestion," and indigestion, which are hereinafter separately discussed, the symptoms, manifestations, and conditions, referred to in Paragraph Four, subparagraph (d), hereof, may occur in almost any condition affecting the human body, and, when they are not associated with and due to constipation, the respondent's preparation will have no beneficial effect on them. When they are associated with and due to constipation, the respondent's preparation will not correct or favorably influence in any way the basic conditions causative of

constipation; and its benefits in the treatment of any of the symptoms, manifestations and conditions accompanying constipation are limited to such temporary relief as may result from laxation. Carter's Little Liver Pills, the Commission concludes therefore, do not constitute a competent and effective treatment for these manifestations when they are associated with or caused by constipation.

As earlier noted, the respondent has represented that its preparation is an effective treatment for "indigestion" and "lazy digestion." When indigestion, that is, a failure to digest or absorb food occurs in the human system, diarrhea rather than constipation frequently ensues. The use of the respondent's preparation would not bring about digestion of food in either case. Furthermore, treatment of symptoms indicating disturbance or irritation of the intestines looks to soothing such conditions rather than the introduction of an additional irritant in the form of a laxative. The expression "lazy digestion" has no scientific meaning but refers vaguely to retarded digestion. A laxative will not stimulate the digestion or absorption of food. It will, however, increase the rate of passage of indigestible and undigested masses through the large intestine for evacuation from the body, which refers to egestion not digestion. Discomforts of the gastrointestinal tract, examples of which are abdominal distress and gas, may result from constipation and such discomforts may be relieved temporarily by the release of pressure in the colon afforded by laxation. The Commission concludes that the respondent's preparation is not an effective treatment for indigestion, or of "lazy digestion" or retarded digestion in any circumstances in which such conditions may occur.

Biliousness is a general term often used in a broad sense to refer to a group of symptoms or conditions supposed by some, without any supporting evidence, to be caused by or due to disorders in the secretion and flow of bile. Constipation does not in any manner impair the flow of bile. Inasmuch as the respondent's preparation will have no therapeutic action, effect or influence on the secretion or flow of bile, it does not constitute an effective treatment for biliousness or for any symptoms or conditions, under whatever name or names designated, which are caused by or due to disorders in the secretion or flow of bile.

The subjective feeling of discomfort which sometimes accompanies constipation comes largely from abnormal stimulation of the sensory nerves in the mucous membrane and musculature. However, it has no connection with poison or auto-intoxication. Contrary to the representations appearing in the respondent's advertising, constipation does not poison the human body.

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PAR. 18. Through use of the word "Liver" in the name "Carter's Little Liver Pills" which is featured in the advertising, the respondent represents, directly and by implication, that the preparation "Carter's Little Liver Pills" will have some therapeutic action, effect, and influence on the liver, and is for use in the treatment of conditions, disorders, and diseases of the liver. Said representations are false and misleading. The ingredients in the preparation "Carter's Little Liver Pills," alone or in any combination of one with the other, will have no therapeutic action, effect, or influence, corrective or otherwise, on the liver. The preparation will have no therapeutic value in the treatment of any condition, disorder, or disease of the liver or the biliary system. Upon consideration of the remedy which should be applied in this connection, the Commission is of the opinion that only excision of the word "Liver" from the product name will serve to eliminate the deception engendered by its use.

PAR. 19. (a) The complaint charges also that the respondent's advertisements constitute false advertisements for the further reason that they fail to reveal certain facts as to potential dangers inherent in the use of such preparation under conditions described in the advertisements or conditions as are customary and usual by persons suffering from abdominal pains, nausea, vomiting, or other symptoms of appendicitis. The Commission is unable to find, however, that the potential danger to the public health inherent in the use of the respondent's preparation is so serious as to require a disclosure in the advertising of the matters to which this charge relates and, in the circumstances, is of the opinion that dismissal of such charge without prejudice is warranted.

(b) Additional allegations of the complaint charge that the respondent has falsely represented that calomel is a drastic and dangerous laxative compound, the use of which is an ordeal. Although testimony was introduced into the record directed to showing, among other things, that calomel, when taken in proper doses, would not be painful, it is not believed that these charges are supported by the record, and they are, accordingly, dismissed.

(c) Named also as a respondent in this proceeding is Street & Finney, a corporation, an advertising agency, which assisted respondent Carter Products, Inc., in the preparation and placing of the various advertisements used in promoting the sale of the preparation here involved. Its service to Carter Products, Inc., and participation, terminated, however, approximately one year prior to the institution of this proceeding. It does not appear, therefore, that the public interest now requires that the respondent Street &

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Finney be included as a party to the order to cease and desist which is issuing herein, and the charges of the complaint are, accordingly, being dismissed without prejudice as they relate to the respondent Street & Finney.

PAR. 20. The Commission, therefore, finds that the representations appearing in the advertising for the preparation "Carter's Little Liver Pills," as set forth in Paragraph Four and Paragraph Eighteen hereof, are misleading in material respects, and that the advertisements thus disseminated by the respondent Carter Products, Inc., constitute "false advertisements," as that term is defined in the Federal Trade Commission Act. The use of such representations and of the word "Liver" in the name "Carter's Little Liver Pills," by the respondent has had, and now has, the tendency and capacity to mislead and deceive a substantial portion of the purchasing public into the erroneous and mistaken belief that all such statements and representations are true, and to induce a substantial portion of the purchasing public, because of such erroneous and mistaken belief, to purchase the respondent's preparation.

#### CONCLUSION

The acts and practices of the respondent, as herein found, are all to the prejudice and injury of the public and constitute unfair and deceptive acts and practices in commerce within the intent and meaning of the Federal Trade Commission Act.

#### ORDER

*It is ordered,* That the respondent, Carter Products, Inc., a corporation, and its officers, agents, representatives and employees, directly or through any corporate or other device, in connection with the offering for sale, sale, or distribution of the product now designated "Carter's Little Liver Pills," or any other product of substantially similar composition or possessing substantially similar properties under whatever name sold, do forthwith cease and desist from:

(1) Disseminating or causing to be disseminated any advertisement by means of the United States mails or by any means in commerce, as "commerce" is defined in the Federal Trade Commission Act, which advertisement represents directly or by implication—

(a) That said preparation represents a fundamental principle of nature in self-treatment;

(b) That said preparation will bring on or restore regularity of bowel movement, or is a cure, remedy or competent or effective

treatment for constipation, or has any beneficial value in the treatment of any of the symptoms thereof in excess of the temporary relief afforded by its laxative action;

(c) That said preparation does not contain strong medicines;

(d) That said preparation is unqualifiedly safe;

(e) That said preparation is an effective treatment for sluggish liver function or that it will have any therapeutic action on any condition, disease or disorder of the liver;

(f) That said preparation will make bile flow freely, increase or beneficially influence the formation, secretion or flow of bile, or prevent or overcome discomforts caused by over-indulgence in food or other pleasures;

(g) That said preparation will provide two-way relief or that it possesses therapeutic properties in addition to those afforded by laxative action;

(h) That said preparation will cause the proper flow of, or beneficially affect, the gastric juices or digestive juices, or lessen food decay;

(i) That said preparation is based on the fundamental principle of the operation of the digestive system;

(j) That said preparation will help food digestion, or regulate digestion or the digestive system;

(k) That said preparation will have any influence in inducing a state of "bounce," vigor or well-being except in those instances in which a lack thereof is due solely to constipation;

(l) That constipation poisons the body;

(m) That said preparation has any value in the treatment of headache, ugly complexion, bad breath, coated tongue or a bad taste in the mouth, or for those conditions in which an individual feels "Down-and-out," "blue," "down-in-the-dumps," "worn out," "sunk," "logy," "depressed," "sluggish," "all-in," "listless," "mean," "low," "cross," "tired," "stuffy," "heavy," "miserable," "sour," "grouchy," "irritable," "cranky," "peevish," "fagged out," "dull," "sullen," "what's-the-use," "bogged down," "grumpy," "run-down," or "gloomy," in excess of such temporary relief therefrom as may be afforded by an evacuation of the bowels in those cases in which such symptoms or conditions are associated with and caused by constipation;

(n) That said preparation is a competent or effective treatment for indigestion or retarded digestion;

(o) That said preparation is a competent or effective treatment for biliousness.

(2) Disseminating or causing to be disseminated any advertisement by means of the United States mails or by any means in com-

merce, as "commerce" is defined in the Federal Trade Commission Act, in which the word "Liver" is used in the trade name for the respondent's preparation.

(3) Disseminating or causing to be disseminated any advertisement by any means for the purpose of inducing or which is likely to induce, directly or indirectly, the purchase of said product in commerce, as "commerce" is defined in the Federal Trade Commission Act, which advertisement contains any representation prohibited in paragraphs (1) and (2) hereof.

*It is further ordered*, That the charges of the complaint as they relate to the respondent Street & Finney, a corporation, be, and the same hereby are, dismissed without prejudice to the right of the Commission to take such further action as future conditions may warrant.

*It is further ordered*, That the respondent, Carter Products, Inc., shall, within sixty (60) days after service upon it of this order, file with the Commission a report in writing setting forth in detail the manner and form in which it has complied with this order.

Commissioner Mason not participating.

#### OPINION OF THE COMMISSION

By KERN, Commissioner:

The issues in this proceeding relate to whether the advertising disseminated by the respondent for the product designated "Carter's Little Liver Pills" has constituted false advertisements within the meaning of the Federal Trade Commission Act.

After the United States Court of Appeals for the Ninth Circuit granted the petition of Carter Products, Inc., to review and set aside the Commission's order and subsequently remanded this matter to the Commission with authority to reopen it for further evidence, the Commission issued its order reopening the proceeding. Additional hearings were convened at which the respondent further cross-examined two scientific witnesses called in support of the charges of the complaint at the original hearings. On motion by the respondent, all evidence relating to certain medical experiments introduced through another witness whose career was closed by death was stricken by the hearing examiner. The Commission having considered the record as presently constituted, including the evidence additionally received at the supplemental hearings, has made its modified findings as to the facts and reached determinations that certain of the practices of the respondent, Carter Products, Inc., as therein designated have been in violation of the Federal Trade Commission Act. Our decision contains an appropriate order. While

those findings include statements of reasons controlling to the Commission's decision on the merits of the charges, supplemental discussion of certain of them and matters of law especially emphasized by the respondent in its briefs is deemed warranted.

The respondent's position that the charges of the complaint have inadequate record support rests in part on its contentions of alleged defects and undue limitations inherent in the procedures adopted in the scientific experiments introduced in support of the charges of the complaint. The hearing examiner's rulings in receiving that evidence initially and in denying the respondent's subsequently interposed motions to strike certain of that evidence have sound legal basis. The Commission's findings as to the facts include statements of reasons why exceptions to the reliability of certain of those test procedures are not well taken and why the results of the animal experiments are transferable to human beings. Save for the experiments which utilized the less conclusive duodenal drainage method, we think that their results are material to the issues here and there can be no doubt that they, in the aggregate, constitute a very impressive and persuasive body of scientific evidence.

In urging that its evidence concerning experiments which utilized duodenal drainage methods outweighs other evidence received, the respondent maintains that this drainage procedure is a generally accepted and accurate scientific method. The Commission's findings as to the facts contain a discussion of various record matters which detract from the reliability of the scientific experiments introduced by the respondent and which render those studies inconclusive. While duodenal drainages are apparently a reliable basis for many diagnostic determinations, the fact remains that the comparative results of a relatively small number of such drainages do not constitute authoritative determinations as to the relative capacity of an individual's biliary system at different times. As also noted in the Commission's findings as to the facts, this is partly due to the circumstance that the rate of bile flow is subject to great variations in the same person.

One of the various exhibits pertaining to experiments relied upon by the respondent in support of claims for product efficacy includes comparisons of the averages of biliary values for drainages made for nine subjects following a stimulant to bile flow but without medication with those afforded by the same stimulant but after medication with Carter's Little Liver Pills. It was conceded that 7 of the 9 subjects yielded one or more drainages during control periods, with or without the stimulant but without medication by the pills, in which bile constituents were as high as or higher than

others with like stimulation plus medication. This manifestly tends to detract from the conclusiveness of the experimental results; and further illustrating the highly variable nature of bile flow is the fact that one subject's values for bile acids during his 3 control drainages which were listed in the exhibit were reported as 128, 1783, and 432, while his 2 drainages with medication showed values of 2458 and 953. For another subject in the group, those values in the absence of medication represented 59, 384, and 1038, and with medication were 397 and 600.

The respondent also argues in effect that the conflicts of medical opinion presented in the record preclude informed determinations that its product does not influence bile flow and reflect a scientific controversy requiring this proceeding's dismissal. It is true that the results of experiments reported in the scientific literature dealing with effects exerted by aloes and podophyllum have presented some conflict. However, the scientific studies received in support of the charges of the complaint relate in the aggregate to a wide range of experimental conditions and constitute highly probative evidence as to the limitations of the respondent's preparation.

The circumstances, among others, emphasized by the respondent, that biliary disturbances and constipation may occur contemporaneously in an individual, that a complete absence of bile in the intestine is a predisposing factor to constipation, and that a possibility of a connection between some function of the liver and physiological processes resulting in constipation exists do not reach to the core of the scientific issues. It is controlling, on the other hand, that there is no known disease of the liver or biliary system which is beneficially affected by the ingredients of the respondent's preparation. There is no authoritative scientific evidence that constipation could decrease the secretion of bile by the liver to such an extent that there would be insufficient bile in the system to carry on the function of that fluid. Furthermore, the greater weight of the evidence establishes, among other things, that these drugs are not specific stimulants either to the flow of bile or its formation. Although the respondent offered some evidence to the contrary, the record contains other clear and convincing evidence that laxation does not reflexly increase bile flow and, conversely, that constipation or poor intestinal mobility does not act physiologically to reduce the formation or flow of bile. Having considered the conflicts in the evidence, we think that the record supports informed determinations that the respondent's preparation is devoid of any beneficial influence on the formation or flow of that body fluid.

At the close of the supplemental hearings, the respondent filed certain motions to strike evidence previously received and other

motions or offers of proof, together with affidavits in support of the latter. One of the motions requested the hearing officer to strike all the X-Ray studies introduced through Dr. Case and all testimony pertaining in any way thereto. At the original hearings held in 1943, prints of films relating to 7 of 25 participants were received in evidence subject to subsequent motion by the respondent to strike, and the original thereof later were received. While the conclusiveness of the testimony and documentary evidence presented through Dr. Case was challenged when the case was heard originally by the Commission, the propriety of their reception in evidence does not appear to have been raised until the hearings on remand were being held in 1954. Included in the errors assigned under the motion was that the radiologists who made the films were not called; that patients' medical records were not made available for counsel's use; and that not all the films for any one of the 25 participants were produced.

It appears, however, that during the original hearings an offer was made to the respondent to produce additional films relating to the 7 subjects to which the exhibits related and others as well. In view of the particular experimental design adopted furthermore, it is immaterial that medical data for the subjects were not produced for inspection. Reverting now to the error alleged incident to failure to produce the radiologists responsible for the pictures, the record shows that minutest details in posing the subjects and setting the button received Dr. Case's attention in the studies for 3 of the subjects to whom the exhibits relate. The films for the other 4 were made in a departmental clinic which was under his supervision and by technicians trained in the procedures effective there for making X-Rays of this type.

Although sanctions are not to be imposed unless supported by reliable, probative and substantial evidence, the Administrative Procedure Act states that any oral or documentary evidence may be received. Some of the evidence introduced through Dr. Case clearly was based on his personal participation in the experiments he had devised. Evidence resting in part on the personal observation of a witness and in part on hearsay is manifestly competent and unobjectionable insofar as it rests on the personal observation of the witness. *U.S. v. Aluminum Co. of America*, 35 F. Supp. 820, 822 (S.D.N.Y. 1940). Not only did the witness deem the films to be reliable and trustworthy bases for the opinions expressed by him, but they represented professional services performed for clinical patients. Hence, there can be no doubt but that this evidence is of the kind "on which responsible persons are accustomed to

rely in serious affairs." *N.L.R.B. v. Remington Rand, Inc.*, 94 F. 2d 862, 873 (C.A. 2, 1938).

Having reviewed all the matters urged by the respondent on this aspect, we are convinced that it was proper for the hearing examiner to deny its request to strike. We also have considered the motion which requested the hearing examiner to strike all evidence relating to Dr. Bollman's experiments. The matters relied on in support of that motion essentially pertained to evidentiary weight and its denial likewise was fully warranted.

Proceeding on to consideration of the adverse rulings on the motions or offers of proof, the categories of proof which the respondent requested the hearing examiner's leave to introduce included (a) the evidence of a scientific witness, Dr. John R. Twiss, and a statistician witness in corroboration of evidence submitted by the respondent during the original hearings; (b) other evidence by that scientific witness to refute evidence presented through Dr. Bollman and Dr. Case, who were called in support of charges of the complaint; (c) data relating to new experiments conducted by Dr. Twiss, which assertedly show that Carter's Little Liver Pills have a significant effect on flow and formation of bile; and (d) certain medical texts or treatises including those marked for identification during the course of Dr. Bollman's cross-examination in the supplemental hearings.

The procedural situation which existed when the respondent filed its motions was that the supplemental hearings had drawn to a close. These supplemental hearings had been held pursuant to the Commission's order of December 18, 1953, under which the case was remanded to the hearing examiner "for such further proceedings as may be necessary to correct the errors in the original hearings specified by the Court of Appeals." The errors referred to in that order were those pointed out by the Court of Appeals for the Ninth Circuit in its opinion rendered January 19, 1953 (*Carter Products, Inc. v. Federal Trade Commission*, 201 F. 2d 446); and the remand to the hearing examiner was made pursuant to authority granted by the Court in its mandate of November 18, 1953, whereby the Commission was authorized "to open the proceeding for further evidence and a new order consistent with the opinion of this court."

In its opinion of January 19, 1953, the Court had stated:

Questions pertaining to the sufficiency of the evidence or to the merits are not presented by the petition. What is claimed, principally, is that a fair hearing was denied petitioner in that the trial examiner unduly and prejudicially restricted its right of cross-examining certain of the Commission's expert witnesses upon whose testimony, in large measure, the findings and order were based. The witnesses in question were Doctors Carlson, Bollman, Lockwood

and Case. We are of the opinion that petitioner's claim is well grounded in respect of the three experts last named, but not in respect of the witness Carlson.

And, after pointing out the rulings wherein the errors were made, the Court ended its opinion as follows:

It is argued that there was ample evidence from other quarters to sustain the findings and order of the Commission, hence the rulings, even if wrong, were not prejudicial. We are of opinion, however, that the cumulative effect of these unjustifiable restrictions on the cross-examination of key witnesses for the Commission was to deprive petitioner of a fair hearing. Such being the case the court is not disposed to speculate as to what would have been the outcome had a fair and impartial hearing been accorded. (Citing authorities.)

The order of the Commission is set aside.

It seems obvious to us, therefore, that the reason for the Court's action setting aside the Commission's order to cease and desist was that the respondent had been denied a fair hearing before the Commission in that the hearing examiner unduly and prejudicially restricted the respondent's right to cross-examine Doctors Bollman, Lockwood and Case. It seems equally obvious that the purpose and effect of the remand was to enable the Commission to correct the errors in this respect by recalling these witnesses for full cross-examination. This the Commission had undertaken in good faith to do. At a hearing held in Santa Barbara, California, Dr. Case had been recalled to the stand and tendered to the respondent for further cross-examination. After 130 pages of testimony had been received, the respondent's counsel had announced "I have asked all the questions I want to ask." (R. 10,838) At a subsequent hearing held in Washington, D.C., Dr. Bollman had been recalled to the stand and thereafter further cross-examined. After 268 pages of testimony had been received, the respondent's counsel had again announced "I have no [further] questions." (R. 11,193) Dr. Lockwood, the third witness whose cross-examination the Court held had been improperly curtailed had, in the meantime, died. In view of his unavailability for further cross-examination, all of his testimony and all exhibits theretofore offered in support thereof had been, on the respondent's motion, stricken from the record. Thus, the purpose and intent of the remand had been fully served. The additional matters proffered by the respondent essentially constituted cumulative evidence similar in vein to that introduced by the respondent at the original hearings. They were in no sense within the purview of the Court's remand to the Commission or the Commission's remand to the hearing examiner, neither of which contemplated use of the supplemental hearings for retrial of the issues and matters as to which full hearing or opportunity therefor had been afforded in the

original hearings, and the hearing examiner's action in rejecting this additional evidence is not regarded as erroneous.

Counsel supporting the complaint has stated that he would not oppose a proper motion filed by the respondent requesting the reception of evidence relating to Dr. Twiss' experiments as newly discovered evidence. In presenting its arguments to the Commission on the merits, the respondent averred that such evidence is material and was unavailable to it at the time of the original hearings; but the respondent likewise then indicated clearly that it does not now desire the reception of such evidence by the hearing examiner. The respondent instead urges that a choice of two courses of action is now incumbent on the Commissions, namely, hearings *de novo* before another hearing officer because of alleged bias and prejudice by the present hearing examiner, or dismissal of this proceeding for failure of proof. The Commission having determined that the respondent's motion to disqualify the hearing examiner was not well taken, we must reject the respondent's contention that it is entitled to a trial *de novo*. The respondent having elected not to pursue the matter further by filing for our consideration a proper motion and having an evident intent to rely on the rulings below as constituting prejudicial error invalidating all prior proceedings herein, it was appropriate that the Commission proceed to a consideration of the case on its merits. This the Commission has done and its decision, representing the result of its own exhaustive examination of the record, is issuing herewith.

Our consideration of the arguments advanced by the respondent in support of its request for dismissal has included those presented under its original exceptions as well as others urged for the first time after the supplemental hearings. Their separate discussion and individual rulings in respect thereto would unduly lengthen this opinion and, to the extent that they are in conflict with our decision herein, such exceptions and objections are denied.

Commissioner Mason did not participate in the decision herein.

IN THE MATTER OF  
PUGET SOUND SALMON CANNERS, INC., ET AL.

ORDER, ETC., IN REGARD TO THE ALLEGED VIOLATION OF THE  
FEDERAL TRADE COMMISSION ACT

*Docket 6376. Complaint, June 28, 1955—Decision, Oct. 8, 1956*

Order requiring a fishing vessel owners' association and a fishermen's union in the Puget Sound salmon fishing area and the members of both (the respondents remaining after acceptance of a consent order by 13 canner respondents and dismissal of the complaint as to a fourteenth canner and the cannery's trade association<sup>1</sup>) to cease entering into and maintaining an unlawful price-fixing combination among themselves and with members of the cannery's association; fixing and adhering to minimum prices at which raw or fresh salmon was to be purchased or sold; and preventing boats leaving for the fishing grounds and crews moving vessels from home ports for the purpose of maintaining any price agreement.

*Mr. Lewis F. Depro, Mr. Fletcher G. Cohn and Mr. John J. McNally* for the Commission.

*Mr. Herald A. O'Neill*, of Seattle, Wash., for Puget Sound Salmon Cannery, Inc. and Anacortes Canning Co.

*Mr. John F. Evich*, of Seattle, Wash., for Purse Seine Vessel Owners Ass'n.

*Walther, Oseran, Warner & Keefe*, of Seattle, Wash., for Local No. 3, Fishermen & Allied Workers Division, International Longshoremen & Warehousemen's Union.

INITIAL DECISION BY WILLIAM L. PACK, HEARING EXAMINER

1. The complaint in this proceeding charges a price fixing combination in the salmon fishing industry in the Puget Sound area. The respondents are Puget Sound Salmon Cannery, Inc., a trade association, and fourteen of its members, all of whom are or have been engaged in processing, canning and selling salmon caught in the Puget Sound area; Purse Seine Vessel Owners Association and its members, all of whom are owners or captains (skippers) of boats engaged in fishing for salmon in that area; and Local No. 3, Fishermen & Allied Workers Division, International Longshoremen & Warehousemen's Union, a labor union, whose members make up the crews of such boats.

2. (a) Respondent Puget Sound Salmon Cannery, Inc. (frequently referred to hereinafter as the "Cannery Association") is a membership corporation organized and existing under the laws of the State

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<sup>1</sup> 52 F.T.C. 1251.