

IN THE MATTER OF
THE ELMO COMPANY, INC.*

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

Docket 5959. Complaint, Feb. 28, 1952—Decision, Nov. 18, 1966

Order setting aside a consent settlement and order against a manufacturer of hearing aids, dated June 10, 1952, 48 F.T.C. 1379, and suspending the effective date of revocation until a new order issues.

CERTIFICATION OF RECORD WITH FINDINGS OF FACT, CONCLUSIONS
AND RECOMMENDATIONS THEREON IN CONFORMANCE WITH
COMMISSION'S REOPENING ORDER OF DECEMBER 1, 1965

JUNE 15, 1966

HISTORY OF THE PROCEEDING

Complaint issued against the above respondent on February 28, 1952, charging violation of the Federal Trade Commission Act in the interstate advertising, sale and distribution of drug preparations and devices for treatment of disorders of the human ear. Respondent, prior to hearing, entered into a consent settlement containing a cease and desist order which was accepted by Commission order on June 10, 1952 [48 F.T.C. 1379]. Paragraph 3, page 1387 of the consent settlement provides it may be set aside, in whole or in part, under the conditions and in the manner provided in paragraph (f) of Rule V of the Rules of Practice then in effect.¹ The requirements of paragraph (f) of Rule V in the con-

*The complaint was dismissed on March 18, 1971.

¹ The rule in effect at the time of the consent settlement reads as follows: "(f) Pursuant to a change of law or facts, or when the public interest so requires, a consent settlement may be altered, modified, or set aside, in whole or in part, upon consent of all parties. All consent settlements shall contain an agreement that if consent to a change desired is not obtained, the Commission or any respondent may file a motion in the case to set aside such consent settlement, in whole or in part, on the grounds of change of law or fact or that the public interest so requires; and after opportunity for hearing upon the issues formed, the Commission may,

sent settlement are spelled out in the February 11, 1965, opinion of the United States Court of Appeals for the District of Columbia Circuit in *The Elmo Division of Drive-X Company, Inc., et al v. Federal Trade Commission*, 348 F. 2d 342.

The docket file shows that on September 16, 1965, the Commission entered an order herein entitled Order To Show Cause Why Proceeding Should Not Be Reopened which recited the 1952 consent settlement order to cease and desist, and directed, among other things, that the respondent may show cause why the public interest does not require (1) that the proceeding be reopened, (2) that the order of June 10, 1952, be vacated and set aside, (3) that the complaint be amended as per the amended complaint accompanying this order (4) that after appropriate proceedings the order to cease and desist attached to the amended complaint be entered. The accompanying amended complaint provided for an order to cease and desist more restrictive than that contained in the consent settlement. This order to show cause was vacated by the Commission on December 1, 1965 [68 F.T.C. 1229].

The foregoing vacating Commission order of December 1, 1965, is entitled 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. This reopening order refers the matter to a hearing examiner for the purpose of receiving evidence, provides that the proceeding be conducted pursuant to the Commission's Rules of Practice for Adjudicative Proceedings insofar as applicable, and directs that the hearing examiner upon the conclusion of the hearing, certify the record, together with a report of his findings, conclusions and recommendations with respect thereto, to the Commission for disposition.

A stenographically reported prehearing conference was held herein on February 18 and March 18, followed by a brief hearing on April 18 and 19, 1966. The record consists of the complaint, the consent settlement and order to cease and desist, the instant Commission reopening order, the answer filed thereto by respondent, a record stipulation between respective counsel, Commission Exhibit No. 1 a bound indexed documentary exhibit, and Respon-

if it finds that a change of law or fact, or the public interest so requires, set aside the consent settlement or any part thereof which is separable from the remaining provisions without changing their effect. Thereafter, the Commission may, by adversary proceedings pursuant to the original complaint, or a new or amended and supplemental complaint, undertake corrective action as to any acts or practices not prohibited by any remaining provisions of the consent settlement."

dent's Exhibit Nos. 2 and 3 also bound indexed documentary exhibits.

Commission Exhibit No. 1 in evidence contains reproductions of respondent's magazine and newspaper advertisements, and follow-up literature sent by respondent to potential purchasers of the "Elmo Palliative Home Treatment." Included in the exhibit is a listing of the professional qualifications and published works of three medical doctors and excerpts of the testimony they would give on direct examination if called as witnesses. Respondent's Exhibit No. 1 contains excerpts from the testimony on cross-examination which would be given by these Commission medical witnesses, as well as excerpts from the testimony which would be given on direct examination by respondent's three medical witnesses and their professional qualifications. Included in the exhibit are excerpts from the testimony on direct examination of one of respondent's officials and two lay users of respondent's products if called as witnesses. Respondent's Exhibit No. 2 contains literature connected with claimed satisfactory use by various purchasers of the "Elmo Palliative Home Treatment," a listing of the Published works and professional associations of its three medical witnesses, and extracts from various medical texts.²

Proposed findings of fact, conclusions and supporting briefs were filed by respective counsel and a stenographically reported oral argument was held before the hearing examiner on June 10, 1966. Proposed findings of fact and conclusions submitted and not adopted in substance or form as herein found and concluded are hereby rejected.

After carefully reviewing the entire record of this proceeding as hereinbefore described, it is hereby certified to the Commission in conformance with the reopening order herein of December 1, 1965, together with the following findings of fact, conclusions and recommendations for disposition by the Commission.

FINDINGS OF FACT

1. The Drive-X Company, Inc., trading as The Elmo Company, hereinafter referred to as "respondent" is a corporation organized, existing and doing business under and by virtue of the laws

² The evidentiary material contained in these exhibits was extracted from the record of testimony and exhibits in Docket No. 8615, *In the Matter of The Drive-X Company, Inc., et al., trading as The Elmo Company*. The initial decision in Docket No. 8615 was vacated on September 16, 1965, by the Commission's order therein entitled Order Dismissing Complaint In Part, Vacating Examiner's Initial Decision, and Suspending Proceedings.

of the State of Iowa, with its principal office and place of business at Second and Main Streets, in the city of Madrid, in the State of Iowa. Respondent is successor in interest to The Elmo Company, Inc., a corporation formerly organized, existing and doing business under and by virtue of the laws of the State of Iowa with its principal place of business in Davenport, Iowa.³

The Drive-X Company, Inc., trading as The Elmo Company, the corporate successor to The Elmo Company, Inc., is bound by the order to cease and desist contained in the June 10, 1952 consent settlement in this proceeding in the same manner and to the same extent as its corporate predecessor, The Elmo Company, Inc.⁴

2. Respondent is now, and for some time last past, has been engaged in the sale and distribution of certain drug preparations 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 respondent as the "Elmo Palliative Home Treatment."

The designations and formulae used by respondent for its said preparations and the designation and description for said devices are as shown on pages 1387 through 1393 of the prior findings of fact in this matter (48 F.T.C. 1379) with the addition of 20 pounds of sugar of milk to each 200 pounds of the formula for Elmo Nasal Cleaner No. 2. The directions for use of such preparations and the devices are as shown in Respondent's Exhibit No. 2.⁵

3. Respondent causes its said preparations and devices, when sold, to be transported from its place of business in the State of Iowa to purchasers thereof located in various other States in the United States and in the District of Columbia. Respondent maintains, and at all times mentioned herein has 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.⁶

4. In the course and conduct of its business, respondent has disseminated, and cause the dissemination of, certain advertisements concerning its said preparations and devices by the United States mails and by various means in commerce, as "commerce" is

³ See paragraph 1 of record stipulation between counsel at Tr. 17-18.

⁴ See paragraph 2, page 1 of answer filed by respondent on February 8, 1966, to the Commission's reopening order of December 1, 1965 [68 F.T.C. 1229].

⁵ See paragraph 2 of record stipulation between counsel at Tr. 18.

⁶ See paragraph 3 of record stipulation between counsel at Tr. 18-19.

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 has disseminated, and caused the dissemination of, advertisements, of 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.⁷

5. The unnumbered findings of fact and the conclusion in the 1952 consent settlement, entered into prior to a hearing in this proceeding, are but a reiteration of paragraphs one through twelve of the 1952 complaint issued against the respondent. The paragraph of the consent settlement findings as to the facts, permissive of certain representations in the consent settlement order to cease and desist now in effect in this proceeding, corresponds with the allegations of paragraph seven of the complaint and reads as follows:

The said advertisements are misleading in material respects and constitute "false advertisements" as that term is defined in the Federal Trade Commission Act. In truth and in fact, the use of respondent's preparations, as directed or otherwise, will have no beneficial value whatsoever in cases of deafness and impaired hearing except when caused by catarrh, that is, a chronic, inflammation of, and hypersecretion from, the membranes of the nose, ear or air passages. When deafness or impaired hearing, together with ear or head noises, result from discharging catarrh, the use of respondent's preparations, as directed or otherwise, will have no beneficial effect in the treatment of said conditions in excess of temporarily relieving the catarrhal condition and the resulting deafness or impaired hearing and ear and head noises. In cases of deafness or impaired hearing and head and ear noises resulting from so-called dry catarrh, the benefits derived from the use of said preparations, as directed or otherwise, are limited to the softening of the dried exudates. Respondent's treatment would not usually result in the removal of these exudates from the ear canal and, until removed by other means, the deafness or impaired hearing and head and ear noises due to these exudates would be expected to continue. The use of Elmo No. 8 Ear-Vibrator, as directed or otherwise, will have no beneficial effect in the treatment of deafness or impaired hearing or of ear or head noises due to catarrh. Respondent's method of treatment and the preparations and device employed is not based on the findings of any accepted medical authorities. Catarrh is not the most common cause of deafness. Respondent's Elmo Ear Oil No. 1 and Elmo No. 8 Ear-Vi-

⁷ See paragraphs 4 and 11 of record stipulation between counsel at Tr. 19 and 25.

brator are not safe to use and may cause injury to the user as is more fully set out hereinafter.

The foregoing finding as to the facts in the consent settlement, as translated into the order to cease and desist in the consent settlement, has resulted in the following paragraphs now in effect in the said order to cease and desist:

(a) That the use of its preparations and device, singly or in combination, as directed, or otherwise, will have any beneficial effect upon deafness not caused by a catarrhal condition of the nose, ear or air passages.

(b) That the use of its preparations and device, singly or in combination, as directed, or otherwise, will have any beneficial effect in the treatment of deafness, impaired hearing, or head or ear noises caused by discharging catarrh, in excess of affording temporary relief therefrom.

(c) That the effects of its preparations in the treatment of deafness or impaired hearing or head or ear noises 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 respondent's preparations in the treatment of conditions caused by dry catarrh of the ear canal unless the softened exudates are removed by other means.⁸

6. Subsequent to the consent settlement herein, respondent's advertising was revised in the alleged effort to conform with the various requirements of the order to cease and desist outstanding.⁹ The revised advertising for respondent's products, disseminated as set forth in preceding finding number four, is as shown in Commission's Exhibit No. 1.¹⁰ Typical of such advertising is 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 or throat every day. Hear—but don't understand words. Hear better on clear days—worse on bad

⁸ The balance of the consent settlement order to cease and desist contains no permissive qualifications and further requires disclosures of possible harm to users of respondent's products.

⁹ See paragraph 3, pages 1-2 of answer filed by respondent on February 8, 1966, to the Commission's reopening order of December 1, 1965.

¹⁰ See paragraph 5 of record stipulation between counsel at Tr. 19.

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 the treatment is used as needed. Write now for PROOF of RELIEF & 30 DAY TRIAL OFFER. THE ELMO COMPANY, Dept. H25B Madrid, Iowa.

Respondent's advertising in the main is directed to the elderly, and the volume of respondent's business is substantial. The testimony of respondent's official, Craig W. Sandahl, in Respondent's Exhibit No. 1, at page 116 (f) and Commission's Exhibit No. 1, at pages 72-73 and 83-84, shows that respondent sends out about 15,000 treatments a year and that out of the number of people replying to respondent's advertisements over the past 30 years, approximately 60% or one quarter of a million people have paid respondent either respondent's first asking price of \$10 or the follow-up price of \$7.35.

People replying to respondent's advertising are sent reproduced follow-up testimonial letters¹¹ extolling respondent's treatment, and making claims for its use, for example, as appears in one such letter: "Here I want to say I feel a complete cure." An examination by the hearing examiner¹² of these advertising and follow-up testimonial letter exhibits shows them plainly susceptible of being interpreted and understood by the purchasing public¹³ as representing, directly or impliedly, that respondent's "Elmo Palliative Home Treatment" will have a beneficial effect on and cure or constitute an effective treatment for poor or lost hearing, ear and head noises, and so-called catarrhal conditions of the head.

7. Commission counsel in the absence of the present record stipulation would call the following witnesses: Dr. Donald F. Proctor, Dr. Samuel L. Fox and Dr. David Myers, whose qualifications, experience and publications are as shown in Commission's Exhibit No. 1.¹⁴ The named witnesses if called by Commission counsel would testify under direct examination as shown in Commission's Exhibit No. 1.¹⁵

¹¹ Comm. Ex. No. 1, pages 63-68.

¹² See April 8, 1966, opinion of the Commission and cases therein cited, Docket No. 8635, *In the Matter of Merck & Co., Inc., et al.* [69 F.T.C. 526] as to a finding based on such examination.

¹³ "Advertisements are intended not 'to be carefully dissected with a dictionary at hand, but rather to produce an impression upon' prospective purchasers" and "the law is not made for experts but to protect the public—that vast multitude which includes the ignorant, the unthinking and the credulous, who in making purchases do not stop to analyze but to often are governed by appearances and general impressions." *Aronberg v Federal Trade Commission*, 132 F. 2d 165, 167-168.

¹⁴ See paragraph 6 of record stipulation between counsel at Tr. 19.

¹⁵ See paragraph 7 of record stipulation between counsel at Tr. 19-20.

8. Counsel for respondent in the absence of the present record stipulation would call the following witnesses: Dr. McKeen Cattell, Dr. Benjamin Calesnick and Dr. Harry Cherken, whose qualifications, experience and publications are as shown in Respondent's Exhibit No. 2. In addition, respondent would call certain user witnesses.¹⁶

9. The foregoing named witnesses if called by counsel for respondent would testify under direct examination and the witnesses to be called by Commission counsel would testify on cross-examination as shown in Respondent's Exhibit No. 1.¹⁷ In addition to the foregoing testimony, respondent would offer the exhibits from medical texts and other facts as shown in Respondent's Exhibit No. 2.¹⁸

10. The proffered testimony of respondent's official, Craig W. Sandahl, discloses that Respondent's business records show that the "Elmo Palliative Home Treatment" has been sold under the same formulae for approximately the past 30 years.¹⁹ Commission's medical witness, Dr. Proctor would testify that he was familiar with the formulae of respondent's preparations and the devices used in the "Elmo Palliative Home Treatment," and further in part would state as follows:

Q. Doctor, based on your scientific knowledge, training, research and experience and bearing in mind the quantitative formulae and the directions for use of the preparations and the devices comprising the Elmo Palliative Home Treatment, what is your opinion as to whether or not this product would be of value in curing catarrhal conditions of the head?

A. As I have said before, the term "catarrhal congestion of the head" is such a vague term that I do not think that any medical man would say that any particular thing would cure it. We would have to be more specific about it.

Q. Using the term "catarrhal" in the sense that it was used in the advertising as excess fluid mucus?

A. Well, I can answer, perhaps, in a general way by saying that as far as I know of my own personal knowledge, there is nothing in these treatments as described in the material that I have seen which I would expect to cure any condition related to the problem about which we have been talking.

Q. Would this opinion include poor hearing or ear noises caused by excess mucus?

A. It does, indeed, and an even more important consideration here is that, as I have already mentioned, there are some very serious disease processes

¹⁶ See paragraph 8 of record stipulation between counsel at Tr. 20. See also, *Merck & Co., Inc.*, and cases cited, footnote 12, *supra*, as to the necessity for and the probative weight to be given the testimony of these lay users of respondent's products.

¹⁷ See paragraph 9 of record stipulation between counsel at Tr. 20.

¹⁸ See paragraph 10 of record stipulation between counsel at Tr. 20.

¹⁹ Resp. Ex. No. 1, pages 117-119.

Certification of Record

70 F.T.C.

which can cause these symptoms, such as the brain tumor or any number of things that I could mention, multiple sclerosis and so forth and so on, which might go undiagnosed if the patients were going through any long period of time with treatments such as this thing and he was not getting at the base of his trouble.

Q. What is your opinion as to whether or not this product would be of value as a cure for poor hearing or ear noises caused by any other condition other than excess fluid?

A. There is no condition that I know of that this would be of any use for.

Q. What is your opinion as to whether or not these products would be of value as an effective treatment for the relief of catarrhal conditions of the head?

A. I would suspect that it might do the reverse. There is one thing that is used in these preparations which might lead the patient to believe he was getting some relief, menthol, which is a topical local anesthetic, a rather poor one, but it is to a degree, and this might temporarily lead a person to believe that he felt a little bit better, but at the same time menthol could be harmful to the mucous membrane and do him more injury than good.

Q. What is your opinion as to whether or not this product would be of value as an effective treatment for the relief of poor hearing, deafness, head noises or ear noises caused by excess fluid mucus?

A. I see no reason to think that it would be of use in the treatment of these conditions.

Q. What is your opinion as to whether or not this product would be of value as an effective treatment for the relief of poor hearing, deafness, head noises or ear noises caused by any other condition?

A. None whatsoever—it would be of no help.

Q. What is your opinion as to whether or not this product would have any beneficial effect on hearing losses or head noises or ear noises or catarrhal conditions of the head?

A. I do not believe it would be of any use whatsoever.²⁰

Commission's medical witness, Dr. Fox, would be in agreement with Dr. Proctor, and further would testify in part as follows:

Q. Doctor, what does the word "catarrh" mean to you?

A. Medically, we do not use the word "catarrh," this is a term that is a lay term. It has no specific meaning. The older books on Pathology before we knew about allergies and before we knew about steroid problems, cortisone problems, before we knew about stress problems, the older books spoke of a catarrhal inflammation, meaning tissues that were swollen and looked irritated, but you could not find any infection in the sense of bacteria. You could not put your finger on what was wrong with you. They were not ulcerated, they were not infective—they were just swollen and edematous and irritated. We have not used this term, except as a hang-over in one or two names which have stuck with us over the years, but we have not used this term in relation to disease of the ear, nose and throat, in about 30 years. It has been about 30 years since they, the books, contained it—we have tried to omit this and have gradually been able to do so. There is no specific Pathology. There

²⁰ Comm. Ex. No. 1, pages 22-25.

1374

Certification of Record

is no specific cause. There is no specific disease. This is really a symptom complex when you do not know what else to call it, and you have no way of explaining it to the patient. As sometimes you say to an older patient, "what you have used to be called a catarrh."

Q. Doctor, using the term "catarrh" as meaning excess fluid mucus as it is used in the advertisement of the Elmo Company, can you tell us whether excess fluid mucus conditions of the head can cause ear noises and poor hearing?

A. They cannot.

Q. In your experience, doctor, what percentage of poor hearing and ear noises are caused solely by what is referred to in this advertisement in 1-A as "catarrhal conditions of the head"—which is excess fluid mucus?

A. I would say none, with the possible exception of the acute colds which for a few hours might block up the ears.

Q. Are older people likely to suffer from poor hearing and ear noises?

A. That is right. There is natural loss of hearing with every decade of life, starting at age 20, just as there is a loss of vision by age, and you wear bifocals as—with a natural loss of hearing.

Q. Doctor, is there anything new or unusual about the preparation or the devices contained in the Elmo Palliative Home Treatment?

A. They are very old preparations. All of the ingredients have been known, since, well, since the 1800's, some older than that. Many of these ingredients are listed in the Bible as being present. They are very old preparations. There is nothing new. That is, about the preparations or their uses. There is no new knowledge about them that would make them any more effective than we thought they were 25 or 30 years ago when most of them were discarded.

Q. Have you used or tested the various preparations included in this treatment?

A. Under the name of "Elmo" preparations?

Q. That is correct.

A. No.

Q. Why not?

A. I would have no confidence or faith that they would have any effect from my knowledge of pharmacology and my knowledge of diseases of the ear, nose and throat. I would not subject a patient in this modern era to such drugs.

Q. Doctor, based on your scientific knowledge, your training, your research and experience, and bearing in mind the quantitative formulae and the directions for the use of the preparations and the devices comprising the Elmo Palliative Home Treatment, what is your opinion as to whether or not this product would be of value in curing catarrhal conditions of the head?

A. It would be worthless.

Q. What is your opinion as to whether or not this product would be of value in curing poor hearing caused by catarrhal conditions of the head?

A. It would be worthless.

Q. What is your opinion as to whether or not this product would be of value in curing ear noises caused by catarrhal conditions?

A. It is worthless.

Q. What is your opinion as to whether or not this product would be of value as a cure for poor hearing or ear noises caused by any other condition?

A. It's worthless.

Q. What is your opinion as to whether or not this product would be of value as an effective treatment for the relief of catarrhal conditions of the head?

A. Ineffective.

Q. What is your opinion as to whether or not this product would be of value as an effective treatment for the relief of poor hearing, deafness, head noises or ear noises caused by catarrhal conditions of the head?

A. Ineffective.

Q. What is your opinion as to whether or not this product would be of value as an effective treatment for poor hearing, deafness, head noises or ear noises caused by any other conditions?

A. Ineffective.

Q. What is your opinion as to whether or not this product would have any beneficial effect on hearing loss or head noises or ear noises or catarrhal conditions of the head?

A. It might have a harmful effect.

Q. Would it have any beneficial effect?

A. No, sir.²¹

Commission medical witness, Dr. Myer, also would be in agreement with the prior medical witnesses Dr. Proctor and Dr. Fox and further would testify in part as follows:

Q. Have you reviewed this complaint including the quantitative formulae and the directions for use for the various preparations comprising the Elmo Palliative Home Treatment?

A. Yes, sir.

Q. Are you familiar with the ingredients in the various formulae?

A. Yes, sir.

Q. Are you familiar with the devices included?

A. Yes, sir, I am.

Q. Is there anything new or unusual about any of these preparations or devices?

A. No, sir.

Q. Doctor, based on your scientific knowledge, training, research and experience, and bearing in mind the quantitative formulae and the directions for use of the preparations and the devices comprising the Elmo Palliative Home Treatment, what is your opinion as to whether or not this product would be of value in curing catarrhal conditions of the head?

A. I would say that the treatments outlined in this pamphlet would not cure catarrhal conditions of the head.

Q. What is your opinion as to whether or not this product would be of value in curing poor hearing caused by catarrhal conditions of the head?

A. My opinion would be that the treatment outlined here would have very little effect on deafness or the cure of deafness.

Q. What is your opinion as to whether or not this product would have any value as a cure for poor hearing or ear noises caused by any other conditions?

²¹ Comm. Ex. No. 1, pages 33, 34, 40, 41, 48-50.

1374

Certification of Record

A. In my opinion this would not cure any form of deafness.

Q. Or ear noises?

A. Or ear noises.

Q. What is your opinion as to whether or not this product would be of value as an effective treatment for the relief of catarrhal conditions of the head?

A. I have a very poor opinion of this product as a treatment for catarrhal conditions of the head.

Q. Could you be more explicit? Do you think it has any value for the relief of catarrhal conditions?

A. I think it has no value for the relief of catarrhal conditions.

Q. What is your opinion as to whether or not this product would be of value as an effective treatment for the relief of poor hearing, deafness, head noises or ear noises caused by catarrhal conditions of the head?

A. In my opinion this form of therapy outlined here would not cure the form of catarrhal deafness.

Q. My question, doctor, was directed to the relief of poor hearing, ear noises, head noises or ear noises caused by catarrhal conditions.

A. I feel that it would not relieve these symptoms.

Q. What is your opinion as to whether or not this product would be of value as an effective treatment for the relief of these same symptoms caused by other conditions other than catarrhal conditions of the head?

A. I feel they would have no effect in relieving these conditions or symptoms or curing them.

Q. What is your opinion as to whether or not this product would have any beneficial effect upon hearing loss or head noises or ear noises or catarrhal conditions of the head?

A. In my opinion the product would not affect the deafness or head noises or cure catarrhal conditions of the head.

Q. My question, Doctor, was directed as to whether it would have any beneficial effect disregarding the cure for the moment.

A. As I mentioned before, the use of nasal irrigation gives some comfort to patients who have crusting in their nose and throat, and if their complaint, problem is with dryness or the presence of large crusts or discharge in their nose and throat by washing their nose with the nasal douche they could clear the products of infection from their nose and throat. But this action would not cure the condition or make any change in the symptomatology. It wouldn't actually do any more good than nose flooding or expelling the products of inflammation from the nose or throat.

Q. Doctor, do you use irrigation to relieve patients who have head noises or ear noises?

A. No, sir.

Q. Would you prescribe the Elmo Palliative Home Treatment for any of your patients suffering from poor hearing, deafness or ear noises?

A. No, sir, I wouldn't.²²

11. The professional qualifications and specialized medical ex-

²² Comm. Ex. No. 1, pages 51, 53-54, 55-58.

perience of the witnesses²³ and the excerpts from their medical testimony set forth in foregoing finding number 10, considered together with the preceding findings herein numbered 5 and 6, show grounds to exist and sufficient reason to believe that the public interest requires and would best be served, by the setting aside in part of the consent settlement's findings as to the fact and the order to cease and desist in this proceeding and the undertaking of corrective action as provided in paragraph (f) of Rule V of the Rules of Practice incorporated in the said settlement.²⁴ This would be in accord with the February 11, 1965, holding of the Appellate Court in *The Elmo Division of Drive-X Company, Inc., et al v. Federal Trade Commission*, 348 F. 2d 342, at 346, footnote 7 of the court's opinion.

In making the instant finding, full consideration has been given by the hearing examiner to the cross-examination of the foregoing medical witnesses by the respondent,²⁵ the medical text book exhibits of respondent,²⁶ the direct testimony, professional qualifications and medical experience of respondent's medical witnesses,²⁷ the lay user testimony²⁸ and the testimonial letters and other material contained in respondent's submitted exhibits.²⁹

12. Respondent's answer filed to the Commission's reopening order herein alleges its advertisements as revised conform to the order to cease and desist of the 1952 consent settlement and make no remedial claims beyond the affording of temporary relief from the described symptoms. Respondent's answer also denies that it has represented either, directly or by implication, that its drugs or devices will cure or constitute an effective treatment for poor hearing, ear and head noises and so-called catarrhal conditions of the head.

Respondent's proposed findings of fact are to the effect, in

²³ Comm. Ex. No. 1, pages 3-9, for Dr. Proctor; pages 10-14, for Dr. Fox; pages 15-20, for Dr. Myers.

²⁴ The provisions of this rule appear on page 1374, footnote 1, *supra*.

²⁵ Resp. Ex. No. 1, pages 3-61, for Dr. Proctor; pages 62-88, for Dr. Fox; pages 89-116, for Dr. Myers.

²⁶ Resp. Ex. No. 2, pages 7a-g, 8a-f, 9a-g, 10a-g, 12a-c, 14a-c, 15 a-b, 16a-d, 17a-e, 18a-d. With regard to the use of medical text books on the direct and cross-examination of medical witnesses or as exhibits, see the February 28, 1964, Commission opinions in Docket No. 8490, *Sinkram Incorporated, et al* [64 F.T.C. 1243].

²⁷ Resp. Ex. No. 1, pages 120-136, and Resp. Ex. No. 2, pages 4a-k, for Dr. Cattell; Resp. Ex. No. 1, pages 136, 136a-n, 137 and Resp. Ex. No. 2, pages 11a-c, for Dr. Calesnick; Resp. Ex. No. 1, pages 138, 138a-d, 139-140, and Resp. Ex. No. 2, pages 13-a-b, for Dr. Cherken.

²⁸ Resp. Ex. No. 1, page 141, for Joseph P. McDonald, pages 142-143, for Edna Gildersleeve.

²⁹ Resp. Ex. No. 2, pages 2a-b, directions for use of the "Elmo Palliative Home Treatment"; pages 3a-c, 19a-z29, confidential report blanks and testimonial letters sent to respondent by lay users of its treatment.

brief, that respondent purchased its corporate predecessor in reliance on a negotiated final consent settlement containing findings as to the facts and an order to cease and desist allowing the advertising of the "Elmo Palliative Home Treatment" to represent to the purchasing public that its use would afford not in excess of temporary relief from the advertised symptoms described, and that respondent's advertising of the said treatment is confined to such a represented result and when used as directed the treatment will afford the represented result as advertised.

Preceding finding number 6, at page 1379, *supra*, would show that respondent's advertising of the "Elmo Palliative Home Treatment" and its follow-up sales literature since the consent settlement are susceptible of the understanding by the purchasing public that the represented result from its use is not so confined as respondent contends,³⁰ but would extend to representing³¹ that respondent's treatment will have a beneficial effect on and cure or constitute an effective treatment for poor or lost hearing, ear and head noises, and so-called catarrhal conditions of the head.

Respondent's medical text book exhibits and the testimony of its medical witnesses submitted on the record of this hearing are directed towards respondent's contention that use of the "Elmo Palliative Home Treatment" will afford not in excess of temporary relief from the symptoms described in its advertising. In turn, the testimony of the medical witnesses as submitted by Commission counsel and set forth in preceding finding number 10, at page 1381, *supra*, is in agreement and unequivocal that the use of the "Elmo Palliative Home Treatment" not only would not afford temporary relief from its advertised described symptoms, but further, that the treatment will not have a beneficial effect on and cure or constitute an effective treatment for poor or lost hearing, ear and head noises, and so-called catarrhal conditions of the head.

Respondent's claimed reliance on the finality of a negotiated consent settlement disregards paragraph (f) of Rule V of the Rules of Practice incorporated in the settlement. Further, the purpose of the present hearing is not to determine whether respondent's advertising of the "Elmo Palliative Home Treatment"

³⁰ See *Aronberg v. Federal Trade Commission*, 132 F. 2d 165, at 167-168, holding "The public is not learned in medical technology The term 'relief' is not of definite connotation or entirely free from ambiguity; in a common sense, it connotes permanent removal of organic or functional disturbances, as distinguished from alleviation of discomfort."

³¹ See *Aronberg* case, footnote 30 above, "a representation that a medicine is 'for' or a 'treatment for' a disorder is equivalent to labeling it 'as a cure or remedy.'"

is in compliance with the findings as to the facts and the order to cease and desist of the consent settlement, but to ascertain whether grounds exist which, in the public interest, require that the consent settlement be set aside in whole or in part.³²

Respondent would argue that in assessing the medical evidence of record in this hearing, little weight should be given to the medical testimony submitted by Commission counsel because, allegedly, the witnesses had demonstrated no familiarity with nor tested the preparations and devices in the "Elmo Palliative Home Treatment," and further, that substantial weight is to be given the testimony and the written testimonials of the satisfied lay user purchasers of the treatment submitted of record by counsel for respondent.

Respondent's first argument is answered, to the contrary, in *Feil v. Federal Trade Commission* 285 F. 2d 879 at 893: "In the petitioners' argument much is made of the fact that the medical experts produced by the Commission had little knowledge of the device, knew it only by reputation, or had only seen it demonstrated at the trial. The answer is that given by this Court in a similar case where objection was voiced that experts were allowed to testify as to the efficacy of a medical preparation which they had never prescribed or the effect of which they had not observed in concrete cases: 'The witnesses were shown to possess wide knowledge in the field under inquiry. There is no good reason to suppose them incompetent to express an opinion as to the lack of therapeutic value of petitioner's preparation merely because they had had no personal experience with it in the treatment of the disease. Their general medical and pharmacological knowledge qualified them to testify.'"

Respondent's second argument is also answered, to the contrary, in the *Feil* case above, at page 882, footnote 5, wherein it is stated: "Coincidentally, the petitioner in that case urged, as do the petitioners in this case, that the Commission should not have rejected the testimonials from satisfied customers. The answer of the court was: 'Further, it is sound to say that the fact that petitioner had satisfied customers is not a defense to Commission action for deceptive practices.'"

Respondent would further contend that in contrast to the public interest necessary for the issuance of a complaint, more is

³² Respondent is presently subject to a penalty upon failure to comply with the various other paragraphs of the existing consent settlement order to cease and desist not containing permissive qualifications. If the consent settlement be set aside in whole and the order to cease and desist vacated, this would relegate the entire matter back to the complaint of 1952.

required in the public interest to disturb an allegedly final Commission order accepting a consent settlement such as here. If this be so, the required public interest is clearly present.³³ One quarter of a million people have already paid respondent either the first asking price of \$10 or the follow-up price of \$7.35 for the "Elmo Palliative Home Treatment." Unless the 1952 consent settlement be set aside in part and corrective action undertaken consistent with the preceding findings as herein made, a considerable number of the purchasing public may further go unprotected and suffer substantial monetary loss in the payment for a treatment described on the record of this hearing, by qualified and experienced medical specialists, as worthless for the represented results advertised.

CONCLUSIONS

The foregoing findings of fact show grounds to exist and reason to believe the public interest requires that the 1952 consent settlement in this proceeding be set aside in part and corrective action undertaken as provided in paragraph (f) of Rule V of the Rules of Practice incorporated in the said settlement.

RECOMMENDATIONS

Based on the record in this hearing, which is herewith certified to the Commission, together with the foregoing findings of fact and conclusions, it is recommended that the 1952 consent settlement in this proceeding be ordered set aside in part; that the allegations of the complaint be amended; and that the notice in the complaint contain that form of order to cease and desist which the Commission has reason to believe should be issued if the facts are found to be as alleged in the complaint, as amended.

OPINION OF THE COMMISSION

NOVEMBER 18, 1966

By ELMAN, *Commissioner*:

This case concerns the reopening and modification of Commission orders to cease and desist. Such orders, like judicial injunctions, are not immutable. "A continuing decree of injunction directed to events to come is subject always to adaptation as events may shape the need." *United States v. Swift & Co.*, 286 U.S. 106, 114. With respect to Commission orders that have become final,

³³ Compare, *Exposition Press, Inc. v. Federal Trade Commission*, 295 F. 2d 869, at 872-874.

whether by consent or after litigation, Section 5(b) of the Federal Trade Commission Act provides that "the Commission may at any time, after notice and opportunity for hearing, reopen and alter, modify, or set aside, in whole or in part, any report or order made or issued by it under this section, whenever in the opinion of the Commission conditions of fact or of law have so changed as to require such action or if the public interest shall so require." Cf. *American Chain & Cable Co., Inc. v. Federal Trade Commission*, 142 F. 2d 909, 911 (4th Cir.).

Under the present practice (Section 3.28, Rules of Practice), the Commission, acting on its own motion or at the request of a party, may reopen a proceeding for the purpose of modifying or vacating an outstanding order. In the absence of consent to the proposed modification or vacation of the order, and where substantial issues of fact are involved, the matter is heard initially before a hearing examiner, and then before the Commission, to determine whether and how the order should be altered. Normally, the question whether, by reason of changed conditions or the public interest, the outstanding order should be vacated is intertwined with the question of determining the terms of a new superseding order to be entered. Under the present practice, the Commission enters a single new order determining both of these related questions which is, of course, subject to judicial review in the same manner as other Commission orders.

In the instant case, however, we are obliged by the decision of the Court of Appeals for the District of Columbia Circuit in *The Elmo Division of Drive-X Company v. Dixon*, 348 F. 2d 342 (1965),¹ to consider and decide separately the question whether the existing order should be set aside, before taking up the question of the content and scope of a new superseding order. The Court of Appeals upheld respondent's contention that the Commission had bound itself, by entering into the agreement upon the basis of which the consent order in this case was issued on June 10, 1952 [48 F.T.C. 1379], to follow the procedure prescribed by Rule V (f) of the Commission's Rules in effect at that time, which was construed by the Court of Appeals to require the Commission to enter a separate order (which would be judicially reviewable immediately) setting aside the old consent order as a prerequisite to reopening the proceeding for the purpose of issuing a new modified order.

¹ Since this case was regarded as *sui generis* and having no general precedential importance, certiorari was not sought.

We have scrupulously followed the course required by the mandate of the Court of Appeals. On December 1, 1965 [68 F.T.C. 1229], after the case was remanded to us, the Commission issued an order reopening the proceeding in Docket 5959 to determine whether a change of law or fact or the public interest required setting aside, in whole or in part, the consent order issued in 1952. The matter was assigned to a hearing examiner with instructions to take evidence to determine whether changed conditions or the public interest requires that the order be so set aside, and to certify the record, together with a report of his findings, conclusions, and recommendations, to the Commission for final disposition. The hearing before the examiner having been held, the matter is now before the Commission on the examiner's certification of the record.

The only question before the Commission in the present posture of the case, we repeat, is simply whether the outstanding 1952 consent order should be vacated in whole or in part, and not what the terms or scope of a new superseding order should be. Because of the unusual manner in which we have been directed to proceed in this case, the Commission intimates no view whatsoever on the latter question. We have determined only, for the reasons shortly to be stated, that the findings of fact and conclusions of law contained in the hearing examiner's certification are correct and valid; and, with one modification, they are hereby adopted by the Commission as its own. We find and hold that the public interest requires that the consent order issued by the Commission on June 10, 1952, be reopened and set aside in whole, rather than in part as recommended by the examiner. We are this date entering an order to that effect. Under the decision of the Court of Appeals in this case, respondent will have the opportunity it successfully sought of obtaining immediate judicial review. If and when today's order vacating the 1952 consent order should become final, because respondent does not seek court review or because upon such review our order should be affirmed, the Commission will promptly initiate such further administrative proceedings as are found to be warranted by the then existing circumstances.

The reasons for our determination to vacate in its entirety the consent order issued in 1952 may be summarized as follows:

1. The order issued in 1952 and now in effect permits respondent to represent that the use of its preparation and device will have some beneficial effect in the treatment of deafness, impaired hearing, or head or ear noises.

Order

70 F.T.C.

2. The medical testimony in the record, summarized in Finding 10 at pages 1381-1385, supports the conclusion that the preparations and devices comprising the Elmo Palliative Home Treatment have no beneficial effect whatsoever in the treatment of poor hearing, deafness, and head or ear noises.

3. Respondent's current advertising represents that its products will relieve poor hearing and head or ear noises.

4. On the basis of the foregoing, we conclude that the 1952 order fails adequately to protect the public interest.

Accordingly, the Commission's duty to safeguard the public interest requires that the consent settlement and order entered herein on June 10, 1952, be set aside in whole. In order to prevent a hiatus in which respondent would be entirely free from *any* order, we are staying the effective date of today's order until such time as a new superseding order of the Commission, finally disposing of this complaint, shall take effect. Respondent may thus obtain immediate judicial review of our present order, without the harm to the public interest which would result if it were wholly relieved from the prohibitions of any order during the pendency of judicial review.

Complaint counsel's motion to strike the reply brief filed by respondent is denied.

ORDER SETTING ASIDE CONSENT SETTLEMENT AND ORDER

The Commission having issued on December 1, 1965 [68 F.T.C. 1229], its "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," and a hearing before an examiner having been held pursuant to that order; and

The Commission having considered the evidence introduced by the parties at the hearing, the proposed findings and conclusions submitted by the parties, the briefs in support thereof, and having heard oral argument; and

The Commission having determined, for the reasons set forth in its opinion accompanying this order, that such action is now required in the public interest:

It is ordered, That the consent settlement and order entered herein on June 10, 1952 [48 F.T.C. 1379], be, and they hereby are, set aside in whole.

It is further ordered, That this order shall not take effect until such time as a new order of the Commission fully disposing of the

CUSTOM SLEEP SHOPPES, LTD., ET AL.

1393

1374

Complaint

complaint in Docket No. 5959, in its present form or as it may be amended, and superseding the consent settlement and order entered herein on June 10, 1952, shall become final.
