

Complaint

IN THE MATTER OF
THE DRIVE-X COMPANY, INC.
TRADING AS THE ELMO COMPANY ET AL.

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

Docket 8615. Complaint, Feb. 14, 1964—Decision, Dec. 1, 1965

Order dismissing the complaint against an Iowa concern dealing in drugs and medical devices and vacating the initial decision of the hearing examiner issued February 4, 1965, for the reason that the Commission determined it was no longer in the public interest to continue the proceeding.

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that The Drive-X Company, Inc., a corporation trading as The Elmo Company, and Craig Sandahl and Richard Johann, individually and as officers of said corporation, hereinafter referred to as respondents, have violated the provisions of said Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint, stating its charges in that respect as follows:

PARAGRAPH 1. Respondent The Drive-X Company, Inc., trading as The Elmo Company, is a corporation organized, existing and doing business under and by virtue of the laws of the State of Iowa, with its principal office and place of business at Second and Main Streets, in the city of Madrid, State of Iowa.

Respondents Craig Sandahl and Richard Johann are individuals and are officers of said corporate respondent. Their address is the same as that of the corporate respondent.

PAR. 2. Respondents are now, and have been for more than one year last past, engaged in the sale and distribution of certain preparations containing drugs and devices as the terms "drug" and "device" are defined in the Federal Trade Commission Act. The combination of the preparations and the devices is referred to by respondents as the "Elmo Palliative Home Treatment."

The designations used by respondents for their said preparations, the formulae and directions for use thereof and the designations, descriptions and directions for use of their said devices are as follows:

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Designation: Preparation No. 1—Ear Oil

<i>Formula:</i>	Gal.	Pts.	Ozs.
Alcohol		1	4
Methyl Salicylate U.S.P. (oil of wintergreen—synthetic).....			2½
Oil Eucalyptus			2½
Chloroform (Technical)		1	14
White Mineral Oil	2½		
Capsicum			1¾
Total—2 gallons, 7 pints, 13 ounces			

Directions for Use: Do not drop in ears—use the medicine dropper and put 2 or 3 drops—no more—on a piece of clean, sterile, absorbent cotton about ½ the size of a nickel. You can get this cotton at any drug store. Insert this cotton into the ear canal but not so deep that it cannot be easily removed with the fingers. Leave cotton in ears for about 10 minutes, while using the rest of the treatment. Then REMOVE THE COTTON AND THROW IT AWAY. Use Ear Oil once a day for one week. After one week use twice daily.

IMPORTANT—NOTE: If there is infection present in the ear canal do not use No. 1 Ear Oil for use may have the tendency to spread the infection to the deeper parts of the ear. Infection in the ear canal should be healed promptly by a competent physician for the spread of such infection could cause injury to the ear.

DO NOT USE THE MEDICINE DROPPER WITH ANY OTHER MEDICINE.

Designation: Preparation No. 2—Nasal Cleanser*Formula:*

Each 200 lbs. combines the following:

Sodium Chloride	95 lbs. 5 ozs.
Pwd. Sodium Borate.....	100 lbs.
Oil of Eucalyptus.....	3 pts.
Methyl Salicylate	2 pts.
Menthol Approx.	8 oz.
Aniline Pink #7264.....	1 gr. to each 1 lb.
Potassium Iodide	6 lbs. 2 oz. 350 gr.
Sodium Salicylate	2 lbs. 1 oz. 146 gr.
Sodium Benzoate	2 lbs. 1 oz. 146 gr.
Sugar of milk.....	20 lbs. to each 200 lbs.

Directions for Use: Fill No. 7 Nasal Douche about ¾ full with No. 2 Nasal Cleanser liquid from the bottle. Insert bulb end of the douche into one nostril, close the other nostril with finger pressure, and—while bending your head forward and downward—GENTLY snuff the medicine up into your nose. Refill No. 7 Nasal Douche and use in the same way in the other nostril.

Hold the liquid in both nostrils, for about a minute, to let the cleanser soak into the tissue and aid in cleansing catarrhal mucus from the nose. Use No. 2 Nasal Cleanser twice a day.

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If you snuff too hard, some of the nasal cleanser may pass into your throat. Spit it out if you can. If you swallow it will do no harm.

Designation: Preparation No. 3—Throat Gargle

Formula:

Each ounce of Special Formula Powder #3 contains the following:

Salicylate Acid	2-1/5 gr.
Carbolic Acid	9/20 gr.
Eucalyptol U.S.P.	9/20 gr.
Menthol U.S.P.	9/20 gr.
Thymol U.S.P.	9/20 gr.
Zinc Sulphate	55 gr.
Boric Acid	378-1/2 gr.

Directions for Use: Use the gargle to help remove the catarrhal secretions, or mucus, from the throat. Use twice a day—use only 1 teaspoonful from your pint bottle each time.

Designation: Preparation No. 4—Vapor Inhaler

Formula:

	Gals.	Pts.	Ozs.
Oil Peppermint		3	2
Oil Eucalyptus		5	
Oil Mustard (Synthetic)			2
White Mustard Oil	1/2	1/2	3

Directions for Use: First, see that the nose and throat are CLEAN of liquid and mucus. Then remove the corks from each end of the Vapor Inhaler. Insert the tapered end into one nostril, close the other with finger pressure at the side, and GENTLY draw a deep breath. Then hold it, remove the Vapor Inhaler from your nose and pinch BOTH nostrils shut using the thumb and finger. Then, close your mouth and try to blow through your nose. While doing this—try to swallow once or twice.

Repeat this operation in the other nostril. Do this 2 or 3 times each day. KEEP CORKED WHEN NOT IN USE.

Designation: Preparation No. 5—Massage Ointment

Formula:

Cream White Petrolatum	10 lbs.
Oil of Capsicum	1 1/2 ozs.

Directions for Use: Apply just a very little ointment behind and in front of the external ear and rub downward to the angle of the jaw—about 15 or 20 strokes—or until the skin feels slightly warm. Then remove the ointment left on the skin.

Next, stand erect and hold your head straight—throw your shoulders back and move your head from side to side, towards each shoulder, 8 or 10 times. Then move it from the front to the back, 8 or 10 times. Do this mildly at first. Use No. 5 Massage Ointment and do this exercise twice a day.

Designation: Preparation No. 6—Nasal Ointment

Formula:

Cream White Petrolatum	15 lbs.
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32 oz. Oil Eucalyptus	} No. 6	
20½ oz. Oil Wintergreen		
16½ oz. Oil Peppermint		
	Oil	30 ozs.
Oil of Pine Needles		1½ ozs.
Oil of Sassafras		1½ ozs.

Directions for Use: Place a small amount on your little finger and spread well over the mucous membrane in each nostril. Do this twice a day.

Designation: Elmo No. 7 Nasal Douche

Elmo No. 7 Nasal Douche is a glass U-Shaped tube with openings at both ends, and one end tapered.

Directions for Use: Fill Nasal Douche three-fourths full with No. 2 solution. Insert tapered end in nose, holding head WELL FORWARD and DOWN. Snuff up contents of douche. Repeat in other nostril. Retain solution for a minute or two before gently blowing nose. Use twice daily, night and morning.

Designation: Elmo No. 8 Ear Vibrator

Elmo No. 8 Ear Vibrator is a glass tube device with a plunger or piston at one end and a bulb containing a small opening at the other end.

Directions for Use: Place glass bulb into hole in ear, holding so air cannot escape around bulb. Then draw piston SLOWLY in and out ten or twelve times. USE ONCE A DAY. When ear becomes accustomed to Ear Vibrator, use morning and night. For indicated ear conditions only. Read direction sheet before using.

IMPORTANT—NOTE: If there is infection present in the ear canal, do not use No. 8 Ear Vibrator for use may have the tendency to spread it. Read accompanying Directions before using.

Designation: Preparation No. 9—Re-Charge Liquid

Formula:

This preparation is the liquid used in the No. 4 Vapor Inhaler and the formula is the same as set out there. It is used to recharge the Inhaler.

PAR. 3. Respondents cause their said preparations and devices, when sold, to be transported from their place of business in the State of Iowa to purchasers thereof located in various other States of the United States and in the District of Columbia. Respondents maintain, and at all times mentioned herein have maintained, a course of trade in said preparations and devices in commerce, as "commerce" is defined in the Federal Trade Commission Act. The volume of business in such commerce has been and is substantial.

PAR. 4. In the course and conduct of their business, respondents have disseminated, and caused the dissemination of, certain advertisements concerning their said preparations and devices by the United States mails and by various means in commerce, as "com-

merce" is defined in the Federal Trade Commission Act, including, but not limited to, advertisements inserted in newspapers, magazines and by means of circulars and other advertising media, for the purchase of inducing and which were likely to induce, directly or indirectly, the purpose of said preparations and devices; and have disseminated, and caused the dissemination of, advertisements concerning said preparations and devices, by various means, including, but not limited to, the aforesaid media, for the purpose of inducing and which are likely to induce, directly or indirectly, the purchase of said preparations and devices in commerce, as "commerce" is defined in the Federal Trade Commission Act.

PAR. 5. Among and typical of the statements and representations contained in said advertisements disseminated as hereinabove set forth are the following:

EAR NOISES

relieved!

* * * thousands reported.

Wonderful relief from years of suffering from miserable ear noises and poor hearing caused by catarrhal (excess fluid mucus) conditions of the head! That's what these folks (many past 70) reported after using our simple Elmo Palliative HOME TREATMENT during the past 23 years. This may be the answer to your prayer. NOTHING TO WEAR. Here are SOME of the symptoms that may likely go with your catarrhal deafness and ear noises: Mucus dropping in throat. Head feels stopped up by mucus. Mucus in nose and throat every day. Hear—but don't understand words. Hear better on clear days—worse on bad days, or with a cold. Ear noises like crickets, bells, whistles, clicking or escaping steam or others. You, too, may enjoy wonderful relief if your poor hearing or ear noises are caused by catarrhal conditions of the head and when treatment is used as needed. Write TODAY for PROOF OF RELIEF and 30 DAY TRIAL OFFER.

The Elmo Palliative Home Treatment is a "time-tested" treatment used by thousands during the past 25 years. PROOF OF RELIEF is to be found in the great many letters I have received from people after using it as directed and as needed. * * *

Our treatment is designed for catarrhal (excess fluid mucus) conditions of the head and for poor hearing and ear noises caused by such conditions. * * *

This method of treatment is probably different than anything else you have tried before. DIFFERENT because it is based upon * * *.

* * * Medicines "time-tested" through more than 25 years of use, as its name indicated, our treatment is not intended nor recommended to take the place of professional attention but consists of proprietary medicines designed for palliative relief of catarrhal conditions of the head and for poor hearing and ear noises caused by such conditions.

My catarrhal condition is very much better. My hearing is now very good and seems back where it used to be. My ear noises are relieved. * * *

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Have not had any head noises since using your treatment. I can lay in bed now and hear my alarm clock tick and before I could not. * * *

PAR. 6. Through the use of said advertisements and others similar thereto not specifically set out herein, respondents have represented and are now representing, directly and by implication, that the use of its said preparations and devices, in combination, as directed, will cure or constitute an effective treatment for poor hearing or ear noises or head noises or catarrhal conditions of the head.

PAR. 7. In truth and in fact, the use of respondents' preparations and devices, in combination as directed, or otherwise, will not cure nor have any beneficial effect on hearing loss or ear noises or head noises or catarrhal conditions of the head, including the nose, ear and air passages.

Therefore, the advertisements referred to in Paragraph Five were and are misleading in material respect and constituted, and now constitute, "false advertisements" as that term is defined in the Federal Trade Commission Act.

PAR. 8. The dissemination by the respondents of the false advertisements, as aforesaid, constituted, and now constitutes, unfair and deceptive acts and practices in commerce, in violation of Sections 5 and 12 of the Federal Trade Commission Act.

Mr. Francis J. Charlton supporting the complaint.

Steadman, Leonard & Hennessey, by *Mr. Geo. Stephen Leonard* of Wash., D.C., for respondents.

INITIAL DECISION BY JOHN LEWIS, HEARING EXAMINER

FEBRUARY 4, 1965

STATEMENT OF PROCEEDINGS

The Federal Trade Commission issued its complaint against the above-named respondents on February 14, 1964, charging them with engaging in unfair and deceptive acts and practices in commerce, in violation of Sections 5 and 12 of the Federal Trade Commission Act, by the dissemination of false advertisements concerning certain preparations, containing drugs and devices, sold and distributed by them. After being served with said complaint, respondents appeared by counsel and thereafter filed their answer denying in substance, having engaged in the illegal practices charged.

Pursuant to notice duly given, a pre-hearing conference was convened on May 5, 1964, before the undersigned, theretofore duly designated to act as hearing examiner in this proceeding. An order

was issued by the undersigned on May 13, 1964, embodying the stipulations, admissions and agreements made at said pre-hearing conference, and controlling the conduct of this proceeding. In accordance with the understandings reached at the aforesaid pre-hearing conference, respondents filed separate motions for discovery of certain medical reports in the files of the Commission, and to dismiss the complaint on the ground that the institution of the present proceeding is in contravention of the Federal Trade Commission Act and of the Commission's Rules of Practice. By separate orders issued May 15, 1964, the undersigned (a) granted in part and denied in part the aforesaid motion for discovery, and (b) denied the motion to dismiss. Application by respondents for permission to file an interlocutory appeal from the examiner's order denying their motion to dismiss was denied by the Commission on June 9, 1964.

Hearings on the charges were thereafter held between August 17, 1964 and September 10, 1964, in Washington, D.C. and Philadelphia, Pennsylvania, in accordance with the prior order of the Commission granting leave to hold hearings in more than one place. At said hearings, testimony and other evidence were received in support of and in opposition to the allegations of the complaint, said evidence being duly recorded and filed in the Office of the Commission. All parties were represented by counsel, participated in the hearings and were afforded full opportunity to be heard and to examine and cross-examine witnesses. At the close of all the evidence, and pursuant to leave granted by the undersigned, proposed findings of fact, conclusions of law and an order were filed by the parties on October 26, 1964, and a reply to the proposed findings of complaint counsel was filed by respondents on November 5, 1964, complaint counsel electing to file any reply to respondents' proposed findings.

After having carefully reviewed the evidence in this proceeding, and the proposed findings and conclusions, the undersigned finds that this proceeding is in the interest of the public and, based on the entire record and from his observation of the witnesses, makes the following:¹

¹ Proposed findings not herein adopted, either in the form proposed or in substance, are rejected as not supported by the evidence or as involving immaterial matters. References to the proposed findings are made with the abbreviations, "CPF" for the findings of complaint counsel, "RPF" for the findings of respondents and "RR" for respondents' reply. References to the transcript in connection with the examiner's findings are made with the abbreviated symbol "Tr." References to exhibits introduced by complaint counsel or respondents are made with the respective abbreviated symbols "CX" or "RX." All such citations are intended to refer to the principal portions of the record relied upon by the undersigned, in connection with particular findings, but do not purport to be an exhaustive compendium of the portions of the record reviewed and relied upon by him.

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FINDINGS OF FACT

Identity of Respondents

1. Respondent The Drive-X Company, Inc., trading as The Elmo Company, is a corporation organized, existing and doing business under and by virtue of the laws of the State of Iowa, with its principal office and place of business at Second and Main Streets, in the city of Madrid, State of Iowa. Respondent Craig Sandahl is the president and chief executive officer of the corporate respondent, and owns approximately 90 percent of its stock. Respondent Richard Johann is vice-president and assistant treasurer of the corporate respondent and owns approximately 10 percent of its stock. Respondent Johann is also the general manager of the corporate respondent and handles the placing of its advertising and related functions. The business address of the individual respondents is the same as that of the corporate respondent. It is concluded and found that the individual respondents formulate, direct and control the acts and practices of the corporate respondent.²

The Drugs and Devices

2. Respondents are now, and have been for more than one year last past, engaged in the sale and distribution of certain preparations containing drugs and devices, as the terms "drug" and "device" are defined in the Federal Trade Commission Act. The combination of the preparations and the devices is referred to by respondents as the "Elmo Palliative Home Treatment."

The designations used by respondents for their said preparations, the formulae and directions for use thereof and the designations, descriptions and directions for use of their said devices are as follows:

Designation: Preparation No. 1—Ear Oil

<i>Formula:</i>	Gal.	Pts.	Ozs.
Alcohol		1	4
Methyl Salicylate U.S.P. (oil of wintergreen—synthetic).....			2½

² The above findings are based on the substantially admitted allegations of the complaint, as amplified by the testimony with respect to the stock ownership and positions occupied by the individual respondents (Tr. 497, 548). In addition to admitting the allegations of the complaint respondents allege in their answer that the corporate respondent is the legal successor of The Elmo Company, Inc., respondent in Docket No. 5959. The examiner considers this fact immaterial to the disposition of the issues in this proceeding. However, to the extent such fact may be considered material, the uncontradicted evidence in the record supports the claim of respondents that the corporate respondent herein is the legal successor of The Elmo Company under the laws of the State of Iowa (RX 1; Tr. 498-502).

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Formula:—Con't	Gal.	Pts.	Ozs.
Oil Eucalyptus			2½
Chloroform (Technical)		1	14
White Mineral Oil.....	2½		
Capsicum			1¾
Total—2 gallons, 7 pints, 13 ounces			

Directions for Use: Do not drop in ears—use the medicine dropper and put 2 or 3 drops—no more—on a piece of clean, sterile, absorbent cotton about ½ the size of a nickel. You can get this cotton at any drug store. Insert this cotton into the ear canal but not so deep that it cannot be easily removed with the fingers. Leave cotton in ears for about 10 minutes, while using the rest of the treatment. Then REMOVE THE COTTON AND THROW IT AWAY. Use Ear Oil once a day for one week. After one week use twice daily.

IMPORTANT—NOTE: If there is infection present in the ear canal do not use No. 1 Ear Oil for use may have the tendency to spread the infection to the deeper parts of the ear. Infection in the ear canal should be healed promptly by a competent physician for the spread of such infection could cause injury to the ear.

DO NOT USE THE MEDICINE DROPPER WITH ANY OTHER MEDICINE.

Designation: Preparation No. 2—Nasal Cleanser

Formula:

Each 200 lbs. combines the following:

Sodium Chloride	95 lbs. 5 ozs.
Pwd. Sodium Borate.....	100 lbs.
Oil of Eucalyptus.....	3 pts.
Methyl Salicylate	2 pts.
Menthol Approx.	8 oz.
Aniline Pink #7264	1 gr. to each 1 lb.
Potassium Iodide	6 lbs. 2 oz. 350 gr.
Sodium Salicylate	2 lbs. 1 oz. 146 gr.
Sodium Benzoate	2 lbs. 1 oz. 146 gr.
Sugar of milk.....	20 lbs. to each 200 lbs.

Directions for Use: Fill No. 7 Nasal Douche about ¾ full with No. 2 Nasal Cleanser liquid from the bottle. Insert bulb end of the douche into one nostril, close the other nostril with finger pressure, and—while bending your head forward and downward—GENTLY snuff the medicine up into your nose. Refill No. 7 Nasal Douche and use in the same way in the other nostril.

Hold the liquid in both nostrils, for about a minute, to let the cleanser soak into the tissue and aid in cleansing catarrhal mucus from the nose. Use No. 2 Nasal Cleanser twice a day.

If you snuff too hard, some of the nasal cleanser may pass into your throat. Spit it out if you can. If you swallow it will do no harm.

Designation: Preparation No. 3—Throat Gargle

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Formula:

Each ounce of Special Formula Powder #3 contains the following:

Salicylic Acid	2-1/5 gr.
Carbolic Acid	9/20 gr.
Eucalyptol U.S.P.	9/20 gr.
Menthol U.S.P.	9/20 gr.
Thymol U.S.P.	9/20 gr.
Zinc Sulphate	55 gr.
Boric Acid	378-1/2 gr.

Directions for Use: Use the gargle to help remove the catarrhal secretions, or mucus, from the throat. Use twice a day—use only 1 teaspoonful from your pint bottle each time.

Designation: Preparation No. 4—Vapor Inhaler

Formula:

	Gals.	Pts.	Ozs.
Oil Peppermint		3	2
Oil Eucalyptus		5	
Oil Mustard (Synthetic).....			2
White Mustard Oil.....	1/2	1/2	3

Directions for Use: First, see that the nose and throat are CLEAN of liquid and mucus. Then remove the corks from each end of the Vapor Inhaler. Insert the tapered end into one nostril, close the other with finger pressure at the side, and GENTLY draw a deep breath. Then hold it, remove the Vapor Inhaler from your nose and pinch BOTH nostrils shut using the thumb and finger. Then, close your mouth and try to blow through your nose. While doing this—try to swallow once or twice.

Repeat this operation in the other nostril. Do this 2 or 3 times each day. KEEP CORKED WHEN NOT IN USE.

Designation: Preparation No. 5—Massage Ointment

Formula:

Cream White Petrolatum.....	10 lbs.
Oil of Capsicum.....	1 1/2 ozs.

Directions for Use: Apply just a very little ointment behind and in front of the external ear and rub downward to the angle of the jaw—about 15 or 20 strokes—or until the skin feels slightly warm. Then remove the ointment left on the skin.

Next, stand erect and hold your head straight—throw your shoulders back and move your head from side to side, towards each shoulder, 8 or 10 times. Then move it from the front to the back, 8 or 10 times. Do this mildly at first. Use No. 5 Massage Ointment and do this exercise twice a day.

Designation: Preparation No. 6—Nasal Ointment

Formula:

Cream White Petrolatum.....	15 lbs.
32 oz. Oil Eucalyptus	No. 6 Oil
20 1/2 oz. Oil Wintergreen	
16 1/2 oz. Oil Peppermint	
	30 ozs.

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Oil of Pine Needles.....1½ ozs.
 Oil of Sassafras1½ ozs.

Directions for Use: Place a small amount on your little finger and spread well over the mucous membrane in each nostril. Do this twice a day.

Designation: Elmo No. 7 Nasal Douche

Elmo No. 7 Nasal Douche is a glass U-Shaped tube with openings at both ends, and one end tapered.

Directions for Use: Fill Nasal Douche three-fourths full with No. 2 solution. Insert tapered end in nose, holding head WELL FORWARD and DOWN. Snuff up contents of douche.

Repeat in other nostril. Retain solution for a minute or two before gently blowing nose. Use twice daily, night and morning.

Designation: Elmo No. 8 Ear Vibrator

Elmo No. 8 Ear Vibrator is a glass tube device with a plunger or piston at one end and a bulb containing a small opening at the other end.

Directions for Use: Place glass bulb into hole in ear, holding so air cannot escape around bulb. Then draw piston SLOWLY in and out ten or twelve times. USE ONCE A DAY. When ear becomes accustomed to Ear Vibrator, use morning and night. For indicated ear conditions only. Read direction sheet before using.

IMPORTANT—NOTE: If there is infection present in the ear canal, do not use No. 8 Ear Vibrator for use may have the tendency to spread it. Read accompanying Directions before using.

Designation: Preparation No. 9—Re-Charge Liquid

Formula:

This preparation is the liquid used in the No. 4 Vapor Inhaler and the formula is the same as set out there. It is used to recharge the Inhaler.³

Sale and Dissemination in Commerce

3. Respondents cause their said preparations and devices, when sold, to be transported from their place of business in the State of Iowa to purchasers thereof located in various other states of the United States and in the District of Columbia. Respondents maintain, and at all times mentioned herein have maintained, a course of trade in said preparations and devices in commerce, as "commerce" is defined in the Federal Trade Commission Act. The

³ The findings above made with reference to respondents' various preparations, including the designation, formula and directions for use thereof, are based on the allegations of the complaint which were substantially admitted in respondents' answer. Although respondents raised some question at the pre-hearing conference whether the allegations of the complaint properly reflected the directions for use or combination of use of their preparations (see Pre-Hearing Order of May 13, 1964, Paragraph 2), they conceded at the hearings that the allegations of the complaint are accurate with respect to the formula of their preparations and the directions for use (Tr. 117).

volume of business in such commerce has been and is substantial.⁴

4. In the course and conduct of their business, respondents have disseminated, and caused the dissemination of, certain advertisements concerning their said preparations and devices by the United States mails and by various means in commerce, as "commerce" is defined in the Federal Trade Commission Act, including, but not limited to, advertisements inserted in newspapers, magazines and by means of circulars and other advertising media, for the purpose of inducing and which were likely to induce, directly or indirectly, the purchase of said preparations and devices; and have disseminated, and caused the dissemination of, advertisements concerning said preparations and devices, by various means, including, but not limited to, the aforesaid media, for the purpose of inducing and which are likely to induce, directly or indirectly, the purchase of said preparations and devices in commerce, as "commerce" is defined in the Federal Trade Commission Act.⁵

The Advertising

5. Respondents' initial contact with prospective purchasers of their preparations is made through advertisements inserted in various newspapers and magazines. Among the newspapers in which respondents' advertisements have appeared are: San Diego Tribune, Philadelphia News, Los Angeles Herald Examiner, and Lancaster (Pennsylvania) New Era-Intelligencer Journal. Among the magazines in which their advertisements have appeared are: New England Homestead, Our Sunday Visitor-Register Unit, St. Anthony's Messenger, and T.V. Guide. Typical of the advertisements inserted by respondents in such newspapers and magazines is the following (Tr. 105; CX 1-2):

⁴ The above findings as to commerce are based on the allegations of the complaint, which were admitted in respondents' answer except as to the substantiality of such commerce. However, such qualification in respondents' answer was later withdrawn and it was admitted that the volume of their sales in commerce was substantial (Tr. 493).

⁵ The above findings are based on the allegations of Paragraph 4 of the complaint and the advertisements. Respondents admitted in their answer the placing of advertisements in the media referred to in the complaint "for the purpose of informing potential users of the nature of respondents' medications and seek[ing] thereby to interest such persons in the purchase thereof." Respondents contend that there is no basis for finding that their advertisements were "for the purpose of inducing * * * the purchase of said preparations" since readers of the advertisements were invited merely to send for applications for respondents' preparations (RR, p. 2). It is clear from the statements, made in respondents' advertisements, which will be hereinafter more fully described, that the purpose of respondents' advertising was for the purpose of inducing the purchase of its said preparations and not merely the inviting of applications.

EAR NOISES

relieved!

* * * thousands reported.

Wonderful relief from years of suffering from miserable ear noises and poor hearing caused by catarrhal (excess fluid mucus) conditions of the head! That's what these folks (*many past 70*) reported after using our simple Elmo Palliative HOME TREATMENT during the past 23 years. This may be the answer to your prayer. NOTHING TO WEAR. Here are SOME of the symptoms that may likely go with your catarrhal deafness and ear noises: Mucus dropping in throat. Head feels stopped up by mucus. Mucus in nose and throat every day. Hear—but don't understand words. Hear better on clear days—worse on bad days, or with a cold. Ear noises like crickets, bells, whistles, clicking or escaping steam or others. You, too, may enjoy wonderful relief if your poor hearing or ear noises are caused by catarrhal conditions of the head and when treatment is used as needed. Write TODAY for PROOF OF RELIEF and 30 DAY TRIAL OFFER.

6. Persons responding to one of these advertisements receive a form letter in which respondents offer to sell the "30 Day Elmo Palliative Home Treatment" on a "trial" basis, *i.e.*, the purchaser will not have to pay the purchase price (\$10) for 30 days, at the end of which period payment will be expected if the user determines that the treatment has helped him (CX 3 C-D). The form letter, which is signed by L. A. Johann, contains the following statements with respect to respondents' preparations:

The Elmo Palliative Home Treatment is a "time-tested" treatment used by thousands during the past 26 years. PROOF OF RELIEF is to be found in the great many letters I have received from people after using it as directed and as needed. I am enclosing a pamphlet in which I have printed the substance of a few of their letters. These are taken from actual case records on file from folks, MANY PAST 70, who once may have suffered just like you! * * *

Our treatment is designed for catarrhal (excess fluid mucus) conditions of the head and for poor hearing and ear noises caused by such conditions. * * *

This method of treatment is probably different than anything else you have tried before. DIFFERENT because it is based upon * * *.

* * * Medicines "time-tested" through more than 27 years of use. As its name indicates, our treatment is not intended nor recommended to take the place of professional attention but consists of proprietary medicines designed for palliative relief of catarrhal conditions of the head and for poor hearing and ear noises caused by such conditions.

7. The pamphlet referred to in the above letter contains excerpts from letters which are stated to have been received from actual users of the Elmo Treatment, and the prospective purchaser is urged to: "Take the Word of Others" (CX 3 E-H). In most instances, the users purport to have been afflicted for a number of years with

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deafness or other forms of hearing difficulty, and with ear noises, and report that they were benefited by the Elmo Treatment. Concerning ear noises, the testimonial extracts contain statements that the ear noises "have stopped," or "are relieved," or "are cleared up now," and other statements to similar effect. Concerning difficulty in hearing or deafness, the extracts contain such statements as the following: "I can hear good again." "My hearing is so much better." "My hearing seems extra good." "My hearing has been improved to the point it seems nearly perfect."

8. Accompanying the form letter is an application for the Elmo Treatment, in which the prospective user is invited to "accept your generous offer to send me your REGULAR 30 DAY TREATMENT on Trial, postage prepaid" (CX 3-A). The application form requests the prospective user to answer the following three questions:

1. Do you have symptoms of CATARRHAL CONDITIONS OF THE HEAD?
2. Do you want Treatment for HARD-OF-HEARING due to Catarrhal Conditions of the HEAD?
3. Do you want Treatment for EAR NOISES due to Catarrhal Conditions of the Head?

The reverse side of the application form contains an explanation of these three conditions, and includes the following admonition: "If your poor hearing or ear noises are caused by accidents, auditory nerve trouble, any of the destructive fevers or running or discharging ears, this treatment is NOT indicated NOR recommended."

9. Of those responding to the invitation to send for the Elmo Home Treatment on a "trial" basis, respondents decline about one-third of the orders on the basis of answers to the questionnaire in the application form which indicate that the individuals may have an ear infection, traumatic injury or a disease for which the treatment would be ineffective (Tr. 106). Of the remaining two-thirds who receive the treatment, approximately 60% pay for it at the end of the 30-day trial period. Two follow-up letters are sent to the 40% who did not pay for the treatment at the end of the trial period to ascertain whether they have used the preparations and secured relief (Tr. 542). There is no indication in the record as to the reason these persons have not paid for the preparations.

10. Where persons responding to respondents' contact advertising do not reply to respondents' initial form letter inviting them to apply for respondents' home treatment on a 30-day trial basis, respondents send them a second form letter inviting them to apply for the treatment (Tr. 106; CX 4 A-B). The second letter suggests

that the individual may not have responded because of his uncertainty as to "how a catarrhal condition in my nose and throat can affect my ears." The letter attempts to briefly explain how "catarrhal conditions of the nose or throat can easily affect the Middle Ear and cause ear noises as well as be dangerous to your hearing." Enclosed with the letter is a pamphlet containing a much more detailed explanation of the physiology of the ear and how respondents' preparations have "helped so many people with this kind of poor hearing and ear noises" (CX 4E-F). Also enclosed is a further series of extracts from testimonial letters purporting to have been received from users, similar in content to those previously described (CX 4G-J). Persons who do not respond to the second form letter receive a third letter offering them the home treatment at a reduced rate of \$7.35, instead of the \$10 price offered in the original letter (Tr. 106; CX 5A-B). Attached to this letter is a further group of extracts from testimonial letters (CX 5E-H).

The Nature of the Representations Made

11. The complaint alleges that through the above and similar statements made by them in newspaper and magazine advertisements, and in the circular and other literature sent to prospective customers, respondents have represented and are now representing, directly and by implication, that the use of their preparations and devices "will cure or constitute an effective treatment for poor hearing or ear noises or head noises or catarrhal conditions of the head." In their answer respondents deny that their advertisements are subject to such a broad interpretation and allege that the only statements and representations which they have made with respect to their products is that "they will temporarily relieve a catarrh caused deafness or impaired hearing and ear or head noises by the softening of the dried exudates." Respondents' position, in essence, is that their advertising claims with respect to the therapeutic value of their preparations are limited to (a) "temporary relief," rather than "cure" or "effective treatment," and (b) "symptoms only," rather than the "underlying disorders" responsible for these symptoms (Tr. 380; RR p. 3). In support of their position concerning the limited character of the representations made by them respondents cite the fact that their advertising literature, (a) uses the word "relief," and nowhere refers to their preparations as a "cure," (b) uses the word "palliative" in connection with the name of their preparations (the dictionary definition

of which is, "to mitigate" or "to ease without curing"), and (c) uses the words "symptoms" and "catarrhal conditions" in referring to what they offer relief for, rather than "an ailment or a disease" (RR, pp. 3-4). While recognizing that their advertising literature does not use the word "temporary" in connection with the word "relief," respondents contend that the former word is superfluous since "the word 'temporary' is assumed in the word 'relief,'" when used in connection with symptoms rather than a basic disorder. They also contend that the words "as needed" in connection with their treatment "necessarily negate any concept of permanent relief" (RR, p. 5).

12. It is the opinion and finding of the examiner that through the statements made in their advertising literature, portions of which have been cited above, respondents have represented and are now representing, directly and by implication, that the use of their preparations and devices, in combination, as directed, will cure or constitute an effective treatment for poor hearing or ear noises or head noises or catarrhal conditions of the head, and that their claims of therapeutic value for said preparations and devices are not limited to mere "temporary relief." While it is true that respondents nowhere expressly use the word "cure," the over-all impression created in their newspaper and magazine advertising, and in the circulars thereafter sent to prospective users, is that the use of their preparations is likely to bring about a cure or, at the very least, an extended cessation of the poor hearing or ear noises caused by catarrhal conditions of the head. The references made in advertisements to "[w]onderful relief from years of suffering from miserable ear noises and poor hearing," and the excerpts from the testimonial letters referring to ear noises as being "stopped" or "cleared up" after the use of the preparations, and to hearing being "good again" or "extra good" or "nearly perfect," after many years of suffering from these infirmities, would hardly suggest to readers and potential users of the preparations that all that was being offered to them was the possibility of achieving "temporary relief" from these conditions.⁶

13. Whether or not respondents' advertising literature can be interpreted as representing that their preparations will "cure" the indicated conditions, there is no question but that they constitute a representation that the preparations and devices are an effective method of treatment for these conditions, and that users can

⁶ Although many of the testimonial letters speak of the writers' having received "relief," at least one of them refers to the individual's having received "a complete cure" (CX 3-E).

reasonably expect to receive some type of extended therapeutic benefits from the use thereof. Respondents' contact advertising expressly refers to the preparations as a "treatment" for ear noises and poor hearing caused by catarrhal conditions of the head (CX 1-2). The initial form letter sent to persons who respond to respondents' advertising states that: "Our treatment is designed for catarrhal * * * conditions of the head and for poor hearing and ear noises caused by such conditions" (CX 3-C). The application form refers to the preparation as a "30 Day Treatment" and the recipient is asked whether he wants "Treatment for Hard-of-Hearing" and "Treatment for Ear Noises" (CX 3-A). From the attestations of users (with which the prospective customer is deluged, and whose "word" he is urged to "take") of a complete cessation of or material improvement in auditory difficulties of long standing, the average reader would hardly infer that the "treatment" he is being offered will afford him temporary surcease from these afflictions.

14. Respondents' argument, that their use of such words as "relief," "palliative," "symptoms," and "as needed" can only be interpreted as implying temporary relief from symptoms, and not a cure for the basic disorders responsible for such symptoms, is one which might find a responsive chord in the rarefied disputations of medieval scholastic philosophers, but would hardly be appreciated by the generality of readers of respondents' advertising literature. As the court of appeals said in *Positive Products v. FTC*, 132 F. 2d 165, 167 (CA 7), where a similar argument was made:

The weakness of this position * * * lies in the fact that such representations are made to the public, who, we assume, are not, as a whole, experts in grammatical construction. Their education in parsing a sentence has either been neglected or forgotten.

As previously indicated, there is nothing about the word "relief," in the context of its use, to imply that the therapeutic benefits being offered are merely "temporary" in nature. While it may be that one of the dictionary definitions of "palliative" is "to ease without curing," the examiner doubts that one in a hundred readers would be aware of this fact or would take the trouble to read the dictionary. Furthermore, even if some readers would understand that the preparations were being offered to "ease," rather than to "cure," their condition, they would, at the very least, have every reason to infer from the advertising literature as a whole that the remedy offered would bring about an extended easing of their ear difficulties. The fact that the advertisements refer to "symptoms" does not, in the context of the use of this word, imply that any

lesser degree of relief is being offered. In the first place, the "symptoms" referred to in the advertising are "mucus dropping in the throat," etc., whereas the "catarrhal deafness and ear noises" are referred to as if they were basic maladies.⁷ More importantly, however, whether the latter are mere symptoms or are a basic disorder, respondents' advertising literature clearly implies that its preparations will cure or effectively treat them.

15. It is now well settled that to offer a preparation "for" some medical condition or as "treatment for" the condition, as respondents admittedly do here, "is equivalent to labeling it 'as a cure or remedy.' *Hall v. U.S.*, 267 Fed. 795, 798 (CCA 5)." *Aronberg (Positive Products) v. FTC*, *supra* at 168; *Rhodes Pharmacal Co. v. FTC*, 208 F. 2d 382 (CA 7). The fact that the word "relief" is used in this connection does not imply that any lesser degree of therapeutic effectiveness is being offered. *Positive Products v. FTC*, *supra*. Respondents seek to distinguish the *Positive Products* case on the ground that the product there was offered as relief for some "underlying disorder," whereas here it is offered only to relieve "symptoms." This agreement is substantially similar to that made in *Positive Products*, where respondent contended that its product was being offered merely to relieve a "functional" disturbance, rather than to remove the "organic" causes of the disturbance, to which the court responded that: "The term 'relief' * * * in a common sense * * * connotes permanent removal of organic or functional disturbance, as distinguished from alleviation of discomfort." Similarly here, whether catarrhal deafness and ear noises are symptoms, basic disorders, disturbances or conditions, respondents' claims that their preparations will afford relief from them and that they are a treatment for them clearly imply, in the context in which these claims are made, that the preparations are a cure or an effective treatment for catarrhal deafness and ear noises.

16. Respondents seek to further distinguish *Positive Products* on the ground that under the later holding in *Rhodes Pharmacal Co. v. FTC*, *supra*, the word "relief" necessarily implies the "temporary" character of the therapy being offered (RR, p. 5). This argument is wholly lacking in merit. The court in *Rhodes Pharmacal*

⁷ The examiner is not unaware that in the instructions accompanying the preparations respondents make the statement that: "Catarrhal conditions of the head are a condition rather than an ailment or disease" (RX 2-C). This revelation, after the customer has ordered the preparations, has no exculpatory effect since the law is violated "if the first contact * * * is secured by deception." *FTC v. Carter Products Co.*, 186 F. 2d 821, 824 (CA 7). Furthermore, it is immaterial, since the prospective customer is interested in knowing whether the preparation will help his condition, not whether its medical classification is that of a symptom, a condition or an ailment. Calling it a "condition" does not imply that the preparation offers him a lesser degree of relief.

actually cited, with approval, the holding in *Positive Products (Aronberg)*, that offering a preparation as relief "for" a disease or condition "is equivalent to labeling it a cure or remedy for such disease," unless the advertising makes it clear that the claimed relief is merely for pains or aches associated with the disease (208 F. 2d at 386). While it is true that the court struck the word "temporary" from the Commission's Order, it did not do so because the word "relief" implies "temporary," as respondents suggest, but because the word temporary "carries an uncertain meaning" in the context of its use (208 F. 2d at 388). Furthermore, this modification of the Commission's Order was subsequently set aside by the Supreme Court (348 U.S. 940).

17. Even assuming, arguendo, that respondents' advertising literature can be interpreted as offering the prospective user only temporary relief from his catarrhal caused deafness and ear noises, it is the opinion and finding of the examiner that, at the very least, they constitute a representation that the prospective user may expect a cessation of his catarrhal deafness and ear noises for some period of time that is of more than merely momentary or fleeting duration. The very words cited by respondents as suggesting that a permanent cure is not being offered, *viz*, that the preparation should be "used as needed," carry the implication that when the treatment has been used as needed it will achieve a cessation or remission of ear noises and hearing for some period of time sufficient to make the effort and expenditure worthwhile. Respondents' characterization of its preparation as "Our Regular 30-day Treatment," and the reference in numerous testimonial excerpts to the users' ear problems having been terminated or materially improved within 30 days or less, would certainly convey, to a prospective user, the minimum expectation that he could reasonably expect some extended period of relief from the ear problems referred to, whether they be considered a basic disorder or a symptom thereof.

The Truth or Falsity of the Representations

18. The complaint alleges that respondents' advertising literature is false and misleading since the use of respondents' preparations and devices, in combination as directed, or otherwise, will not cure nor have any beneficial effect on hearing losses or ear noises, or head noses or catarrhal conditions of the head, including the nose, ear and air passages. In their answer respondents denied knowledge or information sufficient to form a belief as to the truth or falsity of this allegation of the complaint. The basis of their indirect denial is

respondents' contention that they make no claim that their preparations constitute a cure of the conditions alleged in the complaint or that they will have any beneficial effect on these conditions, except in one limited respect, *viz*, that they will afford temporary relief for "a catarrh caused deafness or impaired hearing and ear or head noises by the softening of dried exudates." (Pre-Hearing Order, Par. 6-7). In essence, therefore, respondent concede, for purposes of this proceeding, that their preparations have no therapeutic efficacy in excess of affording temporary relief from loss of hearing and ear noises when these conditions are caused by a catarrh, and that the temporary relief afforded in such cases arises from the softening of dried exudates (Tr. 380).

19. The position taken by respondents in this proceeding with respect to the limited therapeutic value claimed for their preparations is an outgrowth of an earlier Commission proceeding brought against respondents' predecessor, *The Elmo Co., Inc.*, Docket No. 5959, 48 F.T.C. 1379. The complaint in that proceeding was based on Elmo's advertising claims with respect to preparations and devices identical with those in the instant proceeding. The earlier proceeding was terminated by a consent settlement under which respondents were ordered to cease and desist from claiming, (a) that the use of their preparations "will have any beneficial effect on deafness not caused by a catarrhal condition of nose, ear or air passages," (b) that the beneficial effect of these preparations in the treatment of deafness or head or ear noises by a discharging catarrh is "in excess of affording temporary relief therefrom," and (c) that the effect of the preparations in the treatment of such conditions when due to dry catarrh is "in excess of softening of the dry exudates, or that any benefit can be expected by reason of this action of respondents' preparations in the treatment of conditions caused by dry catarrh of the ear canal unless the softened exudates are removed by other means." In the earlier proceeding the Commission made findings by consent, and without the taking of testimony, (a) that the use of respondents' preparations will have no beneficial value in cases of impaired hearing, "except when caused by catarrh," (b) that the only beneficial effect of the preparations in the latter type of situation is that of "temporarily relieving the catarrhal condition and the resulting deafness or impaired hearing and ear and head noises," and (c) that when these conditions are due to a so-called dry catarrh, the benefits derived from the use of respondents' preparations are "limited to the softening of the dried

exudates." Respondents contend that the claims they now make for their preparations are limited to those permitted under the order and findings in the *Elmo* case (RR, p. 8).⁸

20. While, as previously stated, it is the position of complaint counsel that respondents' advertising is not limited to a claim of mere temporary relief of the indicated conditions, they contend that even if respondents' advertising is deemed to be so limited it is false, since their preparations and devices have no therapeutic value in the treatment of these conditions, either as a cure or effective treatment, or as affording even temporary relief. For this purpose counsel called three prominent otolaryngologists (ear, nose and throat specialists). One of these, Dr. Donald F. Proctor, is Associate Professor of Laryngology and Otology at the Johns Hopkins University Medical School, and is Otolaryngologist in Charge of Baltimore City Hospitals (CX 6-A). The second, Dr. Samuel L. Fox, is Associate Professor of Otolaryngology and a Lecturer in Pharmacology at the University of Maryland Medical School. In addition, Dr. Fox is engaged in private practice specializing in diseases of the eye, ear, nose and throat and is a prominent staff member of a number of hospitals in Baltimore City (CX 7-A; Tr. 290). The third physician, Dr. David Myers, is Professor of Otorhinolaryngology at the University of Pennsylvania Medical School, and Director of the Institute of Otology at Presbyterian Hospital, Philadelphia. In addition, he is engaged in private practice specializing in diseases of the ear, nose and throat (CX 9-A; Tr. 423). All three physicians are the authors of numerous articles appearing in medical journals dealing with diseases of the ear, nose and throat. It was the burden of their testimony that respondents' preparations and devices have no therapeutic value, either as a cure or treatment, or even as affording temporary relief in cases involving poor hearing or ear noises, whether caused by catarrh or otherwise. The testimony of these witnesses will be hereafter discussed in greater detail.

21. In support of their position that their preparations and devices will afford temporary relief for catarrhal caused hearing impairment and ear noises, respondents rely principally on the testimony of three medical witnesses and on extracts from certain

⁸ Respondents' motion to dismiss the complaint herein, which has been heretofore referred to, was based on the ground that if its preparations had no therapeutic value, even that of affording temporary relief for the indicated conditions, the Commission should have reopened the earlier proceeding, rather than issuing a new complaint against them. As previously stated, this motion was denied by the undersigned and respondents' application to file an interlocutory appeal from this order was denied by the Commission.

textbooks in the fields of Pharmacology and Otolaryngology.⁹ The first of respondents' medical witnesses, Dr. McKeen Cattel, although possessing an M.D. degree, was actually a pharmacologist. While prominent in the field of pharmacology, he made no pretense to being an expert in the field of drugs used in diseases of the ear, nose and throat (Tr. 596). His testimony was limited principally to a pharmacologic properties possessed by the drugs used in respondents' preparations. The second witness, Dr. Benjamin Calesnick, while also possessing a medical degree and engaging in a limited amount of general medical practice, was principally engaged in research in the field of human pharmacology at a medical college in Philadelphia, where he was dealing mainly with the use of drugs in persons not in a state of disease (Tr. 652). Although knowledgeable in the field of drugs used in the treatment of persons with upper respiratory infections, he conceded his lack of expertise in diseases of the ear, nose and throat (Tr. 670). Neither his testimony nor that of Dr. Cattel established that respondents' preparations have any value in the alleviation of ear noises or hearing impairment due to catarrhal conditions of the head. The third medical witness called by respondents, Dr. Harry K. Cherken, is a practicing otolaryngologist, who identified certain textbooks as authoritative and testified concerning his examination of certain users of respondents preparations. He expressed no opinion as to the efficacy of respondents' preparations beyond the fact that there was a "possibility" they might relieve ear noises under certain limited conditions (Tr. 743). In addition to these three professional persons, respondents called two users of respondents' preparations who claimed to have received some relief from their ear difficulties by the use thereof.

22. Before seeking to resolve the issue of whether respondents' preparations and devices will or will not achieve the therapeutic benefits claimed for them, it is necessary to first define more precisely the nature of the conditions for which it is claimed such benefits will be achieved. As previously noted, respondents' claim that their preparations and devices will have a beneficial effect on poor hearing and ear noises is limited to cases where these ear problems are "caused by catarrhal (excess fluid mucus) condi-

⁹ The textbooks in question were identified by respondents' medical witnesses as being "authoritative" texts in their field, and were received in evidence by the undersigned over objection of complaint counsel. Although of the opinion that textbooks (even authoritative ones) should not ordinarily be received as direct evidence, lest hearings in medical cases degenerate into "trial by textbook," the examiner was constrained to overrule the objection of complaint counsel, under the authority of the Commission's decision in *Sinkram, Inc.*, Docket No. 8490, February 28, 1964 [64 F.T.C. 1243].

tions of the head." In present day medical parlance there is no such disease or condition as a "catarrh." The word "catarrh" was used in earlier medical practice, when doctors had a poorer understanding of these conditions, as referring to a symptom complex in which there was an inflammation of the mucous membrane of the head or throat, whose origin was uncertain and which was accompanied by an excess secretion of fluid from, and a swelling of, the membrane of the affected areas (Tr. 100, 119, 303, 335, 430, 709). The term "catarrh" is still used and understood by members of the lay public, as involving an excess secretion of fluids in areas of the head and throat, accompanied by a feeling of stuffiness or congestion, and sometimes by a cough. However, very often people think they are suffering from what they refer to as a "catarrh," but they are merely overly conscious of the mucus which is a normal secretion from the membranes (Tr. 100, 225, 462).

23. It is respondents' contention that a catarrhal inflammation of the membrane in the nasopharyngeal tract will tend to spread to and block the eustachian tube, causing a drop in pressure within the tube and the production of a serous fluid within the middle ear (RPF, p. 10). This condition is known as serous otitis media,¹⁰ and is frequently accompanied by an impairment of hearing and tinnitus (ear noises). While it is true that a blockage of the eustachian tube may cause serous otitis media and resultant hearing impairment and tinnitus, as respondents contend, it is not true that such blockage is commonly caused by a catarrhal condition (excess fluid) in the nasopharynx.¹¹ The greater weight of the persuasive medical evidence in the record is to the effect that only an "insignificant proportion" of cases of poor hearing or ear noises is due to an excess of mucus alone and without infection or other pathological factors being present (Tr. 101, 222, 307, 310, 353). Furthermore, a catarrhal inflammation of the nose and throat does not necessarily spread to the ear canal and thereby affect the eustachian tube (Tr. 129, 452).

24. The commonest cause of eustachian tube blockage is the mechanical blockage of the tube due to enlarged adenoid tissue. Other frequent causes of blockage are discharge from sinus infection and allergic rhinitis (nasal allergy). (Tr. 128, 205). While serous otitis media may be caused by blockage of the eustachian tube,

¹⁰ The medical term of the disease derives from the Latin, serous being the serous fluid given off by the membrane, otitis being "ear" and media being "middle" (Tr. 356).

¹¹ In their advertising literature respondents state that "Catarrhal conditions of the head are a common cause of poor hearing and ear noises," and that the blocking of the eustachian tube "is a common cause of poor hearing and ear noises" (CX 3-I, 4-E).

it is not uncommon to have serous otitis and resultant ear difficulty without any blockage of the eustachian tube and despite the fact that the tube is wide open (Tr. 355, 406). In any event, whether resulting from blockage of the eustachian tube or not, in the condition known as serous otitis media the middle ear cavity becomes filled with a serous fluid secreted by the membrane. Such fluid, after a period of time, may become hardened. The serous secretion interferes with the conduction of sound and causes varying degrees of hearing impairment. It may also be accompanied by ear noises. This type of middle ear condition involves an inflammation and swelling of the mucous membranes of the middle ear, without any evidence of infection being present. It is sometimes referred to as secretory otitis media or as catarrhal otitis media. Where the condition is brought about by, or involves some form of, infection in the middle ear it is referred to as suppurative otitis media (Tr. 120, 128, 130, 345, 354-356, 394, 398, 431-433).

25. Respondents claim that their preparations and devices will afford relief for hearing difficulties or ear noises is limited to cases where these conditions are of catarrhal, *i.e.*, inflammatory, but not infectious, origin. Such therapeutic value as they may have in relieving deafness and ear noises is conceded to be limited to cases where a catarrhal inflammation in the head has affected the eustachian tube-middle ear complex (CX 3 I-J; CX 4 A, E, F; RX 2 C). Essentially, this means that the only persons who could conceivably receive relief from poor hearing or ear noises, by the use of respondents' preparations, are those persons whose auditory difficulties are due to serous (catarrhal) otitis media which has been brought about by closure of the eustachian tube. No claim is made that persons with suppurative (infectious) otitis media will receive relief from respondents' preparations. On the contrary, respondent advises prospective users that "if there is infection present in the ear canal" the treatment should not be used "since use may have the tendency to spread it [the infection]" (CX 3 B). Nor is it contended that respondents' preparations have any efficacy in cases of hearing impairment or ear noises arising from difficulties in the inner ear.

26. Before considering whether respondents' preparations and devices will or will not afford relief in the narrow class of cases where it is claimed they have utility, it should be noted that respondents' claims presuppose (a) that eustachian tube blockage and resultant hearing difficulties are commonly brought about by

excess mucus secretion in the nasopharynx,¹² and (b) that the average person suffering from hearing impairment or ear noises is able to determine, without a medical examination, that his difficulties are the result of serous otitis media brought about by blockage of the eustachian tube, and are not the result of suppurative otitis media (infection in the middle ear) or of some disease in the inner ear. With respect to the first supposition, it has been previously noted that only an "insignificant proportion" of cases of eustachian tube blockage and hearing impairment is due solely to an excess of mucus in the nasopharyngeal tract. With respect to the second supposition, the evidence in the record establishes that the symptoms contained in respondents' advertising literature are applicable to a number of different diseases of the middle ear and inner ear, and that the average layman cannot determine what is causing his hearing difficulties without a medical examination. Where the condition is of infectious origin, persons using respondents' preparations may delay in seeking necessary medical treatment, with the result that they may sustain a permanent impairment in hearing or suffer more dire consequences (Tr. 107, 143, 150, 152, 306, 310, 361-362, 435-436).

27. The greater weight of the credible evidence establishes that even in cases of hearing impairment or ear noises brought about by catarrhal conditions of the head, respondents' preparations and devices are of no value, either as a cure or a method of treatment, or as affording any type of effective relief from such hearing impairment or ear noises. The examiner will hereafter separately discuss the purported therapeutic properties of each of respondents' preparations and devices. However, it is sufficient to note at this point that, with one exception, they consist of drugs which are applied to the ear, nose or throat. The essential drugs which are claimed to have any therapeutic value in most instances purport to possess analgesic, anesthetic, antiseptic, astringent or counter-irritant properties, or a combination of such properties. It is the burden of the credible medical evidence in this record that none of these drugs has any value in relieving catarrhal conditions of the head, or hearing impairment or ear or head noises caused by a catarrhal condition of the head or caused by any other condition (Tr. 114-115, 162, 185, 311, 318-319, 441-443). None of the drugs is capable of reaching the areas of the middle ear which are the situs of the hearing impairment or ear noises. While conceivably

¹² See n. 11, *supra*.

some of them might reach the opening of the eustachian tube this would have no substantial beneficial effect since in most instances of serous otitis media with eustachian tube blockage, the entire tube and middle ear cavity are inflamed and swollen. To the extent any of the drugs might conceivably open the tube, the effect would be momentary and fleeting, and the tube would close again unless the underlying cause of the inflammation was removed. In cases of hearing impairment and ear noises due to an inflammation in the middle ear there is no such thing as affording effective relief, short of taking measures to clear up the basic condition which is causing the inflammation. This may involve the prescribing of decongestants or antibiotics by mouth, or the opening of the middle ear cavity surgically. While drugs such as some of those sold by respondents were used in the past by physicians in treating ear conditions, their use was abandoned a great many years ago because they were found to be harmful and ineffective. To the extent drugs are used in the ear cavity or nasal area for hearing difficulties they should be applied by a physician through a nasopharyngoscope or be used under his direction. The only portion of respondents' treatment not involving the use of drugs is the ear vibrator. This method of treatment is not only ineffective, but is dangerous and may force infection into the inner ear (Tr. 207, 230, 235, 261, 237, 349, 372, 391, 396-400, 469, 471, 478, 482, 486, 311, 439).

28. The examiner is not persuaded by the medical evidence offered on behalf of respondents that their preparations and devices will have any material benefit in the cure, treatment or relief of hearing difficulties or ear noises. While Dr. Cattell (the pharmacologist) testified that such preparations would "tend to relieve" catarrhal conditions by "liquefying, moving and washing out the mucus" (Tr. 637), he made no direct claim that they would be effective in relieving hearing impairment or ear noises due to a catarrhal condition of the head. Dr. Cattell admittedly is not an "expert" in the therapeutic effectiveness of drugs used in the field of ear, nose and throat medicine (Tr. 569, 591, 596). While claiming to be familiar with the "pharmacological properties" of "most" of the drugs contained in respondents' preparations, he was frank enough to admit that "we would like to know a lot more about some of them" (Tr. 573-574). Dr. Calesnick, a physician and human pharmacologist (specializing in the action of drugs on nondiseased persons), made no claim to being an expert in the treatment of diseases of the ear. While having some experience in the treatment of colds, coughs and upper respiratory infections, he conceded that

when the inflammation involved the eustachian tube and the patient had catarrhal otitis media, even he would not attempt to treat the patient, but would refer him to "an otolaryngologist" (Tr. 669-670). Dr. Calesnick agreed that there were "101 different causes of tinnitus," and that he would ordinarily refer such patients "to the specialist" (Tr. 661). Dr. Cherken, the only otolaryngologist called by respondents, testified that some of the drugs contained in respondents' preparations had been used in earlier medical practice and had given people "relief" (Tr. 723). The nature of the "relief" afforded was not specified by Dr. Cherken, but from his concurrence with the views expressed in one of the texts offered by respondents, concerning the use of such medications, it seems apparent that he was talking about relief of pain and discomfort, and not relief of hearing difficulties (Tr. 720).¹³ The nearest Dr. Cherken came to testifying that respondents' preparations would relieve ear noises was that there was a "possibility" that they would do so (Tr. 743).

29. The examiner does not find the extracts from the medical texts offered by respondents any more persuasive than their medical testimony, on the issue of the efficacy of respondents' preparations in the treatment or relief of catarrhal deafness or ear noises. Some of the texts were of rather ancient vintage and the examiner is not satisfied that they represent current medical opinion.¹⁴ Because of changes which have taken place in scientific knowledge in the field, a great many of the textbooks are out of date and practicing physicians tend to rely more on current medical journals than on texts (Tr. 488). It is noteworthy that the extensive textual material offered by respondents did not include anything from the work by Dr. Francis Lederer, which the doctors on both sides agreed was the outstanding and recognized textbook in the field of otolaryngology (Tr. 338, 722).¹⁵ Aside from whether the textual material offered by respondents is current, it largely fails to support their position concerning the effectiveness of their preparations in the treatment of hearing difficulties and ear noises. Much of the material refers to drugs similar to respondents', as being

¹³ See n. 16, *infra*, for further reference to this text, by Dr. Lawrence R. Boies (RX 10).

¹⁴ One of the texts was published in 1928 (RX 14), and another in 1931 (RX 15). Another of the texts, purporting to have been published in 1959 (RX 17), was actually a republication of a text published in the 1930's. One of the otolaryngologists called in support of the complaint, who had written a chapter in the earlier version and was asked to review the 1959 edition before it was republished, advised the editor not to publish the material because at least half of it was out of date. The book was nevertheless republished without change. (Tr. 337, 464).

¹⁵ Respondents' witness, Dr. Cherken, characterized Dr. Lederer's text as a "favorite of mine," and had no recollection of "having seen any mention about those [respondents' drugs] in his book" (Tr. 722).

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useful in relieving pain and discomfort, and not for the treatment or relief of hearing impairment or ear noises.¹⁶ In general, the texts agree with the position of the doctors called in support of the complaint that in any middle ear disease treatment should be directed at eliminating the cause.¹⁷ Several of the texts refer to the use of certain mechanical devices and procedures to help inflate the eustachian tube. Aside from the fact that the texts contemplate application thereof by a physician, not a layman, such methods are now regarded as ineffective and dangerous, and have been largely abandoned (Tr. 481-483, 212-214, 317).

30. As heretofore mentioned, respondents offered the testimony of two so-called "user" witnesses, in an effort to establish that their preparations afford relief. Respondents sought to give this lay testimony an aura of scientific validity by having these individuals, along with three other users, examined by Drs. Calesnick and Cherken. Dr. Calesnick did not actually conduct a physical examination of the five individuals, either prior to or subsequent to their use of respondents' preparations, but merely took their case histories and referred them to Dr. Cherken. The latter conducted a limited otoscopic examination and sent them to a hospital for audiometric tests and X-ray examination. Only two of the five individuals examined actually testified. In the opinion of the examiner the testimony regarding the use of respondents' preparations by the five individuals in question has little probative value on the issues here presented. If anything, it tends to establish the lack of therapeutic value of the preparations. Of the five persons who had used respondents' preparations, at least three continued to have some type of ear noise after their completion of the recommended treatment.¹⁸ Furthermore, there is no substantial medical evidence that whatever auditory difficulties these individuals were suffering from were caused by catarrhal conditions of the head. Dr. Calesnick conceded that he could not tell from the

¹⁶ For example, the text by Dr. Lawrence R. Boies refers to the use of ear drops "for the pain accompanying otitis media," and "to relieve earache in acute middle ear disease." It also refers to nose drops and sprays as "add[ing] somewhat to the patient's comfort." Reference is also made to nasal douching as "useful for the patient's comfort" (RX 10 C-D).

¹⁷ One text states that treatment should be directed to "cure the primary affection and to restore the patency of the Eustachian tube" (RX 14-B). Another stresses that treatment should be "directed to the various etiologic [causative] factors" (RX 16-C). Still another states: "Primarily, the cause should be sought and, if possible, removed" (RX 17-C).

¹⁸ According to Dr. Calesnick's testimony, Joseph Akle and Edna Gildersleeve, were still complaining of ear noises at the time he examined them in July 1964 (Tr. 698, 699, 701). While claiming that Joseph McDonald did not complain of ear noises at that time, McDonald testified that he still had noise in one ear, although he claimed it had ceased in the other (Tr. 752). With respect to the other individuals, Dr. Calesnick testified that "[a]s far as I can tell," they were not complaining of noises at the time he saw them (Tr. 700). Mrs. Gildersleeve was still complaining of ear noises at the time of her testimony in September 1964 (Tr. 760).

symptoms described by them, and without a medical examination, what the cause of their difficulties was (Tr. 685, 687, 701). The testimony of Dr. Cherken tends to rule out, in at least three of the cases, the possibility that the ear noises were of catarrhal origin.¹⁹ Dr. Cherken's testimony also establishes that the hearing impairment some of these individuals were suffering from (in addition to ear noises) was not due to catarrhal causes.²⁰ Dr. Cherken made no claim that respondents' preparations could bring, or had brought, relief to any of the individuals examined, except to the limited extent that their hearing noises were purely subjective and they had become convinced that the preparations were doing them some good (Tr. 739-741). The examiner finds nothing in the lay testimony of the two user witnesses to establish that the preparations have any value for the indicated conditions.

31. The examiner now turns to a consideration of each of respondents' preparations, in terms of their pharmacologic properties, with a view to determining the possible therapeutic value of each of them for the conditions at issue. In making this analysis it must be borne in mind that the relief which respondents claim for their preparations is limited to that of softening the dried exudates produced by a catarrhal condition of the head. The softening and removal of the exudates, it is contended, help to restore the patency of the eustachian tube, the blocking of which by catarrhal secretions results in the production of a serous fluid in the middle ear and interferes with the conduct of sound, thereby causing ear noises and a lack of hearing acuity (Tr. 380; Answer, Par. 6-7; Pre-Hearing Order, Par. A6-7; RPF, pp. 8-11). It has heretofore been found that excess catarrhal secretions are responsible for only an insignificant proportion of cases of deafness and ear noises, and that a serous condition of the middle ear frequently occurs without any blockage of the eustachian tube. The question which will now be considered is what value each of respondents'

¹⁹ There is no dispute that, to the extent hearing impairment arises from a catarrhal inflammation which blocks the eustachian tube, there is a drop in pressure within the tube which causes the tympanic membrane (eardrum) to retract (Tr. 728). In the cases of Joseph Akle and Edna Gildersleeve, both of whom were still suffering from ear noises at the time of their examination, Dr. Cherken found that their tympanic membranes were normal (Tr. 726, 729). In the case of Joseph McDonald, who claimed that he still had noise in his *left* ear at the time he testified, Dr. Cherken's examination revealed that "both tympanic membranes appeared normal except for the *right* that was slightly pulled in or retracted" (Tr. 727).

²⁰ The only case in which the medical history revealed a hearing impairment, in addition to ear noises, was that of Joseph McDonald (Tr. 687). However, his audiometric examination revealed that his hearing loss was "due to deterioration of the nerve of hearing rather than mechanical obstruction in the ear itself" (Tr. 733). Joseph Akle was found to be suffering from a loss of hearing in high frequencies, which was due to "acoustic trauma" caused by "working around noise" (Tr. 735).

preparations has in the narrow class of cases in which it is claimed that they afford relief.

a. *Preparation No. 1 (Ear Oil)*. According to respondents' expert in pharmacology, Dr. Cattell, this preparation has "a mild irritant effect * * * is an emollient [and] is a mild antiseptic. It would tend to increase the circulation somewhat," mainly through the action of the methyl salicylate, oil of eucalyptus and capsicum, which act as counterirritants (Tr. 600, 582). Dr. Cattell made no claim that the preparation would have any effect in the softening or removing of dried exudates or otherwise unblocking the eustachian tube. In the instructions which accompany the preparations, respondents claim that this preparation "should help to stimulate the nerves and blood supply to the ear and to lubricate the ear canal and help to relieve any stiffness of the eardrum" (RX 2-A). Nothing is said with reference to the removal of exudate. According to the textual material in Pharmacology offered by respondents, counterirritant drugs are "used to irritate the intact skin for the purpose of relieving pain" and their action in relieving pain has "a strong psychic component" (RX 8-B). This comports with statements in the textual material in Otolaryngology, previously referred to, that ear drops are used principally to relieve pain (n. 16, p. 960, *supra*). The credible testimony of the expert witnesses called by complaint counsel (which includes that of Dr. Fox, who is a pharmacologist as well as an otolaryngologist)²¹ is to the effect that such preparations are of no value in releasing obstructions in the ear and may even make the condition worse (Tr. 239-243, 312, 413, 449-450).

b. *Preparation No. 2 (Nasal Cleanser)*. According to respondents' expert, Dr. Cattell, the effect of this preparation would be that "of a mild antiseptic, a mild local anesthetic, a mild irritant," which would "tend to liquefy, wash out mucus * * * [o]ut of the nose and throat, wherever it gets to" (Tr. 601). No claim was made by Dr. Cattell that the preparation would loosen dried exudate in the ear canal, or would otherwise unblock the eustachian tube. According to the credible testimony of the experts called in support of the complaint, nasal irrigation with drugs of this type has no value in clearing up ear troubles and, moreover, is actually harmful since it may wash away the mucus which is a protective coating of the mucous membrane and may slow down

²¹ Dr. Fox was responsible for the revision of the chapters relating to the eye, ear, nose and throat in Krantz & Carr's textbook on Pharmacology, portions of which were offered in evidence by respondents (RX 8). This is the most widely used book on Pharmacology in the English language (Tr. 295).

ciliary activity, making the patient more liable to infection (Tr. 177, 191, 202, 272, 312, 389-391, 397, 461, 473). This testimony comports with the textual material offered by respondents, to the effect that "[a]ny medication which arrests ciliary activity is considered to be harmful," and advises nasal spraying only in cases where there is *extreme dryness and crusting* in the nose since "in this situation we are not concerned with ciliary activity." Nasal douching is prescribed merely as "useful for the patient's comfort" (RX 10-D).

c. *Preparation No. 3 (Throat Gargle)*. According to respondents' expert, Dr. Cattell, this preparation has "mild anesthetic, mild astringent and mild analgesic effects" (Tr. 602). There is nothing in his testimony to suggest that it will be effective in removing dried exudates or otherwise unblocking the eustachian tube. In their directions for use, respondents indicate that the gargle is intended "to help remove the catarrhal secretions, or mucus, from the *throat*" (emphasis supplied). The textual material offered by respondents makes only two references to throat gargling. In one it is stated that it "may afford relief," the nature of the relief afforded not being specified (RX 17-D). In the other instance it is stated that the "actual value of gargling as a treatment for throat infection has always seemed doubtful" (RX 10-E). The latter comports with the credible testimony of Dr. Fox, the otolaryngologist-pharmacologist, who testified that gargling will not reach the affected areas, will not remove mucus or catarrhal secretion and may be harmful (Tr. 300, 314).

d. *Preparation No. 4 (Vapor Inhaler)*. The only preparation with respect to which respondents make any specific claim of opening the eustachian tube is the vapor inhaler. The instructions accompanying this preparation state that: "This method should help to open or inflate the Eustachian Tubes * * * and send these vapors into the tubes and middle ear, where possible" (RX 2-A). Respondents' expert witness, Dr. Cattell, testified that the drugs would have "primarily" a "counterirritant" action, but would also act as a "local anesthetic" and "an antiseptic" (Tr. 602). The action of a counterirritant has previously been discussed as being that of "relieving pain" and as having "a strong psychic component" (p. 962, *supra*). Dr. Cattell confirmed the fact that the action of such drugs is that of relieving "pain and congestion," but conceded that such action "isn't too well understood." While claiming that the ingredients in the inhaler would reach the opening of the eustachian tube, he made no claims that they would remove

dried exudates (Tr. 603, 605). According to the credible testimony of Dr. Fox, the ingredients in this preparation will merely anesthetize or numb the tissue and cause a person to "feel as though it is opened up because it is anesthetized," but will actually "irritate the eustachian tube and cause them to then become more blocked" (Tr. 316). The only textual material introduced by respondents referring to this type of treatment recommends its use only in cases of "acute laryngitis" and makes no reference to the therapeutic value of the oils and ingredients other than the water, stating that it is the "warm moist air" which is the "most important ingredient in the inhalation" (RX 10-F). According to the greater weight of the credible evidence, even if the ingredients in this preparation were to reach the opening of the tube, they would not be effective since they would not reach or remove the inflammation in the middle ear which is responsible for the difficulty (Tr. 391, 396-399, 468, 482).

e. *Preparation No. 5 (Massage Ointment)*. The claim made for this preparation by respondents in the instructions accompanying it is that it "should help to stimulate the nerves and blood supply to the external ear" (RX 2-B). Their witness, Dr. Cattell, classified its action as being that of a counterirritant, with the petrolatum being merely an oily solution for the capsicum, but he conceded that he wasn't "qualified to testify" whether the preparation would relieve any pain or discomfort in the middle ear (Tr. 606). The credible testimony of Drs. Proctor and Fox establishes that the preparation is wholly ineffective since it will not be able to penetrate the inch of bone and tissue between the back of the ear and the middle ear (Tr. 284, 316). None of the textual material offered by respondents recommends the use of such preparations in the treatment of middle ear diseases.²²

f. *Preparation No. 6 (Nasal Ointment)*. The claim made for this preparation in the instructions accompanying it is that it "should help to relieve much of the catarrhal mucus in the nose and assist in controlling catarrhal congestion and irritation at the mouth of the Eustachian Tubes" (RX 2-B). No claim is specifically made that the preparation will soften and remove dried exudates,

²² Extracts from a 1928 textbook make reference to a procedure called "Otomassage," which is not described in the textual material offered by respondents. However, from the discussion of the procedure it would appear to involve the use of mechanical devices by a physician, and one type of such massage is referred to as "of doubtful efficiency" (RX 14-C). Reference to "judicious massage with a hand-or engine-driven masseur" is made in another text, which was written in the 1930's (n. 14, *supra*), as being "of benefit" (RX 17-E). The procedure obviously contemplates use by a physician. Such mechanical devices are now regarded as ineffective and as dangerous, even when used by a physician (Tr. 482-483).

but the ambiguous statement is made that "if these tubes are open or can be opened, the vapor should penetrate to the middle ear." According to the credible testimony of Drs. Proctor and Fox such ointments have no value in opening the eustachian tube. They merely anesthetize the tissues and make them feel cool, while actually having an irritating effect. The use of such oily preparations can actually be harmful (Tr. 285, 302, 317). Dr. Cattell, respondents' witness, testified that the ingredients would have a slightly antiseptic and anesthetic action, and would tend to increase circulation, but made no claim that they would help to open the eustachian tubes (Tr. 588, 607). No claim is made in any of the textual material offered by respondents that this method of treatment will help open the eustachian tube.²³

g. *Elmo No. 7 (Nasal Douche)*. This device is merely used to apply the ingredients in Preparation No. 2, the nasal cleanser, which has been previously discussed. No further comment is required since whatever efficacy the device has is by virtue of the ingredients in Preparation No. 2.

h. *Elmo No. 8 (Ear Vibrator)*. The instructions which are in evidence do not include any explanation as to what is expected to be achieved by the use of this device. It is merely referred to as being "included in the second month's treatment * * * if you need a second month's treatment" (RX 2-B). Presumably, its purpose is to inflate and open the eustachian tubes. Some of the textual material offered by respondents refers to the use of such mechanical devices as being for the purpose of "tympanic inflation" (RX 16-C, 17-B). However, according to the credible testimony of all the expert witnesses called in support of the complaint, while such equipment was used years ago by doctors, it has fallen into disuse, is regarded as ineffective, and is particularly dangerous when used by a layman because of the possibility of puncturing the eardrum and forcing infection into the inner ear (Tr. 207, 212, 317, 482, 485-487). While the instructions accompanying the device do state that it should not be used if "infection is present in the ear canal," laymen cannot ordinarily determine whether infection is present except when there is an actual discharge from the ear (Tr. 310).

32. Respondents make a final argument for the efficacy of their preparations, based on the manner in which the preparations are ordered and paid for. As previously noted, respondents decline

²³ A 1931 text recommends the application of "an oily solution" in cases of chronic nasal catarrh, following the spraying of the nose (RX 15-B). A more current text recommends the use of nose drops "infrequently and only to allay prolonged nasal obstruction" (RX 18-B). Medical opinion views the use of any oily preparation in the nose as dangerous (Tr. 283, 285).

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approximately one-third of the orders they receive, on the basis of answers to the questionnaire which suggest that the treatment would be ineffective (Tr. 106). The balance of the orders is sold on a 30-day trial basis, under which the user need not pay unless he is satisfied that the treatment has helped him. Approximately 60% of those receiving the treatment pay for it. Respondents suggest that some inference favorable to the therapeutic value of the treatment should be drawn from the fact that there have been "a quarter of a million persons over 30 years who have secured sufficient relief to justify them in writing to Elmo to pay for the treatment" (RR, p. 13).²⁴

33. In the opinion of the examiner there is no merit to respondents' position in this respect. In the first place, the fact that one-third of the orders is declined does not give rise to any inference that the remaining two-thirds is sold only to persons with a catarrhal condition of the head (the only condition for which the treatment is claimed to be effective).²⁵ The declination or acceptance of an order is not made upon the basis of sufficiently reliable information, or by a sufficiently knowledgeable person, to insure that only persons with catarrhal deafness or ear noises will receive the treatment.²⁶ Secondly, and more importantly, the fact that 60% of the persons receiving the treatment pay for it has no probative value. The record suggests any number of reasons why payment was made, other than the fact that relief was secured from the preparations. For example, the evidence which respondents introduced indicates that many cases of tinnitus are of purely subjective origin (Tr. 741; RX 18-C). Very often persons imagine they have a catarrhal condition when they are merely overly conscious of normal mucus secretions (Tr. 100, 225, 462). Even in cases of actual excess mucus secretion and resultant serous otitis media, the condition is frequently self resolving and the patient recovers spontaneously (Tr. 679, 739; RX 10-B, 18-C). It is obvious that persons who were merely over-conscious of normal mucus secretions, or whose tinnitus was subjective or would have disappeared without any treatment, may have paid for respondents' preparations under the impression

²⁴ The figure of 225,000 is based on the fact that respondents sell 15,000 treatments annually, of which 9,000 are paid for, and that they and their predecessor have been in business for 30 years (Tr. 545).

²⁵ Although it was stipulated that one-third of the orders were declined, the actual testimony is that 25% or 30% were declined (Tr. 524).

²⁶ The decision to accept or reject orders is made by respondent Johann's wife, whose only claim to competence in evaluating the applications is that she formerly worked as a medical records librarian (Tr. 553). Her decision is based solely on the "yes" or "no" answers by lay persons as to whether they have symptoms of a catarrhal condition of the head and whether they want treatment for hearing impairment and ear noises (Tr. 552).

that they had been helped when actually the treatment was merely a placebo.²⁷ Since some of the preparations merely anesthetize the tissues, and may produce a feeling, but not the reality, of relief, it seems likely that many persons may have paid for the preparations under the mistaken impression they had actually been helped. There could be any number of additional explanations why persons paid for the treatment even though they had not secured relief, such as the natural tendency of many people to pay for what they have ordered. However, in the light of the overwhelming medical and scientific evidence in the record to the contrary, it is clear that no inference favorable to the therapeutic value of respondents' preparations can be drawn merely from the fact that many users paid for them under the 80-day trial arrangement.

Concluding Findings As To Falsity of Advertisements

34. From the record as a whole, including the evidence hereinabove discussed, it is concluded and found that:

a. Respondents have represented and are now representing in their advertising literature that the use of their preparations and devices will cure or constitute an effective treatment for poor hearing or ear noises or head noises or catarrhal conditions of the head.

b. Even if respondents' advertising literature may be interpreted as offering prospective users merely temporary, and not permanent, relief from the foregoing conditions, respondents have represented and are now representing therein that such relief will be effective for a reasonably extended period.

c. Respondents concede, for purposes of this proceeding, that their preparations and devices have no therapeutic efficacy in excess of affording temporary relief for deafness or impaired hearing and ear or head noises caused by a catarrhal (excess fluid mucus) condition of the head. Respondents contend that the temporary relief afforded by its preparations and devices in such conditions is secured by the softening of dried exudates, which have blocked the eustachian tube and interfered with the conduction of sound in the middle ear.

d. Respondents have represented and are now representing that catarrhal conditions of the head are a common cause of poor hearing and ear noises. In offering their preparations for the relief of catarrhal deafness and ear noises respondents have implied and

²⁷ There is a strong suggestion that the two user witnesses, one of whom was in the 70's and the other in the middle 60's, were merely overly conscious of normal mucus secretions. Both paid for the treatment despite the fact that they continued to have ear noises. The principal relief they claimed was from mucus in the nose and throat (Tr. 750, 758).

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now imply that the prospective users thereof are able to determine whether their hearing impairment or ear noises are of catarrhal origin.

e. Only an insignificant proportion of cases of poor hearing or ear noises are the result of a catarrhal (excess fluid mucus) condition of the head. The average layman cannot determine, without a medical examination, whether his hearing impairment or ear noises are of catarrhal origin. While respondents purport to describe the symptoms of catarrhal deafness and ear noises in their advertising literature, a number of such symptoms are applicable to deafness and ear noises arising from a variety of diseases and conditions in the middle ear and inner ear, other than from a catarrh.

f. The record establishes, and respondents concede, that respondents' preparations and devices, when used as directed or otherwise, will not cure and do not constitute an effective treatment for poor hearing or ear noises or head noises or catarrhal conditions of the head. The record also establishes that respondents' preparations and devices, when used as directed or otherwise, will not afford effective relief from any of the foregoing conditions and will not have any beneficial effect thereon.

g. It is concluded and found that the respondents' advertisements, portions of which are set forth in Paragraphs 5-10 of this decision, were and are misleading in material respects and constituted, and now constitute, "false advertisements," as that term is defined in the Federal Trade Commission Act.

CONCLUSION OF LAW

The dissemination by respondents of false advertisements, as hereinabove found, constituted, and now constitutes, unfair and deceptive acts and practices in commerce, in violation of Sections 5 and 12 of the Federal Trade Commission Act.

ORDER

It is ordered, That respondents Drive-X Company, Inc., a corporation, trading as The Elmo Company, and its officers, and Craig Sandahl and Richard Johann, individually and as officers of said corporation, and respondents' representatives, agents and employees, directly or through any corporate or other device, in connection with the offering for sale, sale or distribution of preparations and devices referred to as the "Elmo Palliative Home Treatment," or any other preparations or devices of similar composition or possessing substantially similar properties, do forthwith cease and desist from, directly or indirectly:

1. Disseminating, or causing the dissemination of, 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 represents directly or by implication, that the use of its said preparations and devices, singly or in combination, as directed or otherwise, will have any beneficial effect on hearing loss or head noises or ear noises or catarrhal conditions of the head, including the nose, ear and air passages.

2. Disseminating, or causing to be disseminated by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase of respondents' preparations and devices, in commerce, as "commerce" is defined in the Federal Trade Commission Act, any advertisement which contains any of the representations prohibited in Paragraph 1 hereof.

ORDER DISMISSING COMPLAINT AND VACATING EXAMINER'S

INITIAL DECISION

The Commission having this day issued an "Order Vacating Order to Show Cause and Reopening Proceeding to Determine Whether a Change of Law or Fact or the Public Interest Requires Setting Aside Consent Settlement in Whole or in Part" in Docket No. 5959 [p. 1229 herein], and it thus appearing to the Commission that it is no longer necessary or appropriate to continue the proceeding herein; accordingly

It is ordered, That

The complaint in Docket No. 8615 be, and it hereby is, dismissed as to all respondents, and the initial decision of the hearing examiner issued February 4, 1965, be, and it hereby is, vacated.
