including but not limited to merger, acquisition, consolidation or joint venture in any market referenced herein.

VIII

It is further ordered, That Airco cease and desist from taking any steps to implement any provision of the agreements between Airco and BOC of July 25, 1973, and of Dec. 10, 1973. The foregoing provision shall not apply (1) to Airco's right of first refusal as set forth in paragraph 4 of the Dec. 10, 1973 agreement, subject, however, to Commission final approval of the exercise of that right; (2) to the restrictions on dissemination of information contained in the July 25, 1973 agreement.

IX

It is further ordered, That Airco cease any and all representation on the board of directors of BOC, and cease and desist from taking any steps to nominate, seat, or admit any representative of BOC to the board of directors of Airco.

X

It is further ordered, That Airco shall within sixty (60) days from the date this order becomes final, submit in writing to the Federal Trade Commission a verified report setting forth in detail the manner and form in which Airco has complied with this order.

IN THE MATTER OF

MICHAEL MILEA/PETER SINCLAIR, LTD., ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF THE FEDERAL TRADE COMMISSION, TEXTILE FIBER PRODUCTS IDENTIFICATION AND WOOL PRODUCTS LABELING ACTS

Docket C-2764. Complaint, Dec. 8, 1975—Decision, Dec. 8, 1975

Consent order requiring a New York City importer of wearing apparel, among other things to cease mislabeling the fiber content of wool and textile products; failing to disclose on labels manufacturer identification; falsely invoicing textile fiber products; and furnishing false guaranties.

Appearances

For the Commission: *Charles Peterson.*
For the respondents: *Pro se.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended, the Wool Products Labeling Act of 1939, and the Textile Fiber Products Identification Act and by virtue of the authority vested in it by said Acts, the Federal Trade Commission, having reason to believe that Michael Milea/Peter Sinclair, Ltd., a corporation, and Bernard Rein, individually and as an officer of said corporation, hereinafter referred to as respondents, have violated the provisions of said Acts and the rules and regulations promulgated under the Wool Products Labeling Act of 1939 and the Textile Fiber Products Identification 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 Michael Milea/Peter Sinclair, Ltd. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Florida with its main office and principal place of business located at 475 Park Ave., South, New York, N.Y. The firm also maintains warehousing and distribution facilities at 3240 W. 16th Ave., Hialeah, Fla., where the firm maintained its principal place of business under the name Imperial Imports, Inc., until October 1973. In October 1973, Imperial Imports, Inc., a Florida corporation, merged with its wholly-owned subsidiary Michael Milea/Peter Sinclair, Ltd., a New York corporation, to form the corporate respondent.

Respondent Bernard Rein is an officer of the corporate respondent. He formulates, directs and controls the acts and practices of the corporate respondent's Hialeah, Fla., facility, including the acts and practices hereinafter set forth. His address is 3240 W. 16th Ave., Hialeah, Fla.

Respondents are now, and for some time last past have been, engaged in the importation of wearing apparel for sale to retailers throughout the United States.

COUNT I

Alleging violation of the Wool Products Labeling Act of 1939 and the implementing rules and regulations promulgated thereunder, and the Federal Trade Commission Act, as amended, the allegations of Paragraph One hereof are incorporated by reference in Count I as if fully set forth verbatim.

PAR. 2. Respondents, now and for some time last past, have imported for introduction into commerce, introduced into commerce, sold, transported, distributed, delivered for shipment, shipped, and offered

for sale in commerce, as "commerce" is defined in the Wool Products Labeling Act of 1939, wool products, as "wool product" is defined therein.

PAR. 3. Certain of said wool products were misbranded by the respondents within the intent and meaning of Section 4(a)(1) of the Wool Products Labeling Act of 1939 and rules and regulations promulgated thereunder, in that they were falsely and deceptively stamped, tagged, labeled or otherwise identified with respect to the character and amount of the constituent fibers contained therein.

Among such misbranded wool products, but not limited thereto, were sweaters identified by respondents as "50% acrylic, 30% wool, 20% cotton" whereas in truth and in fact, said wool products contained substantially different amounts of fibers than as represented.

PAR. 4. Certain of said wool products were further misbranded by respondents in that they were not stamped, labeled, tagged or otherwise identified as required under the provisions of Section 4(a)(2)(A) of the Wool Products Labeling Act of 1939 and in the manner and form as prescribed by the rules and regulations promulgated under said Act.

Among such misbranded wool products, but not limited thereto, were wool products, namely sweaters, with labels on or affixed thereto which failed to disclose the percentage of the total fiber weight of the said wool products, exclusive of ornamentation not exceeding five percentum of said total fiber weight, of (1) wool; (2) reprocessed wool; (3) reused wool; (4) each fiber other than wool, where said percentage by weight of such fiber was five percentum or more; and (5) the aggregate of all fibers.

PAR. 5. Certain of said wool products were further misbranded by respondents in that they were not stamped, labeled, tagged or otherwise identified as required under the provisions of Section 4(a)(2)(C) of the Wool Products Labeling Act of 1939 and in the manner and form as prescribed by Rule 13 promulgated under said Act.

Among such wool products, but not limited thereto, were sweaters whose labels failed to disclose the name, or other identification issued and registered by the Commission, of the manufacturer of the wool product or one or more persons subject to Section 3 of the Act with respect to such product.

PAR. 6. The acts and practices as set forth above were, and are, in violation of the Wool Products Labeling Act of 1939 and the rules and regulations promulgated thereunder and constituted, and now constitute, unfair methods of competition and unfair and deceptive acts and practices in or affecting commerce, under the Federal Trade Commission Act, as amended.

COUNT II

Alleging violation of the Textile Fiber Products Identification Act and the implementing rules and regulations promulgated thereunder and of the Federal Trade Commission Act, as amended, the allegations of Paragraph One hereof are incorporated by reference in Count II as if fully set forth verbatim.

PAR. 7. Respondents are now, and for some time last past have been, engaged in the introduction, delivery for introduction, sale, advertising and offering for sale in commerce, and in the transportation or causing to be transported in commerce, and in the importation into the United States of textile fiber products; and have sold, offered for sale, advertised, delivered, transported and caused to be transported textile fiber products which have been advertised or offered for sale in commerce; and have sold, offered for sale, advertised, delivered, transported and caused to be transported after shipment in commerce textile fiber products either in their original State or contained in other textile fiber products, as the terms "commerce" and "textile fiber product" are defined in the Textile Fiber Products Identification Act.

PAR. 8. Certain of said textile fiber products were misbranded by respondents within the intent and meaning of Section 4(a) of the Textile Fiber Products Identification Act and the rules and regulations promulgated thereunder in that they were falsely and deceptively stamped, tagged, labeled, invoiced, advertised or otherwise identified as to the name or amount of the constituent fibers contained therein.

Among such misbranded textile fiber products, but not limited thereto, were textile fiber products, namely ladies knitted blouses, which contained substantially different amounts and types of fibers than as represented.

PAR. 9. Certain of said textile fiber products were misbranded by respondents in that they were not stamped, tagged, labeled or otherwise identified as required under the provisions of Section 4(b) of the Textile Fiber Products Identification Act and in the manner and form as prescribed by the rules and regulations promulgated under said Act.

Among such misbranded textile fiber products, but not limited thereto, were textile fiber products with labels which failed:

1. To disclose the true generic names of the fibers present;
2. To disclose the percentages of such fibers by weight;
3. To disclose the name, or other identification issued and registered by the Commission, of the manufacturer of the product or one or more persons subject to Section 3 of said Act with respect to such products.

PAR. 10. Respondents have furnished their customers with false guaranties that certain textile fiber products were not misbranded or falsely invoiced by falsely representing in writing on invoices that respondents have filed a continuing guaranty under the Textile Fiber Products Identification Act with the Federal Trade Commission in violation of Section 10(b) of said Act and Rule 38(d) of the rules and regulations promulgated thereunder.

PAR. 11. The aforesaid acts and practices of respondents as set forth in Paragraphs Seven through Ten above were, and are, in violation of the Textile Fiber Products Identification Act and the rules and regulations promulgated thereunder, and constituted, and now constitute, unfair methods of competition and unfair and deceptive acts and practices in or affecting commerce under the Federal Trade Commission Act, as amended.

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondents named in the caption hereof, and the respondents having been furnished thereafter with a copy of a draft of complaint which the Atlanta Regional Office proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondents with violation of the Federal Trade Commission Act, as amended, the Wool Products Labeling Act of 1939 and the Textile Fiber Products Identification Act; and

The respondents and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondents of all jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondents that the law has been violated as alleged in such complaint and waivers and other provisions as required by the Commission's rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondents have violated the said Acts, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of sixty (60) days, now in further conformity with the procedure prescribed in Section 2.34 of its rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent Michael Milea/Peter Sinclair, Ltd. is a corporation

organized, existing and doing business under and by virtue of the laws of the State of Florida, with its main office and principal place of business located at 475 Park Ave., South, New York, N.Y. The firm also maintains warehousing and distribution facilities at 3240 W. 16th Ave., Hialeah, Fla., where the firm maintained its principal place of business under the name Imperial Imports, Inc., until October 1973. In October 1973, Imperial Imports, Inc., a Florida corporation, merged with its wholly-owned subsidiary Michael Milea/Peter Sinclair, Ltd., a New York corporation, to form the corporate respondent.

Respondent Bernard Rein is an officer of said corporation. He formulates, directs and controls the acts and practices of said corporation's Hialeah facility, including the acts and practices hereinafter set forth. His address is 3240 W. 16th Ave., Hialeah, Fla.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondents, and the proceeding is in the public interest.

ORDER

COUNT I

It is ordered, That Michael Milea/Peter Sinclair, Ltd., a corporation, its successors and assigns and its officers, and Bernard Rein, individually and as an officer of said corporation, and respondents' agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the introduction or manufacture for introduction into commerce or the offering for sale, transportation, distribution, delivery for shipment or shipment in commerce of wool products, as "commerce" and "wool product" are defined in the Wool Products Labeling Act of 1939, do forthwith cease and desist from misbranding such products by:

1. Falsely and deceptively stamping, tagging, labeling or otherwise identifying such products as to the name or amount of the constituent fibers contained therein;

2. Failing to securely affix to or place on each product a stamp, tag, label or other means of identification showing in a clear, legible and conspicuous manner each element of information required to be disclosed by Section 4(a)(2) of the Wool Products Labeling Act of 1939.

COUNT II

It is further ordered, That respondents Michael Milea/Peter Sinclair, Ltd., a corporation, its successors and assigns and its officers, and Bernard Rein, individually and as an officer of said corporation, and respondents' agents, representatives and employees, directly or

through any corporation, subsidiary, division or other device in connection with the introduction, delivery for introduction, manufacture for introduction, sale, advertising or offering for sale in commerce, or the importation into the United States of any textile fiber product; or in connection with the sale, offering for sale, advertising, delivery, transportation or causing to be transported of any textile fiber product which has been advertised for sale in commerce; or in connection with the sale, offering for sale, advertising, delivery, transportation or causing to be transported after shipment in commerce of any textile fiber product whether in its original State or contained in any other textile fiber product, as the terms "commerce" and "textile fiber product" are defined in the Textile Fiber Products Identification Act, do forthwith cease and desist from:

1. Misbranding textile fiber products by:

(a) falsely or deceptively stamping, tagging, labeling, invoicing, advertising or otherwise identifying such products as to the name or amount of the constituent fibers contained therein;

(b) failing to affix a stamp, label, tag, or other means of identification to such textile fiber products showing in a clear, legible and conspicuous manner each element of information required to be disclosed by Section 4(b) of the Textile Fiber Products Identification Act.

It is further ordered, That respondents Michael Milea/Peter Sinclair, Ltd., a corporation, its successors and assigns and its officers, and Bernard Rein, individually and as an officer of said corporation, and respondents' representatives, agents and employees, directly or through any corporation, subsidiary, division or other device do forthwith cease and desist from furnishing a false guaranty that any textile fiber product is not misbranded or falsely invoiced or advertised under the provisions of the Textile Fiber Products Identification Act.

It is further ordered, That the respondent corporation shall forthwith distribute a copy of this order to each of its operating divisions.

It is further ordered, That respondents notify the Commission at least thirty (30) days prior to any proposed change in the corporate respondent such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in the corporation which may affect compliance obligations arising out of the order.

It is further ordered, That the individual respondent named herein promptly notify the Commission of the discontinuance of his present business or employment and of his affiliation with a new business or employment. Such notice shall include respondent's current business address and a statement as to the nature of the business or

employment in which he is engaged as well as a description of his duties and responsibilities.

It is further ordered, That the respondents herein shall, within sixty (60) days after service upon them of this order, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

IN THE MATTER OF

LEESIN INTERNATIONAL, INC., ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF THE FEDERAL TRADE COMMISSION AND WOOL PRODUCTS LABELING ACTS

Docket C-2765. Complaint, Dec. 8, 1975—Decision, Dec. 8, 1975

Consent order requiring a Croton-On-Hudson, N.Y., importer and distributor of fabrics, among other things to cease misrepresenting the wool content of their wool blend fabrics and further, that respondents notify their customers that the fabrics they have purchased were misbranded.

Appearances

For the Commission: *Jerry R. McDonald.*
For the respondents: *Pro se.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended, and the Wool Products Labeling Act of 1939, and by virtue of the authority vested in it by said Acts, the Federal Trade Commission, having reason to believe that Leesin International, Inc., a corporation, and Leon Sinder, individually and as an officer of said corporation, hereinafter referred to as respondents, have violated the provisions of said Acts and the rules and regulations promulgated under the Wool Products Labeling Act of 1939, 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 Leesin International, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of New York, with its office and principal place of business located at Quaker Bridge Road E., Croton-On-Hudson, N.Y.

Respondent Leon Sinder is an officer of Leesin International, Inc. He

formulates, directs, and controls the acts and practices of the corporate respondent, including the acts and practices hereinafter set forth. His business address is the same as that of the corporate respondent.

Respondents are engaged in the importation and sale of fabrics including but not limited to wool products.

PAR. 2. Respondents, now and for some time past, have imported for introduction into commerce, introduced into commerce, transported, distributed, delivered for shipment, shipped, offered for sale, and sold in commerce as "commerce" is defined in the Wool Products Labeling Act of 1939, wool products as "wool product" is defined therein.

PAR. 3. Certain of said wool products were misbranded by the respondents within the intent and meaning of Section 4(a)(1) of the Wool Products Labeling Act of 1939 and the rules and regulations promulgated thereunder, in that they were falsely and deceptively stamped, tagged, labeled, or otherwise identified with respect to the character and amount of the constituent fibers contained therein.

Among such misbranded wool products, but not limited thereto, were certain wool fabrics stamped, tagged, labeled, or otherwise identified by respondents as 40 percent wool, 60 percent polyester; whereas, in truth and in fact, said products contained substantially different fibers and amounts of fibers than represented.

PAR. 4. Certain of said wool products were further misbranded by respondents in that they were not stamped, tagged, labeled or otherwise identified as required under the provisions of Section 4 (a)(2) of the Wool Products Labeling Act of 1939 and in the manner and form as prescribed by the rules and regulations promulgated under said Act.

Among such misbranded wool products, but not limited thereto, were wool products, namely wool fabrics, with labels on or affixed thereto, which failed to disclose the percentage of the total fiber weight of the said wool products, exclusive of ornamentation not exceeding 5 per centum of said total fiber weight, of (1) wool, (2) reprocessed wool, (3) reused wool, (4) each fiber other than wool, when said percentage by weight of such fiber was 5 per centum or more, and (5) the aggregate of all other fibers.

PAR. 5. The acts and practices of respondents as set forth above were, and are, in violation of the Wool Products Labeling Act of 1939 and the rules and regulations promulgated thereunder, and constituted, and now constitute, unfair methods of competition and unfair and deceptive acts and practices, in commerce, under the Federal Trade Commission Act, as amended.

PAR. 6. Respondents are now and for some time past have been engaged in the importation, offering for sale, sale, and distribution of certain products, namely fabrics. In the course and conduct of their

business as aforesaid, respondents now cause and for some time last past, have caused their said products, when sold, to be shipped from their place of business in the State of New York to purchasers located in various other States of the United States, and maintain and at all times mentioned herein have maintained, a substantial course of trade in said products in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, as amended.

PAR. 7. Respondents in the course and conduct of their business have made statements on invoices to their customers misrepresenting the fiber content of certain of their products.

Among such misrepresentations, but not limited thereto, were statements setting forth the fiber content thereof as 40 percent wool, 60 percent polyester; whereas, in truth and in fact, said products contained substantially different fibers and amounts of fibers than represented.

PAR. 8. The acts and practices set out in Paragraph Seven have the tendency and capacity to mislead and deceive the purchasers of said products as to the true content thereof.

PAR. 9. The aforesaid acts and practices of the respondents as herein alleged in Paragraph Seven were, and are, all to the prejudice and injury of the public, and constituted, and now constitute, unfair and deceptive acts or practices in or affecting commerce, within the intent and meaning of the Federal Trade Commission Act, as amended.

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondents named in the caption hereof, and the respondents having been furnished thereafter with a copy of a draft of complaint which the New York Regional Office proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondents with violation of the Federal Trade Commission Act, as amended, and the Wool Products Labeling Act of 1939 and;

The respondents and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondents of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondents that the law has been violated as alleged in such complaint, and waivers and other provisions as required by the Commission's rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondents have

violated the said Acts, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of sixty (60) days, now in further conformity with the procedure prescribed in Section 2.34 of its rules, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

1. Respondent Leesin International, Inc., is a corporation organized, existing and doing business under and by virtue of the laws of the State of New York, with its office and principal place of business located at Quaker Bridge Road E., Croton-On-Hudson, N.Y.

Respondent Leon Sinder is an officer of said corporation. He formulates, directs and controls the acts, practices and policies of said corporation and his address is the same as that of said corporation.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondents, and the proceeding is in the public interest.

ORDER

It is ordered, That respondents Leesin International, Inc., a corporation, its successors and assigns, and its officers, and Leon Sinder, individually and as an officer of said corporation, and respondents' representatives, agents, and employees, directly or through any corporation, subsidiary, division, or any other device, in connection with the introduction, or importing for introduction, into commerce, or the offering for sale, sale, transportation, distribution, delivery for shipment or shipment, in commerce, of wool products, as "commerce" and "wool product" are defined in the Wool Products Labeling Act of 1939, do forthwith cease and desist from misbranding such products by:

1. Falsely and deceptively stamping, tagging, labeling, or otherwise identifying such products.

2. Failing to securely affix to or place on, each such product a stamp, tag, label, or other means of identification showing in a clear and conspicuous manner each element of information required to be disclosed by Section 4(a)(2) of the Wool Products Labeling Act of 1939.

It is further ordered, That respondents Leesin International, Inc., a corporation, its successors and assigns, and its officers, and Leon Sinder, individually and as an officer of said corporation, and respondents' representatives, agents and employees, directly or through any corporate or other device, in connection with the importing, advertising, offering for sale, sale or distribution of fabrics in or affecting commerce, as "commerce" is defined in the Federal

Trade Commission Act, as amended, do forthwith cease and desist from misrepresenting the amount or character of constituent fibers contained in such products on invoices or shipping memoranda applicable thereto, or in any other manner.

It is further ordered, That respondents notify, by registered mail, each of their customers that purchased the wool products which gave rise to this complaint of the fact that such products were misbranded.

It is further ordered, That the individual respondent named herein promptly notify the Commission of the discontinuance of his present business or employment and his affiliation with a new business or employment. Such notice shall include respondent's current business address and a statement as to the nature of the business or employment in which he is engaged, as well as a description of his duties and responsibilities.

It is further ordered, That the respondent corporation shall forthwith distribute a copy of this order to each of its operating divisions.

It is further ordered, That respondents notify the Commission at least thirty (30) days prior to any proposed change in the corporate respondent such as dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in the corporation which may affect compliance obligations arising out of the order.

It is further ordered, That respondents shall, within sixty (60) days after service upon them of this order, file with the Commission a report in writing setting forth in detail the manner and form in which they have complied with the order to cease and desist contained herein.

IN THE MATTER OF

MR. MARTINEZ OF MIAMI, INC., ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF THE FEDERAL TRADE COMMISSION AND TEXTILE FIBER PRODUCTS IDENTIFICATION ACTS

Docket C-2766. Complaint, Dec. 8, 1975—Decision, Dec. 8, 1975

Consent order requiring a Miami, Fla., manufacturer of women's wearing apparel, among other things to cease furnishing customers with false guaranties that certain textile fiber products were not misbranded, mislabeling products as to their constituent fibers, failing to maintain and preserve proper records, and failing to disclose on labels all information required by the Textile Fiber Products Identification Act.

Appearances

For the Commission: *Charles Peterson.*
For the respondents: *Pro se.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act and the Textile Fiber Products Identification Act and by virtue of the authority vested in it by said Acts, the Federal Trade Commission, having reason to believe that Mr. Martinez of Miami, Inc., a corporation, and Leonel Martinez, individually and as an officer of said corporation, hereinafter referred to as respondents, have violated the provisions of the said Acts and rules and regulations promulgated under the Textile Fiber Products Identification 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 Mr. Martinez of Miami, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Florida, with its office and principal place of business located at 525 N.W. 29th St., Miami, Fla.

Respondent Leonel Martinez is an individual and an officer of the corporate respondent. He formulates, directs and controls the acts and practices of the corporate respondent, including the acts and practices hereinafter set forth. His business address is the same as that of the corporate respondent.

Respondents are manufacturers of textile fiber products, including, but not limited to, wearing apparel in the form of women's suits, dresses, blouses and slacks.

PAR. 2. Respondents are now, and for some time last past have been, engaged in the introduction, delivery for introduction, manufacture for introduction, sale, advertising and offering for sale, in commerce, and in the transportation and causing to be transported in commerce, of textile fiber products; and have sold, offered for sale, advertised, delivered, transported and caused to be transported textile fiber products which have been advertised or offered for sale in commerce; and have sold, offered for sale, advertised, delivered, transported and caused to be transported, after shipment in commerce, textile fiber products either in their original State or contained in other textile fiber products, as the term "commerce" and "textile fiber products" are defined in the Textile Fiber Products Identification Act.

PAR. 3. Certain of said textile fiber products were misbranded by respondents within the intent and meaning of Section 4(a) of the

Textile Fiber Products Identification Act and the rules and regulations promulgated thereunder, in that they were falsely and deceptively stamped, tagged, labeled, invoiced or otherwise identified as to the name or amount of the constituent fibers contained therein.

Among such misbranded textile fiber products, but not limited thereto, were textile fiber products, namely women's suits, dresses, blouses and slacks, which contained substantially different amounts and types of fibers than as represented.

PAR. 4. Certain of said textile fiber products were misbranded by respondents in that they were not stamped, tagged, labeled or otherwise identified as required under the provisions of Section 4(b) of the Textile Fiber Products Identification Act and in the manner and form prescribed by the rules and regulations promulgated under said Act.

Among such misbranded textile fiber products, but not limited thereto, were textile fiber products with labels which failed:

a. To disclose the true generic names of the fibers present in the order of predominance by weight; and

b. To disclose the percentages of such fibers by weight.

PAR. 5. Certain of said textile fiber products were misbranded in violation of the Textile Fiber Products Identification Act in that they were not labeled in accordance with the rules and regulations promulgated thereunder in the following respects:

a. Fiber trademarks were placed on labels without the generic names of the fibers appearing on such labels in immediate conjunction therewith as required by Rule 17(a) of the aforesaid rules and regulations; and

b. Required information as to fiber content was not set forth in a manner that would separately show the fiber content of the separate units of textile fiber products containing two or more units, each of which was of different fiber composition as required by Rule 29 of the aforesaid rules and regulations.

PAR. 6. Respondents have failed to maintain proper records showing the fiber content of the textile fiber products manufactured by them in violation of Section 6(a) of the Textile Fiber Products Identification Act and Rule 39 of the rules and regulations promulgated thereunder.

PAR. 7. Respondents have furnished their customers with false guaranties that certain of the textile fiber products were not misbranded or falsely invoiced by falsely representing in writing on invoices that respondents have filed a continuing guaranty under the Textile Fiber Products Identification Act with the Federal Trade Commission in violation of Rule 38(d) of the rules and regulations under said Act and Section 10(b) of such Act.

PAR. 8. The acts and practices of respondents as set forth above were, and are, in violation of the Textile Fiber Products Identification Act and the rules and regulations promulgated thereunder and constituted, and now constitute, unfair methods of competition and unfair and deceptive acts and practices in commerce under the Federal Trade Commission Act.

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondents named in the caption hereof, and the respondents having been furnished thereafter with a copy of a draft of complaint which the Atlanta Regional Office proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondents with violation of the Federal Trade Commission Act, as amended, and the Textile Fiber Products Identification Act; and

The respondents and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondents of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondents that the law has been violated as alleged in such complaint, and waivers and other provisions as required by the Commission's rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondents have violated the said Acts, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of sixty (60) days, now in further conformity with the procedure prescribed in Section 2.34 of its rules, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

1. Respondent Mr. Martinez of Miami, Inc., is a corporation organized, existing and doing business under and by virtue of the laws of the State of Florida, with its office and principal place of business located at 525 N.W. 29th St., Miami, Fla.

Respondent Leonel Martinez is an officer of said corporation. He formulates, directs and controls the policies, acts and practices of said corporation, and his principal office and place of business is located at the above stated address.

2. The Federal Trade Commission has jurisdiction of the subject

matter of this proceeding and of the respondents, and the proceeding is in the public interest.

ORDER

It is ordered, That respondents Mr. Martinez of Miami, Inc., a corporation, its successors and assigns, and its officers and Leonel Martinez, individually and as an officer of said corporation and respondents' representatives, agents and employees, directly or through any corporation, subsidiary, division or other device in connection with the introduction, delivery for introduction, manufacture for introduction, sale, advertising, or offering for sale in commerce, or the importation into the United States, of any textile fiber product, or in connection with the sale, offering for sale, advertising, delivery, transportation or causing to be transported, after shipment in commerce, of any textile fiber product, whether in its original State or contained in other textile fiber products, as the terms "commerce" and "textile fiber products" are defined in the Textile Fiber Products Identification Act, do forthwith cease and desist from:

A. Misbranding textile fiber products by:

1. Falsely or deceptively stamping, tagging, labeling, invoicing, advertising or otherwise identifying such products as to the name or amount of the constituent fibers contained therein.

2. Failing to affix a stamp, tag, label or other means of identification to each such product showing in a clear, legible and conspicuous manner each element of information required to be disclosed by Section 4(b) of the Textile Fiber Products Identification Act.

3. Failing to separately set forth the required information as to fiber content in such a manner as to show the fiber content of the separate units of textile fiber products containing two or more units which are of different fiber composition where such form of marking is necessary to avoid deception as required by Rule 29 of the rules and regulations promulgated under authority of the Textile Fiber Products Identification Act.

B. Failing to maintain and preserve proper records of fiber content of textile fiber products manufactured by respondents as required by Section 6(a) of the Textile Fiber Products Identification Act and Rule 39 of the rules and regulations promulgated thereunder.

It is further ordered, That respondents Mr. Martinez of Miami, Inc., a corporation, and its officers, and Leonel Martinez, individually and as an officer of said corporation, and respondents' representatives, agents and employees, directly or through any corporate or other device, do forthwith cease and desist from furnishing a false guaranty that any

textile fiber product is not misbranded or falsely invoiced under the provisions of the Textile Fiber Products Identification Act.

It is further ordered, That respondents notify the Commission at least thirty (30) days prior to any proposed change in the corporate respondent, such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in the corporation which may affect compliance obligations arising out of the order.

It is further ordered, That the individual respondent named herein promptly notify the Commission of the discontinuance of his present business or employment and of his affiliation with a new business or employment. Such notice shall include respondent's current business address and a statement as to the nature of the business or employment in which he is engaged as well as a description of his duties and responsibilities.

It is further ordered, That the respondent corporation shall forthwith distribute a copy of this order to each of its operating divisions.

It is further ordered, That the respondents herein shall within sixty (60) days after service upon them of this order, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

IN THE MATTER OF

WARNER-LAMBERT COMPANY

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

Docket 8891. Complaint, June 27, 1972—Order, Dec. 9, 1975

Order requiring a Morris Plains, N.J., manufacturer and distributor of "Listerine" mouthwash preparation, among other things to cease misrepresenting the medicinal, therapeutic qualities, beneficial effects, and germicidal nature of its product. Respondent is further required to include a corrective advertising disclosure in its advertisements. The order dismisses the complaint allegation regarding the effects of "Listerine" on children who gargle with it twice a day.

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 Warner-Lambert Company, a corporation, hereinafter referred to as respondent, has 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 Warner-Lambert Company, is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its principal office and place of business located at 201 Tabor Rd., Morris Plains, N.J.

PAR. 2. Respondent is now, and for some time last past has been, engaged in the manufacture, advertising, offering for sale, sale and distribution of a mouthwash preparation designated "Listerine" to retailers for resale to the consuming public.

PAR. 3. In the course and conduct of its business as aforesaid, respondent now causes, and for some time last past has caused the said Listerine, when sold, to be shipped from its plants and facilities to purchasers thereof located in various States other than the State of origination, and maintains, and at all times mentioned herein has maintained, a substantial course of trade in said Listerine in commerce, as "commerce" is defined in the Federal Trade Commission Act.

PAR. 4. In the course and conduct of its business and for the purpose of inducing the sale of its said Listerine, respondent has made, and is now making numerous statements and representations in print advertisements, including product packaging and labels, and in television broadcasts transmitted by television stations located in various States of the United States and in the District of Columbia having sufficient power to carry such broadcasts across state lines, respecting the effects of said product in the prevention, cure, treatment and mitigation of colds.

Typical and illustrative of said statements and representations, but not all inclusive thereof, are the following:

On packages or labels:

LISTERINE
Antiseptic
Kills Germs
By Millions
On Contact
For Bad Breath, Colds and
Resultant Sore Throats

* * * * * * *

For Colds and Resultant Sore Throats—Gargle with Listerine Antiseptic Full Strength at the First Sign of Your Cold.

In print advertisements:

FIGHT BACK—The colds-catching season is here again! Nothing can cold-proof you * * * but Listerine Antiseptic gives you a chance to fight back!

* * * * * * *

Fight back with Listerine Antiseptic. Gargle twice a day—starting now—before you get a cold. You may find the colds you do get will be milder, less severe. That's why more people use Listerine during the colds-catching season than any other oral antiseptic. Why don't you?

* * * * * * *

Colds-catching season is here again! Nothing can cold-proof you—but Listerine Antiseptic gives you a fighting chance! For fewer colds, milder colds, try this:

Get plenty of rest.
Watch your diet.
Gargle twice a day with full-strength Listerine.

* * * * * * *

Want to write fewer of these this winter?

Dear Miss Bell,

Johnny's absence from school last week was due to *another* cold.

Yours truly,

Mrs. C. Ryan

Nothing can cold-proof Johnny but for a fewer colds, milder colds, have him try this:

Get plenty of rest.
The right diet.
Gargle twice a day with full-strength Listerine.

Tests over a 12-year period proved that people who gargle with Listerine twice a day had fewer colds, milder colds than those who did not.

Have your family try it.

In television commercials:

Those statements and representations appearing in Attachments "A" and "B" hereto and incorporated herein.

PAR. 5. By and through the use of the aforesaid statements and representations, and others of similar import and meaning but not expressly set out herein, respondent has represented, and is now representing, directly or by implication that the use of Listerine:

1. Will cure colds and sore throats.

2. Will prevent colds and sore throats.

3. Will cause colds and sore throats to be less severe than they otherwise would be.

PAR. 6. In truth and in fact, the use of Listerine:

1. Will not cure colds or sore throats.

2. Will not prevent colds or sore throats.

3. Will not cause colds or sore throats to be less severe than they otherwise would be.

Therefore, the statements and representations set forth in Paragraphs Four and Five hereof and in Attachments "A" and "B" hereto were and are false, misleading and deceptive.

PAR. 7. The severity of a cold is judged or measured by the severity of its accompanying symptoms. Therefore, when respondent represented that the use of Listerine would make colds milder or less severe as aforesaid it thereby represented, directly or by implication, that such use of Listerine would relieve or lessen the severity of cold symptoms to a significant degree.

PAR. 8. In truth and in fact the use of Listerine as directed will not have a significant beneficial effect on cold symptoms.

Therefore the representation set forth in Paragraph Seven hereof is and was false, misleading and deceptive.

PAR. 9. In the further course and conduct of its business as aforesaid respondent has represented, directly or by implication, that the latest or most recent tests conducted by or for it, or available to it, prove that children who gargle with Listerine twice a day have fewer and milder colds and miss fewer days of school because of colds than do those children who do not so use Listerine.

PAR. 10. In truth and in fact the most recent studies or tests conducted by or for respondent, do not prove or support the representation that children who gargle with Listerine twice a day have fewer and milder colds and miss fewer days of school because of colds than do those children who do not gargle with Listerine twice a day.

Therefore, the representations set forth in Paragraph Nine hereof are false, misleading and deceptive.

PAR. 11. In the further course and conduct of its business, through the use of the statement, "Kills Germs By Millions On Contact," respondent has represented, and now represents, directly or by implication, contrary to the fact, that the ability of Listerine to kill germs is of medical significance in the prevention, cure or treatment of colds and sore throats.

PAR. 12. In the course and conduct of its business, and at all times mentioned herein respondent has been, and now is, in substantial

competition with corporations, firms and individuals in the sale in commerce of mouthwashes.

PAR. 13. The use by respondent of the aforesaid false, misleading and deceptive statements and representations has had, and now has, the capacity and tendency to mislead members of the purchasing public into the erroneous and mistaken belief that said statements and representations were and are true and into the purchase of substantial quantities of Listerine by reason of said erroneous and mistaken belief.

PAR. 14. The aforesaid acts and practices of respondent, as herein alleged, were and are all to the prejudice and injury of the public and of respondent's competitors and constituted and now constitute unfair methods of competition and unfair and deceptive acts and practices in commerce in violation of Section 5 of the Federal Trade Commission Act.

ATTACHMENT A

JWT

As-Filmed Photo-Script
Date NOVEMBER/1999
Producer

Client WARNER-LAMBERT
Product LISTERINE ANTISEPTIC

Film No. 99-01206-60
Film Title "KEEPS YOU DRY"
Film Length 60 SECONDS

1. (SFX: KNOCKING ON WINDOW)

2. (SFX: KNOCKING ON WINDOW)

3. MOM: Well, if it isn't the abominable snowmen!

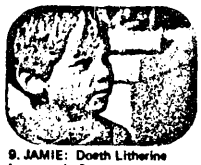
4. JACKIE: It's gonna blizzard, Mom!

5. MOM: Oh, Jackie! Wipe your feet. Come on fellas ... boots off and then upstairs . . .

6. to gargle with Listerine.

7. JACKIE: Do I have bad breath?

8. MOM: No, but you're soaking wet .....



9. JAMIE: Doeth Litherine keep me dry?

10. MOM: No, silly ... but remember all those colds we had last winter .....

11. JAMIE: Yeth ....

12. MOM: Well ... nobody's found a sure way to stop 'em ... but this year we're going to fight ...

13. back with lots of sleep ... JACKIE: Awwwww. Mom!

14. MOM: Lots of good food ... and gargle twice a day with Listerine.

15. I bet that'll help keep you in . . .

16. school. DAD: Hi gang.

17. MOM: Alright Jack ... upstairs. You need Listerine too.

18. DAD: Do I have bad breath?

19. JAMIE: No Daddy, Litherine keepth you dry. MOM: No Jamie. ANNCR: (VO) This cold season . . .

20. fight back with Listerine Antiseptic.

ATTACHMENT A

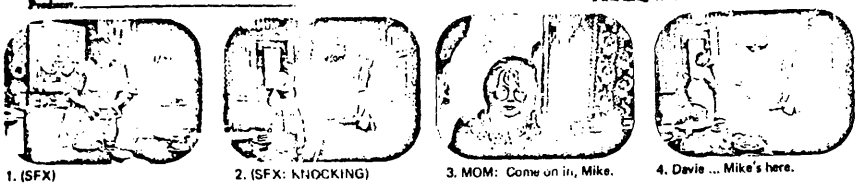
ATTACHMENT B

JWT

As-filmed Photo-Script
Date JANUARY/1970
Producer

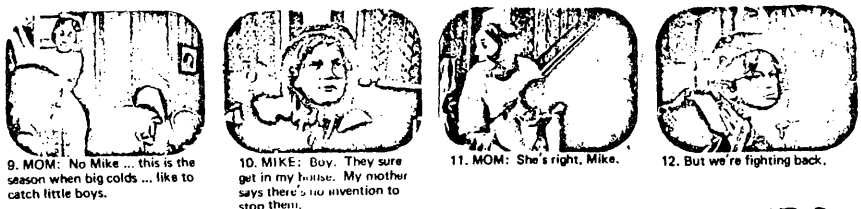
Client WARNER-LAMBERT
Product LISTERINE ANTISEPTIC

Film No. 69-0862-60
Film Title "JUST A MOTHER"
Film Length 60 SECONDS

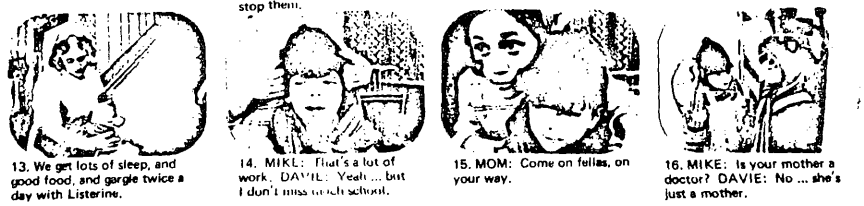


1. (SFX)
2. (SFX: KNOCKING)
3. MOM: Come on in, Mike.
4. Davie ... Mike's here.

5. Ready for school? DAVIE: Yup.
6. MOM: Did you gargle with Listerine?
7. DAVIE: Yup.
8. MIKE: How come he has to gargle? Does he have bad breath?



9. MOM: No Mike ... this is the season when big colds ... like to catch little boys.
10. MIKE: Boy. They sure get in my house. My mother says there's no invention to stop them.
11. MOM: She's right, Mike.
12. But we're fighting back.



13. We get lots of sleep, and good food, and gargle twice a day with Listerine.
14. MIKE: That's a lot of work, DAVIE: Yeah ... but I don't miss much school.
15. MOM: Come on fellas, on your way.
16. MIKE: Is your mother a doctor? DAVIE: No ... she's just a mother.

17. ANNCR: (VO) This colds season fight back with Listerine Antiseptic.

Appearances

For the Commission: *Edward F. Downs, Wallace S. Snyder* and *William S. Busker.*

For the respondents: *Herbert A. Bergson, James H. Kelley* and *Larry D. Sharp, Bergson, Borkland, Margolis & Adler*, Wash., D.C. and *Mudge, Rose, Guthrie & Alexander*, New York City.

INITIAL DECISION BY ALVIN L. BERMAN, ADMINISTRATIVE LAW JUDGE

NOVEMBER 25, 1974

PRELIMINARY STATEMENT

The Commission's complaint charges respondent Warner-Lambert Company ("Warner-Lambert") with having engaged in unfair methods of competition and unfair and deceptive acts and practices in violation of Section 5 of the Federal Trade Commission Act by virtue of various statements and representations made in connection with, and to induce the sale of, its "Listerine" mouthwash preparation. More specifically, it is charged that, through various advertisements, including product packaging and labels, respondent has represented that the use of Listerine will cure colds and sore throats, will prevent colds and sore throats and will cause colds and sore throats to be less severe than they otherwise would be; that these representations are false, misleading and deceptive. It is alleged that the severity of a cold is judged or measured by its accompanying symptoms, that the representation that the use of Listerine would make colds less severe constituted a representation that such use would relieve or lessen the severity of cold symptoms to a significant degree, and that this representation is false, misleading and deceptive.

Another allegation of the complaint is that respondent misrepresented that the most recent tests conducted by or for it, or available to it, prove that children who use Listerine have fewer or milder colds and miss fewer days of school than children who do not use Listerine. Still another allegation is that respondent has misrepresented that the ability of Listerine to kill germs is of medical significance in the prevention, cure or treatment of colds and sore throats.

Respondent, by its answer, admitted that it has represented that the use of Listerine as directed, in conjunction with a regimen of proper rest and diet, will cause fewer colds and will help reduce the severity of colds. It denied representing that the use of Listerine would cure or would totally prevent colds or sore throats. It admitted that Listerine would not cure colds or totally prevent colds or sore throats, but

averred that the use of Listerine as directed, in conjunction with a regimen of proper diet and rest, had been demonstrated to result in fewer colds, milder colds and milder symptoms thereof and less severe colds and sore throats.

Respondent admitted that the severity of a cold is judged or measured by its accompanying symptoms, and that the representation that the use of Listerine would make colds less severe constituted a representation that such use would relieve or lessen the severity of cold symptoms to a significant degree. It denied, however, that the use of Listerine as directed will not have a significant beneficial effect on cold symptoms. Respondent denied other material allegations of the complaint.

Subsequent to its answer, respondent moved for partial summary decision dismissing all allegations of the complaint which are related to the labeling of Listerine. It contended that the Federal Trade Commission lacks jurisdiction over the labeling of drugs—that such jurisdiction rests solely with the Food and Drug Administration. Administrative Law Judge Allard, on Dec. 14, 1972, held that labeling can be considered as advertising under Section 5 of the Federal Trade Commission Act and so denied the motion. Permission to apply to the Commission for review of the order pursuant to Section 3.23(b) of the Commission's Rules was denied by Judge Allard and, on Mar. 2, 1973, the Commission refused to consider an application for review in the absence of a Section 3.23(b) type ruling by the administrative law judge. The undersigned was assigned to hear this matter in place of Judge Allard following Judge Allard's departure from the Federal Trade Commission. After a review of all of the various pleadings and papers filed by the parties with respect to this issue, and upon consideration of this matter, the undersigned finds himself in agreement with Judge Allard's order and it remains the ruling on this issue.

Extensive hearings were held during which a large volume of testimony and documentary evidence was received. Among the evidence received or officially noticed was some from the record in a prior matter entitled *Lambert Pharmacal Co.*, 38 F.T.C. 726 (1944) [Dkt. 4232].[1]

This initial decision is based upon the entire record including proposed findings of fact and conclusions of law and briefs and supporting memoranda filed by the parties, as well as their responses. The undersigned has also taken into account his observation of the witnesses who appeared before him and their demeanor. Proposed findings not herein adopted, either in the form submitted or in

[1] The significance of this prior case to the instant matter will be discussed *infra*, as appropriate.

substance, are rejected either as not supported by the evidence or as involving immaterial matters.

FINDINGS OF FACT[2]

1. Respondent Warner-Lambert is a corporation, organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its principal office and place of business located at 201 Tabor Rd., Morris Plains, N.J. (Admitted, Ans. par. 1).

2. Respondent is now, and for some time last past, has been engaged in the manufacture, advertising, offering for sale, sale and distribution of a mouthwash preparation designated "Listerine" to retailers for resale to the consuming public (Admitted, Ans. par. 2).

3. In the course and conduct of its business respondent now causes, and for some time past has caused, Listerine, when sold, to be shipped from its plants and facilities to purchasers thereof located in various States other than the States of origination, and maintains, and at all times mentioned herein has maintained, a substantial course of trade in said Listerine in commerce, as "commerce" is defined in the Federal Trade Commission Act. The advertisements which are the subject of this proceeding have been disseminated by respondent in "commerce" within the meaning of the Federal Trade Commission Act (Admitted, Ans. pars. 3, 4).

4. In the course and conduct of its business, and at all times mentioned herein, respondent has been, and now is, in substantial competition with corporations, firms and individuals in the sale, in commerce, of mouthwashes (Admitted, Ans. par. 12). For the years 1964 through the first six months of 1972, Listerine's annual share of the mouthwash market was, respectively, 43.3 percent, 45.6 percent, 44.5 percent, 39.4 percent, 42.7 percent, 45.7 percent, 47.5 percent, 51.2 percent and 51.4 percent (CX 139-O).[3]

5. Listerine antiseptic was first marketed by the Lambert Pharmacal Company, now respondent Warner-Lambert, in 1879, and has been continuously marketed across State lines by respondent or its predecessors since that time. The Listerine formula (CX 48, *in camera*) has been unchanged since 1879. Its essential ingredients include thymol, eucalyptol, methyl salicylate and menthol. These ingredients are present in amounts within the limits for the internal doses of such ingredients generally recognized as safe (CX 139A).

6. Throughout its history, Listerine has been presented as being,

[2] Findings of fact, for the most part, are made in numbered paragraphs which appear on pages 3-71, 75-77 and 80-95 [pp. 1406-1459, 1463-1465, 1467-1480 herein]. Discussions and applications of findings, as well as consideration of legal and other matters, appear where deemed appropriate. Some follow particular findings which pertain thereto; others follow all of the numbered findings. Findings which appear in unnumbered paragraphs are, nevertheless, findings.

[3] The following are among the abbreviations used herein: CX—Commission exhibit; RX—Respondent exhibit; Tr.—Transcript of hearings; CPF—Proposed finding of complaint counsel; RPF—Proposed finding of respondent.

inter alia, beneficial in certain respects for colds, cold symptoms and sore throats and to be beneficial for certain antiseptic purposes (CX 139B).

7. Since prior to 1938, Listerine labeling has included the claims regarding colds and sore throats as set forth in CX 49 and 50 (See Finding 25, *infra*). These claims have been made continuously since prior to the effective date of the Federal Food, Drug and Cosmetic Act of 1938, and up to and including the date of the issuance of the complaint herein (CX 139B).

8. From April 1965 to June 1973, respondent spent several million dollars on its Listerine "colds" advertising (CX 45, 46; RX 100, all *in camera*).

9. In the course and conduct of its business, and for the purpose of inducing the sale of Listerine, respondent has made, and is now making, numerous statements and representations concerning the efficacy of Listerine in print advertisements and in television broadcasts transmitted by television stations located in various States of the United States and in the District of Columbia, having sufficient power to carry such broadcasts across State lines (Admitted, Ans. par. 4).

Representative Advertisements

The first major issue to be resolved is as to what representations have been made by respondent. Following is a description of some representative advertisements.

A. Print Advertisements

10. A number of advertisements depict a Listerine bottle showing the label on which appears, "Listerine Antiseptic Kills Germs By Millions On Contact. For Bad Breath, Colds and resultant Sore Throats." (CX 1, 5, 7, 11, 13, 15, 28, 30).

11. An advertisement widely disseminated in many newspapers in January 1968 (CX 21) shows a man with a handkerchief held against his nose and reads, "This man has something to give you—a rotten cold! Fight back with Listerine! Nothing can make you cold-proof. * * * But-for fewer colds, milder colds, try this:—Get plenty of rest.—Watch your diet.—Gargle twice a day with full-strength Listerine. Tests made over a twelve-year period proved that people who gargled with Listerine full strength twice a day, every day, had fewer colds and milder colds than those who did not. With a fighting chance like that * * * it's no wonder more people use Listerine during the colds-catching season than any other oral antiseptic. Why don't you?" (CX 20).

12. "Want to write fewer of these this winter? 'Dear Miss Bell, Johnny's absence from school last week was due to *another* cold. Yours truly, Mrs. Ryan.' Nothing can cold-proof Johnny but for fewer colds, milder colds, have him try this:—Get plenty of rest.—The right diet.—Gargle twice a day with full-strength Listerine. Tests over a 12-year period proved that people who gargle with Listerine twice a day had fewer colds, milder colds than those who did not. Have your family try it." (Emphasis in original) (CX 9, 25). This advertisement was widely disseminated from December 1968 through February 1969 and in September 1969 (CX 10, 26).

13. "FIGHT BACK. The colds-catching season is here again! Nothing can cold-proof you. * * * but Listerine Antiseptic gives you a chance to fight back! Try this:

1. Get plenty of rest. 2. Watch your diet. 3. Gargle twice a day with full-strength Listerine. Fight back with Listerine Antiseptic. Gargle twice a day—starting now—before you get a cold. You may find the colds you do get will be milder, less severe. That's why more people use Listerine during the colds-catching season than any other oral antiseptic. Why don't you?"

Featured in the middle of the advertisement is a hand in a boxing glove holding a bottle of Listerine with the statement on the label, "Listerine Antiseptic Kills Germs By Millions On Contact. For Bad Breath, Colds and resultant Sore Throats." (CX 27). This advertisement was widely disseminated in many newspapers in November 1969 (CX 29).

14. In an advertisement placed in a number of newspapers in December 1970 (CX 33), the following appears, "COLDS SEASON SPECIAL. Here comes the colds-catching season again, and nothing's going to stop it. But at least this year you can give your family a fighting chance. Make sure they get lots of sleep, good food, and gargle with Listerine Antiseptic, twice a day. * * * 7 OFF ON THE COLD FIGHTER." (CX 32).

15. "Fight Back. You Can't Stop Colds, But You Don't Have To Give Up. The colds-catching season is now in full swing and there is no way to keep your kids warm and dry all the time. So what do you do? Give up? No! You fight back. You make sure your family gets plenty of rest, dresses properly and eats lots of good food. And you make them gargle twice a day with Listerine Antiseptic. You can't stop colds, but at least this way you have a fighting chance. This colds season, fight back with Listerine Antiseptic." At the top of this advertisement, there is depicted an inverted bottle of Listerine with the words on the label, "Listerine Antiseptic Kills Germs By Millions On Contact" (CX 17). This advertisement was run in February 1972 (CX 18).

B. Television Commercials

16. In a commercial entitled "Rubber Stamp-Boy," a woman and young boy (obviously mother and son) are shown. The words "Cold Proof" appear on the boy's forehead. The following announcement covers the action that takes place: "Wouldn't it be great if you could make him cold-proof? Well, you can't. Nothing can do that (boy sneezes). But there is something you can do that may help. Have him gargle with Listerine Antiseptic. Listerine can't promise to keep him cold-free, but it may help fight off colds. During the cold-catching season, have him gargle twice a day with full-strength Listerine. Watch his diet, see he gets plenty of sleep, and there's a good chance he'll have fewer colds, milder colds this year (the words "Fewer Colds, Milder Colds" are superimposed on the picture). It's a fact that more families use Listerine during these cold-catching months than any other oral antiseptic. So be sure your family gargles regularly with Listerine Antiseptic. We can't promise to keep your family cold-free, but Listerine may help you fight off colds" (the words "Fight Colds" are shown with a bottle of Listerine) (CX 34A, 140A). This type commercial was run in March and April 1967 (CX 39).

17. In a commercial entitled "Boxer," a boy wearing boxing gloves is shown as the announcer says, "Can a 12 year old boy * * * wage a one-boy fight against the common cold? Well, he can give it a good try if right behind him there's a mother armed with Listerine Antiseptic (Mother appears). We can't promise that Listerine will keep him cold-free, no product can do that. But Listerine may help him fight off colds (the words "Fight Colds" are superimposed on the picture). If you have him gargle twice a day with full-strength Listerine, if you watch his diet and see that he gets plenty of sleep, there's a good chance that he'll have fewer colds, milder colds this year (the words "Fewer Colds, Milder Colds" are superimposed on the picture while the boy gargles). Many mothers see that their families gargle regularly with Listerine. In fact, during the cold-catching season, more people use Listerine than any other oral antiseptic. We can't promise to keep your family cold-free, but Listerine may help you fight off colds." (The words "Fight Colds" are superimposed on the picture.) (CX 34C, 140C). This type commercial was run in March and April 1967 (CX 39).

18. In a cartoon commercial entitled "Survival Kit," one character designated Mrs. Smith says, "Betsy gets a cold, Dad gets a cold and so does Junior!" A second female character says, "Well, nothing can guarantee to keep colds away see, but my Winter Survival Kit may help." Mrs. Smith, "What's that?" Second character, "My three-way way to ward off colds. Plenty of sleep * * * a balanced diet * * * and

gargle twice a day with full-strength Listerine Antiseptic. * * *" The announcer concludes with, "Try it, your family may have fewer colds, milder colds this season." (A pillow, pitcher of orange juice and a bottle of Listerine are depicted with the words "Fewer Colds, Milder Colds.") (CX 34E, 140E). This type commercial was run from November 1967 through March 1968 (CX 39).

19. In a commercial entitled "School Bus," two mothers are standing in the rain near a school bus. First mother, "Muriel, where's Davey and Sue?" Second mother, "Ah, down with colds again." First mother, "Again?"-Second mother, "Oh, yes, and your family always seems fine." First mother, "I've got a theory." Second mother, "A theory? Nothing can prevent colds." First mother, "You can help. * * * I watch their rest and diet and have them gargle twice a day with Listerine. * * * I think we've cut down on colds, and those we do catch, don't seem to last as long." The announcer concludes, "For fewer colds, milder colds, more people use Listerine than any other mouthwash" (the words "Fewer Colds, Milder Colds" are superimposed on the picture) (CX 34F, 140F). This type commercial was run from October 1967 through March 1968 (CX 39).

20. In a commercial entitled "Keeps You Dry," two small boys are shown coming into the house. The following dialogue occurs: Mom, "Okay kids. Upstairs and gargle with Listerine, you're soaking wet." Jamie, "Doeth Litherine (sic) keep me dry?" Mom, "No silly, it's colds I'm worried about. We can't really stop 'em, but this year we're gonna gets lots of sleep * * * and good food and gargle twice a day with Listerine. I bet that'll help keep colds away." Jamie, "Do grownups do this too?" Jackie, "Of course we do." Announcer, "Listerine Antiseptic. Try it. And your family may have fewer colds, milder colds this season" (the words "Fewer Colds, Milder Colds" are superimposed on the picture) (CX 35C, 141B). This type commercial was run during the 1968-1969 period (RPF 274).

21. In a commercial entitled "Just A Mother," Mike comes out of the snow into Davie's house to go with him to school. Mom, "Did you gargle with Listerine?" Davie, "Yup." Mike, "How come he has to gargle? Does he have bad breath?" Mom, "No, Mike, this is the season when big colds like to catch little boys." Mike, "Boy. They sure get in my house. My mother says there's no invention to stop them." Mom, "She's right, Mike. But we're fighting back. We get lots of sleep and good food and gargle twice a day with Listerine." Mike, "That's a lot of work." Davie, "Yeah, but I don't miss much school." * * * Mike, "Is your mother a doctor?" Davie, "No, she's just a mother." The announcer closes, "This colds season, fight back with Listerine Antiseptic" (a bottle of Listerine

is shown above the words "Fight Back!") (CX 35B, CX 142A). This type commercial was run from November 1969 through March 1970 (CX 39).

22. In a commercial entitled "Rain," a mother is shown at home. She speaks, "My oldest son is somewhere out there in the rain. He's supposed to be coming home from school and I can tell you right now he isn't wearing his hat or galoshes. Oh, I made sure he had them on when he left this morning. But this afternoon I found them in the front yard. That's my son. I know you're thinking how can I sit here so calmly while he's out getting wet and cold. Well, I'll tell you worrying won't keep him dry and as for colds? Nothing's going to stop 'em. But at least this year, I have a system. Plenty of sleep and good food, of course. And this cold-season, he gargles twice a day, everyday, with Listerine Antiseptic. Look, I'm not asking for miracles * * * but if it'll help keep him in school, I'll be happy." The announcer concludes, "This cold-season, fight back with Listerine Antiseptic." (CX 37C, 143C). This type commercial was run from October 1970 through March 1971 (CX 39).

23. In a commercial entitled "Snow," two boys are looking out of a window. The following dialogue takes place: Pete, "Look, Ma, it's snowing." Rick, "Last one outside's a big ape." Mother, "Hold it, before you guys go anywhere, you're gonna gargle with Listerine." Pete, "I haven't got bad breath." Mother, "I know. I know. But everytime it snows, it seems you guys catch colds." Rick, "Yeah, but so do you and Dad." Mother, "And we can't stop 'em, but this year we're gonna fight back with lots of sleep, good food and Listerine twice a day." Pete, "That means I can't stay home from school." Mother, "Exactly, that's the whole idea. Now, last one to the bathroom is a big ape." * * * The announcer concludes, "This cold-season fight back with Listerine Antiseptic" (the words "Fight Back" are superimposed on the picture with a bottle of Listerine) (CX 37E, 143E). This type commercial was run from October 1970 through March 1971 (CX 39).

24. In a commercial entitled "Rain" (Rev.), a mother is shown at home. She speaks, "This morning I told my son please keep your hat and galoshes on. I should know better. I just can't keep him dry. Oh I still worry about the colds. Because nothing is going to stop them. But this year, I have a system * * * plenty of sleep and good food, of course. And this cold season he gargles twice a day every day with Listerine Antiseptic. Look, I'm not looking for miracles. All I want is a fighting chance." The announcer concludes, "This cold season, fight back with Listerine Antiseptic." (the words "Fight Back" are superimposed on the picture with a bottle of Listerine) (CX 38, 144A). This type commercial was run from October 1971 through March 1972 (CX 39).

C. Labels

25. Listerine labels have read, "Listerine Antiseptic Kills Germs By Millions On Contact. For Bad Breath, Colds and resultant Sore Throats" and

"For colds and resultant sore throats, gargle with Listerine Antiseptic full strength at the first sign of your cold." (CX 49, 50).

26. Since December 1972, following issuance of the complaint in this matter, the label claims have read, "Listerine Antiseptic Kills Germs By Millions On Contact * * * For Relief of Colds Symptoms and Minor Sore Throats due to Colds" (CX 139-O, P).

Representations Made by Respondent

In evaluating what representations have been made, "[t]he important criterion is the net impression which the advertisement is likely to make upon the general populace." *Charles of the Ritz Dist. Corp.* v. *FTC*, 143 F.2d 676, 679 (2d Cir. 1944). When an advertisement is susceptible of two or more meanings, one of which is false, the advertisement is misleading under Section 5 of the Federal Trade Commission Act. *Murray Space Shoe Corp.* v. *FTC*, 304 F.2d 270, 272 (2d Cir. 1962); *Rhodes Pharmacal Co., Inc.* v. *FTC*, 208 F.2d 382, 387 (7th Cir. 1953), *aff'd*, 348 U.S. 940 (1955). With these principles in mind, the following findings are made relative to the representations that have been made by respondent as to the efficacy of Listerine for colds and sore throats.

27. The statement that Listerine is "for colds and resultant sore throats" clearly implies that the use of Listerine will cure colds. This is a reasonable understanding of the import of the statement. See, *Positive Products Co.* v. *FTC*, 132 F.2d 165, 168 (7th Cir. 1942); *D.D.D. Corp.* v. *FTC*, 125 F.2d 679, 681 (7th Cir. 1942). The statement in CX 34 (140F) that "those [colds] we do catch, don't seem to last so long" is a clear claim of termination or cure of colds by the use of Listerine.

28. In addition, those advertisements that state that you can help with Listerine or that Listerine provides a fighting chance or a means of fighting off colds or fighting back are reasonably subject to the construction that a cure is represented. All that such words could be understood to be directed at are the prevention or cure of colds or the amelioration of cold symptoms. To the extent that the advertisements containing such statements may be understood by some not to claim cold prevention, the representations as to cure or amelioration come through that much more strongly.

29. The complaint charges respondent with having represented that the use of Listerine will prevent colds and sore throats. Respondent

admitted representing that the use of Listerine, as directed, will cause fewer colds, but denied representing that its use would totally prevent colds or sore throats. Further, respondent contends that, starting in November 1969, its advertisements no longer represented that the use of Listerine would result in fewer colds. The charge here considered encompasses the prevention of some colds and sore throats and representations as to total prevention need not be shown. Respondent's answer, therefore, constitutes an admission that the representation alleged was made.

30. While a representation of total prevention need not be shown, respondent's advertisements may well be understood to represent total prevention or prevention to a substantial degree—even to a degree approaching total.

31. The statement that Listerine kills germs by millions on contact and that it is for colds and resultant sore throats, together with the directive to gargle with Listerine twice a day (even in the absence of cold symptoms) is a representation that Listerine will prevent colds and resultant sore throats.

32. Statements to the effect that Listerine will not cold-proof (CX 10, 20, 26, 27, 140A), you can't stop or prevent colds (CX 17, 32, 140F, 141B, 142A, 143C, 143E, 144A), we can't promise to keep your family cold free (CX 140A, 140C), there is no guarantee to keep colds away (CX 140E) are *pro forma* statements of no absolute prevention followed by promises of fewer colds (CX 10, 20, 26, 140A, 140C, 140E, 140F, 141B). The message that gets across is that Listerine will prevent colds. Perhaps it won't prevent all in the sense of cold-proofing or being an absolute guarantee, but it will, for all practical purposes, prevent colds. Perhaps in the reader's own family, it will prevent all colds.

33. The instructions to fight off colds or fight back with Listerine, since the user has a fighting chance with Listerine (see, *e.g.*, CX 20, 29, 140A, 140C), help buttress the belief that the particular reader can put up the good fight and prevent colds in her family. In CX 140F, it is stated to the mother who uses Listerine, "Oh, yes, and your family always seems fine." This is deemed an absolute cold prevention representation.

34. The advertisements run after November 1969, while they no longer specifically promise fewer colds, also represent that Listerine will prevent colds to a significant, if not total, extent. As in advertisements placed prior to November 1969, the *pro forma* statements to the effect that nothing will stop colds imply that nothing will stop all colds. However, the instruction remains to use Listerine daily in the absence of a cold, thus representing that Listerine should be used to prevent colds.

35. In CX 17 and CX 144A, the representation is made that the reader has a fighting chance by using Listerine. In CX 142A and CX 144A, Listerine is represented as a means of fighting back. In CX 143C and 144A Listerine, in conjunction with proper sleep and good food, is represented as a system and a means of fighting back. In CX 143E, Listerine is represented as a means of fighting back. In none of these advertisements is the representation limited to a claim with regard to the severity of colds. Hence, the representation is made that Listerine offers a system, a fighting chance or a means of fighting back against getting colds.

36. In CX 32, it is stated that nothing is going to stop the *colds-catching season,* but that the reader by using Listerine, "can give [her] family a fighting chance." It is thus represented that the use of Listerine affords a fighting chance against catching any colds despite the advent of the colds catching season.

37. In CX 143E, after being told that he is going to fight back with Listerine twice a day, the boy states, "That means I can't stay home from school." And the mother replies, "Exactly, that's the whole idea." This is another total prevention representation.

38. Despite respondent's position that it intended the advertisements after November 1969 to constitute only mildness claims, they come through loud and clear as representing, in addition, that Listerine, to some appreciable extent, will prevent colds. Even if respondent had no intent to make prevention claims, that does not change the fact that such claims were made.[4]

39. Respondent has admitted representing that the use of Listerine as directed will cause colds and sore throats to be less severe than they otherwise would be and that such a representation encompasses the representation that such use of Listerine will relieve or lessen the severity of cold symptoms to a significant degree.

40. It is also found that, by use of the statement "Kills Germs By Millions On Contact" in conjunction with "for * * * Colds and resultant Sore Throats," as well as in conjunction with the other statements described above, respondent has represented that the ability of Listerine to kill germs is of medical significance in the prevention, cure and treatment of colds and sore throats.

41. The above findings as to what representations have been made

[4] One of respondent's officials who was directly responsible for Listerine advertising testified (Tr. 3475-78) that a basic difference between pre-November 1969 and subsequent advertising is the change from "I bet that will keep colds away" in CX 141A to "I bet that will keep you in school" in CX 142C; that the former was a fewer colds claim while the substitute is a mildness claim. It is doubted that the average listener would draw the distinction and would reason that the child would stay in school, not because he didn't have a cold, but only because the cold was more moderate. Similarly rejected is the witness' explanation that listeners would perceive "fight off" as a fewer colds claim, but would understand "fighting chance" and "fight back" used since November 1969 as mildness claims (Tr. 3481). The purported distinctions are much too sophisticated to be realistic.

by respondent are based upon the pleadings and the undersigned's own evaluation of the advertisements in question. Such evaluations are also supported by other evidence in the record.

42. The J. Walter Thompson Company, respondent's advertising agency, in analyzing advertising techniques to be used for Listerine, reported in April 1969 that the public recognizes germs, followed by virus/bacteria, as the cause of colds, and that mouthwash is considered by most people as a means of obtaining symptomatic relief and as a germ killer (CX 97A, B). Respondent has capitalized on these beliefs. The advertising agency evaluated then current Listerine advertising as depicting "a need to prevent colds and sore throats." (CX 97B). The same analysis, of course, would equally apply to similar representations made after November 1969.

43. In reporting a so-called "Burke Test" study on the effect of the use of the phrase "fights back" as a substitute for "fewer colds," a Warner-Lambert interdepartmental memorandum prepared in January 1970, stated (CX 98C):

> "Fight back" is apparently an effective device for inducing consumer perception of Listerine as a colds preventive.

44. A Burke Test is a telephonic survey of 250 female heads of households in each of several selected representative cities to ascertain, on the day after a one-time test commercial is run on television, just what message has been perceived. The viewers are asked what they recall and verbatim answers are taken. These tests have been shown to be reliable by extended use and reliance upon them by respondent and other major package goods manufacturers. Standard procedures are utilized to insure the validity of reports based upon the interviews (Tr. 1110-43).

45. Burke Tests in evidence (CX 82-89) report on the following advertisements: "Boxer," "Rubber Stamp," "School Bus" (CX 34, 140A, C, F); "Relentless" (CX 1), "Survival Kit" (CX 34, 35); "Keeps You Dry" (CX 35, 141A), "Just A Mother" (CX 36, 142A); and "Rain" (CX 37, 143C). These tests show that of those contacted and who were deemed to have had an opportunity to view the test commercials, substantial percentages perceived the general message that Listerine was effective against colds and sore throats and, more specifically, prevented colds and sore throats and caused fewer colds and sore throats. This high recall is even more significant in view of the fact that the surveys were made on the basis of a one-time showing of the commercial, and the percentages were of individuals who had an opportunity to view the commercial, but who, in fact, may not have watched or listened to it. With repeated exposure, it is to be anticipated

that respondent's message would get across to more listeners and viewers. Commission exhibits 82L, M, Q, 83J, 85-O, P, 86I, 87M, N, O, P, Q, 88I, K, L, and 89I contain examples of verbatim responses to Burke Test interviews that show the viewers' understandings that the Listerine commercials make cold and sore throat prevention claims.

46. Respondent has relied heavily on Burke Test results in evaluating the effectiveness of relaying messages or copy points to the public (Tr. 3488, 3507, 3519; CX 93C, 95A). "Use to prevent colds" was such a copy point of the commercial "Keeps You Dry" (CX 141B) and this copy point got across at a high level (CX 141B, 92D).

47. In summary, the findings as to what respondent has represented are based upon the pleadings and the undersigned's own evaluation of the advertisements in question. They are also found upon the basis of the facts recited in Findings 42-46.

Respondent (RPF 253) asserts that a company's intent in presenting an advertisement is probative of the actual meaning of, and the impression conveyed by, that advertisement, and that it exercised good faith to insure the truthfulness of its advertising. To the contrary, here, where the issue is the truth or falsity of respondent's representations, good faith and lack of intent to deceive is irrelevant. *National Dynamics Corp.*, 82 F.T.C. 488, 553 (1973). An unintentional misrepresentation and lack of knowledge as to the falsity of a representation is no defense to a charge of misleading advertising. *Gimbel Bros. Inc.* v. *FTC*, 116 F.2d 578, 579 (2d Cir. 1941). As stated in *Ford Motor Co.* v. *FTC*, 120 F.2d 175, 181 (6th Cir. 1941), "The question [of whether an advertisement is false or has the capacity or tendency to mislead] does not depend upon the purpose of the advertisement nor upon the good or bad faith of the advertiser."

The Truth of Warner-Lambert's Representations as to the Efficacy of Using Listerine as Directed for the Prevention, Cure and Relief of Colds and Sore Throats and Cold Symptoms

For the reasons and on the basis of the findings stated below, the undersigned finds that the use of Listerine will not prevent or result in fewer colds or sore throats, will not cure colds or sore throats and will not cause colds or their symptoms, including sore throats, to be less severe than they otherwise would be; and that the ability of Listerine to kill germs is of no medical significance in the prevention, cure or treatment of colds and sore throats.

In support of the allegations of the complaint, Commission counsel produced highly qualified and eminent physicians and pharmacologists who stated their opinions as to the efficacy of Listerine and gave sound

bases therefor. This is in contrast with the opinions given by respondent's experts which were founded on weak and unreliable bases. Some of their tenuous and unfounded theories reflect, in part, long-standing connections these witnesses have had with respondent. Respondent, and some of its expert witnesses, in large part, rely upon the results of the Reddish and St. Barnabas tests or studies that were conducted on behalf of respondent. These tests are inadequate to constitute probative evidence in support of respondent's cold claims as to Listerine. Consequently, to the extent respondent's experts have relied upon these tests for their expert opinions, their opinions are of little or no weight. Other tests and matters relied upon by respondent provide little of probative value in this case.

48. The common cold is caused by virus particles being inhaled into the nose. These virus particles become attached to cells in the nasal pharynx. They enter the cells where they multiply. Some viruses cause the cells to rupture allowing the viruses to spread to other cells. Other types of viruses spread directly from cell to cell by a budding process. Thus, the cells are damaged causing the patient to perceive that he has a cold. Cold viruses do not involve the oral cavity (Gwaltney 384-86; Hornick 477-78; Seal 546-48, 591; Proctor 606-07, 654; Parrott 898-99; Sanders 852-53, Kilbourne 1053-54, 1089-90).

49. Whether or not one gets a cold is not affected by diet, rest or exposure to the elements (Gwaltney 394, 396; Hornick 479, 481; Proctor 631; Parrott 907).

50. A common cold is a viral infection of the upper respiratory tract which manifests itself as a combination of symptoms including, to varying degrees, stuffy nose, runny nose, postnasal drip, burning sensation in the nose, sore throat, sneezing, coughing, burning eyes, fever, general malaise, muscle ache, and mild headache. Not all symptoms are always present (Gwaltney 380; Hornick 475; Seal 544-45; Sanders 836; Parrott 894; Kilbourne 1054; Knight 1095; Sadusk 3201).

51. Bacteria play very little part in the common cold. Apart from viruses, cold type symptoms may be caused by the bacteria called Beta Hemolytic Streptococci or Group A Hemolytic Streptococci, more commonly referred to as a strep throat, and another organism somewhere in between a virus and a bacteria called microplasma pneumonia. These agents may cause at most 5 to 10 percent of the occurrences of cold-like symptoms. These ailments, however, must be treated with specific medicinal agents. In the case of strep throat, failure to treat properly may result in rheumatic fever, valvular heart disease and kidney infections, which are very serious to the point of being life-threatening. Microplasma pneumonia is a lingering ailment if antibiotics are not used. It would be inappropriate to treat patients

with strep throat or microplasma pneumonia with Listerine or with anything other than the specific medications that should be prescribed (Gwaltney 380-81, 384-85, 438, 453-54, 486, 493-94; Proctor 610; Rammelkamp 767-71, 799-800; Sanders 836-40, 870; Parrott 896-97, 900-01, 918-19; Knight 1925-26, 2037-40, 2048).

52. The foregoing finding buttresses all of the other evidence to the effect that common colds are caused by viruses and those other agents which cause cold-like symptoms should be ignored in this case.

53. The duration of a cold is the same whether it is treated or untreated. It is self-limiting in the sense that if you do nothing for it, it will go away on its own (Hornick 476; Seal 549-50; Haggie 1810-11).

54. The use of Listerine will not prevent or result in fewer colds or sore throats (Gwaltney 391; Hornick 479; Seal 556; Proctor 617; Schwartz 642; Rammelkamp 781-82; Sanders 832-38; Parrott 901; Modell 1011; Kilbourne 1057). Respondent has admitted that Listerine will not totally prevent colds (Ans., par. 6).

55. The use of Listerine will not cure colds or sore throats (Ans., par. 6; Gwaltney 389; Hornick 479; Proctor 618; Parrott 905).

56. The use of Listerine will not cause colds or sore throats to be milder nor will it relieve or have a beneficial effect on cold symptoms (Gwaltney 392, 448, 451; Hornick 483-85; Seal 556-57; Proctor 618; Schwartz 692-93; Rammelkamp 782; Sanders 859-60; Parrott 906-07; Modell 1005-12; Kilbourne 1057-58).

57. Gargling may give transient relief to a sore throat to the extent that it may remove the debris that has accumulated. It also may provide a soothing effect for a short period of time. Gargling, however, may reach only the forward portion of the throat, but not the posterior pharynx. Any type of material removed would soon be replaced. This relief, however, is provided by any type gargle, warm for soothing effect, and Listerine does not add to these transient benefits (Gwaltney 395, 446-47; Hornick 483; Seal 557, 566; Proctor 616-17; Schwartz 682-83; Rammelkamp 777, 781-83; Sanders 860, 862; Parrott 906-07; Modell 1011, 1038-39). Thus, any relief to a sore throat by gargling with Listerine is not peculiarly attributable to Listerine. Further, the relief so afforded is not to any significant degree.

58. Colds are not caused by bacteria. Bacteria in the oral cavity play no role in cold symptoms. The ability of Listerine to kill millions of germs on contact, therefore, is of no medical significance in the prevention, cure or treatment of colds or sore throats (Gwaltney 397, 453; Hornick 486, 488-89; Seal 551-53; Proctor 609, 616-18; Rammelkamp 776-77; Sanders 836; Parrott 918-19; Kilbourne 1058; see also Knight 2048).

The above findings, to the extent not grounded on admissions, are

based primarily upon the opinions of physicians who have spent most of their medical careers in the field of respiratory diseases, who have achieved high positions and eminence in that field, both in research and practice, and who have maintained a current and thorough knowledge of what is known and what has transpired in this field. Also relied upon are the opinions of two highly qualified pharmacologists. As previously indicated, the undersigned has observed and been impressed with the demeanor and forthrightness of these experts and the sound bases for their opinions. To the extent not already incorporated in the above findings, some of these factual bases are as follows:

59. Dr. Sanders' explanation, in part, as to the factual bases of his opinion of the lack of efficacy of Listerine in the prevention, cure or treatment of colds and sore throats is illustrative:

> * * * Obviously, I have been taught, I have read a great deal. I have had a lot of experience with patients and patient care. We have been very, very concerned about viral and bacterial respiratory infections. * * * We have been through any number of decades of attempts to prevent or treat these kinds of infections by topical applications of preventive agents to surfaces of highly active microbial agents like the penicillins or the tepacillins or the various other highly potent anti-microbial agents. In addition, a variety of other agents with known anti-bacterial activity of high potency have been applied topically and have just been not effective in preventing infections (Tr. 838).
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> * * * * * * *
>
> I begin with my teaching wherein I hear these things taught in lectures and so forth as I go through medical school, internship, residency—I continue to read—I am involved in patient care. I inquire of patients what they have done, what they have not done in attempts to prevent, treat, and so forth, and with this kind of information, you formulate an opinion, and the opinion, as well as the weight of scientific evidence, says that topically applied agents have no role in prevention or treatment of colds. My colleagues, my peers, patient experience, it is a combination of those things (Tr. 850-51).

60. There is no acceptable rationale for the gargling of Listerine to be of any benefit in curing or ameliorating a cold (Gwaltney 393; Proctor 621-23; Kilbourne 1058).

61. Cold viruses enter through the nose, sometimes through the eye. They do not enter through the mouth. Experiments attempting to infect people through the mouth have been unsuccessful (Gwaltney 385-86; Seal 546-47; Proctor 618, 654, 660).

62. The site of a cold infection is confined to the nose and nasopharynx (Gwaltney 384; Hornick 477; Seal 568-69).

63. Viruses penetrate cells very quickly once they contact the cell walls. Viruses live in and do damage to cells. Viruses propagate rapidly within cells and spread almost immediately to other cells as they are released upon killing the cells they have invaded (Seal 576, 578; Proctor 607, 655; Sanders 853).

64. Children have six to eight colds a year. Adults have two to three. Viruses may be distinguished as lipids (which include influenzas, parainfluenzas and coronas) and nonlipids (which include rhinoviruses, adenoviruses and enteroviruses). Rhinoviruses account for some 30 percent of adults' colds (Gwaltney 383, 432-33). The ingredients of Listerine have little or no virucidal effect on rhinoviruses (Gwaltney 393).

65. There is no known compound taken orally that will alter the natural history of a cold. There are no drugs which will cure the common cold (Rammelkamp 781-82; Parrott 902). Only two agents are known to prevent colds—a rhinovirus vaccine administered in the nose which acts against the particular strain involved and an antiviral substance made from the body called interferon. There is also a drug called amantadine which is limited in its effect to certain influenza viruses. It is not commonly used because its efficacy is questionable (Hornick 474; Seal 550; Parrott 901, 922).

66. In order for a product to be efficacious with respect to a cold it must be able to interfere with the activities of the virus. This is much more complex than merely trying to kill a bacteria or a virus. Hence, over the past 10 to 15 years, experiments with various substances known to be capable of killing viruses in solutions have been found ineffective (Hornick 516-17). There is no known way a cold can be aborted or the course of the infection changed. There is no known substance, certainly not those in Listerine, capable of affecting the pathogenesis of a cold. Gargling with Listerine offers no mechanism for affecting the course of a cold or lessening its duration (Proctor 618; Kilbourne 1055, 1057-58).

67. Antibodies have been shown by studies to be valueless against viruses that cause colds. This includes antiviral and antibiotic agents. Penicillin and sulfanomides breathed directly into the nose, the nasopharynx and the lungs proved valueless, even though taken systemically, they are helpful in killing off pathogenic material. The use of antibiotics is useless in the prevention or treatment of a cold in any respect (Hornick 480, 516-17; Proctor 619-20; Sanders 838, 852-53, 872-73).

68. Not only have antibiotics been found valueless, but their indiscriminate use should be avoided because it disturbs the ecological balance and may cause the regrowth and spread of resistant microorganisms. Also it may cause the disappearance of impeding ones. Thus, there may be the overgrowing and invasion of undesirable bacteria which may become resistant to antibiotics when they are subsequently required. Secondary infections thus may be incurred by

the indiscriminate use of antibiotics (Sanders 872-73). Antibiotics are not used to treat colds (Seal 590).

69. The mechanism of gargling makes it virtually impossible for the gargle to reach the nasal passages or the lower respiratory tract. When gargling, the palate closes off the nasal passage and nasopharynx and the glottis closes off the entrance to the lower respiratory tract. The gargle is confined to the mouth chamber. Hence, Listerine would not reach the site of infection or manifestation of symptoms in any medically significant concentration. Any vapors that might reach the site where the action is would not be in therapeutic concentration and, in any event, would soon be swept away. Thus, the gargling with Listerine would be ineffective in preventing or producing fewer cold infections or in relieving or reducing the severity of cold symptoms (Gwaltney 393, 448; Hornick 483; Seal 554-56, 571, 573; Proctor 616-19; Rammelkamp 787; Sanders 854; Parrott 904).

70. Even if gargling with Listerine caused its ingredients to reach the nose and nasopharynx, they would not penetrate the cells where the action of the viruses would be taking place. Hence, Listerine would still be ineffective in this regard (Hornick 481-82; Parrott 904). If Listerine's ingredients were in a concentration strong enough to be effective and reached the infected cells in therapeutic strength and did and could penetrate the cells, the cells would be killed. This would be undesirable as it would destroy the protective covering of the lining of the nose and throat and so provide portals of entry for various bacteria (Hornick 482-83).

71. Colds are sometimes followed by secondary infections caused by bacteria known as secondary invaders. Instances are sinusitis and otitis media (middle ear infection) where drainage from the sinuses or middle ear is impaired by the cold, and bacteria which are already in those sites get the opportunity, because of the lack of drainage, to cause trouble. Another secondary infection is peritonsillar cellulitis. The ingredients of Listerine, however, would not reach the resting places of the secondary invaders. Listerine could not reach the sinuses, the middle ear or the deep crypts of the tonsils or adenoids or other deep-seated places where such bacteria might be. Listerine, therefore, would be ineffective to prevent, cure or alleviate such secondary infections (Seal 552-54, 572; Proctor 614-15, 618; Rammelkamp 772-74, 811-12; Sanders 842, 844).

72. While Listerine kills millions of bacteria in the mouth, it also leaves millions. It is impossible to sterilize any area of the mouth, let alone the entire mouth. There are significant numbers of bacteria in various tissues, tissue folds and crypts which Listerine can't reach. For example, there is more flora in the crevices of the teeth than on the

roof of the mouth. The bacteria grow back quickly or the voids are quickly replaced by other bacteria. The use of Listerine has only a transient effect on the flora (Hornick 488-89, 523-24; Seal 554; Proctor 620; Sanders 847, 881-83).

73. To the extent that Listerine may kill millions of bacteria in the mouth, it would do so only ahead of the soft palate. This would have nothing to do with the throat, nose or the posterior pharynx. Consequently, the killing of germs in the mouth would have nothing to do with preventing, curing or relieving colds or coughs or cold symptoms (Hornick 483; Seal 554; Rammelkamp 777). The bacteria in the normal flora of the mouth play no role in the causation of colds or in the symptoms of colds. Thus, killing some of those bacteria would have no effect on the prevention, cure or symptoms of colds or coughs (Sanders 846-47, 879-80; And see Findings 48, 51, 52, 58 and 62, *supra*).

74. Methyl salicylate is a derivative of salicylic acid, which is used as a systemic analgesic (Schwartz 682). Methyl salicylate is generally used in a liniment for analgesic purposes, but it must be in sufficient quantity so it can be absorbed. Even when used topically as a rub-on, there would have to be up to five times as much methyl salicylate as there is in Listerine to be effective as an analgesic. Used as part of a gargle, the amount of methyl salicylate is insufficient and the time of the gargle is too brief to be of any analgesic benefit. After the gargle, the amount left in vapor form would be insignificant and would soon be washed away (Modell 1004-07, 1014-18; Schwartz 683-84).

75. Methyl salicylate acts as a counter-irritant by increasing the blood flow. Even if the methyl salicylate in Listerine were in a high enough concentration and reached the area of the sore throat, which it does not (other than for a very small portion thereof), it would increase the blood flow. This would be counter-soothing because a sore throat, in large part, is the result of too much blood flow (Schwartz 682-83).

76. Menthol, when inhaled as a vapor in high concentration, would act as a coolant and decongestant. The relief, however, would be transient, ceasing almost immediately after the stopping of the inhalation. The amount of menthol in Listerine, however, is so low that any quantity that might reach the cold-affected areas would be insufficient to have any significant effect (Schwartz 684-86, 712-13; Modell 1009, 1028). Menthol, can also have an anesthetic effect if applied in sufficient concentration to the mucous membrane. Even when applied directly to the affected area, as contrasted to what might reach that area by gargling, there would have to be a concentration of from two to five times as much menthol as there is in Listerine (Modell 1009, 1025-26).

77. Thymol has been used as an expectorant, but is not now

recognized as being effective for that purpose. It has also been used as an antibacterial agent (Schwartz 678, 690). Thymol has also been used to relieve congestion of the respiratory tract. When so used, however, it is generally applied directly as a steam vapor. Any relief is transient. Even when so applied directly for nasal congestion and inflammation, to be effective, two to five times as much thymol as there is in Listerine is required. The amount present in Listerine is insufficient, particularly since the gargle is for a relatively short period of time and gargling does not afford the direct application to the affected parts (Schwartz 678-79; Modell 1008, 1029).

78. Eucalyptol is related to thymol. It too has been discredited as an expectorant agent. Eucalyptol and thymol have been applied directly to the nose to relieve nasal congestion. Eucalyptol could act as a topical analgesic if applied directly and if about five times as much were used as is found in Listerine. Dentists use eucalyptol as a topical anesthetic but, when so used, the product is placed directly in the tooth cavity. Again, to relieve nasal congestion, a direct steam vapor application would be required in concentrations two to five times that of Listerine. Application by means of a gargle is too brief and the concentration of what is being gargled is too weak, even if all of it were to reach the desired site (Schwartz 688-90; Modell 1010, 1029-30).

79. Respondent contends that the pharmacologists called by complaint counsel, Drs. Schwartz and Modell, testified as to the effects of the individual active ingredients in Listerine but failed to take into account the cumulative effects of such ingredients. To the contrary, Dr. Schwartz made it clear that everything he testified to with respect to the individual ingredients applies collectively to the entire preparation and that if all of the Listerine gargled could vaporize, it would still not be an effective dosage (Tr. 710, 712). Dr. Modell similarly had in mind the cumulative effects of the various active ingredients of Listerine when he testified to its lack of efficacy (Tr. 1010-11, 1023, 1037).

80. This record does not establish the percentage of the active ingredients of Listerine that vaporize when that product is gargled and what portion of such vapors reach the nose and nasopharynx. Taking into account, however, the insufficient concentration to start with and the loss of ingredients by such normal activities as smoking, drinking and eating, it is obvious that only a small percentage of such insufficient quantities would vaporize and reach the nose and nasopharynx.

Clinical Studies

Before discussing the opinion testimony of the experts produced by respondent, it would be well to consider the clinical studies conducted

on behalf of respondent. This is because much of respondent's experts' opinions were based upon their results, particularly the results of the St. Barnabas study. Preliminary to discussing the studies, it is important to understand what has been termed the placebo effect of medicines on users and the bias that is built into a study if the control group, those who are not taking the agent being tested and who are being compared with those being tested, is not provided with a "placebo" agent that simulates the product being tested. Another built-in bias to be considered is that of the investigator if he knows which of the persons he is examining are receiving the tested medication and which are not.

81. People who are given medication for an ailment frequently feel better because they think they should, even though the product has no therapeutic value. There are very few people who are not susceptible to this phenomenon (Seal 562, 566; Proctor 659; Rammelkamp 785). As Dr. Proctor testified, "Even with severe pain, you can substitute sugar for morphine and about 30 percent of the people will be relieved of their pain." (Tr. 659). And as Dr. Rammelkamp explained, "[Y]ou see paralysis even stopped where you just give an injection of salt water." (Tr. 783). This is known as the placebo effect. The placebo effect is always present when medication is taken (Shirkey 2635).

82. Because of the placebo effect, it is important, when attempting to conduct a meaningful clinical study, that the control group be given a placebo which simulates in appearance and taste the product being given to the test group. By this procedure, no one in the study group knows whether he is taking the medication in question or the placebo. In this manner, the placebo effect is neutralized between the test and control groups, and any recorded difference between the two groups can more reliably be attributed to the medication being tested. The importance of utilizing a placebo and of the subjects not knowing whether they are taking the tested medication or the placebo is extremely critical when conducting a cold test. This is because colds are subjective ailments, being related in terms of relative degrees of severity by the subjects, and the ailment is self-limiting and improves even without medication. Narrative descriptions of cold symptoms are not too reliable, particularly when the subject must recall the severity of symptoms for any past period. Also, the differences to be measured are very small. This makes a cold study a very difficult and tricky one to conduct and calls for rigid controls including the use of a proper

placebo and lack of knowledge on the part of the subjects as to whether they are in the test or control groups.[5] (Gwaltney 407, 408; Hornick 476, 497, 499, 502; Seal 549-50, 562; Rammelkamp 783-84; Haggie 1794, 1808-11; Knight 2051; Shirkey 2637, 2655-56; Nitzberg 2816-20, 2823; Lamm 2935; Carson 3055-56, 3585-86, 3589; Bogarty 3072-73, 3115-16; Sadusk 3206, 3209, 3217-26, 3277; Jawetz 3698-99, 3742; Charache 3838-39; Wehrle 3995, 4011, 4013-15, 4037-39; Lasagna 4108, 4126, 4130-31, 4134, 4160, 4162; CX 162G-T). Without such precautions, it is clear that the test results will reflect bias in favor of the tested agent.

83. Another bias that must be avoided is that of the investigator who is recording the results as narrated to him by the subjects or as observed by him when he conducts his examination. Every investigator has his own biases. It is important that the investigator not know whether the subjects are taking the test agent or are in the control group. Otherwise, he will subconsciously try to give his employer the answers the employer wants (Gwaltney 407; Haggie 1794; Knight 2051; Lamm 2934, 2937; Sadusk 3206; Carson 3589, 3601; Jawetz 3698-3701; Wehrle 3995, 4013-15, 4037-39; Lasagna 4126, 4133-34; CX 162G-I). As Dr. Knight reported to respondent (CX 162G-H):

> * * * In the absence of double blind controls, however, there is no way to exclude the possibility of some bias. There is a tendency of both patients and experimentalists to see a favorable effect of medication in any experiment.

As respondent's statistical expert testified (Lamm 2934):

> * * * [T]he important thing in this type of study is that your investigator be blind.

And, as one of respondent's expert medical witnesses testified (Sadusk 3228-29):

> If the doctor knew [which subject that came to him was a control and which was a test]—and this would indicate that the doctor was dishonest because he would actually ask each person—the experiment, of course, would not be valid.

With these basic requirements in mind, we now consider the two major studies conducted on behalf of the respondent and upon which the respondent relies.

(1) The St. Barnabas Test

84. A clinical study purporting to show the efficacy of Listerine on the common cold was conducted at the St. Barnabas Catholic School, Bronx, N.Y., during the four year period 1967-1971. The purpose of this

[5] For example, investigators at the National Institutes of Health have questioned a cold study they conducted regarding the use of Vitamin C because they discovered that a significant number of subjects guessed correctly whether they were in the placebo group or the group taking Vitamin C (Hornick 501).

study was to determine the effect of twice daily rinsing and gargling with Listerine on the incidence, duration and severity of the common cold and its symptoms. It was conducted during the 26-week cold season of each year, *i.e.*, November to April. Four 26-week interim reports were compiled which include statistical analyses (CX 51; RX 81, 83, 84).

85. The St. Barnabas School administration and parents of the students agreed to participate in the test. The St. Barnabas School consisted of an all girl high school (grades 9 to 12) and an elementary school, with boys and girls from grades 3 to 8 participating in the study. The two schools were in separate buildings. Two medical practitioners participated, one assigned to the elementary school and one to the high school. Dr. Benjamin W. Nitzberg, a board certified pediatrician with an active pediatrics practice in Roslyn Heights, N.Y., served as the elementary school examining physician. Dr. David Granger, another pediatrician, served as examining physician in the high school (CX 51D; RX 81C, 83P; Haggie 1792; Baron 2708-09; Nitzberg 2784-88, 2804). Prior to the fourth year of the study, the high school population was dropped. For that year, Dr. Nitzberg continued as the examining physician in the elementary school, and Dr. Granger served as "back-up" in the event of Dr. Nitzberg's absence (RX 84H).

86(a). The study was conducted in a coded and randomized fashion. The subjects were re-randomized each year. Randomization was in accord with a standard statistical procedure based on the Rand Table of Random Numbers. Each year, about 750 elementary school children participated so that there were some 3,000 elementary school subjects over the four-year period. Counting the high school students, there were about 4,000 subjects. Many students participated more than one year and so could be subjects a multiple number of years up to four. Such children could have been in the control group some years and in the test group in other years.

86(b). During the first two years of the study the subjects, both elementary and high school students, were randomly assigned to either a treatment group which rinsed twice daily with Listerine antiseptic or to a control group which used no mouthwash at all. In the second two years, the control group gargled with a water rinse colored to be similar to the color of Listerine (Nitzberg 2789-90, 2796-97; Lamm 2870-73, 2924, 2949).

87. The gargling by the control group during the third and fourth years of a water rinse colored the same as Listerine did not afford the study a true placebo. It did not keep the subjects unaware of which were gargling with the test material. The placebo did not at all match the strong and unique taste and smell of Listerine. It cannot be

considered an acceptable placebo (Sadusk 3205-06, 3226-27, 3276; Bogarty 3115-16; Carson 3055-56; Baron 2748; Lamm 2935, 2971).

88(a). During the first two years of the study, when the control group was given nothing, those in the test group knew that the effect on colds of the gargled substance was being tested. Many complaints were received from parents because their children were not placed in the gargle group (Nitzberg 2828, 2830-31). This is an example of the bias in favor of using a medication. This bias was also carried over into the third and fourth years of the study, particularly since many of the same students participated in multiple years and would carry their biases with them.

88(b). It is also obvious that many of the children knew what product was being tested. The school "smelled of Listerine. It was like walking into a Listerine factory. As you opened the door it permeated the school" (Nitzberg 2802). When the children gargled at home during the first two years, and on weekends and holidays throughout the study, their parents would certainly examine what was being used and would smell the product. The bottle contained the identification, "Warner-Lambert Research Institute" (RX 79D; Baron 2707). Also, it is likely that Listerine was being or had been used in many of the subjects' homes, so the children and their parents could identify the test product furnished to them. Further, many of the children and their parents had been subjected to Listerine colds advertising claims on television and elsewhere (Charache 3839), so they were further biased in favor of expecting favorable results as represented.

89. It is unlikely that this knowledge acquired by many of the subjects about the test product would not have been passed on to their fellow students. Thus, it must have been common knowledge throughout the entire four years of the study that Listerine was being tested as a cold remedy and who was using Listerine and who was not.

90. It is clear, therefore, that the St. Barnabas study results lack probative value to show that the use of Listerine is efficacious for colds and cold symptoms; that the results were heavily biased in favor of the product being tested since the subjects knew whether or not they were in the test group and indeed appear to have known the identity of the product being tested and what results were expected (Charache 3839; Jawetz 3719).[6]

91. All subjects assigned to the Listerine regimen were instructed to rinse and gargle with 20 ml. of Listerine for 30 seconds, twice daily throughout the study. In the first two years of the study, on each school

[6] Dr. Lasagna, an expert called by respondent, rejected the first two years of the study because of the lack of a placebo (Tr. 4108, 4130-31, 4160, 4162). His testimony is also given weight in rejecting test results purportedly in favor of Listerine for the third and fourth years of the study since no effective placebo was used in those years and the subjects were not blinded.

day, students in the test group gargled under supervision in their respective classrooms in the morning and were instructed to gargle at home during the evening. During the third and fourth years, both the morning and afternoon gargles were performed in the school during school hours. On days when school was not in session, the students were instructed to gargle at home twice daily, once in the morning and once in the evening (RX 82B-C, 83D; Baron 2704-06, 2710-11; Nitzberg 2790, 2812, 2855-56).

92. All subjects, whether members of the test or control group, were instructed to report to the medical office at the first sign of a cold episode. Either the teacher or the child could decide whether the child was to see the doctor. Upon reporting to the medical office, the subjects received their "Monthly Report Forms," which were pre-printed with each student's name, identification number, class and room number. These forms were presented to the examining physician for recording the cold symptoms, their severity, and any concomitant medication the child was taking. The child returned to the physician to be examined each day for the duration of that particular cold episode (RX 81D-E; CX 51E; Nitzberg 2790-91, 2802, 2812, 2814, 2819-21).

93. Initially, the common cold was defined as an acute, self-limiting, upper respiratory infection of from three to seven days duration, accompanied by any or all of the following signs and symptoms: sneezing, nasal discharge, nasal congestion, postnasal drip, cough, watery eyes, minor sore throat, headache, fever and chest congestion. Subjects who presented themselves with symptoms which, in the opinion of the examining physician, were suggestive of a complicated cold were excluded from the study during that period in which the complications persisted and were referred to their own family physician for specific treatment. Symptoms not indicative of a cold were also excluded, including ear infections, allergic rhinitis, tonsilitis, septic sore throat, pronounced cough, chronic bronchitis, otitis media and diarrhea (RX 82D; CX 51D; Nitzberg 2792, 2797, 2839, 2843-44, 2847-48).

94. Although the definition of cold for purposes of the study was limited initially to episodes of from three to seven days duration, the physician collected and reported the indicated information for each day the subject reported to him with a cold. Thus data was collected from the first day until the subject no longer reported (Baron 2719; Nitzberg 2801-02). In addition to recording on a daily basis an estimate of the overall severity of the cold, in each of the first two years the examining physician also evaluated and recorded the severity of the following cold-related symptoms: 1. Nasal Discharge 2. Nasal Congestion 3.

Postnasal Drip 4. Watery Eyes 5. Sneezing 6. Sore Throat 7. Headache 8. Cough

Records also were kept to indicate various types of concomitant medication taken by the subjects, *e.g.*, nosedrops, aspirin, cough drops, etc. (RX 78, 81J, 83W, 84U).

95. Those subjects reporting with a cold on Mondays or the day after a holiday were queried by the physician regarding the extent and intensity of the cold and symptoms present on Saturday and Sunday or the holiday, and these data were recorded on the report forms. Absent students were asked about their absence to determine if it was due to a cold. The investigation always went back 48 hours to ascertain when the cold had started. The incidence of cold episodes was not recorded during extended vacations, such as the Christmas holidays (RX 81; CX 51; Nitzberg 2792, 2799, 2800-01, 2835, 2853).

96. Cold episodes occurring in the same subject more than 48 hours following cessation of previous symptoms were considered as new cold episodes (RX 81E, 83S, 84A; CX 51E).

97. Starting with the third year, six additional symptoms (ear infection, sinusitis, malaise, conjunctival erythema, hoarseness and muscle aches) were added. This meant that the examining doctor had to examine for, request information about, evaluate and then record the estimated severity of fourteen symptoms rather than eight. During the first two years, the rating scale for the overall severity of a cold and the various symptoms ran from 0-3 (0 = no symptoms; 1 = mild; 2 = moderate; 3 = severe). Starting with the third year, the scale was expanded to 0-6 (0 = no symptoms; 1 = mild; 2 = mild to moderate; 3 = moderate; 4 = moderate to severe; 5 = severe; 6 = extremely severe). The common cold was redefined as having a 1-10 day duration (RX 83D-E, 84N-Q; Baron 2718-19, 2723-25; Bogarty 3072-73, 3075).

98. In preparing a report on the four years of study, the conversion of the 0-3 scale used during the first two years to the 0-6 scale used in the last two years was made as follows:

	1967-1969		*1969-1971*
Extremely Severe	(no rating)		6
Severe	3	=	5
Moderate to Severe	(no rating)		4
Moderate	2	=	3
Mild to Moderate	(no rating)		2
Mild	1	=	1
None	0	=	0

(RX 85B; Lamm 2890, 2932)

99. The children gargled at 9:00 a.m. (RX 81D; CX 51D). Dr.

Nitzberg began his examination of the children, including an examination of their throats, at 10:00 a.m. During the first two years, this took about one hour. During the last two years, because of the increased number of symptoms to check, this took about an hour and one half. Dr. Nitzberg examined about 30 children a day. On Mondays, he would see more (Nitzberg 2811, 2826). Listerine can be smelled on the breath for one and one half to two hours after gargling (Sadusk 3215; Krantz 1867, 1879, 1901).[7] As respondent's medical expert Dr. Sadusk testified, if the doctor examined the subjects within an hour or two of their having gargled, he would know which ones had gargled with Listerine (Tr. 3228-29). It is thus obvious that Dr. Nitzberg, who knew that Listerine was being tested for its value with regard to colds (Nitzberg 2809), also knew which of the subjects he was examining had been gargling with Listerine.

100. Since the examining physician was not "blind" as to which subjects had been using Listerine, the test results reflect bias in favor of the use of Listerine. The necessity to avoid such bias has been recognized both by experts presented by complaint counsel and by those presented by respondent (Finding 83). Here, neither the subjects nor the investigator were "blind" and the test results are biased in favor of Listerine on both counts.

Respondent has argued that the test results should be accepted, contending that the test was the best that could be conducted in light of the peculiar characteristics of Listerine which make it impossible to prepare a true placebo. Without passing upon what more reliable tests could be developed, suffice it to say that merely because an unbiased study cannot be conducted, the results of a patently biased one has little or no probative value.

101. There are still other factors that detract from the St. Barnabas test's reliability. For example, Dr. Nitzberg's practice of recording the scores for the subject on the same sheet that contained prior days' recordings (Nitzberg 2824) would tend to bias his scores by the knowledge of what he had done previously. He would not be making an independent judgment each day as he should (Hornick 500; Wehrle 4045-46).

102. Dr. Nitzberg spent only one and one half to two minutes with each child to record the scores on eight to fourteen observed and related symptoms as well as the severity of the overall cold itself. This included the requirement to examine and question the child with regard to each pertinent symptom (Nitzberg 2820). Dr. Shirkey, one of respondent's experts, estimated, "You might be able to do it nicely in five minutes" (Tr. 2670). Dr. Wehrle, an expert introduced by complaint

[7] Respondent advertises that Listerine lasts for hours (CX 1, 7, 11, 13, 15, 28, 30).

counsel, estimated that it would take at least 15 minutes as of the third year of the study (Wehrle 4041-44). Upon consideration of the testimony, a study of the form to be filled out and an evaluation of the scope of information to be elicited from the subjects and the examination to be conducted by the doctor, it is found that the time spent by Dr. Nitzberg on each subject was inadequate.

103. Recognizing that the St. Barnabas test results are biased in favor of Listerine, even those results do not substantiate respondent's claims for the product and, indeed, discredit some of them.

104. Based upon the 0-6 rating schedule, a comparison of the average overall severity of colds and symptoms recorded over the entire four year period of the study, shows the following differences that are statistically significant (RX 85C, 93A):

	Listerine Group	*Control Group*
Overall Severity	2.191	2.305
Symptom Severity		
Nasal Discharge	2.341	2.457
Nasal Congestion	2.657	2.787
Postnasal Drip	2.015	2.178
Sneezing	1.811	1.946
Sore Throat	1.321	1.466
Cough	1.920	2.112

The differences for the following symptoms or factors were found to be either in favor of the control group or not of statistical significance in favor of Listerine: ear infection, sinusitis, malaise, watery eyes, headache, conjunctival erythema, hoarseness, muscle ache, *duration of colds, number of colds and days absent from school* (RX 85C).

105. Statistical significance, or the standard of statistical reliability, refers to a mathematical computation whereby it is determined that a difference found between two groups is not caused by chance—that there is indeed a difference. This does not indicate the size of the difference or how much benefit is to be expected because of the difference. If a large enough sample is used a very, very small difference can be found to be statistically significant (Lamm 2881, 2885-86, 4315-16; Sadusk 3162-63; Lasagna 4151, 4163). In the St. Barnabas test, a large sample was used, over 3,000 subjects, and, as previously found, to the extent the differences were not caused by chance they were, at least in large part, caused by the biases of the subjects and the medical investigator. Therefore, the statistically significant differences found may not be held attributable to gargling with Listerine.

106. In any event, the existence of a *statistically* significant difference does not mean that the difference is *medically* significant or meaningful. There is a difference between statistical significance and

medical significance (Bogarty 3132-33; Sadusk 3261-62; Jawetz 3707; Lasagna 4095, 4127, 4151).[8]

107. Statistical differences developed by respondent's St. Barnabas test cannot be read as evidencing therapeutic or medical significance. The differences cannot be evaluated to show such a medical result (Sadusk 3264[9]; Wehrle 4018-21, 4067-68; Lasagna 4116-17, 4139, 4148-49; Gittelsohn 4183-85). In fact, the small differences indicate that there is no therapeutic or medical significance (Wehrle 4018-21, 4067-68; Jawetz 3706-07, 3711-12; Charache 3848-49; Lasagna 4116-17, 4148-49). One could not differentiate between a person suffering from a cold at the average level of severity reported for the Listerine test group and a person suffering a cold at the average level of severity reported for the control group (Sadusk 3258-59, 3262-63; Lasagna 4116-17, 4129).

108(a). The meaninglessness of the differences developed between the test and control subjects is demonstrated by the minimal differences claimed by respondent. Bearing in mind that the average cold symptom severities are in terms of a 0-6 scale, it is observed that the averages for both the Listerine and the control groups for overall severity, nasal discharge, nasal congestion, and postnasal drip fall between 2 and 3, making them all fall in the mild to moderate range. For sneezing and sore throat, the averages for both groups are between 1 and 2, making them fall in the mild to mild to moderate range. For cough they are both essentially a 2, giving both groups an average severity of mild to moderate.

108(b). The minimal nature of the alleged differences is further demonstrated by the specific differences developed by the test: Overall severity—.114; nasal discharge—.116; nasal congestion—.130; postnasal drip—.163; sneezing—.135; sore throat—.145; cough—.192. Thus, on a rating scale of 0-6, not one of the alleged improvements is as much as two tenths of a point. Indeed, the results in most of the categories are closer to the one tenth of a point differential. It is obvious that these claimed differentials for milder cold symptoms do not begin to approach significant levels.

109. As already noted, any difference, if a large enough number of subjects is studied, can be found to be statistically significant. On the other hand, it is not common for a medicinal preparation to work sometimes and not at other times. If a product is capable of relieving symptoms, it should do so year after year (Parrott 921; Jawetz 3718;

[8] Dr. Lasagna referred to a study he had conducted for the Federal Trade Commission comparing five proprietary analgesic compounds wherein he found that differences "although sometimes statistically significant were not terribly important." (Tr. 4095).

[9] Dr. Sadusk would interpret the study as indicating that three or five people of 100 would have less severe symptoms by taking Listerine, but he was unable to tell from the test results how much less severe the symptoms would be. Hence, there is no showing that even the few people claimed to be helped were helped significantly.

Charache 3878-79; Wehrle 4034-45). However, as of the end of the first year of the St. Barnabas study, there were no statistically reliable or significant differences with regard to the severity of colds overall or for any symptoms (Lamm 2880). For the fourth year, only one symptom (sneezing) showed a statistical significance in favor of Listerine (Lamm 2971; RX 84). Indeed, in no two years of the study was there a statistically significant difference in favor of Listerine users with respect to the same symptom (Lamm 2972). This in itself demonstrates the lack of medically significant differences.

110. Over the four years of the St. Barnabas study, Listerine users had slightly more colds than the control group (RX 85D; Lamm 2950). This confirms the opinion evidence of experts produced by complaint counsel that gargling with Listerine will not prevent or result in fewer colds (Carson 3053, 3057-58; Sadusk 3265-66). Such a finding has been previously made and is reaffirmed at this point as supported by respondent's own St. Barnabas test.

111. Over the four years of the St. Barnabas study, the colds of Listerine users lasted slightly longer than those in the control group (RX 85D; Lamm 2950-51). This result from a study so biased in favor of Listerine in itself establishes as a fact that the colds of Listerine garglers do not last a shorter period of time than the colds of non-users. There were also more days of total cold symptoms in the Listerine group than in the control group (Charache 3894) and, based on records kept only for the first two years of the study, students in the Listerine group were absent more days than students in the control group (RX 85D).

112. Of all the elements measured, the duration of a cold, the number of colds and the number of days absent reflect the least subjective matters and, hence, are more reliable. In none of these aspects was Listerine reported to be of any benefit (Gittlesohn 4204).

113. The results narrated above pertain to the elementary school subjects who participated in the St. Barnabas test. It is to be recalled that students in the St. Barnabas all girls high school were also included in the test for the first three years, but were dropped after the third year. It is significant that the results of the third year for the high schools girls did not show a single element in which there was a statistically significant result in favor of the group using Listerine. Indeed, on overall severity, ear infection, nasal discharge, nasal congestion, postnasal drip, headache, sneezing, conjunctival erythema, hoarseness, muscle ache, cough, number of colds and days absent, the results favored those in the control group (RX 83N).

114. In an effort to salvage something out of the St. Barnabas

study, respondent has analyzed the symptom days under the 0-6 unit ratings as follows:

Combined 4-year Data (1967-71); Elementary School

Number of Days of Overall Severity and Symptom Scores at Different Levels

Element Measured	*Group*	*Severity Scores**						
		0	*1*	*2*	*3*	*4*	*5*	*6*
Overall	Listerine	-	4339	1570	4876	1046	433	0
Severity	Control	-	3743	1569	5015	1079	593	3
Nasal	Listerine	452	4071	1335	3833	266	2307	0
Discharge	Control	358	3561	1402	3881	293	2507	0
Nasal	Listerine	55	3460	1306	4443	337	2663	0
Congestion	Control	47	2871	1371	4426	362	2922	3
Postnasal	Listerine	1340	4074	1396	3519	208	1727	0
Drip	Control	1126	3382	1483	3912	204	1895	0
Sneezing	Listerine	3697	3111	955	2438	111	1952	0
	Control	3369	2783	898	2596	166	2190	0
Sore	Listerine	5546	2612	736	1891	157	1322	0
Throat	Control	5130	2407	807	1950	204	1501	3
Cough	Listerine	3188	3473	823	2463	153	2163	1
	Control	2941	2926	820	2549	180	2582	4

* The higher number is the greater severity.

(Taken from RX 86.)

115(a). This analysis shows that more Listerine users had mild cold days (rating of 1) than did non-Listerine users, while less Listerine users had severe cold days (rating of 5) than did non-Listerine users. This analysis of the results of the St. Barnabas study, however, reflects the same biases in favor of the Listerine group that have already been found. The results, therefore, cannot be attributed to the use of Listerine. Also, when non concomitant medication was taken, Listerine users had more severe cold days than did those in the control group (RX 88D). Further, even under these biased results, Listerine users had 435 days of number 5 rated colds compared to 593 days for non-Listerine users in that category; and under categories 4, 3 and 2, the number for both groups are substantially the same. Even in category 1, the figures favor Listerine users only by 4,339 to 3,743.

115(b). As respondent's expert witness Dr. Lasagna testified concerning this analysis, he could not tell how much better any of the Listerine users who might otherwise have been in category 5 might be. "My interpretation is if someone asked what would happen if I gargled with Listerine with a cold, I would say you have some chance of feeling better, a little better, you might not feel better at all." (Tr. 4150). This is far from the significant relief promised in respondent's advertising.

116. A curious aspect of this breakdown is that in categories 1-3, the number of days of overall severity correlate roughly with the number of days of severity of the six symptoms that are listed (nasal discharge, nasal congestion, postnasal drip, sneezing, sore throat and cough). In category 5, however, many fewer days of overall severity are estimated than days of severity for the individual symptoms. The ratio in favor of the individual symptoms ranges from three to one to five to one. On the other hand, in the next less severe category 4, many more days of overall severity are reported than there are days of symptoms. The ratio in favor of days of overall severity over days of individual symptoms ranges from three to one to eight to one. This disparity between categories 4 and 5 cannot be explained away by the suggestion that the lower the severity of the cold overall the more numerous the days of lower rated symptoms. The correlation between days of overall severity and days of symptoms under categories 1, 2 and 3 disproves such a suggestion.

117(a). Also, while this analysis of the test results purports to show that Listerine users had only 73 percent as many category 5 days (severe cold days) as those in the control group, according to the same analysis, they had 92 percent as many category 5 nasal discharge days, 91 percent as many category 5 nasal congestion days, 91 percent as many category 5 postnasal drip days, 89 percent as many category 5 sneezing days, 88 percent as many category 5 sore throat days, and 83 percent as many category 5 cough days. On the other hand, in the less severe category 4, Listerine had 97 percent as many overall cold days as those in the cold group, but 91 percent as many nasal discharge days, 93 percent as many nasal congestion days, about the same number of postnasal drip days, 67 percent as many sneezing days, 77 percent as many sore throat days and 85 percent as many cough days.

117(b). Thus, in the more severe category 5, Listerine users are reported as having an appreciably smaller percentage of overall cold days in comparison to the control group than is shown when comparing individual symptoms of the two groups. On the other hand, in the less severe category 4, where Listerine users are reported as having about the same number of days as those in the control group, the comparison of individual symptom days is more favorable to Listerine. These inconsistencies cast still further doubts upon the validity of the study.

118. Another curious aspect of the breakdown of the number of days of severity under the severity table is exemplified by the fact that under category 3, there are 3,833 days of nasal discharge for Listerine users. Under category 4, the number of days drops to 266, but under category 5, it jumps to 2,307 days. Similar patterns are reported both for Listerine users and those in the control group for each of the six

symptoms tested. As Dr. Charache testified (Tr. 3884), such a pattern is medically unlikely. Such skip areas should not appear.

119. Respondent (RPF 177-85, 187-88) has relied upon other compilations of mean scores of severity and days of severity comparing Listerine users and others participating in the St. Barnabas study. These further compilations, however, are basically additional means of presenting the same results that have already been considered, and no further discussion is deemed necessary.

(2) The Reddish Cold Tests

120. The Reddish Cold studies took place during the winter seasons from 1932 to 1942. They were conducted, to a large extent, in respondent's own factories with respondent's own employees as the subjects. There were 2,500 subjects over the 12 years. Some participated in more than one year. About 600 of the tests were performed on employees of respondent and another 900 were performed on employees of a subsidiary of respondent. Another 500 were conducted on employees of a company that manufactures Listerine cough drops. Half of the subjects gargled with Listerine twice a day. The other half were specifically instructed not to gargle with anything. An exception was made for a small number in the control group for 1938-1939, who gargled with a saline solution. In 1935-1936, some gargled with tap water (RX 103D, F, Z-17-19, 48, 55, 109, 234-36, 239-40, 469, 481-82).

121. In assigning the subjects to the test and control groups, persons were placed in the test group because they preferred to gargle for their colds. Conversely, many were placed in a control group as they did not want to bother to gargle (RX 103, Z-105-06). This procedure of election defeated the purpose of random selection. The placement of persons in the test group who believed they would be helped by gargling obviously increased the placebo effect in favor of the test group results. The doctor in charge of the study also had a predetermined belief that Listerine was good for colds (RX 103Z-232-33).

122(a). No definition of a cold was provided to the investigators. The different nurses over the years at the different plants where the tests were being conducted used their own judgments which, of course, could vary from investigator to investigator. Thus, pharyngitis could be counted as a sore throat and pneumonia, influenza and sinusitis could be counted as a cold or as cold complications. Their judgments would similarly vary on whether to categorize the cold as severe (RX 103Z-116-17, 184-85, 255, 323, 353).

122(b). Dr. Reddish, who was in charge of the study, believed that the average cold lasted about ten days to two weeks and that a normal

cold could last 25 days without there being any complications (RX 103Z-185, 247). Thus, the record contains numerous examples of ailments well in excess of ten days that were counted as colds, *e.g.*, 25 days, 38 days, 35 days, 31 days, 38 days, 17 days, 20 days, 28 days, 23 days, 21 days, 32 days, 21 days, 25 days, 26 days, 33 days, 25 days, 24 days, 21 days, 36 days, 25 days, 23 days, 43 days, 50 days and as high as 69 days (RX 103Z-246, 259, 343, 345, 373, 404, 459, 484, 485, 492, 503, 509, 510, 511, 512, 515, 516, 517, 520, 540; Charache 3818). These examples are by no means exhaustive. Complaint counsel ceased examining as to the length of individual colds at the request of the hearing examiner (RX 103Z-532).

123. Common colds do not last more than ten days (Hornick 479; Seal 549; Proctor 607; Charache 3818). Even respondent's own St. Barnabas study originally defined the common cold as lasting from three to seven days and subsequently revised the definition to include up to ten-day colds. It is not clear, therefore, just what illnesses in addition to the common cold were included in the Reddish study. What is clear is that, in large measure, the results reflect ailments other than the common cold.

124. It is recognized, of course, that the Commission relied, in part, on the Reddish tests in its dismissal without prejudice of the complaint in Dkt. 4232 in 1944. However, such tests would be unacceptable to the scientific community today. The standards for evaluating clinical tests are different today (Jawetz 369-80). As Dr. Knight, expert witness for respondent, reported to the respondent in June 1970:

> Whatever the opinions concerning the mode of action of Listerine in the 1935-1942 experiments, those experiments must be considered incomplete in light of present knowledge of the etiology of common cold (sic). I believe that present opinion would hold that satisfactory evidence for efficacy is no longer provided by these early studies. (CX 162G-H).[10]

125. The Reddish studies are meaningless. Colds weren't defined. No effort was made to define or evaluate symptoms or signs. No objective basis for judging was employed. Each observer was on his own. Pneumonia, sinusitis, bronchitis, high fever and various other conditions now excluded from the definition of a cold were covered including lingering ailments of up to 69 days. Except for a very short period of time, no placebo was used for the control subjects. This was an important bias in favor of Listerine since at that time, gargling was thought by many to be effective in the treatment of colds. Subjects

[10] Dr. Haggie, who at the time of the commencement of the St. Barnabas study was respondent's vice president for Consumer Products Research (Tr. 1703), persuaded Warner-Lambert's management to conduct the more recent study for the following reason: Essentially my position was that some 20-odd years had elapsed since the Reddish Studies—And what would we find in a modern study. Would we find additional support or would another study raise some doubts?

could and did choose which group they would be in, thus exercising their biases at the very outset. Dr. Reddish and the various observers were biased in favor of Listerine while the tests were being conducted. Many of the subjects were employees of respondent (Knight 2052; Jawetz 3697-3700; Charache 3817-21, 3823-32; Wehrle 4006-14).

126. The lack of a placebo, the ability of the subjects to choose which group to be in, the use of subjects who were employees of respondent, and the predetermined beliefs of the investigators all combined to create a very strong bias in favor of the Listerine test group. These biases, together with the other defects of the test, make the test results meaningless (CX 162G-H; Jawetz 3697; Charache 3817, 3823). The Reddish study would not be acceptable for publication in a medical journal under today's method of evaluating studies of this nature (Charache 3835). As Dr. Wehrle testified, "This series of studies is perhaps the poorest example of clinical research I have been privileged to review. * * * It is a lousy study." (Tr. 4013-14).

Respondent's Expert Witnesses

As previously noted, discussion of the opinion testimony of experts produced by respondent has been delayed until after consideration of the two major clinical studies upon which respondent relies. This is because respondent's experts based their opinions in large part upon the results of the St. Barnabas study. The following discussion of the testimony of respondent's witnesses is not to be taken as an exhaustive rationale for accepting the opinions of witnesses who testified in support of the complaint over those who testified on behalf of respondent. That determination was made upon the basis of the entire record and the opportunity to observe those witnesses who appeared before the undersigned. The following discussion merely points up some of respondent's expert witnesses' testimony.

127. *Dr. Haggie* was a vice president of Warner-Lambert from 1962 until his retirement in January 1971 (Haggie 1701-04, 1788). In his various capacities, Dr. Haggie was involved in all scientific and medical affairs associated with all the consumer products of the company, including Listerine (Haggie 1703). Dr. Haggie was responsible for the approval of Listerine advertising from 1962 until his retirement (Haggie Tr. 1704). Dr. Haggie, therefore, can hardly be considered an impartial witness. Dr. Haggie's education and experience is in the field of chemistry. He holds a Ph.D in organic chemistry (Haggie 1698). Dr. Haggie is not a pharmacologist. He performed no clinical testing, but "farmed out" clinical testing to experts in the field (Haggie 1699).

128. Recognizing that Dr. Haggie was a chemist and not a pharmacologist, the undersigned allowed Dr. Haggie to express his

opinion with respect to Listerine on the basis of what he had read and limited to his own field of expertise (Tr. 1782). One reason for allowing him to express his beliefs was that an expert witness for the complaint had interpreted respondent's advertising, basing his interpretation in part upon what he conceived to be respondent's intent (Mendelsohn 1308-10, 1318).[11] In order to rebut that testimony as to intent and also as bearing upon the scope of any order that might issue, Dr. Haggie was allowed to testify as to his understanding of the efficacy of Listerine (Tr. 1787). Dr. Haggie's opinions were based, in large part, upon the results of the Reddish and St. Barnabas studies (Tr. 1727, 1732, 1784, 1815). As already found, however, those studies furnish no basis for concluding that Listerine is efficacious for colds and sore throats. Dr. Haggie's opinion was also founded in part upon his belief that the secondary invasion by bacteria is part of the etiology of the common cold (Tr. 1795), a belief that has been rejected (see Findings 51 and 58).

129. Even Dr. Haggie agreed that Listerine would not cure colds or eliminate symptoms (Tr. 1787, 1810) and that the St. Barnabas test was not as double blind as he would like to have seen it (Tr. 1794).

130. *Dr. Krantz* is a pharmacologist who has been a paid consultant for respondent on an annual retainer for over ten years (Tr. 1828, 1851-52, 1872, 1906). While he testified that all of the active ingredients of Listerine (menthol, eucalyptol, thymol and methyl salicylate) were virucidal (Tr. 1857, 1877), he admitted that none of these ingredients were listed in the United States Pharmacopeia or in his own textbook as virucidal (Tr. 1876-77, 1898).[12] Dr. Krantz readily testified that if one were to gargle with Listerine every 2 hours, practically every type of a cold would be prevented. His only basis for making this claim for cure of the common cold was that he and his wife could smell Listerine for up to two hours after use (Tr. 1867, 1879, 1901-02). While he was unaware of the quantity of Listerine's ingredients that would reach the nasopharynx (Tr. 1882), he testified that so long as one could smell Listerine at all, it would kill cold viruses and so prevent colds (Tr. 1902-03).

131. Dr. Krantz' willingness to ascribe to Listerine the cure for the common cold makes his testimony suspect. Further, Dr. Krantz' opinion that gargling with Listerine would be beneficial is flatly contradicted by statements in his own textbook, Krantz, Carr and LaDu, *The Pharmacologic Principles of Medical Practice* (7th Ed. 1969), at p. 819:

> The use of gargles accomplishes little. In the act of gargling the fauces are completely closed, and the medicaments in the gargle do not reach beyond the anterior pillars of the

[11] Of course, if a representation is false and misleading, intent is immaterial.

[12] Neither were the ingredients listed in the United States Pharmacopeia as analgesics or anesthetics (Tr. 1876).

throat, whereas the areas of infection are posterior to this region. It is far better to place such cleansing gargles in an atomizer and spray the throat with them. In this way some palliative effect can be attained. (CX 161B).

Despite his averred belief in the benefits of Listerine, Dr. Krantz never taught his students to use Listerine for the treatment of colds (Tr. 1874).

132. Of the four active ingredients in Listerine, Dr. Krantz rated thymol as the least volatile and least likely to get into the nasal area. He would not expect very much thymol, if any, to get there (Tr. 1881-82, 1904-05, 1908). This was confirmed by Dr. Rieger's test (RX 73; Tr. 2506, 2508; see Finding 205).

133. *Dr. Knight* has been a paid consultant of the Warner-Lambert Company for the past three years at $5,000 per annum. In addition, respondent has issued grants to Dr. Knight's medical school and to Methodist Hospital in Texas to support viral research of considerable interest to Dr. Knight for the past four years in the sums of $37,000, $50,000, $60,000 and $60,000. This grant money has been used to finance all of the studies Dr. Knight performed on Listerine (Knight 1922, 2001-02).

134. Dr. Knight performed *in vitro* tests on Listerine and its ingredients and a series of tests using white mice (RX 40-43). As Dr. Knight testified, "None of the tests have been in man. So, I have nothing—there is nothing I can say about man." Also, none of Dr. Knight's tests have been directed at the relief of cold symptoms (Knight 2045). *In vitro* tests on Listerine have only the most marginal relevance to the issues in this proceeding. The only *in vitro* tests that have any relevance are those performed with Listerine dosages comparable to that used by the consumer as recommended on the label. And the dose of Listerine gargled by the consumer is a far cry from what, if any, dosage actually reaches the nasal passage.

135. Respondent's exhibits 40 and 41 contain results of the effect of Listerine and some of its ingredients on certain viruses at various time intervals. Exhibit 41 contains data only on thymol and in 11 cases out of 14, the concentrations of thymol were approximately twice those found in Listerine (Knight 1960, 1963, 2008; RX 41F). The experiments with Listerine (RX 40) show that no significant results occurred after application of Listerine for 30 seconds (Knight 1946), the recommended amount of time for gargling. The first significant results in RX 40 occurred after a five-minute application of the full dosage. In RX 41, the tests only on thymol, no results were measured until 30 minutes after application of thymol to the virus solution.

136. Respondent's exhibit 42 is a chart showing the titer of mycoplasma pneumoniae after exposure of five minutes and 30 minutes

to thymol in different concentrations and alcohol in different concentrations. Again, this is much longer than the 30 second gargle whereby Listerine is used. Further, Dr. Knight testified that Listerine would be an inappropriate treatment for mycoplasma pneumoniae in humans (Knight 2038).

137. Dr. Knight conceded that Listerine would not inhibit the growth of non-lipid enveloped viruses even *in vitro* (Knight 2006). This, according to Dr. Knight, would leave the rhinovirus, which causes 40 percent of adult colds and 10 percent of children's colds, and the adenovirus, which causes 15 percent to 20 percent of colds in children and 5 percent of adult colds, unaffected even in *in vitro* tests (Knight 1957, 2005-07, 2055).

138. Dr. Knight testified that the experiments reflected in RX 41 could not be extrapolated to the use of Listerine in human beings as a gargle, do not prove that Listerine would inhibit the lipid-enveloped viruses in human beings, and would not prove that fact even if the concentration of thymol was comparable to the dose in Listerine (Knight 2008-10).

139. Dr. Knight agreed that the results of his test tube experiments depended upon and varied with the concentrations used, but that he did not know in what concentrations the active ingredients of Listerine would reach the nasopharynx (Knight 2014-15). Dr. Knight's tests showed that thymol has the major antiviral activity of all of the constituents of Listerine and that methyl salicylate has a minimal effect (Knight 1953, 1955, 1957, 2003-04, 2021). As indicated above, most of his tests used thymol. Yet, Dr. Krantz, also one of respondent's expert witnesses, testified that thymol was the least volatile of the four active ingredients in Listerine and he would not expect very much thymol, if any, to reach the nasal area (Finding 132). This was confirmed by Dr. Rieger's test (RX 73; Tr. 2506, 2508; see Finding 205). Thus, Dr. Knight's *in vitro* tests which show the virucidal properties of the active ingredients of Listerine have even less probative value. Even if we were to assume that Listerine had virucidal properties, this would be of no significance for, over the past 10 to 15 years, experiments with various substances known to be capable of killing viruses in solution have been found ineffective for colds (Finding 66).

140. Respondent's exhibit 43A-W records the results of Dr. Knight's experiments with Listerine, thymol and other ingredients of Listerine, utilizing white mice. Of ten experiments only two (experiments 1 and 3) came out in favor of Listerine. In the other experiments, the results with Listerine were negative. There was an "excess of deaths" in mice inhaling 100 percent Listerine for 4 days, (Experiment 8, RX 43U; Knight 1979-80), a "moderate excess of deaths

in animals given 100% Listerine small particle aerosol for 2 days in comparison to untreated controls," (Experiment 9, RX 43V; Knight 1981), and "Lack of effect of 50% Listerine or a mixture of thymol, menthol, methyl salicyclate as in 50% Listerine in mice infected with influenza A Hong Kong 68." (Experiment 10, RX 43W; Knight 1982). Further, the experiments using thymol, which Dr. Knight testified was "conceivably the only substance for real significance" in Listerine (Knight 2004), indicated that, "thymol, through a wide range of concentration, was ineffective." (Knight 1978, 1979, 1982; RX 43Q, R, S).

141. In several of the experiments, the mice were treated with Listerine prior to being infected with influenza and some were treated after being infected. Yet, in none of them did Listerine prevent infection (Knight 2010-12). Dr. Knight's experiments measured the difference in mortality rates caused by pneumonia between mice treated with Listerine and those untreated. However, he doubted that Listerine would reduce the mortality rate in man as far as influenza is concerned (Knight 2012). The mice experiments "wouldn't prove anything about what might have happened in man," and Dr. Knight was unable to state that Listerine would prevent infection in man (Knight 2026). Dr. Knight also testified that none of his mice experiments would be publishable because "it's an incomplete investigation." (Knight 2033).

142. The mice were forced to inhale specific amounts of the test materials into the lungs by use of a machine called a nebulizer (Knight 1974). In contrast, when one gargles, the larynx is closed so the substance does not get into the lungs (Knight 2027-38). The only thing Dr. Knight's test purported to show was a difference in mortality caused by pneumonia in mice infected with influenza (Knight 2010-11). This is in no manner related to any issue in this case.

143. Dr. Knight did testify that Listerine could be beneficial for cold symptoms. This opinion was based on the results of his test tube studies, his mice tests and his reading of the results of the Reddish and St. Barnabas studies (Tr. 1991-94, 1999). When pressed, however, he conceded that his tests did not establish this; and that none of his tests were directed at the relief of symptoms. He did not know if merely being able to smell Listerine meant it was present in an effective dosage. He retreated to the position that there were threads of evidence upon which one could put together a theoretical basis for the efficacy of Listerine, but that there were also threads of evidence to the effect that Listerine was ineffective (Tr. 2045-48).

144. Dr. Knight's qualified opinion, based as it is upon his test tube and mice studies, which lack probative value, and the Reddish and St. Barnabas studies, which prove nothing favorable with respect to the use of Listerine, is clearly entitled to little or no weight.

145. *Dr. Noller* gave no opinion as to the efficacy of Listerine. His testimony (Tr. 2070-2101) related to tests he had conducted which purported to show the efficacy of menthol as a nasal decongestant. He applied menthol in a vaseline base either just below the nostril or inserted into the nostril. (His testimony was inconsistent as to just which he did—Tr. 2105, 2145-46, 2157-58). Dr. Noller also applied menthol by rubbing ointment on the chest of the patient and directing a stream of menthol to the nose by use of a vaporizer (Tr. 2113-14, 2118). These procedures, however, are of little or no weight in evaluating the value of gargling Listerine for use as a nasal decongestant. Further, Dr. Noller's inconsistencies in testifying as well as his vague and evasive responses to inquiries (see, *e.g.*, Tr. 2087-89, 2119) detract from his reliability as a witness.

146. *Dr. McNamara* is a microbiologist who was employed by respondent in its Department of Dental Science from 1962 to 1973 (Tr. 2212). Dr. McNamara did not qualify as a virologist (Tr. 2219-20). Relying upon various tests, studies and articles (RX 51-64), this witness expressed his opinion that Listerine, gargled as directed, would kill in humans any pathogen with which it might come in contact, that it has substantivity wherever it reaches and that the killing of pathogens other than viruses would prevent complications caused by secondary invaders (Tr. 2222-36).

147. Dr. McNamara's opinion that Listerine would kill all pathogens is, of course, disproved by Dr. Knight's tests that Listerine would not kill or inhibit the growth of non-lipid enveloped viruses. Further, the ability to kill pathogens in the mouth has already been found to be irrelevant to the prevention or treatment of colds. Cold complications have been found to be caused by secondary invaders inaccessible to the ingredients of Listerine. And, notwithstanding any virucidal claim for Listerine, experiments over the past 10 to 15 years have shown the application of known virucidal agents to be ineffective.

148. To a large extent, Dr. McNamara's testimony and the tests and articles he relied upon were limited to showing what Dr. McNamara relied upon as a responsible official of respondent for purposes of considering the scope of an order to cease and desist should one be issued. The following exhibits fall in that category: RX 51, 52, 54, 55, 58, 59 (Tr. 2230-31, 2236, 2249-50, 2257, 2280, 2287-88). And RX 62, upon which Dr. McNamara also relied, was rejected as an exhibit (Tr. 2296).

149. RX 53 is an *in vitro* study conducted by Dr. McNamara which purports to show that Listerine killed certain bacteria in a test tube. Again, as discussed with regard to Dr. Knight's testimony, this does not show what would happen in the human mouth, and the ability to kill bacteria is irrelevant when considering possible effects on the common

cold. Dr. McNamara conceded on cross-examination that bacteria do not cause the common cold or affect cold symptoms such as runny nose (Tr. 2345).

150. A portion of RX 55 was subsequently admitted following the testimony of the doctor who performed the test. It is entitled to little weight because of admitted unresolved statistical errors. The other portion of the test report was rejected, in part, because the doctor in charge of the test concluded that "The significance of findings using this method is therefore questionable" (RX 55C, P; Tr. 2252, 2255, 2257; Frances 3362, 3371-72, 3375).

151. RX 56 is a test introduced to show that Listerine is retained in the mouth after gargling (substantivity). It was conducted on hamsters' cheeks, not on humans (Tr. 2263). Also, the test was not of Listerine, but of thymol and eucalyptol (McNamara 2320). Dr. Krantz rated thymol as the least likely of any ingredient in Listerine to get into the nasal area. This was confirmed by Dr. Rieger's test (RX 73; Tr. 2506, 2508; Findings 132, 205). Further, the test did not quantify the amount of the ingredients actually retained (McNamara 3226).

152. RX 57 is a report of a test conducted for the Federal Trade Commission by the Food and Drug Administration. Six volunteers swished and gargled 25 ml. of Listerine for ten seconds, then expectorated. They then immediately rinsed the mouth twice with 25 ml. of 25 percent strength alcohol in exactly the same manner. Measurements were made of the expectorations after both alcohol garglings to determine the amount of the active ingredients of Listerine collected in the two alcohol garglings. Two to three percent of the original concentrations were collected. Respondent (RPF 74(b)) contends that, as reported by the Food and Drug Administration official in charge of the test, the substantially lower percentage recovered after the second alcohol gargle indicates there was a binding of the ingredients to the cheek membranes which the alcohol could not recover. To the contrary, the test results equally, and indeed more probably, indicate that after fully expectorating the Listerine in the mouth, the first alcohol gargle got most of what remained so that the second gargle gathered a much smaller residual amount. Indeed, Dr. McNamara's interpretation of the test was that the two to three percent that the alcohol obtained was what had been absorbed in the tissue when gargling with Listerine (Tr. 2329, 2331).[13] And, of course, the residual amounts would wear off even more quickly than usual if the subject were to eat or drink (McNamara 2331-33). The witness did modify his position by stating that additional rinses might have gathered more of the ingredients (Tr. 2330).

[13] No witness was presented who was involved in the test.

153. RX 60 is a test conducted by Dr. McNamara to see whether a group of microorganisms would develop resistance to Listerine. This adds nothing of probative value. RX 61 is a journal article which does not relate to the common cold and similarly lacks probative value. RX 63 and 64 are *in vitro* antibacterial studies and afford little basis for Dr. McNamara's opinion for the reasons previously stated with regard to *in vitro* studies.

154. Dr. McNamara conceded that there are sites in the oral cavity which contain large quantities of bacteria, including pathogenic bacteria, where Listerine cannot reach (McNamara 2339-42, 2349-50); and that bacteria killed by Listerine would rebound to the point that, for periods of up to an hour, more bacteria can be present than there were originally (McNamara 2345-46).

Dr. McNamara's testimony, therefore, contributes little in support of respondent's position.

155. *Dr. Ritchie* is a physician who had been employed by the Health Department in Scotland and later in England (Ritchie 2361-64). It was his opinion that, while most colds are caused by viruses, virus-caused symptoms usually last two days, rarely as long as three days. This he called the promodal stage. The remaining term of a cold, according to Dr. Ritchie, is caused by the patient's own nasopharyngeal bacteria. He called this phase of the cold the sequela (RX 65, 66, 67; Ritchie 2376, 2387, 2410-11, 2413-14, 2416-17, 2426). Based on tests which he conducted, Dr. Ritchie was of the opinion that antibiotics could prevent or lessen the severity of the sequela portion of a cold. From this he reasoned that the use of disinfectants such as Listerine would have the same effect (Tr. 2412, 2427-31). In addition to viruses, Dr. Ritchie was of the opinion that such things as wet feet, cold clothing, general chill and dust lowered the body's resistance to its own normal bacteria so that a cold would ensue (Tr. 2411-12).

156. Dr. Ritchie's opinion of the role bacteria play in the etiology of the common cold is completely contrary to findings already made based upon the testimony of both complaint counsel's and respondent's witnesses (Findings 51, 58). His theory that wet feet, cold clothing, general chill and dust trigger bacteria-caused colds is directly contrary to the otherwise unanimous view that colds are caused by viruses (Finding 48).

157. Further, if one were to accept Dr. Ritchie's testimony and experiments at face value, it would appear that, despite the inability of the medical profession to do so, he found the cure for the common cold in the 1930's. For it was then, according to Dr. Ritchie, that by a weekly injection of a vaccine made from each subject's own sputum, he prevented practically all colds for his clerk, several others and then

members of the Birkenhead, England, departmental staff and the police department (Ritchie 2371-72).

158. Inexplicably, when Dr. Ritchie repeated the tests in 1948, his reports (RX 65, 66) no longer reflected any prevention of colds. Rather, all subjects caught colds, but the colds lasted only two days (Ritchie 2373-76). After a time, instead of using the subject's sputum as the vaccine, Dr. Ritchie used antibiotics chosen specially for each subject's types of bacteria (Ritchie 2378-79).

159. Dr. Ritchie's test results are inconsistent in that first he purportedly found an absolute prevention and then went on to find merely a means of curing colds after two days. Not only are Dr. Ritchie's theories as to the role of bacteria in colds contrary to sound and uniformly accepted medical opinion, but studies conducted through the years by competent and eminent authorities have shown that antibodies such as those used by Dr. Ritchie are useless in the prevention or treatment of a cold in any respect. Further, the indiscriminate use of such antibodies should be avoided because of the resultant harm and immunities that may be caused (Findings 67 and 68).

160. Dr. Ritchie's belief that reactions to dust and other non-viral elements cause colds leads to the probability that conditions that were not colds were included in his studies. He also included chronic cold sufferers, which he defined as "people who took colds for a long time" (Ritchie 2372). Common colds, however, do not last for more than ten days (Finding 123).

161. In addition to his own studies (RX 65 and 66), Dr. Ritchie relied upon a similar study conducted by a Dr. McKerrow (RX 68). However, in a 1973 article written by a Dr. Banks and Dr. Ritchie, it is conceded that the "evidence submitted * * * [by Dr. Banks', Dr. Ritchie's and Dr. McKerrow's studies] does not reach statistical significance" (RX 67G), meaning that the results could be due to chance alone.

162. Dr. Ritchie's tests involved administering an autogenous vaccine made from the subject's sputum subcutaneously and later having the subject suck such antibiotics as penicillin, various forms of tetracycline including terramycin, aureomycin and chloramphemicol (Ritchie 2371-73, 2379-81, 2397, 2418). There is simply no basis for carrying over the results obtained from such methods of application of such products to the gargling of Listerine.

163. In view of all of the foregoing, neither Dr. Ritchie's testimony nor the tests upon which he relied have any probative value in this case. Respondent has admitted that Listerine will not prevent all colds and is not a cure for the common cold. Therefore, to the extent respondent

attempts to rely upon and apply Dr. Ritchie's tests to the use of Listerine, it is being inconsistent with its own admissions.

164. *Dr. Shirkey* has been a paid consultant for respondent for the past nine years (Tr. 2592-93). Dr. Shirkey had no opinion on whether the use of gargling Listerine would prevent colds. In his opinion, it would not cure colds, but it would provide relief for some cold symptoms (Tr. 2607, 2616, 2628, 2667-69, 2674). It is clear, however, that Dr. Shirkey relied, in large part, upon the reported results of the St. Barnabas study in reaching the opinion that Listerine would provide such symptomatic relief (Shirkey 2605-07, 2615-16, 2645, 2659, 2660-61, 2662, 2673-76).[14] He testified that if it were demonstrated to him that the St. Barnabas studies were unreliable, he would change his testimony (Tr. 2662). As has been found, the St. Barnabas studies are unreliable upon which to base an opinion that Listerine is efficacious for the treatment of colds.

165. Dr. Shirkey stressed the safety of Listerine and at the same time recognized the value of the placebo effect of over-the-counter preparations such as Listerine for colds, a self-limiting ailment (Tr. 2619, 2627, 2633, 2635-37, 2643, 2674). Dr. Shirkey summarized his position as follows:

> *We have got some studies which show that it has some value which I hope would be expanded to show more value or show that it doesn't do anything, one or the other,* but at this point in time as a Pediatrician and with this kind of background interested in kids, I think the preparation Listerine, what it claims for treating the symptoms of the common cold, I hope they are not wiped out because I would hate to see the results when something else fills its place which is less safe and I don't know anything that is as safe as this.
>
> That is my whole reason for coming here. (Tr. 2675; emphasis added)

166. Thus, Dr. Shirkey himself has expressed dissatisfaction with the tests to the point that he would want further tests to show Listerine has more value or that it has none. His support of cold claims for Listerine because of its relative safety and placebo effect is of no probative value in resolving whether respondent's representations are false and deceptive.

167. *Dr. Carson* is a pharmacologist who is affiliated with an independent research company (Tr. 3012-13). He has served as a consultant to respondent for the past eight to ten years (Tr. 3026). Dr. Carson described the pharmacological properties of the active ingredients of Listerine (Tr. 3028-29). Based upon studies that he had

[14] Having stated, "We do the best we can with what we have got and right now, we are in a pretty sad situation and we have got something that is safe and has some efficacy," Dr. Shirkey was asked, "We have had it all these years. How come we haven't found out about it?" Dr. Shirkey answered, "Because the studies have only been done; * * *" (Tr. 2676).

conducted, he gave his opinion that Listerine's active ingredients were pharmacologically and therapeutically effective dosages to provide relief for cough and nasal congestion (Tr. 3032-34).

168. To support his opinions with respect to the efficacy of Listerine for the relief of coughs, Dr. Carson relied, in large part, on RX 97. This was an experiment he performed for respondent in 1965, using only nine subjects (RX 97E), the purpose of which was "to determine the effectiveness of the aerosol room vaporizer when tested by a modification of the directions on the printed label of the product." (RX 97C). In addition to menthol, thymol and eucalyptol (ingredients contained in Listerine), the aerosol room vaporizer then tested also contained camphor and dipropylene glycol (RX 97A; Carson 3568, 3597). There was no way of determining what part of the results of RX 97 were attributable to camphor and there was no way of separating the results (Carson 3568; Shellenberger 2201-03). Dr. Carson testified that he thought camphor "played a role" in the results (Tr. 3597). Listerine contains no camphor (CX 48, *in camera*).

169. The tests reported by RX 97 were performed in the following manner:

> * * * Tests were carried out in a room which was completely sealed from outside air currents. The subjects were exposed in this room following aerosolization of the test formulation into the atmosphere and subsequent inhalation through a handkerchief treated with the aerosol. The subjects were challenged by a citric acid aerosol approximately two hours before the test for control purposes, and at seven intervals through the next two hours in order to evaluate the effectiveness of the antitussive agent * * *.
>
> * * * * * * *
>
> The subjects were exposed for 3 minutes in a closed room 8' x 10' and approximately 8' high in which the contents of a can had been expressed for 10 seconds. At the end of the 3-minute period each subject was given a large-sized folded handkerchief into which the aerosol was expressed for a 10-second period at a distance of 12". The subjects were then instructed to hold the impregnated handkerchiefs against their nostrils for 30 seconds. (RX 97C-D)

The procedures utilized in this experiment differed from those normally employed in this kind of test:

> It will be noted that *in contradistinction to the procedure described in the appendix, it was necessary to challenge the subjects at shorter intervals than are ordinarily employed.* It was realized that the shorter than usual intervals between the citric acid challenges *might have an undesired effect on the responses* but they were unavoidable since the object of this study was to evaluate the early responses. (RX 97D; emphasis added)

170. On direct examination, Dr. Carson testified that the dosages of

the ingredients inhaled in RX 97 would be lower than those gargled with Listerine; and that his calculations were based on the amount of aerosol sprayed into the closed room and the inspiration rates of the subjects (Tr. 3036-38). On cross examination, Dr. Carson admitted he had forgotten a very important element in his calculations—the additional amount of aerosol inhaled by applying the impregnated handkerchief directly to the nostrils, a factor which Dr. Carson agreed should have been taken into consideration (Tr. 3554-55). The test report itself clearly revealed that the "effectiveness [of the material tested] was reinforced by inhalation of additional aerosol sprayed into a handkerchief." (RX 97E).

171. Dr. Carson agreed that his RX 97 study, which tested the results of a product upon coughs artificially induced in healthy people, was preliminary and exploratory; that "[i]f you wanted to evaluate the antitussive claim, one would go to a clinically ill group." (Tr. 3568-69).

172. RX 97, therefore, provides no reasonable basis for Dr. Carson's testimony as to the efficacy of Listerine. The number of subjects was limited; the active ingredients differed from those in Listerine; the method of application differed from that of Listerine; the test procedure itself differed from that normally utilized with recognized possible undesired results; the strength of ingredients which reached the critical portions of the respiratory tract was not reliably compared with that portion of Listerine's active ingredients which reaches the critical areas; and the test itself was admittedly preliminary and exploratory in that it purported to test the effect of a product upon coughs artificially induced in healthy people.

173. Dr. Carson also relied on a clinical report entitled, "Antitussive Effect of Aerosolized Medication on Experimentally Induced Cough in Man" (RX 50). The purpose of RX 50 was "to determine the effectiveness of an aerosolized preparation containing *camphor*, eucalyptol, thymol, menthol, *triethylene glycol*, *dipropylene glycol* and alcohol as an antitussive agent under experimental conditions" (RX 50A; emphasis added). Both Dr. Carson and Dr. Shellenberger, through whom the article was introduced, agreed that there was no way of telling what part of the results were attributable to camphor and that the results could only be attributed to the product as a whole (Shellenberger 2201-02; Carson 3568). Listerine does not contain camphor, triethylene glycol or dipropylene glycol (CX 48, *in camera*). RX 50 was conducted in a manner similar to RX 97, except that a handkerchief impregnated with the medication was not used (RX 50C). The amount of the test material that would be inspired by the subject was not calculated (CX 50; Carson 3567-68). This exhibit, therefore,

provides no more reasonable basis for Dr. Carson's opinion testimony as to the efficacy of Listerine than does RX 97.

174. Dr. Carson also relied on RX 47, an article entitled, "A Bronchomucotropic Action in Rabbits From Inhaled Menthol and Thymol," by E. M. Boyd and E. P. Sheppard. The study reported in RX 47 was performed on healthy rabbits who inhaled the test material "through a T-cannula ligated into the trachea" (RX 47B-C). The animals inhaled the test material for four to six hours during which time the respiratory tract fluid upon which the results were based was collected (RX 47C). RX 47 indicates that eucalyptus oil, which Dr. Carson testified would have a similar effect to that of eucalyptol (Tr. 3575), had no effect at doses recommended for use in man (RX 47B). Dr. Carson agreed with this conclusion, "Yes, remembering the conditions of this test which is steam inhalation" (Carson 3575). This comment implies that the result with respect to menthol and thymol in RX 47 are also dependent on "conditions of this test" which involved steam inhalation, *not* gargling.

175. Thymol produced no significant changes in volume output of respiratory fluid at any dose studied. Menthol had no effect in doses up to and including 27 mg/kg (RX 47C-D). Even under Dr. Carson's calculations, only 4.4 ml. of menthol would be available after gargling Listerine for 30 seconds (Carson 3557-58). In RX 47, the inhalation was from four to six hours.

176. Thymol produced significant changes in the specific gravity of respiratory tract fluid at doses of 81 and 243 mg/kg (RX 47D). These doses far exceed the amount of thymol available in gargling one ounce of Listerine for 30 seconds (CX 48, *in camera;* Carson 3038-39). The authors of RX 47 concluded that the therapeutic significance of the inhibition of respiratory tract fluid, if any, remains obscure (RX 47G-H). Again, as he did with regard to RX 97, Dr. Carson admitted that the test reported in RX 47 was preliminary and in order to draw conclusions for the effect of a drug in man, clinical tests in man are required (Tr. 3575-76).

177. RX 47, therefore, provides no more reasonable basis for Dr. Carson's opinion testimony as to the efficacy of Listerine than do RX 97 and RX 50.

178. Dr. Carson relied to some extent (Tr. 2188-89) on RX 48, an article entitled "On the Expectorant Action of Volatile Oils" by E. Boyd and G. Pearson, published in 1946. RX 48 reports the results of the expectorant action of various ingredients, only one of which (eucalyptol) is found in Listerine. The drug was administered by stomach tubes to guinea pigs (RX 48B). This procedure, of course, is entirely different than gargling. Although the results of the 1946

experiment showed some expectorant action of eucalyptol, these results were completely contradicted by Dr. Boyd's more recent article, RX 47B-H, which was written in 1969, and upon which respondent and Dr. Carson also rely. RX 48, therefore, provides no reasonable basis for Dr. Carson's opinion testimony as to the efficacy of Listerine.

179. Dr. Carson also relied on decongestant studies he had done on Pertussin. The ingredients of Pertussin are similar to those of the products tested in RX 97 and RX 50. Pertussin contains camphor. The studies on Pertussin involved room dispersion and a hankerchief method of administration of the test material (Carson 3576-77). It is clear, therefore, that the Pertussin studies are irrelevant to this case and provide no sound basis for Dr. Carson's opinions concerning the efficacy of Listerine.

180. While Dr. Carson testified at length concerning, and relied upon, the ingestion of medicinal properties into the stomachs and lungs of animal subjects, he limited his opinion on the efficacy of Listerine for coughs to irritant induced coughs (Carson 3601).

181. Dr. Carson relied upon the volatile nature of the active ingredients of Listerine (Tr. 3592-93). However, he conceded that there was a fall-off for every volatile product and that he did not know the fall-off point for the ingredients of Listerine (Tr. 3603). The witness was unable to quantify the amount of Listerine's ingredients he asserted would reach the sites of cold infection (Tr. 3572-73). His testimony in no way weakens that of the experts who testified that, apart from the ineffectiveness of Listerine's ingredients, they would not reach the critical areas in therapeutic concentration.

182. Dr. Carson relied, in large part, upon the results of the St. Barnabas test (Tr. 3047-48, 3051-52, 3057). As previously found, this test affords no basis for an opinion that gargling with Listerine is efficacious for colds. Further, Dr. Carson would equate statistical significance with clinical significance (Tr. 3605). See Finding 105 to the contrary. Even Dr. Carson evaluated the St. Barnabas test as establishing that the use of Listerine will not result in fewer colds (Tr. 3057-58).

183. *Dr. Sadusk*, from mid-1967 until November 1971, was vice president of Parke, Davis & Company and later its group vice president for Medical and Scientific Affairs. Parke, Davis was acquired by respondent in 1970 (Sadusk 3172-73, 3178-79, 3180). After the merger, he became senior vice president of Warner-Lambert and its director of Medical and Scientific Affairs until February 1974, at which time he became an employee-consultant to the company (Sadusk 3180-81).

184. Dr. Sadusk testified that he would recommend Listerine for the relief of cold symptoms. This opinion was based upon the safety of

the product and the results of the St. Barnabas study (Sadusk 3211, 3268). As former Medical Director of the Food and Drug Administration, he would have approved a label claiming relief of overall severity of colds, nasal discharge, nasal congestion, post-nasal drip, sneezing and sore throat—the elements for which the four-year St. Barnabas study showed statistical significance in favor of Listerine. He would not have approved a label that said "for the relief of cold symptoms" since that would indicate all symptoms, nor would he have approved a label which read "for colds." All of this testimony was based on the results of the St. Barnabas study (Sadusk 3268-72). Inasmuch as the St. Barnabas study does not demonstrate that Listerine is efficacious for colds in any respect, Dr. Sadusk's testimony that Listerine is efficacious in certain respects is entitled to no weight.

185. Further, it is clear that Dr. Sadusk, who testified that he was familiar with the St. Barnabas test and had carefully studied its results and the manner in which it was conducted (Tr. 3204, 3210-11), had, at the very least, overstated his familiarity with the tests. For example, he thought the children determined the overall severity of their own colds and that they gargled at home before going to school. He was also vague and uninformed in other respects, including the fact that Dr. Nitzberg examined the children while the odor of Listerine was still on their breaths (Sadusk 3215, 3225, 3229-33). Dr. Sadusk simply assumed that the timing was set up properly so the examining doctor could not smell the breaths of the subjects (Sadusk 3230-31). The record, however, establishes the contrary (Finding 99).

186. Dr. Sadusk conceded that, if by smelling the breath of the children, the investigating doctor could tell which group they were in, "the theoretical objection might be rendered that he might be biased" (Tr. 3230); that, "[i]f the doctor knew—and this would indicate that the doctor was dishonest because he would actually ask each person—the experiment, of course, would not be valid" (Tr. 3228).

187. Dr. Sadusk testified on direct examination that the fact a placebo was not used in the St. Barnabas test would make no essential difference because (1) there was a control group and (2) "many of the symptoms of the common cold are obviously objective in nature and not just subjective" (Tr. 3205). However, on cross examination, Dr. Sadusk testified that every symptom examined in the St. Barnabas test was either completely subjective in nature or a combination of subjective and objective elements (Tr. 3217-25). This was also the evaluation of the examining doctor (Nitzberg 2816-18). Under Dr. Sadusk's own testimony, it is clear that a placebo was necessary in the St. Barnabas test, but that there was none.

188. Dr. Sadusk appears to have equated statistical significance

with clinical significance (Sadusk 3211, 3268-69). To the contrary, statistical and medical significance are different matters (Finding 106). Bearing on this very point, Dr. Sadusk testified that a doctor could not tell the difference between a student with a 2.5 severity cold and one with a 2.6 severity cold, although the differences were statistically significant (Tr. 3259).[15] Dr. Sadusk also testified that the statistics show that only three to five people out of 100 would be benefited by using Listerine, but he could not testify how much less severe their colds would be from the data (Tr. 3260, 3264).

189. Dr. Sadusk would not recommend Listerine for the prevention of colds or for fewer colds. On the basis of the St. Barnabas test results, he would have to state that Listerine does not prevent colds; that the test disproves any theory upon which it could be reasoned that Listerine would prevent colds (Tr. 3211-12, 3265-66).

190. *Dr. Lasagna's* opinion as to the efficacy of Listerine for colds was based upon the results of the St. Barnabas test. His opinion, however, was quite guarded and his brief for the benefits of Listerine was rather weak:

> My interpretation is if someone asked what would happen if I gargled with Listerine with a cold, I would say you have some chance of feeling better, a little better, you might not feel better at all.* * *
>
> * * * * * * *
>
> No, I don't know how anyone could promise them relief. You could say it looks as though you have a chance to feel better, you might feel better if you use this. (Tr. 4150-51)
>
> I think they [the consuming public] cannot expect a guarantee of improvement. I would like to see the advertising phrased in such a way that they get the same impression I have from the study which is if you gargle with Listerine regularly there is a chance that you will feel somewhat better when you have a cold. (Tr. 4154)

He agreed that, on the basis of the St. Barnabas test, "all we can say is Listerine might help some elementary school children sometimes." (Tr. 4164).

191. This is a far cry from the significant relief from symptoms that respondent promises. However, as we have seen, the St. Barnabas test affords no basis for concluding that Listerine affords any relief from colds, so that there is no foundation even for Dr. Lasagna's guarded opinion.

192. Dr. Lasagna was critical of the first two years of the St. Barnabas test because no control substance was used. He conceded that this was a potential for bias that would distort the results of the test in

[15] Neither could a doctor tell the difference between two subjects, one with a 2.170 severity cold and one with a 2.262 severity. These figures represent the results of the four years of the St. Barnabas study and the differences are statistically significant (Sadusk 3262-63; RX 85D).

favor of the group taking Listerine (Tr. 4108, 4130-31, 4160, 4162). He was very much concerned, therefore, with the reliability of any of the test results which pooled data relating to the first two years with those of the second two years (Lasagna 4109). However, the control substance used in the third and fourth years was not an acceptable placebo and the subjects knew, in those years, who were using the test material (Findings 87, 88, 89 and 90), so that bias in favor of Listerine was present in the third and fourth years as well as in the first two years. RX 114, a tabulation for the last two years upon which Dr. Lasagna relied for his opinion, therefore, is no more reliable than the test results which include the first two years and to which Dr. Lasagna objected. Indeed, Dr. Lasagna agreed that the control substance used in the last two years may have been inadequate as a placebo (Lasagna 4132-33). And, of course, the bias of the investigating doctor was present all four years, since he knew who was using Listerine (Findings 99 and 100).

193. As already found (Findings 105, 106), instances of statistical significance do not necessarily indicate medical significance. Dr. Lasagna agreed with this distinction (Tr. 4095, 4127, 4151). Dr. Lasagna also testified that he could not examine a table of mean severity scores for Listerine and the control group and tell whether the Listerine users would feel discernibly better; that one could not tell what such mean figures represent (Tr. 4116-17, 4139, 4148, 4149). RX 114, which showed results for only years three and four, was prepared at Dr. Lasagna's request (Tr. 4119) in order to avoid his criticism of including data for the first two years. This exhibit, however, compares mean severity scores for the Listerine and control groups and is meaningless under Dr. Lasagna's own evaluation of such comparisons.

194. The only document relating to the St. Barnabas study, other than RX 114, for which Dr. Lasagna could have any feeling, was RX 86, which reported the number of days the participants in the test had various degrees of severity of symptoms and of the cold overall (Lasagna 4149). This exhibit, however, incorporated information covering the first two years of the study, which Dr. Lasagna felt should not be used (See Finding 192). There is, therefore, no basis for Dr. Lasagna to have expressed an opinion as to the efficacy of Listerine, since neither RX 86 nor RX 114 meet Dr. Lasagna's own stated requirements.

195. From the foregoing, it is clear that, to the extent the opinion testimony of experts called by respondent controverts the opinions of experts called by complaint counsel, there is no reasonable basis for such opinions; and that the opinions of experts called by complaint

counsel are, to a large extent, supported by the testimony of experts called by respondent.

Additional Tests Relied upon by Respondent

In addition to the testimony of its expert witnesses and the St. Barnabas and Reddish studies, respondent has introduced, and relies upon, a number of other studies and writings which, it asserts, support its position. Many of these studies and reports have already been discussed and discounted in the course of discussing and evaluating the testimony of experts called by respondent. There is no need to restate the findings already made with respect to such exhibits. The additional exhibits, therefore, will be discussed to the extent deemed pertinent and not already covered above.

196. A number of the studies relate to the alleged antibacterial properties of Listerine. Since a cold is an infection caused by virus particles inhaled into the nose which enter into and damage the cells there, the antibacterial properties of Listerine are, for all practical purposes, irrelevant. Bacteria play no part in the common cold, and the ability of Listerine to kill millions of bacteria in the oral cavity is of no medical significance in the prevention, cure or treatment of colds or sore throats. Listerine does not reach the site of infection or manifestation of symptoms in medically significant concentration and the tests and writings relied upon by respondent do not tend to show otherwise. Listerine will not reach the sites of secondary offending bacteria and will not attack bacteria in deep-seated tissue folds and crypts. There are many other areas in the oral cavity which Listerine will not affect. Numerous tests conducted in the ongoing research on the common cold have demonstrated the lack of efficacy of using virucidal and antibiotic agents in the prevention or treatment of colds.

197. Apart from the irrelevance of Listerine's antibacterial effect, the tests relied upon by respondent provide no evidence as to the concentration of Listerine's ingredients that reach the critical sites nor the period of time they remain in particular concentrations. Respondent's tests fail to contribute any information tending to show that the ingredients of Listerine reach the critical sites in sufficient concentrations to kill such viruses as may be exposed or to perform the other therapeutic accomplishments claimed for them by respondent.

198. Respondent (RPF 74D) relies upon a test (RX 44) done under the supervision of Dr. Knight for the proposition that when thymol contacts a cell of the upper respiratory tract, it will attach to and penetrate that cell and that the concentration in the cell of thymol would be much greater than in the surrounding medium. The red blood cells in the test, however, were suspended in a buffered liquid solution

(Knight 1988). The test, therefore, provides no evidence as to thymol's effect on cells surrounded by the normal constituents of the upper respiratory tract. As Dr. Knight conceded, "The concentration, with gargling, may have very little relationship to the concentration that would be present in—within the cells that we're supposed to examine" (Tr. 2016). The direct application of thymol by suspending the cells in a liquid solution, therefore, has no bearing upon what happens to the thymol in Listerine when it is gargled. Listerine does not reach the nasal pharynx in liquid form (McNamara 2343-44). And thymol is the least volatile of all of the active ingredients in Listerine and very little, if any, reaches the nasal pharynx (Findings 132, 205).

199. Respondent (RPF 74A) relies on a test (RX 69, 70, 71) conducted by one Norman Oksman, a Warner-Lambert employee, to establish that, after gargling with Listerine, the product's ingredients are retained in the subject at the following percentages of the quantities gargled:

Eucalyptol	36%
Menthol	33%
Methyl Salicylate	27.5%
Thymol	23.4%

In this test, ten subjects rinsed and gargled with 15 ml. of Listerine, which is one-half the ordinary dose. They immediately expectorated into a beaker, including two extra spits. The amounts of the active ingredients were quantified and compared with the amounts in a 15 ml. quantity of Listerine. The average differences between what is contained in a 15 ml. amount of Listerine and what was found in the beaker provides the percentage figures reproduced above.

200. At the very outset, the following question occurs. Why, if respondent wanted to ascertain the percentages of Listerine ingredients retained by users, did it have the test subjects gargle with only one-half of the ordinary dose? One answer that immediately suggests itself is the possibility that the larger the quantity gargled, the larger the percentage of that quantity that can be readily expectorated. The fact that the test was conducted with only one-half of the normal quantity does not indicate what percentage would have been retained under usual gargling conditions.

201. The data does not establish what was retained in the mouth after gargling. Some could have escaped through the mouth while gargling and some could have been swallowed (Oksman 2461-63). Further, the test was conducted immediately after gargling and expectorating three times in rapid succession. There is no evidence, therefore, as to the length of retention and how quickly whatever was

retained after that short period of time was expelled in the course of eating, drinking, talking or otherwise (Oksman 2463-64). This does not purport to be a substantivity test (Oksman 2464). It neither establishes that the amounts retained are in therapeutic quantities nor that they reach critical sites. To the contrary, the active ingredients in Listerine are in insufficient concentration to be of therapeutic value even if they were applied directly to the critical areas (Findings 74-80). Respondent's exhibits 69, 70 and 71 show that at least 64 percent to 76 percent of those already insufficient quantities are disposed of immediately after gargling.

202. In the test reported by RX 73, ten subjects gargled with 20 ml. of Listerine. Immediately after gargling, one nostril was plugged and a tube connected with a device known as a gas chromatograph was inserted into the other nostril. This device drew air from the nostril by use of a suction pump and recorded peaks of when various elements were detected. The results were: ethanol—.8 minutes; eucalyptol—3.2 minutes; menthol—7.1 minutes; methyl salicylate—9 minutes; and thymol—13.8 minutes. The conclusion in the test report was that "alcohol, eucalyptol, menthol, methyl salicylate and thymol were detected in the nasal passage during a 0-10 minute interval after gargling with Listerine Antiseptic" (RX 73; Rieger 2475-79).[16]

203. An immediately noted inconsistency is that the test report states that "sampling of the nasal passage was continued for 10 minutes" (RX 73B), whereas the very same test report recites that the thymol peak was at 13.8 minutes (RX 73A). The results are not totally objectively obtained by machine. In order to ascertain what ingredients were registering, it was necessary for respondent's employees to smell the vapors in the machine and make subjective determinations. These determinations were often based upon what was expected (Rieger 2482, 2500-04). Thus, we have employees of respondent in a position to make subjective judgments in line with what respondent would like to develop. The machine itself was created for a different purpose and was adapted by respondent's employee, Mr. Rieger, for the tests he conducted. He had no previous experience in conducting this type of test (Rieger 2489-90).

204. The vapors were drawn from the subjects by a vacuum pump, with vacuum pressure level set at 300 mls. per minute. It could have been set at 30 utilizing a longer period of time. Thus, the vapors could have been pulled from the oral cavity through the nasal cavity into the machine. It cannot be concluded that the vapors were in the nasal

[16] Mr. Rieger testified that he had also performed tests on a small number of subjects where air was collected between 10 and 20 minutes after gargling. He stated that the ingredients were noted and that after 20 minutes, the method failed (Tr. 2485-86, 2505-06). No such tests were offered into evidence.

cavity. The machine collects only air. It provides no information as to the materials in the mucous membrane of the nose (Rieger 2484, 2494, 2500).

205. The machine was very sensitive and reacted to small quantities in terms of parts per million. A very small amount of an ingredient would register on the machine. The test did not measure the quantities of any ingredient (Rieger 2478-79, 2494-97, 2505). According to Mr. Rieger, the test showed that thymol was the least volatile of any of the active ingredients of Listerine (Tr. 2509).

206. RX 73, therefore, both because of the matters noted with respect to the manner of conducting the test and because it supplies no information as to the quantities of any ingredients that are alleged by respondent to reach the nasopharynx, provides nothing material to the issue of this case.

207. RX 75 is the report of a test conducted by Mr. Konigsbacher, vice president of a company that has run various tests for Warner-Lambert (Konigsbacher 2514, 2520). In the test in question, six employees of the testing company were trained to smell thymol, eucalyptol, menthol and methyl salicylate. They gargled with Listerine and also with a control. While gargling with Listerine, they were able to detect the odors of its four active ingredients (RX 75; Konigsbacher 2540).

208. The panelists were also trained to recognize the odor of Listerine as a whole (RX 75E; Konigsbacher 2537), and some of them may have known that Listerine was being tested because of its characteristic odor (Konigsbacher 2538-39). The general level of test competence and performance is discussed with each panel member when he is not doing well. They are quite competitive in their ability to do well (Konigsbacher 2541). The test report is dated September 19, 1973, well after the present litigation commenced, so that it is probable that the panelists were aware of the litigation and the issues involved. As employees of a company engaged by respondent, they may well have exercised bias in favor of Listerine, particularly since they are trying to do "well."

209. The currently accepted theory is that all odor receptors are in the nose. There are only four taste senses—salt, sour, bitter and sweet (Konigsbacher 2530, 2536, 2544, 2547, 2565). It is apparent, therefore, that for the body to experience all of the other sensory perceptions from what is eaten or imbibed, the odor receptors in the nose must be extremely sensitive to the slightest stimulus. Therefore, the ability to

smell thymol, eucalyptol, menthol and methyl salicylate while gargling Listerine is no indication that the ingredients move into the nose[17] or that they are there in therapeutic quantity. The test reveals nothing as to how long the odor endures or in what strength it is present (Konigsbacher 2547-48, 2556). The test, therefore, lacks probative value.

210(a). Respondent (RPF 74G) relies upon the results of tests performed by Dr. Hunter (RX 108P-R, Z-26) for the proposition that Listerine penetrates into crypts, folds and crevices of the oral membranes and into the upper layers of the epithelial tissues; that it reaches the tonsils and tonsillar crypts, the hypopharynx, the oropharynx, and a portion of the nasopharynx in liquid form. These results, which were introduced during the trial involving Listerine thirty years ago, are totally and conclusively contravened by the testimony of today's experts, including that of respondent's own expert microbiologist, Dr. McNamara (Findings 57, 69, 71, 72, 154).

210(b). Dr. McNamara testified that there are several sites in the oral cavity where large amounts of bacteria reside, but where Listerine cannot penetrate to make contact; that Listerine cannot penetrate to the full depth of dental plaque, which he described as "the organic film that covers the teeth, and all the soft tissues in the mouth;" that there are tremendous amounts of bacteria in this dental plaque, and that Listerine certainly does not reach all of them; that there are millions of bacteria per gram in the crypts of the tongue that Listerine could not penetrate to contact; that Listerine cannot penetrate deeply into the crypts of the tonsils to contact the bacteria that reside there; that Listerine would not reach the nasal pharynx in liquid form; and that Listerine does not penetrate into tissue cells (McNamara 2339-44).

211. It is, therefore, found that the use of Listerine will not prevent or result in fewer colds or sore throats, will not cure colds or sore throats, and will not cause colds or their symptoms, including sore throats, to be less severe than they otherwise would be; and that the ability of Listerine to kill germs is of no medical significance in the prevention, cure or treatment of colds and sore throats. These findings are based upon consideration of the entire record. Upon such consideration, it is clear that the overwhelming weight of probative evidence compels such findings.

Discussion of Other Contentions of Respondent Bearing upon Finding 211

Respondent (RPF 222, 223) appears to challenge the probative value and substantiality as evidence of the opinions of medical experts called

[17] Mr. Konigsbacher's reported conclusion that the thymol, eucalyptol, menthol and methyl salicylate in Listerine migrate into the nasal passage during gargling was stated to be tentative (RX 751).

by complaint counsel because they had not conducted actual tests on Listerine or had no personal experience with it. This challenge of the opinions of experts in the field who were otherwise highly qualified to give such opinions is baseless. *Reilly* v. *Pinkus*, 338 U.S. 269, 274 (1949). Such testimony has been held to constitute substantial evidence even where witnesses who had personally observed the effect of the product have testified to the contrary. *Bristol-Myers Co.* v. *FTC*, 185 F.2d 58, 62 (4th Cir. 1950). Here, all of the evidence has been weighed and has been found not merely substantial, but overwhelming in establishing the above findings.

Respondent (Memorandum 12-21) argues that what it asserts are the standards utilized by the Food and Drug Administration in approving a new drug must be applied in this case. These standards are termed the "substantial evidence" test, *i.e.*, there need only be substantial evidence consisting of adequate and well-controlled investigations upon which qualified experts can fairly and responsibly conclude that the drug has the effects claimed for it. This, according to respondent, must be accepted as justifying a claim even though the preponderant evidence would establish that the claim is false. The responsible minority opinion based upon such tests would control.

Respondent's argument is untenable because the basic question in this proceeding under the *Federal Trade Commission Act* is whether the claims made for Listerine have the tendency and capacity to mislead the consuming public. This is a question of fact to be determined under the normal standards of the Federal Trade Commission Act, not under standards established by the Federal Food, Drug and Cosmetic Act. Respondent's argument has, in effect, already been rejected by the Commission in its order denying respondent's interlocutory appeal from the ruling of the administrative law judge striking portions of respondent's answer, when the Commission stated, "The complaint in this case, unlike that in *Pfizer*, [*In the Matter of Pfizer, Inc.*, (81 F.T.C. 23 (1972))] does not charge as a separate violation that respondent 0 did not have a reasonable basis for its claims. It alleges that respondent's claims are false, misleading and deceptive. Whether or not respondent had a reasonable basis for making such claims is therefore totally irrelevant." (82 F.T.C. 749, 752 (1973)).

Even if the standards contended for by respondent were applicable here, it still could not prevail, for it has failed to meet the "substantial evidence" test. As found above, the Reddish and St. Barnabas tests, upon which respondent relies, do not constitute the "adequate and well controlled investigations upon which qualified experts can fairly and responsibly conclude [that Listerine] has the effects claimed for it."

Respondent (RPF 246-51) contends that the efficacy of Listerine as a cold remedy is demonstrated by consumer satisfaction. It relies primarily upon survey data for its conclusion that there is consumer satisfaction. In evaluating any such data, it must be noted that Listerine is the only mouthwash sold with respect to which cold claims are made. Having been sold as a cold remedy, there is the resultant placebo effect, particularly since colds are self-limiting and improve without medication (Findings 81, 82). The contention of consumer satisfaction, as derived by respondent from its surveys, cannot begin to approach in probative value the overwhelming weight of the expert testimony adduced by complaint counsel. Upon an overall evaluation, it is entitled to very little, if any, weight. Indeed, as held in *Erickson* v. *FTC*, 272 F.2d 318, 322 (7th Cir. 1959), "* * * [T]he fact that petitioner had satisfied customers is not a defense to Commission action for deceptive practices." Accord, *Feil* v. *FTC*, 285 F.2d 879, 883 n.5 (9th Cir. 1960).

Respondent's reliance (Reply 45) upon *Evis Mfg. Co.* v. *FTC*, 287 F.2d 831 (9th Cir. 1961), *cert. denied*, 368 U.S. 824 (1961), is misplaced. In *Evis*, a case which involved the efficacy of a water softener, the Commission relied upon experts whose testimony was based upon experiments and laboratory tests performed upon the device in question. They did not know the theory upon which the device purportedly worked; they did not know the composition of the metal; and they were not acquainted with the claimed special processing thereof. In performing their experiments, they did not follow instructions of operation which, according to evidence adduced by the company, was important to achieve desired results. Further, the Commission relied upon a purported admission to the effect that 3,000 dissatisfied users could be called. This was construed by the court to mean that of 100,000 purchasers, 3,000 dissatisfied ones could be called.

It was only under such circumstances that the court in *Evis* ruled that the Commission had failed to adduce substantial evidence in the face of the sworn testimony of satisfied consumers, subject to cross examination, many of whom were themselves qualified experts in the field. The situation in *Evis* is a far cry from that in the case at hand.

The Bearing of "Future Facts" upon the Foregoing Findings

Respondent (RPF 318-20; Memorandum 22-25) contends that under the Commission's order in *Lambert Pharmacal Co.*, 38 F.T.C. 726, 730

(1944), a finding of violation may not be made without a showing of "future facts" [18] and that no such future facts have been developed that would warrant a resolution of the issues against respondent. Respondent appears to argue that it is incumbent upon complaint counsel to introduce different types of evidence than what was introduced in the prior proceeding; that since the expert opinion evidence offered by complaint counsel in the prior proceeding was not deemed sufficient, they cannot now prevail on the basis of opinion evidence.

Respondent's position has, in effect, been ruled upon by the Commission when it denied respondent's motion for interlocutory appeal (82 F.T.C. 749 (1973)). There, the Commission held that it was unnecessary for the complaint to allege "future facts." Its opinion quoted at length from *Manco Watch Strap Co.*, 60 F.T.C. 495 (1962), where, following the principles enunciated in *FTC* v. *Raladam Co.*, 316 U.S. 149 (1942), it was held that dismissal of a complaint for failure of proof did not preclude a finding of violation in a subsequent proceeding based on like allegations, but covering a subsequent period of time; that the later record constituted new and different facts upon which a finding of violation may be made.

In the instant case, the undersigned has considered all portions of the prior record that have been incorporated into the present record, either by introduction as exhibits or by means of official notice. Consideration has also been given to the vast amount of new evidence introduced. The overall record, therefore, is a new one and presents new facts, not limited by the prior record. It is partly because of this situation that the undersigned has gone into some detail in discussing the testimony of witnesses produced by both sides and the tests introduced by respondent. By "future facts" the Commission meant future knowledge and facts that could be established in the future. In the undersigned's opinion, the facts found above have clearly and overwhelmingly been established.

In the Commission's dismissal of the prior complaint, it took note of the views of many medical practitioners that the use of a product such as Listerine would assist in resisting invasion of pathogenic cold-causing organisms (38 F.T.C. at 739). This is clearly not the view of knowledgeable medical men today, and respondent's own St. Barnabas test establishes that the use of Listerine will not cause fewer colds. In its prior opinion, the Commission relied, in large part, upon the Reddish tests as constituting clinical support of the representation that the use of Listerine resulted in fewer and less severe colds and the

[18] In *Lambert Pharmacal Co.*, it was ordered "That the complaint herein be, and the same hereby is, dismissed without prejudice to the right of the Commission to institute further proceedings should future facts so warrant." 38 F.T.C. at 730.

complications thereof (38 F.T.C. 740, 741, 746, 749). The Reddish tests, however, would be unacceptable to the scientific community today and must be disregarded on the basis of the entire record (Findings 120-126). Another "former fact" upon which the Commission relied was that bacteria play a very important role with respect to the common cold including complications caused by secondary invaders (38 F.T.C. at 744). It is clear, under the present record, that bacteria play no part in the common cold (Findings 51, 58, 67), and that Listerine would be ineffective to prevent, cure or alleviate infections caused by secondary invaders (Finding 71).

Finding 212, which follows, further disposes of respondent's position relative to the necessity to show "future facts."

ADDITIONAL FINDINGS OF FACT

212. Much has been learned about colds in the last 30 years (Gwaltney 397-98, 403-04; Hornick 490-91, 515; Parrott 908). There were clues, generally accepted as valid, prior to the 1940's that common colds were caused by viruses, but 30 years ago bacteria were not ruled out as a cause of colds. Most people thought that bacteria were somehow involved and it was popular to inject toxins from killed bacteria to try to prevent colds. When antibiotics were developed after 1942, there was a time when most colds were treated with antibiotics (Seal 590; Proctor 622; Rammelkamp 785, 787). Today, the theory that bacteria play a part in the common cold has been ruled out (Findings 51, 58, 67). The record, therefore, clearly demonstrates that there are "future facts" even under respondent's position.

Representation that Tests Support Listerine Cold Claims

213. In advertisements published in periodicals and newspapers during the period extending from Dec. 27, 1968 to Feb. 22, 1969, and then again on Sept. 13, 1969 (CX 10, 26A-B), the following statement appears:

> Tests over a 12-year period proved that people who gargled with Listerine twice a day had fewer colds than those who did not (CX 9, 25).

It has been stipulated that the phrase "Tests over a 12-year period" refers to the Reddish tests conducted between 1930 and 1942; and that final approval by Warner-Lambert for dissemination of CX 9 was given on Aug. 15, 1968 (CX 139C).

214. CX 51, the interim report covering the results of the first year of the St. Barnabas study, was issued on Sept. 18, 1968, after final approval for dissemination of CX 9 for the 1968-1969 "colds" season.

The second interim report, which covered the second year of the study, was not issued until Mar. 16, 1970, subsequent to the last publication of the representation in question (CX 139D). In the late summer or early fall of 1969, Dr. Haggie, who was then respondent's vice president for Consumer Products Research (Tr. 1703), received the top-line results of the second year of the St. Barnabas study which showed what overall results were going to be reported (Tr. 1770).

215. The results of the first year of the study and the top-line results of the second year both showed no statistically significant difference between the Listerine group and the control group insofar as fewer colds were concerned (Haggie 1771). Dr. Haggie recommended to management officials that advertising claims for fewer colds be suspended pending a resolution of the differing results between the Reddish and St. Barnabas studies (Tr. 1770-71, 1774). The recommendation was accepted to the extent of stopping the representation that appears in Finding 213 (Haggie 1777-78).[19]

216. A representation that tests prove a claim is a representation as to the most recent tests available. Respondent had the first year of the St. Barnabas study, which did not substantiate the claim, prior to its 1968-1969 colds season advertising. It received, in addition, the top-line report of the second year of the St. Barnabas study, which also failed to substantiate the claim, around the time of the last publication of the representation.

217. The circumstances under which respondent acted were most unusual. The representation referred to a test which had been run for a period of 12 years. The test in question had been found by one Commissioner to constitute a measure of clinical support for the claim of fewer colds (38 F.T.C. at 740) and by another not shown to be incorrect and untenable (38 F.T.C. at 749). It was, in large measure, because of the Reddish test that the complaint in Dkt. 4232 was dismissed. Under these circumstances, respondent cannot be said to have acted unreasonably when it waited until it received an indication of what the second year of the St. Barnabas study would show before it abandoned reference to the Reddish tests in its advertising. Upon receipt of top-line results of the second year of the St. Barnabas study, respondent acted promptly to cease reference to the older study. The last such reference was made in an advertisement placed on Sept. 13, 1969, long before the instant complaint was issued on June 27, 1972.

218. Under the particular and unusual circumstances surrounding the dissemination of the challenged representation and its withdrawal, it is found that respondent was not engaged in a separate and distinct

[19] Dr. Haggie's testimony was actually broader—to the effect that all "fewer colds" claims were stopped. An evaluation of respondent's advertisements has shown that this was not done (See Findings 31-38, 40).

violation of Section 5 of the Federal Trade Commission Act, as alleged in Paragraphs Nine and Ten of the complaint, by referring to the results of the Reddish studies when it did.[20] This finding in no manner detracts from the other findings of misrepresentation.

CONSIDERATION OF APPROPRIATE ORDER

Complaint counsel request issuance of an order that would require respondent "in connection with the labeling, advertising, offering for sale, sale or distribution of Listerine *or any other non-prescription drug product* in commerce" to cease and desist representing that the product will cure colds or sore throats, will prevent colds or sore throats or will cause users to have fewer colds than nonusers. The record is clear that there is no product that will prevent or cure colds or sore throats. The misrepresentation to be proscribed, therefore, is not peculiar to Listerine or any mouthwash product, but would be equally false if made for any nonprescription drug product. Section 5 of the Federal Trade Commission Act empowers the Commission to proscribe the use of unfair methods of competition and unfair or deceptive acts or practices. The unfair method of competition and unfair or deceptive practice is that of falsely representing a prevention or cure for colds and sore throats. While the representation was made in connection with a particular mouthwash product, it would be equally false with respect to any nonprescription drug product. Since respondent is engaged in the manufacture, sale and distribution in commerce of a number of nonprescription drug products, an order proscribing such representation in connection with any nonprescription drug product is deemed warranted and in the public interest.

Complaint counsel also seek an order requiring respondent to cease and desist from "misrepresenting the efficacy of * * * [Listerine or any other non-prescription drug product] or the benefit to be derived from the use of any such product." Such a proscription is deemed to be unwarranted and unauthorized in the instant matter. This case involves misrepresentations as to one product only—Listerine mouthwash—and, as to that one product, only one type of misrepresentation—the product's efficacy for colds. The following excerpt from *American Home Products Corp.* v. *FTC*, 402 F.2d 232, 237 (6th Cir. 1968), is equally applicable here:

> We are also of the opinion that the order must be modified by striking the provision which prohibits petitioner from disseminating any advertisement "In connection with the

[20] While the Reddish tests were performed on adults and not children, the Commission's opinion in *Lambert Pharmacal Co.*, 38 F.T.C. 726, was not limited to a discussion of the effect of Listerine on adults. Hence, complaint counsel's position (CPF 19, 69, 70; Memorandum 14-15, 32-33) that it was false and deceptive to have included a reference to the Reddish tests in advertisements claiming benefits for children is rejected.

offering for sale, sale, or distribution of any 'drug' * * * which misrepresents directly or by implication the efficacy of such drug." An order of the Commission must bear a reasonable relationship to the unlawful practice found to exist. * * * [cases omitted]

The proceedings in this case dealt exclusively with representations as to the efficacy of Preparation H; no other drug was involved. It was not established that petitioner is a habitual violator of the Federal Trade Commission Act, even though it is not a first offender. The effect of this provision of the Commission's order is to admonish petitioner not to violate the law again. Such an order would, in practical effect, transfer the task of enforcing the Federal Trade Commission Act, as regards this petitioner, to the district courts under 15 U.S.C. §56. This is not within the contemplation of the Act.

Accord, *Grove Laboratories* v. *FTC*, 418 F.2d 489, 496-97 (5th Cir. 1969).[21]

ITT Continental Baking Co., Dkt. 8860, Oct. 19, 1973 [83 F.T.C. 865], upon which complaint counsel rely (Memorandum 26-29) is inapposite. There, the Commission approved an order proscribing the misrepresentation of nutritional values of "all food products" rather than limiting the proscription to Wonder Bread, bread or baked goods. There, the deceptive practice found was that of making unwarranted nutritional value representations concerning food products. The deception was not uniquely suited to bread or bread products. Here, respondent's very business is that of developing and promoting the sale of over-the-counter drugs that are efficacious for various purposes. There is no basis in this record for requiring respondent to engage in that business at peril of civil penalties.

Having found that, because of the circumstances under which respondent referred to its Reddish studies and then stopped making such references, respondent had not misrepresented that tests supported its claim of fewer colds, there is no basis for issuing an order relating to such a practice.

Corrective Advertising

The requirement of corrective advertising, in an appropriate case, is within the remedial powers of the Commission. *Firestone Tire & Rubber Co.*, 81 F.T.C. 398, 466-67, 473 (1972); *ITT Continental Baking Co.*, Dkt. 8660, Slip. Op. 31, Oct. 19, 1973 [*supra*]; *Campbell Soup Co.*, 77 F.T.C. 664, 668 (1970). In recognition of the Commission's position that it has such authority, respondent (Reply 59), while denying its existence, reserved argument on this issue for presentation to the Commission if necessary. The following findings bear upon the question of whether it would be appropriate and reasonable to require corrective advertising in this case.

[21] The present case is even more compelling in favor of respondent in that it has never previously been adjudged to have made misrepresentations in violation of Section 5 of the Federal Trade Commission Act.

FINDINGS PERTAINING TO CORRECTIVE ADVERTISING

219. Listerine has been on the market since 1879. Throughout its history, the product has been represented as being, *inter alia*, beneficial in certain respects for colds, colds symptoms and sore throats. Listerine has been advertised directly to the consuming public as a cold remedy since 1921. Since prior to 1938, Listerine labeling has included the claims regarding colds and sore throats as set forth in CX 49 and CX 50 (See Finding 25). These claims have been made continuously since prior to the effective date of the Federal Food, Drug and Cosmetic Act of 1938, up to and including the date of issuance of the complaint on June 27, 1972 (CX 139A-B).[22]

220. The record shows that over the past ten years, respondent has spent large sums of money in all major media for advertising Listerine as a remedy for the prevention and cure of colds and sore throats and as an ameliorative for cold symptoms (Findings 8-46; CX 40A-B, 41A-B, 42A-B, 44, 45, 46, all *in camera*). The vast majority of these expenditures were spent on network and spot television, covering all parts of the day and evening but particularly on prime time network television (CX 40A-B, 45, 46, *in camera*). Spot television commercials covered practically all the major media centers in the United States (CX 41A-B, *in camera*). Listerine "colds" print advertising was disseminated in major magazines and newspapers throughout the country (CX 2, 4, 6, 8, 10, 12, 14, 16, 18, 21A-E, 24A-D, 26A-B, 29A-E, 31, 33A-H).

221(a). Advertising acts both in creating a belief in consumers and in reinforcing a belief once it has been created. It has a large role in creating and shaping beliefs with respect to a new product. Its role with an older, established product such as Listerine is more to reinforce established beliefs and act as a reminder. It serves to keep people from changing their attitudes. It still influences some new beliefs. There are always new people coming into the market, *e.g.*, people who were not users who grow up and form households (Rossi 1451, 1453; Bass 1533, 1560, 1607-12, 1619-21; Achenbaum 3389, 3393, 3438-41; Amerman 3455-56).

221(b). Advertising plays a relatively more important role for packaged goods, such as a mouthwash, than for items such as automobiles (Achenbaum 3392-93). Listerine having been advertised as a cold preventative, cure and symptom ameliorative for so many years, it is clear that it has acted both to create and reinforce beliefs in consumers corresponding with respondent's representations concerning that product. It is not plausible that respondent would have spent

[22] See Finding 26 for description of label claims since December 1972.

the millions of dollars that it has over such a long period of time to create and reinforce beliefs about Listerine's use for colds unless it were convinced that the advertisements were effective. Respondent, of course, has taken issue with what claims were made. This, however, has already been found (Findings 27-46). If effective, the advertisements would have created, influenced and reestablished beliefs corresponding with what was represented.

222. CX 52-65 are market research reports known as "Product Q" reports on the "Mouthwash Market," produced from the files of respondent. The reports contain marketing, advertising and purchase behavior data on Listerine and competing mouthwashes from 1963 through 1971.

223. The purpose of a Product Q test is to relate a number of different types of information, such as (a) product awareness, (b) product use, (c) brand experience, attitudes and beliefs toward the brand (including the degree to which certain attributes and benefits are liked and the degree to which they are important to consumers) and (d) awareness and familiarity with advertising, to the same people at the same time. That is the same group of people is surveyed at different times as to the same types of information (Levitt 1210-11). As respondent's own advertising agency, J. Walter Thompson Company, reported to respondent: "By collecting continuous data on consumer reaction, Product Q is ideally suited to provide guidance in such vital areas as * * * the basic strengths and weaknesses of Listerine and the competitive brands as perceived by the consumer * * * [w]hat qualities do people look for in a mouthwash * * * [and] *[h]ow successful are the current advertising campaigns of different brands on awareness, recall, attitudes, and sales*." (CX 80D-E; emphasis added).

224. Each Product Q study utilized a sample of housewives which was drawn from a nationwide consumer panel maintained by the Home Testing Institute (Levitt 1224-25). The demographic characteristics of the sample used in each of the tests in evidence parallel "what the population at large looks like as reported by the census data." (Levitt 1225). The sample of each test is representative of the total United States in areas of residence, market size, family income, age of housewife, education of housewife and size of family (Levitt 1225-26). The results of the Product Q tests, therefore, represent the opinions of millions of American housewives. The percentages expressed in the Product Q reports would vary only 5 or 10 points in either direction with a band of confidence at the .05 level of significance if a scientifically drawn sample, literally projectable to the entire country, had been employed in lieu of the selected consumer panel samples (Rossi 1420, 1423-27). The Product Q studies, therefore, also provide

information on the opinions held concerning Listerine for the United States as a whole.

225. The Product Q studies (CX 52-65) were commissioned by respondent and used by it from 1963 to 1971. Product Q studies have been used during the past 10 years by over 20 different companies including General Foods, General Mills, Sears, Hunt-Wesson Foods, Kimberly-Clark, Scott Paper Company and Uncle Ben's Rice. No other company has used the Product Q service as continuously and as long as respondent (Levitt 1212).

226. Respondent was actively involved in the planning and evaluation of the Product Q reports. It selected the competitive brands and product qualities to be tested (Levitt 1222-23). Tabulations of the raw data were sent to Warner-Lambert for its independent review. Meetings and telephone conversations were held between personnel of the testing company and Warner-Lambert to discuss the data. Final reports were sent to respondent and oral presentations were made (Levitt 1227, 1230; CX 71A). Respondent's officials reevaluated and summarized Product Q data in internal company documents (CX 66-79). Copies of these memoranda were circulated at management levels of respondent and to J. Walter Thompson, respondent's advertising agency (CX 66A, 67E, 68A, 69C, 70B, 72A, 73A, 74B, 75A, 77D, 78D). Respondent had its advertising agency, J. Walter Thompson Company, prepare a report, "Analysis of Product Q With Some Suggestions For Improvement" (CX 80).

227. Each Product Q report originally cost between $4,000 and $5,000. The price currently approximates $12,000 to $13,000 per test (Levitt 1211). Since there were 23 Product Q reports on the mouthwash market between 1963 and 1971, respondent spent well over $100,000 on these marketing studies.

228. Findings 225, 226 and 227 compel the further finding that respondent placed a high degree of confidence and reliance on the Product Q tests and what they showed.

229. The Burke Recall tests (CX 82-89) indicate that a significant number of consumers remember specific copy points in particular "colds" commercials after only one exposure to an advertisement and after a 24-hour time lapse (Findings 44-46). It is not unexpected that, as is evidenced by the Product Q studies, the long-standing and extensive campaign of advertising Listerine for colds has produced a strong image for Listerine as a "colds" product.

230. A number of the categories used in questions posed in Product Q tests are precoded. The quality or description "effective for colds and sore throats" is such a category established prior to conducting a Product Q survey. It encompasses prevention, cure and relief, but the

Product Q test cannot be broken down so as to separate or quantify the actual beliefs covered by that category (Levitt 1229-30, 1255; Bass 1583-84, 1604; CX 52Z-48-51).

231. The following table summarizes the results of the Product Q reports, covering 1963 to 1971, to the extent of showing the percentage of consumers exposed to a lot of Listerine advertising who recall "effective for colds and sore throats," "effective for killing germs" and "effective for bad breath" as main ideas of Listerine advertising.[23]

[23] The table is based on answers given by consumers who have seen or heard a lot of advertising for Listerine in response to the following question: "Thinking of the recent advertising you've seen or heard for each brand, which one of the following main ideas do you feel the brand has been advertising: effective for colds and sore throats, not too strong tasting, gives long lasting protection, recommended by dentists, leaves mouth feeling refreshed, effective for bad breath, leaves no unpleasant after-taste, effective for killing germs, pleasant flavor."

Selected Advertising Themes Recalled by Consumers as Displayed in Listerine Advertising

Quarterly Period	Effective for Killing Germs	Effective for Colds and Sore Throats	Effective for Bad Breath
4th Qtr 1963	71%	68%	66%
1st Qtr 1964	76	74	69
2nd Qtr 1964	69	62	65
3rd Qtr 1964	68	62	66
4th Qtr 1964	67	65	68
1st Qtr 1965	65	67	68
2nd Qtr 1965	69	65	68
3rd Qtr 1965	68	63	71
4th Qtr 1965	71	66	72
1st Qtr 1966	73	74	71
2nd Qtr 1966	69	69	70
3rd Qtr 1966	67	66	65
4th Qtr 1966	70	68	60
1st Qtr 1967	70	72	57
2nd Qtr 1967	72	73	56
3rd Qtr 1967	.....	Data Missing	.....
4th Qtr 1967	72	71	63
1st Qtr 1968	71	77	60
2nd Qtr 1968	.....	Data Missing	.....
3rd Qtr 1968	72	69	60
4th Qtr 1968	75	78	68
1st Qtr 1969	71	80	62
2nd Qtr 1969	.....	Data Missing	.....
3rd Qtr 1969*	64	62	50
4th Qtr 1969	.....	Data Missing	.....
1st Qtr 1970*	65	69	52
1st Qtr 1971*	67	69	52
Average	69.6	69.1	63.4
Range: High	76	80	72
Low	64	62	50

* Percentages for these quarters based on total respondents rather than just on those who have seen or heard a lot of advertising.

Source: CX 159H

232. The above table shows that Listerine's advertising theme "effective for colds and sore throats" has extremely high recall among American consumers, higher even than recall of Listerine's breath advertising upon which many times as much money is spent (RX 100, *in camera*). As the J. Walter Thompson Company, respondent's advertising agency, reported to respondent, the major distinctive copy points

remembered for Listerine are "effective for colds and sore throats" and "effective for killing germs" (CX 80Z-6).

233(a). Although recall of Listerine's "colds" advertising is at all times very high, such advertising is recalled to an even greater degree during the winter months' "cold season" when Listerine "colds" advertising is disseminated. This indicates that the advertising is especially effective during the months in which it is disseminated. At the same time, it is important to recognize that the "colds" theme is highly recalled as recent advertising even during the 6-month period when there is no such advertising. This is most significant in considering the propriety of requiring corrective advertising, particularly in view of the fact that the subjects are being asked to recall the major themes of recent advertising, not of advertising 3, 4, 5 or 6 months ago. It shows the lasting impression of the non-current advertising.

233(b). The following table presents the seasonal variations in recall of selected Listerine advertising themes for 1963 through 1969, derived by averaging the quarterly recall scores for each attribute (Rossi 1439):[24]

Average Seasonal Variations in Proportions Recalling Selected Listerine Advertising Themes (1963-1969)

Season	Effective for Killing Germs	Effective for Colds and Sore Throats	Effective for Bad Breath
4th Qtr (October through December)	71%	69%	66%
1st Qtr (January through March)	71%	74%	64%
2nd Qtr (April through June)	70%	67%	65%
3rd Qtr (July through September)	68%	64%	62%

Source: CX 159J[25]

234. Listerine's advertising is particularly distinctive when compared to that of its three leading competitors, Scope, Lavoris and Micrin, especially on the attributes "effective for colds and sore throats" and "effective for killing germs" (Rossi 1434, 1440-42, 1448-49;

[24] Calculations are based on proportions shown in Finding 231 excluding data from 3rd Qtr 1969 and later periods since those proportions were calculated on different bases.

[25] See also CX 59Z-16, Z26.

Achenbaum 3407-08; CX 80Z7, 159K). This very distinction in advertising would serve to keep Listerine's advertising messages in the minds of the public after they may have stopped (see Finding 233).

235. Product Q reports measure the percentage of survey respondents who held the belief that Listerine possesses the attribute of being "effective against colds and sore throats." The reports establish that Listerine is perceived by the majority of those surveyed as being effective against colds and sore throats. Below is a table derived from Product Q data (Rossi 1435-36; Levitt 1234-35; CX 159E) which shows the percentage of the total sample who rate Listerine "One of the Best" mouthwashes for the qualities "effective against colds and sore throats," "effective against germs," and "effective against bad breath" for a 7 1/2 year period from 1963 to 1971:

Proportions Rating LISTERINE as "One of the Best" with Respect to Certain Qualities

Quarterly Period	Effective Against Germs	Effective Against Colds/Sore Throats	Effective Against Bad Breath
4th Qtr 1963	51%	43%	49%
1st Qtr 1964	53	47	52
2nd Qtr 1964	53	46	51
3rd Qtr 1964	53	47	51
4th Qtr 1964	53	49	52
1st Qtr 1965	53	50	51
2nd Qtr 1965	52	51	51
3rd Qtr 1965	55	51	54
4th Qtr 1965	56	52	55
1st Qtr 1966	60	59	59
2nd Qtr 1966	58	55	57
3rd Qtr 1966	59	58	57
4th Qtr 1966	57	55	53
1st Qtr 1967	53	53	47
2nd Qtr 1967	56	55	51
3rd Qtr 1967	.....	Data Missing	.....
4th Qtr 1967	58	56	51
1st Qtr 1968	59	59	53
2nd Qtr 1968	.....	Data Missing	.....
3rd Qtr 1968	57	58	53
4th Qtr 1968	59	59	55
1st Qtr 1969	60	59	54
2nd Qtr 1969	.....	Data Missing	.....
3rd Qtr 1969	57	57	50
4th Qtr 1969	.....	Data Missing	.....
1st Qtr 1970	59	60	55
1st Qtr 1971	59	59	56
Average Proportion	56.1	53.8	52.9
Range: High	60	60	59
Low	51	43	47

Source: CX 159D

236. The above table does not fully reflect the extent of the belief that Listerine is effective against colds and sore throats—only the percent that rated it "one of the best." Other possible affirmative ratings not included in the above tabulation are "very good," "good" and "fair" (CX 52Z-50, 53Z-43; 54Z-81). This evaluation reflects the belief of the entire population surveyed regardless of whether the responders have ever used Listerine (see, *e.g.*, CX 52Z-50, 53Z-43, 54Z-81, 65Z-23).

237. While the latest Product Q report in the record is for the first quarter of 1971, it may be anticipated that the 59 percent level of those who thought Listerine was one of the best mouthwashes effective against colds and sore throats would prevail today. This is because of the stability of the percentage since 1968 (the percentage not varying more than two points from the 59 percent level) and because this particular belief with respect to Listerine ranks high in comparison with the level of consumer beliefs on other mouthwash properties of Listerine. Also, consumer beliefs are very stable once they come to exist (Rossi 1433; Bass 1549-50, 1554-55; CX 59P).

238(a). The percentage of people who believe that Listerine is effective for colds and sore throats is very high in comparison with other brands. While *the percentage of those surveyed* believing Listerine to be effective for colds and sore throats was 58 percent in 1968, 59 percent in 1969 and 60 percent in 1970, the corresponding figures for Scope were only 7 percent in 1968, 8 percent in 1969 and 7 percent in 1970. During that period, Scope was Listerine's nearest competitor in mouthwash sales (Bass 1547-48, 1550-52; CX 60Z-4, 64Z-4, 139-0). Among those surveyed *who had an opinion concerning the attribute*, effective for colds and sore throats, 62 percent in 1967 believed Listerine had that attribute and 66 percent in 1968 believed Listerine had it. The levels of belief among the same individuals on Lavoris and Micrin possessing that attribute were 16 percent and 19 percent, respectively, in each year. The figures for Scope were 11 percent in 1967 and 13 percent in 1968 (Bass 1552-53; CX 80Z-11).

238(b). Listerine has the most distinctive brand image among the four competing brands (Listerine, Scope, Lavoris and Micrin). Its distinctiveness is based particularly on the product attributes of "effective for colds/sore throats," "effective for killing germs," and "effective for gum trouble" and, to a lesser extent, "gives long lasting protection" and "effective for bad breath." (CX 159F; Rossi 1433-34; Achenbaum 3408). As respondent's advertising agency summarized the Product Q survey results, "Listerine is perceived as a powerful germ-killer, effective both for bad breath and for colds/sore throats," while "[t]he main negative images[26] for Lavoris, Micrin, and Scope are in the therapeutic field, viz., effective for colds/sore throats, and effective for relief of gum trouble." (CX 80H).

239. The phrase "effective for colds and sore throats" clearly encompasses prevention, cure and relief. The responses under this category, however, cannot be broken down to ascertain what each person had in mind when responding to questions containing that

[26] Negative images are the percentage rating the brand "fair" or "poor" among those with an opinion about the brand (CX 80Z-10; Levitt 1237).

phrase (Finding 230). However, inasmuch as Listerine does not prevent, cure or provide symptomatic relief for colds, the public's belief must, in large part, have come from respondent's extensive advertising over the years. And that advertising has represented that Listerine will prevent and cure colds and sore throats and will ameliorate symptoms and afford symptomatic relief (Findings 27-46). It follows, therefore, that these representations and beliefs are what is reflected by the responses to survey inquiries as to "effective for colds and sore throats."

240. Findings 221 and 239, in and of themselves, establish that the widely held beliefs as to Listerine's efficacy for colds have, in large part, been created and reinforced by respondent's advertising. The Product Q tests themselves recognize that the data collected reflects, in part, the success of current advertising (Finding 223). Those surveyed were requested to give their impression on how good Listerine was for colds and sore throats even though they may never have used the product (see, e.g., CX 52Z-50, 53Z-43, 54Z-81, 65Z-23). Respondent's distinctive Listerine "colds" advertising themes are recalled to a high degree even during the 6-month period of the year when there are no "colds" advertisements (Findings 232, 233 and 234).[27] The very high percentage of belief that Listerine is effective for colds and sore throats compared with the low percentage of such belief for competitive products (Findings 235-38) reflects the impact of Listerine's distinctive "colds" advertising. Listerine "colds" advertising helps generate increased sales of the product (CX 109A).

241. There is a very close relationship between advertising registration and product image and this is true with respect to Listerine (Bass 1571-73; Rossi 1450; CX 59Z-12, 65E-F, 159F, K, L). As concluded in the latest Product Q report (CX 65E-F):

> Listerine continues to be first on most measures and it continues to grow while Scope remains a distant second; its performance relatively static. However, despite this one sided picture, comparable numbers of respondents claim to recall 'a lot' of advertising for each brand. With this dimension constant and Listerine well ahead of Scope on everything else, it would appear that *the quality of Listerine's advertising and/or its media plan are making a vital contribution to the brand's success.*
>
> Also, *there is a very close relationship between Listerine advertising registration and the brand's image.*

* * * * * * *

Therefore, one conclusion appears that a significant change in Listerine ad

[27] While 76 percent of the respondents, in a 1968 survey "who recall a lot of advertising," stated that "effective against colds and sore throats" was an advertising claim made for Listerine, only 23 percent associated "effective against colds and sore throats" with Lavoris advertising, 26 percent with Micrin advertising and 12 percent with Scope advertising (Bass 1563-64; CX 80Z-7).

registration will, in most cases, affect the brand's image in the same direction. (emphasis added)

This analysis demonstrates that there is not only a strong relationship or correlation between Listerine's advertising registration and its product image, but that its product image is largely a result of its advertising.[28]

242. Another factor to be considered, which bears upon the propriety of requiring corrective advertising, is the importance of the belief that has been engendered by the advertising. For, if it is deemed important, people will tend to retain the belief notwithstanding the cessation of the advertising (Bass 1558).

243(a). The quality "effective for colds/sore throats" is important in the consumer's purchase of a mouthwash[29] (Rossi 1455). Over 35 percent of those covered by the Product Q surveys over the 7 1/2 year period from 1963-1971, stated that "effective for colds and sore throats" was "extremely important" in the selection of a mouthwash (CX 159A-B). These statements were in response to the directive: "We have listed some qualities which might be found in various brands of mouthwash. Some of these are probably more important to you than others in helping you to decide which brand to buy. Please rate each quality on its importance to you. Not too important, fairly important, very important, extremely important." (CX 159A).

243(b). Since only those who rated the quality "extremely important" were tabulated in the Product Q studies, there was an undetermined number of additional consumers who rated "effective for colds and sore throats," "very important," "somewhat important" or "fairly important" in their purchase decisions.

244(a). The belief that Listerine is effective for colds and sore throats is a determining factor in a significant number of consumers' decisions to purchase Listerine (Rossi 1460; CX 64D, 66C, 80N, 106A, B, 159G). As respondent has advertised: "It is a fact that more families use Listerine during these cold-catching months than any other oral antiseptic." (CX 34, 140B); "For fewer colds, milder colds, more people use Listerine than any other mouthwash." (CX 34, 140F).

244(b). The 1968 Product Q survey reveals that of those who rated as "extremely important" the property "effective for colds and sore throats," 46 percent bought Listerine last, whereas only 34 percent of the entire sample bought Listerine last (CX 80N). Listerine "colds" advertising generates increased sales of the product (CX 109A).

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[28] This is also demonstrated by the results of a 1-year advertising campaign on the West Coast where Listerine's image was markedly changed with regard to its taste and flavor, while its image on these characteristics remained unchanged throughout the remainder of the country (Rossi 1450-51, 1453; CX 65Z-12, 159M).

[29] Families with both teenagers and young children are more likely to deem this quality important than other demographic groups (CX 80L, M).

245. Finding 244 is, of course, further substantiation of Finding 243 that "effective for colds and sore throats" is important in consumers' purchases of a mouthwash. It also constitutes a direct showing of the unfair competitive impact of respondent's advertising practices. In that respect, Listerine users use mouthwash in connection with colds and sore throats to a significantly higher degree than the users of the next leading brand, Scope (CX 131J). As developed by the Product Q reports, "effective for colds and sore throats" and "effective for killing germs" are the two product qualities where Listerine has its greatest competitive advantage to the point of being unchallenged (CX 54D, 55C, 57D, Z-2, 58E, Z-9, 10). Even if competitive mouthwashes are not sold as cold remedies, to the extent Listerine is purchased as a mouthwash and a cold remedy, it displaces and competitively injures competitors whose mouthwashes might have been purchased rather than Listerine if the products had been in competition solely as mouthwashes. Listerine advertising injures competition by claiming an attribute it does not possess.

246. Consumer beliefs tend to continue once they are created. Consumers would continue to believe that Listerine is effective for colds and sore throats even after the cessation of colds advertising (Bass 1555). Once a belief has been created, the belief lasts much longer than the memory of the copy points of the advertisements that created the belief (Bass 1556-57). In the present case, a very high percentage of consumers recalled "effective for colds and sore throats" as a recent Listerine advertising theme even during the 6-month periods when such advertisements were not being seen (Findings 231, 232, 233); and practically the same high percentage of consumers rated Listerine as "one of the best" for "effective against colds and sore throats" during the 6-month periods when no "colds" advertisements were run (Finding 235).

247. Among the factors that would help maintain the consumer belief that Listerine is effective for colds and sore throats, despite the cessation of "colds" advertising, are (1) the continuous advertising of Listerine as a cold remedy for over 50 years and the exhaustive media presentation of such claims for at least the past ten years to the point that it would be difficult to disassociate the name Listerine from the thought that it is presented as a cold remedy (Findings 219, 220, 221); (2) the high recall of copy points of Listerine advertising after exposure to even a single commercial (Finding 229); (3) the high recall of Listerine's advertising theme "effective for colds and sore throats" even during periods when there were no such advertisements (Findings 231, 232, 233); (4) the distinctive nature of Listerine claims "on effective for colds and sore throats" in comparison to the

advertising representations of its leading competitors (Finding 234); (5) the high and stable belief that Listerine is "one of the best" mouthwashes "effective against colds and sore throats" as opposed to a lack of such belief with respect to other mouthwashes (Findings 235, 236, 237, 238); and (6) the importance to consumers in selecting a mouthwash that is "effective for colds and sore throats" (Findings 242, 243, 244; Bass 1555; 1558; Rossi 1472).

248. The complaint does not challenge respondent's representation that Listerine kills millions of germs on contact. Respondent remains free to continue this representation in connection with its "bad breath" or other advertisements. This representation, however, has been used by respondent in conjunction with its "colds" advertisements to represent that Listerine is of medical significance in the prevention, cure and treatment of colds and sore throats (Finding 40). In so advertising, respondent has capitalized upon public belief that germs, followed by virus/bacteria cause colds and that members of the public consider a mouthwash to be a means of obtaining symptomatic relief from colds (Finding 41). Because of such public belief and the prior use by respondent of the representation that Listerine kills millions of germs on contact in conjunction with its cold claims, future representation of Listerine as a germ killer, without corrective advertising, would automatically constitute, or remind the public of cold claims even in the absence of any reference to colds.

249. Dr. Bass is a highly qualified authority in the field of marketing research which includes the cause, content and durability of consumer beliefs, attitudes and behavior and their relationship to advertising (CX 160; Bass 1531-41). Upon an analysis which took into account the various factors recited above, and based upon his general experience with respect to the stability of beliefs, Dr. Bass expressed his opinion that the belief that Listerine is effective for colds and sore throats would continue at the Product Q reported levels for about two years after "colds" advertising ceased; that even after five years from the cessation of advertising, the belief would still be at a very high level (Bass 1560-61). In giving his opinion, Dr. Bass contemplated that the beliefs as to Listerine's effectiveness against colds and sore throats would vary to include, separately or jointly, beliefs as to prevention, as to it being unlikely to catch a cold and as to relief from cold symptoms (Bass 1553, 1583-84, 1605-06).

250. Dr. Rossi is a highly qualified authority in the design, implementation and analysis of surveys having to do with the ascertainment of public opinion. He has worked with surveys (including consumer panel data) which have measured consumer attitudes and beliefs toward consumer products, trends in purchase behavior and

casual relationships underlying shifts in brand preference and usage (CX 158; Rossi 1397-1404). Dr. Rossi testified that, in his opinion, the belief that Listerine was effective against colds and sore throats, as reflected in the Product Q reports, would, in the absence of "colds" advertising, decline at no greater a rate than 5 percent a year (Rossi 1469-72).

251. Respondent has introduced no evidence to controvert the opinions of Drs. Bass and Rossi. Based upon those uncontroverted opinions and other facts recited above, it is clear that an order merely directing respondent to cease and desist from making the unfair, false and deceptive representations would be insufficient to protect the public interest; that the order should also include a provision requiring corrective advertising.

The purpose of requiring corrective advertising is to terminate continuing injury to the public. "This continuing injury may be in the form of lingering effects which a misrepresentation may have on consumers' minds or in the form of a lessening of competitive vigor in the marketplace due to the deceptive practices." *Firestone Tire and Rubber Co.*, 81 F.T.C. 398, 470 (1972). Both aspects of continuing injury are present in this case.

The Commission, in *Firestone*, held that the order there should not contain a corrective advertising provision. While no clear majority view was stated as to why such an order should not issue, the opinion does recite the conclusions of the hearing examiner as follows (81 F.T.C. at 466):

Although this is a matter of judgment, it appears that such an order is not necessary or desirable in this case for the following reasons:

(1) There has been a considerable lapse of time since the advertising occurred.

(2) There is no reason to believe that many of the tires advertised as safe have enough tread left on them for the owners to believe they are safe.

(3) The evidence shows that the residual effect of the advertising will be slight indeed by the end of this year even if the evidence offered by SOUP is viewed in the most favorable light.

(4) Many of respondent's competitors have made safety claims through the use of brand names similar to "Safety Champion" and are under no cease and desist order of any kind.

The instant case differs from *Firestone* in each of the noted aspects:

1. In the present case, there has been no showing of lapse of time since the advertising occurred. There is no indication that it is not presently occurring.

2. This reason is obviously inapplicable here.

3. The evidence shows that the residual effect of the advertising will be high even after five years from the termination thereof.

4. The representations in question are uniquely those of respondent. Respondent's competitors make no such representations. Indeed, respondent's competitors have been, and will continue to be, at a competitive disadvantage because of respondent's representations until their residual effects are removed by corrective advertising.

In *Firestone*, the only reasons given for not including a corrective advertising order were those expressed in Chairman Kirkpatrick's separate statement (81 F.T.C. 398, 440). He stressed what he described as the lack of showing "that the particular advertisements challenged by the complaint in this matter were in fact commercials which succeeded in achieving the effect desired by advertisers—*i.e.*, to continue to influence consumers' purchasing decisions long after the advertisements had been perceived by consumers." Among the elements he emphasized were the time elapsed since the advertisements in question appeared (in that case four years), the media of advertising (there, print only), the frequency and length of time run (there, two advertisements printed 68 times in 10 publications between January 1967 and September 1968) (81 F.T.C. at 440). In the instant case, the success of the advertising in question was evidenced by tests perceived by respondent's advertising agency to be "ideally suited" for such purpose (Finding 223). The copy points in question are shown to have registered and to have been retained during periods when such advertisements were not placed. The image created and reinforced by the advertising was also shown to be strong and continuing in nature. The advertisements had not been discontinued. They were not limited to print exposure for less than two years, but included print and prime time television coverage for many years.

Form of Corrective Advertising Order

Having determined that an order requiring corrective advertising is necessary and appropriate in the public interest in this matter, it remains to consider the form of such an order.

Relying upon the opinion testimony of (1) Dr. Bass that there would be little decline in the percentage of consumers who would hold the false "colds" belief as to Listerine two years after the cessation of colds advertising and that a substantial number would still retain that belief five years after the cessation of such advertising and (2) Dr. Rossi that the decline in the false belief would be no more than 5 percent per year, complaint counsel (Memorandum 37-38) seek a five-year maximum period of corrective advertising. Respondent, however, upon demonstration by means of a consumer survey that the false beliefs have been

fully dissipated or upon the presentation of other evidence satisfactory to the Commission that corrective advertising is no longer required, could have that period shortened (Memorandum 39-40).

The testimony of Drs. Bass and Rossi, while bearing directly upon the necessity to require corrective advertising and providing an indication of the strength and durability of advertising effects to be overcome, does not provide direct opinion evidence as to the period of time for which corrective advertising would be required to dissipate substantially the advertised-induced false beliefs. Their testimony is as to what may be anticipated in the event "colds" advertising were to stop, not how long it would take corrective advertising to perform its function.

In deciding upon a time period for corrective advertising, it is not necessary to impose a time calculated to remove everyone's belief as to the use of Listerine for colds. Some people will continue to have that belief irrespective of any corrective advertising. One variable that will have an effect upon what is accomplished is the amount of Listerine advertising respondent may see fit to engage in. This, of course, is an unknown. With full knowledge that an exactly appropriate time period cannot be calculated, a period should be selected that would be sufficient to accomplish its purpose. Since the order to engage in corrective advertising is not punitive, it would be preferable to overestimate the time required than to underestimate it. Nevertheless, in reaching a time period, the undersigned has not attempted to overestimate the time required. The time deemed reasonable and necessary, in view of all of the factors previously discussed, is two years.

In view of the two-year period decided upon, which does not appear burdensome at this point of time under any foreseeable circumstances, complaint counsel's suggested escape clause is not deemed appropriate. It would not be deemed appropriate even if a longer period of corrective advertising were required in light of Section 3.72(b) of the Commission's Rules of Practice, which provides a procedure for altering, modifying or setting aside an order upon a showing of changed conditions of fact.

The order specifies the precise language of the disclosure that must be made. This has been done in the instant case since the information to be disclosed is susceptible to this exactitude which is complete and, at the same time, brief so as not to unduly burden respondent. It is not deemed necessary, as urged by complaint counsel (Memorandum 41), that the disclosure recite that the Federal Trade Commission is the source of the correction. Such a recitation would be unduly punitive in

nature by requiring respondent to indicate that it has been found to be a law violator.

CONCLUSIONS

1. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent.

2. Respondent has been, at all times relevant herein, engaged in interstate commerce within the intent and meaning of Section 5 of the Federal Trade Commission Act. The methods of competition herein found to be unfair and the acts and practices herein found to be unfair and deceptive have all been engaged in interstate commerce within the meaning of Section 5 of the Federal Trade Commission Act.

3. Respondent's use of false, misleading and deceptive statements and representations as herein found has had and now has the capacity and tendency to mislead members of the purchasing public into the erroneous and mistaken belief that said statements and representations were and are true and into the purchase of substantial quantities of Listerine by reason of said erroneous and mistaken belief; and, in the absence of an appropriate order, such members of the purchasing public are likely to continue to purchase substantial quantities of Listerine in the mistaken belief that respondent's past statements and representations regarding the efficacy of Listerine with respect to colds and sore throats are true.

4. The acts and practices of respondent noted above as herein found, were and are to the prejudice and injury of the public and of respondent's competitors and constituted and now constitute unfair methods of competition and unfair and deceptive acts and practices in commerce in violation of Section 5 of the Federal Trade Commission Act.

5. Complaint counsel have failed to sustain their burden of proof relative to the allegations of Paragraphs Nine and Ten of the complaint.

6. The following order is warranted both under applicable legal precedent and the facts of the case.

ORDER

PART I

It is ordered, That respondent Warner-Lambert Company, a corporation, its successors and assigns and respondent's officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the labeling, advertising, offering for sale, sale or distribution of Listerine or any other nonprescription drug product in commerce, as "commerce"

is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

1. Representing, directly or by implication, that any such product will cure colds or sore throats.

2. Representing, directly or by implication, that any such product will prevent colds or sore throats.

3. Representing, directly or by implication, that users of any such product will have fewer colds than nonusers.

PART II

It is further ordered, That respondent Warner-Lambert Company, a corporation, its successors and assigns and respondent's officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the labeling, advertising, offering for sale, sale, or distribution of Listerine or any other mouthwash product in commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

1. Representing, directly or by implication, that any such product is a treatment for, or will lessen the severity of, colds or sore throats.

2. Representing that any such product will have any beneficial effect on the symptoms of colds or sore throats.

3. Representing that the ability of any such product to kill germs is of medical significance in the treatment of colds or sore throats or the symptoms of colds or sore throats.

PART III

It is further ordered, That respondent Warner-Lambert Company, a corporation, its successors and assigns, and respondent's officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, do forthwith cease and desist, for a period of two years, from disseminating, or causing the dissemination of, any advertisements for the product Listerine Antiseptic unless it is clearly and conspicuously disclosed in each such advertisement in the exact language below that:

Contrary to prior advertising of Listerine, Listerine will not prevent or cure colds or sore throats, and Listerine will not be beneficial in the treatment of cold symptoms or sore throats.

In print advertisements, this disclosure shall be displayed in type size which is at least the same size as that in which the principal portion of the text of the advertisement appears and shall be separated from the text so that it can be readily noticed. In television advertisements, the

disclosure shall be presented simultaneously in both the audio and visual portions. During the audio portion of the disclosure in television and radio advertisements, no other sounds, including music, shall occur. Each such disclosure shall be presented in the language, *e.g.*, English, Spanish, principally employed in the advertisement.

PART IV

It is further ordered, That the allegations of Paragraphs Nine and Ten of the complaint be, and they hereby are, dismissed.

PART V

It is further ordered, That respondent shall forthwith distribute a copy of this order to each of its operating divisions.

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

It is further ordered, That respondent notify the Commission at least thirty (30) days prior to any proposed change in the corporate respondent such as dissolution, assignment or sale, resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in the corporation which may affect compliance obligations arising out of the order.

OPINION OF THE COMMISSION

BY ENGMAN, *Commissioner:*

I. *Background*

Respondent, the Warner-Lambert Company, manufactures Listerine Antiseptic, a mouthwash preparation. It is the purpose of this proceeding to determine whether respondent, through various labels and advertisements, has misrepresented Listerine's utility. Specifically, the complaint, dated June 27, 1972, charged Warner-Lambert with misrepresenting, through various labels, print advertisements and television commercials, that the use of Listerine Antiseptic will cure colds and sore throats, will prevent colds and sore throats and will cause colds and sore throats to be less severe than they otherwise would be. It also alleged that through the use of the statement "Kills Germs By Millions On Contact" respondent falsely represented that

Listerine's ability to kill germs is of medical significance in the prevention, cure or treatment of colds and sore throats.[1]

In its answer, respondent denied representing either that the use of Listerine will cure colds and sore throats or that it will totally prevent colds and sore throats, but it admitted representing that the use of Listerine, as directed and in conjunction with a regimen of proper rest and diet, will result in fewer colds and will relieve or lessen the severity of cold symptoms to a significant degree. It further admitted that use of Listerine will not cure colds or sore throats and will not totally prevent colds or sore throats.

After extensive hearings covering thousands of pages of testimony, the administrative law judge (hereafter "ALJ") concluded that complaint counsel had sustained their burden of proof on these allegations. He issued an order which prohibits respondent from making the challenged claims in regard to Listerine, other mouthwashes and other nonprescription drugs (Part I and II). His order further requires respondent to include in all Listerine print and television advertisements during the next two years the following statement:

> Contrary to prior advertising of Listerine, Listerine will not prevent or cure colds or sore throats, and Listerine will not be beneficial in the treatment of cold symptoms or sore throats.

Respondent appealed from the initial decision and order claiming, *inter alia*, that the ALJ did not fairly and adequately consider the evidence on the record as a whole. It charged that Judge Berman "engaged in a wholly one-sided and unfair consideration of the factual and legal issues in this case, and that, in so doing, he has deprived respondent of a fair hearing." (RB at 9.)[2] We have reviewed the record thoroughly and have found no indication that the ALJ's findings were the products of bias or that he conducted this proceeding in an unprofessional manner. While we do not agree with every finding in the initial decision, there is not a scintilla of evidence that the ALJ treated respondent unfairly.

II. *Did Respondent Make the Challenged Representations about Listerine?*

We agree with the ALJ's conclusion that respondent did in fact make the challenged representations that Listerine will ameliorate, prevent

[1] The complaint further charged that respondent falsely represented that tests prove that children who gargle with Listerine twice a day have fewer and milder colds and miss fewer days of school because of colds than do children who do not use Listerine. Since complaint counsel have not challenged the ALJ's dismissal of this count, that issue is not before us on this appeal.

[2] The following abbreviations are used in this opinion: IDF - Initial decision of administrative law judge. (cited by paragraph except as otherwise noted); Tr. - Transcript of testimony; CX - Commission exhibit; RX - Respondent's exhibit; RB - Respondent's appeal brief; RRB - Respondent's reply brief; CCB - Complaint counsel's answering brief.

and cure colds and sore throats. In so concluding, we have taken into account respondent's admissions and the views of experts called by both sides to interpret the ads, but most importantly, we have studied each of the challenged labels, print ads and television commercials ourselves.

A. The Amelioration Claim

Respondent admitted making amelioration claims, *i.e.*,

> * * * that the use of Listerine as directed will cause colds and sore throats to be less severe than they otherwise would be and that such a representation encompasses the representation that such use of Listerine will relieve or lessen the severity of cold symptoms to a significant degree. IDF 39.

These amelioration claims were being made at least as late as January of 1974, as is evidenced by respondent's most recent Listerine labels.[3]

B. The Prevention Claim

Respondent also admitted representing that the use of Listerine as directed and in conjunction with a regimen of proper rest and diet will cause fewer colds. The ALJ concluded that this admission satisfies the complaint's allegation that respondent represented that Listerine will prevent colds. We agree.

However, respondent has qualified its admission by contending that *all* prevention claims ceased prior to the fall of 1969. (RB 82.) Respondent's assertion is incorrect. Our review of Listerine television commercials aired in 1970, 1971 and 1972 convinces us that prevention claims were being made during that period.[4] In particular, numerous television commercials of the 1970-72 era urged the viewer to use Listerine twice a day all winter long. The message is inescapable: Use Listerine twice a day, every day, in conjunction with proper rest and diet, and you will improve your chance of warding off colds. (CX 142A-D, CX 143C-F, CX 144A-E.) The prevention claim was also conveyed in the post-1969 period by the claim that Listerine users have a "fighting chance" against catching a cold. This "fighting chance" theme appeared in print ads as well as television commercials. (CX 17, CX 32, CX 142A, CX 143C, CX 143E, CX 144A.) Even respondent's own expert

[3] CX 139b and 139o.

[4] We also note that the ALJ found that respondent made prevention claims subsequent to 1969. In support of this conclusion the ALJ noted that consumer surveys which respondent commissioned, called "Burke Tests," demonstrate that substantial percentages of persons who had an opportunity to view the commercials perceived the message that Listerine prevented colds and sore throats. (IDF 45.) Respondent contends that the Burke Test is not "a reliable test for construing advertisements." (RB 83.) In view of respondent's admission that it made prevention claims prior to the fall of 1969 and our finding, based upon our review of the advertisements, that it made prevention claims subsequent to that date, we need no additional evidence in support of the prevention allegation, and therefore, we do not reach the question of whether the Burke Test adds additional support.

psychologist, Donald E. Payne, agreed that CX 144A, a commercial aired in the 1971-72 season, had a prevention message. (Tr. 3661-3662.)

The ALJ also concluded that although it need not be shown that respondent made claims of *total* prevention, respondent's advertisements may well be understood to represent total prevention. Since the relevant allegations in the complaint are satisfied by a finding that respondent made qualified prevention claims, *i.e.*, that use of Listerine in conjunction with proper rest and diet will result in fewer colds, we need not reach the question of whether respondent made claims of total prevention.

C. The Cure Claims

We agree with the ALJ's conclusion that respondent represented that the use of Listerine will cure colds through the following statements:

(1) that Listerine "is for colds and resultant sore throats" (IDF 27, 25, 10.)

(2) that "those colds we do catch don't seem to last as long" (IDF 27.)

In reaching the conclusion that "for * * * colds and resultant sore throats" is a cure claim, we rely primarily on the Listerine labels and wrappers used from prior to 1938 to December 1972 which proclaimed:

LISTERINE
ANTISEPTIC
KILLS GERMS
BY MILLIONS
ON CONTACT
For General Oral Hygiene
Bad Breath, Colds and
resultant Sore Throats
Minor Cuts, Scratches
Insect Bites, Infectious Dandruff[5]

On this label, the statement "Kills Germs By Millions On Contact" immediately precedes the assertion "For General Oral Hygiene Bad Breath, Colds and resultant Sore Throats."[6] By placing these two statements in close proximity, respondent has conveyed the message

[5] Respondent incorrectly contends that the FTC lacks jurisdiction over the labeling of foods, drugs and cosmetics. *Stanley Laboratories* v. *FTC*, 138 F.2d 388 (9th Cir. 1943); *Justin Haynes* [*Co.* v. *FTC*, 105 F.2d 988 (2d Cir. 1939), *cert. denied*, 308 U.S. 616 (1939); *Fresh Grown Preserve Corp.* v. *FTC*, 125 F.2d 917 (2d Cir. 1942); *Houbigant* v. *FTC*, 139 F.2d 1019 (2d Cir. 1944), *cert. denied*, 323 U.S. 763 (1944).

[6] CX 49 and 50 demonstrate minor variations on this theme. In December 1972 respondent altered the label to read:

LISTERINE
ANTISEPTIC
Kills Germs By Millions
On Contact

(*Continued*)

that since Listerine can kill millions of germs, it can *cure*, prevent and ameliorate colds and sore throats.[7] It has also made this representation in numerous print advertisements which emphasized colds and prominently displayed the Listerine label.[8] However, we do not agree with the ALJ's additional finding that advertisements which simply state that "you can help with Listerine" or that "Listerine provides a fighting chance" or a "means of fighting off colds" or "fighting back" but which do not display the label prominently are reasonably subject to the construction that a cure is represented.

Respondent's television commercial entitled "School Bus" (CX 34F, 140F) also made the claim that Listerine cures colds. In that commercial a mother extolls the virtues of gargling with Listerine twice a day or at the first sign of a cold stating, *inter alia*, "I think we've cut down on colds, and those we do catch, don't seem to last as long." We find that the statement, "those we do catch, don't seem to last as long," conveys the message that Listerine cures colds.

III. *Are Respondent's Representations about Listerine True?*

Respondent admits that "the use of Listerine Antiseptic will not cure colds or sore throats and will not totally prevent colds or sore throats," but it asserts that use of the product "* * * as directed and accompanied by a regimen of proper diet and proper rest has been demonstrated to result in fewer colds, milder colds and milder symptoms thereof, and less severe colds and sore throats." [Answer, Paragraph 6.]

Complaint counsel called numerous medical and scientific experts to the stand. Each of these witnesses had impressive credentials and was well-qualified to testify in this proceeding. It is the consensus of these experts that viruses cause the common cold and that bacteria play very little part. Virus particles enter the body through the nose (or sometimes the eyes), attach to cells in the nasopharynx, ("the back of the nose where the nose turns downward into the pharynx"—Tr. 616)[9] and begin to multiply. The viral activity destroys cells, causing the

For General Oral Hygiene, Bad Breath
Minor Cuts, Scratches,
Insect Bites, Infectious Dandruff
For Relief of Colds Symptoms
and Minor Sore Throats due to Colds

[7] Respondent claims that the ALJ reached the conclusion that "for * * * colds and resultant sore throats" is a cure claim by relying on a *per se* rule of construction that "for" means "cure." Respondent has misread the ALJ's opinion. Rather than posit a *per se* rule, the ALJ emphasized that he rested his opinion on his examination of the evidence in the record. We too rest our conclusion on an evaluation of the evidence.

[8] CX 19, CX 20, CX 23, CX 27. These ads appeared in national publications from 1968 to 1969. We note, in addition, that several advertisements which focus on Listerine's purported breath freshening ability depict a bottle of Listerine and the label thereon. CX 1, CX 7, CX 11, CX 13, CX 15, CX 28, CX 30. To the extent the label is readable in these advertisements, they make the same representation as does the label by itself.

[9] RX 14 illustrates the location of the nasopharynx.

various symptoms of the cold to occur. These symptoms can include stuffy nose, runny nose, postnasal drip, burning sensation in the nose, sore throat, sneezing, coughing, burning eyes, fever, general malaise, muscle ache and mild headache. (ID pp. 16-18 [pp.1417-1418 herein].)

It is also the consensus of the experts called by complaint counsel that Listerine has no efficacy in the prevention of colds and sore throats or in the amelioration of colds symptoms, including sore throats.[10] Several of these medical experts stated that gargling with Listerine could provide temporary relief from a sore throat. We agree with the ALJ that this temporary relief is not the "significant relief" promised by respondent's advertisements. More importantly, the record demonstrates Listerine would be no better than salt water or perhaps simply warm water.[11] Thus, as the ALJ found, any relief to a sore throat by gargling with Listerine is not peculiarly attributable to Listerine. (IDF 57.) It is clearly deceptive to attribute significant medical benefit to a purported medication when, in fact, the same benefit can be obtained from ordinary salt water or perhaps even warm water. *Cf. Stauffer Laboratories* v. *FTC*, 343 F.2d 75 (9th Cir. 1965.)

A. The Experts' Reasons for Concluding that Listerine Has No Efficacy in the Prevention of Colds and Sore Throats and in Amelioration of Cold Symptoms

In order to prevent a cold from developing or to lessen the severity of a cold, an efficacious substance must reach the affected cells of the body in therapeutic concentrations. Experts for complaint counsel concluded that gargling with Listerine would not meet these criteria for the following three reasons, each of which is a sufficient ground for concluding that Listerine lacks the claimed efficacy:

(1)

Listerine's ingredients, considered together, are present *in the bottle* in insufficient concentrations to have any utility in the prevention or treatment of a cold or sore throat when gargled (Tr. 712 and 1010-1111).[12]

[10] *E.g.*, Tr. 837-838, 860, 550, 393, 480-81, 617-18, 903-907, 1057-58.

[11] Tr. 395, 446-47, 483, 566-69, 860, 862, 1011-12. It should be noted that Dr. Modell, a pharmacologist called by complaint counsel, testified that the lower the surface tension of a gargle the better it can remove accumulated debris in the throat (a source of irritation) Tr. 1042-43. The record shows that Listerine does have a lower surface tension than salt water. However, the record does *not* show that this lower surface tension translates into meaningfully greater relief than could be obtained by gargling with salt water.

[12] *See also* Tr. 1016, 1007 (methyl salicylate) Dr. Sorrell Schwartz, a pharmacologist, claimed that the ingredient methyl salicylate, if present in great enough amounts, would increase blood flow to the throat and that this would have a counter-soothing effect because a sore throat, in large part, is the result of too much blood flow. (Tr. 683.) Since the concentration of methyl salicylate in Listerine is insufficient to have *any* effect on sore throats, we need not determine

(*Continued*)

(2)

Listerine does not reach the critical areas of the body. As the ALJ aptly summarized:

The mechanism of gargling makes it virtually impossible for the gargle to reach the nasal passages or the lower respiratory tract. When gargling, the palate closes off the nasal passage and nasopharynx and the glottis closes off the entrance to the lower respiratory tract. The gargle is confined to the mouth chamber. Hence, Listerine would not reach the site of infection or manifestation of symptoms in any medically significant concentration. Any vapors that might reach the site where the action is would not be in therapeutic concentration and, in any event, would soon be swept away. Thus, the gargling with Listerine would be ineffective in preventing or producing fewer cold infections or in relieving or reducing the severity of cold symptoms (Gwaltney 393, 448; Hornick 483; Seal 554-56, 571, 573; Proctor 616-19; Rammelkamp 787 (sic 782); Sanders 854; Parrott 904). IDF 69.[13]

(3)

Listerine would not penetrate the infected cells.[14] Again, as the ALJ correctly noted:

Even if gargling with Listerine caused its ingredients to reach the nose and nasopharynx, they would not penetrate the cells where the action of the viruses would be taking place. Hence, Listerine would still be ineffective in this regard (Hornick 481-82; Parrott 904). If Listerine's ingredients were in a concentration strong enough to be effective and reached the infected cells in therapeutic strength and did and could penetrate the cells, the cells would be killed. This would be undesirable as it would destroy the protective covering of the lining of the nose and throat and so provide portals of entry for various bacteria (Hornick 482-83). IDF 70.

Even when asked to assume that Listerine can kill millions of germs on contact (*i.e.*, that Listerine has bactericidal properties), complaint counsel's experts did not alter their conclusions as to Listerine's lack of

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whether Dr. Schwartz was correct in asserting that a greater amount would be counter-soothing); Tr. 1008 (boric acid); Tr. 1009-1010, 687-688 (benzoic acid, used for the purpose of obtaining a certain level of acidity); Tr. 1010 (alcohol); Tr. 686, 712, 1009, 1025-26 (menthol); Tr. 678-79, 1008 (thymol); Tr. 688-691, 1010 (eucalyptol); IDF 74, 76, 77, 78, 79 and 80.

[13] *See also* CX 161B. Dr. John C. Krantz, a witness for respondent, wrote a textbook which lends support for this view. It states that the mechanical action of gargling will not deliver the gargled substance to the infected regions of the throat.

[14] Respondent claims that a test conducted by the FDA, RX 57, demonstrates that after gargling, some of the ingredients in Listerine are substantive with the membrane lining; that is, some binding between the oral cavity membrane and ingredients of Listerine occurred. In that test, each subject swished Listerine in his ~~mouth for~~ ten seconds, expectorated and rinsed his mouth twice with an alcohol solution. A substantially smaller percentage of Listerine was recovered in the second rinse than in the first. This finding led the ALJ to conclude that rather than demonstrate a binding effect the test results more probably "indicate that after fully expectorating the Listerine in the mouth, the first alcohol gargle got most of what remained so that the second gargle gathered a much smaller residual amount." IDF 152. The FDA did not offer the ALJ's interpretation as an alternate conclusion, and we see no reason to reject the FDA's conclusion. However, this test does not demonstrate that Listerine's *vapors* would have the same binding effect to the membrane in the nasopharynx as would Listerine in liquid form to the buccal membrane. More important, it does not demonstrate that Listerine would penetrate the tissue cells. In fact, respondent's own witness, Dr. Thomas McNamara, has testified that although Listerine may bind to the mucous membrane, it will not enter the tissue cells (Tr. 2343).

effectiveness. The following findings by the ALJ adequately summarize the views expressed by complaint counsel's witnesses:

Bacteria play very little part in the common cold. Apart from viruses, cold type symptoms may be caused by the bacteria called Beta Hemolytic Streptococci or Group A Hemolytic Streptococci, more commonly referred to as a strep throat, and another organism somewhere in between a virus and a bacteria called microplasma [sic: mycoplasma] pneumonia. These agents may cause at most 5 to 10 percent of the occurrences of cold-like symptoms.

These ailments, however, must be treated with specific medicinal agents. In the case of strep throat, failure to treat properly may result in rheumatic fever, valvular heart disease and kidney infections, which are very serious to the point of being life-threatening. Microplasma pneumonia is a lingering ailment if antibiotics are not used. It would be inappropriate to treat patients with strep throat or microplasma pneumonia with Listerine or with anything other than the specific medications that should be prescribed (Gwaltney 380-81, 384-85, 438, 453-54; [Hornick] 486, 493-94; Proctor 610; Rammelkamp 767-71, 799-800; Sanders 836-40, 870; Parrott 896-97, 900-01, 918-19; [*See also*] Knight 1925-26, 2037-40, 2048). IDF 51.

Colds are not caused by bacteria. Bacteria in the oral cavity play no role in cold symptoms. The ability of Listerine to kill millions of germs on contact, therefore, is of no medical significance in the prevention, cure or treatment of colds or sore throats (Gwaltney 397, 453; Hornick 486, 488-89; Seal 551-53; Proctor 609, 616-18 [19 and 20]; Rammelkamp [775] 776-77; Sanders 836; Parrott 918-19; Kilbourne 1058; *see also* Knight 2048). IDF 58.

Colds are sometimes followed by secondary infections caused by bacteria known as secondary invaders. Instances are sinusitis and otitis media (middle ear infection) where drainage from the sinuses or middle ear is impaired by the cold, and bacteria which are already in those sites get the opportunity, because of the lack of drainage, to cause trouble. Another secondary infection is peritonsillar cellulitis. The ingredients of Listerine, however, would not reach the resting places of the secondary invaders. Listerine could not reach the sinuses, the middle ear or the deep crypts of the tonsils or adenoids or other deep-seated places where such bacteria might be. Listerine, therefore, would be ineffective to prevent, cure or alleviate such secondary infections (Seal 552-54, 572; Proctor 614-15, 618, Rammelkamp 772-74, 811-12; Sanders 842, 844). IDF 71.

While Listerine kills millions of bacteria in the mouth, it also leaves millions. It is impossible to sterilize any area of the mouth, let alone the entire mouth. There are significant numbers of bacteria in various tissues, tissue folds and crypts which Listerine can't reach. For example, there is more flora in the crevices of the teeth than on the roof of the mouth. The bacteria grow back quickly or the voids are quickly replaced by other bacteria. The use of Listerine has only a transient effect on the flora (Hornick 488-89, 523-24; Seal 554; Proctor 620; Sanders 847, 881-83). IDF 72.

To the extent that Listerine may kill millions of bacteria in the mouth, it would do so only ahead of the soft palate. This would have nothing to do with the throat, nose or the posterior pharynx. Consequently, the killing of germs in the mouth would have nothing to do with preventing, curing or relieving colds or coughs or cold symptoms (Hornick 483; Seal 554; Rammelkamp 777). The bacteria in the normal flora of the mouth play no role in the causation of colds or in the symptoms of colds. Thus, killing some of those bacteria would have no effect on the prevention, cure or symptoms of colds or coughs (Sanders 846-47, 879-80; And See Findings 48, 51, 52, 58 and 62, *supra*). IDF 73.

B. Respondent's Experts

Respondent sought to refute the prima facie case made by complaint counsel's experts with a battery of ten expert witnesses and numerous studies, clinical as well as nonclinical. Although several of these witnesses offered no support for one or more efficacy claims or substantially qualified their views,[15] the general import of their testimony, taken as a whole, was that Listerine can reduce the number of colds one catches and ameliorate cold symptoms.

Nine of respondent's experts based their opinions to a substantial degree upon laboratory tests and/or clinical studies.[16] We have painstakingly reviewed each of the exhibits introduced for the purpose of establishing Listerine's effectiveness and conclude that they have little or no probative value for this proceeding. We have set forth at length in the Appendix our views as to each of these studies. Since these tests do not provide a sound basis for concluding that Listerine may have the claimed preventive or ameliorative powers, the persuasiveness of those witnesses who relied upon them is greatly diminished.

The tenth witness, Dr. John C. Krantz, Jr., apparently did not rely upon the exhibits in question. However, we accord his testimony little weight, because he was unaware of the quantities of Listerine which would reach the nasopharynx, (Tr. 1882) and his view that gargling with Listerine would be beneficial for a sore throat is contradicted by statements in his own textbook. (CX 161A and 161B, Tr. 1889-95.)[17]

In weighing the evidence we have taken into consideration the fact that the experts called by complaint counsel based their opinions on their general medical and pharmacological knowledge and, in some instances, on their experiences as clinicians. With the exception of Dr. Hornick, none of complaint counsel's witnesses examined the exhibits which respondent presented in support of its assertion that Listerine is

[15] Dr. Noller offered no opinion as to Listerine's efficacy. He merely asserted that an ingredient of Listerine, menthol, acts as a nasal decongestant. Dr. Shirkey asserted only that Listerine could ameliorate some cold symptoms, Tr. 2607, 2616, 2628, 2667-69, 2674. Dr. Carson limited his evaluation of Listerine's efficacy to relief for coughing and nasal congestion, Tr. 3032-34, *See also* Tr. 3057. Dr. Knight on cross examination, "* * * retreated to the position that there were threads of evidence upon which one could put together a theoretical basis for the efficacy of Listerine, but that there were also threads of evidence to the effect that Listerine was ineffective (Tr. 2045-48)." IDF 143. Dr. Lasagna concluded that "if you gargle with Listerine regularly there is a chance you will feel somewhat better when you have a cold," Tr. 4154. Dr. Sadusk would recommend Listerine for relief of cold symptoms, but was not in a position to recommend it for prevention of colds and would not recommend it as a cold cure, Tr. 3211-12.

[16] Haggie, IDF 128; Knight, IDF 143-44; Noller, IDF 145; McNamara, IDF 146; *See also* Tr. 2306; (Dr. McNamara may have relied additionally upon tests admitted into evidence solely for the purpose of "showing what Dr. McNamara relied upon as a responsible official of respondent for purposes of considering the scope of an order to cease and desist should one be issued." IDF 148); Ritchie, IDF 155; Shirkey, IDF 164; Carson, IDF 167 and 182; Sadusk, IDF 184; Lasagna, IDF 190.

[17] The ALJ noted that many of respondent's experts had financial ties to respondent. In view of the reasons we have expressed for placing little reliance on the testimony of respondent's witnesses, we need not consider the possible effect of their financial ties. Finally, in regard to Dr. Noller, although we agree with the ALJ that his testimony was not a model of clarity, we will attribute the ambiguities in his testimony solely to language difficulties.

efficacious. Failure to provide these witnesses with respondent's tests is inconsequential because, as we have set out in the Appendix, these tests lack probative value. Moreover, the experts called by complaint counsel are well versed in their fields, several having devoted their careers to the task of studying and treating respiratory diseases. If valid tests demonstrating Listerine's efficacy as a cold treatment had been conducted, we seriously doubt that such tests would have remained a secret to *all* of complaint counsel's medical and pharmacological experts.

This is not the first proceeding in which the Commission has had to choose between experts who based their views on their general medical and pharmacological knowledge and others who based their views at least in part on deficient studies. It is well established that the Commission has authority to rely on the testimony of the former. *E.g.*, *J. E. Todd* v. *FTC*, 145 F.2d 858 (D.C. Cir. 1944); *Fulton* v. *FTC*, 130 F.2d 85 (9th Cir. 1942), *cert. denied*, 317 U.S. 679 (1942); *Aronberg* v. *FTC*, 132 F.2d 165 (7th Cir. 1942); *Justin Haynes & Co.* v. *FTC*, 105 F.2d 988 (2d Cir. 1939).

C. Consumer Satisfaction

Respondent claims that Listerine's cold-fighting ability is demonstrated by the fact that vast percentages of the population consider Listerine Antiseptic to be effective for colds and sore throats "because a consumer's image of a product and his propensity to purchase it repeatedly is substantially dependent upon his experience with it." (RB 74-75, RRB 20.) The record does show that a consumer's "experience" with a product affects his image of the product and his propensity to purchase it. (Tr. 1199-1200, 1673, 3389-90, 3402-03, 3436-38, 3455-56.) The record also demonstrates that many consumers think Listerine is effective for colds and sore throats. (*Infra*, Sec. V A2.) But this evidence does not, as respondent contends, prove that Listerine works. The flaw in respondent's reasoning is that a consumer may *perceive* a product to be effective when, in reality, it has no efficacy. In short, he may repeatedly purchase the product out of ignorance. A cold is a self-limiting disease, and therefore a cold sufferer who takes Listerine may wrongly attribute the termination of the cold episode to his gargling with Listerine. (Tr. 2039.) Clearly, unless the patient can perform well-controlled clinical tests, he is not in a position to know whether his improvement was attributable to the medication.

In addition, the cold-sufferer who takes Listerine is likely to experience the placebo effect, the phenomenon in which the patient who takes a medication feels better because he thinks he should feel better even though the product has no genuine therapeutic value.

(Appendix at 6A.) The Commission cannot accept as proof of a product's efficacy a psychological reaction stemming from a belief which, to a substantial degree, was caused by respondent's deceptions. (*Infra*, Sec. V A2.)

Since there may be a divergence between what the user *thinks* the product will do for him and what the product actually does (or does not do), evidence of consumer beliefs has little probative value for determining whether Listerine is effective for colds or sore throats.

In support of its contention that consumer satisfaction constitutes persuasive evidence of product efficacy, respondent cites *Evis Mfg. Co.* v. *FTC*, 287 F.2d 831 (9th Cir. 1961), *cert. denied*, 368 U.S. 824 (1961). That case does not stand for so broad a rule. In *Evis* the court merely held that tests conducted by experts who failed to follow the manufacturer's instructions did not constitute substantial evidence of the challenged product's lack of efficacy, and that the Commission erred in failing to consider testimony of user witnesses (many of whom were experts). The court did not hold that evidence of consumer satisfaction is persuasive of a product's efficacy, but merely that the Commission must consider such testimony. In the case at hand we have taken into account the fact that survey evidence shows that many consumers consider Listerine to be effective for colds and sore throats, and for the reasons discussed above, we conclude that this evidence does not demonstrate that Listerine has any efficacy in the prevention or treatment of colds or sore throats.

To summarize, after carefully reviewing the testimony of the experts called by both sides and of the studies admitted into evidence in support of respondent's efficacy claims, we must conclude that the preponderance of the evidence[18] demonstrates that, contrary to respondent's advertising claims, the use of Listerine, as directed, will

[18] This Commission has consistently used a preponderance of the evidence test in evaluating the truthfulness of product claims. Respondent asserts that in evaluating a drug's effectiveness we must follow, instead, the "substantial evidence" standard set forth in the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §355(d), which the Secretary of Health, Education and Welfare must apply when he considers a new drug application. We cannot agree. Of course, we would take into account an evaluation by the Secretary that substantial evidence supported the claimed efficacy, but we find no indication in either the Federal Food, Drug and Cosmetic Act or our own Act that Congress intended that we automatically defer to the Secretary's determinations.

However, the question of which standard to apply is not crucial to the outcome of this proceeding because respondent has not met even the more lenient standard prescribed by §355(d). That section requires that an application for a new drug be denied if "there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." Sec. 355(d) defines "substantial evidence" as: "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof."

The FDA's relevant regulations specify that "essentials of adequate and well-controlled clinical investigations" include the necessity "to minimize bias on the part of the subject and the observer." Sec. 314.111(a)(5)(ii)(a)(3). The Supreme Court has noted that "[L]ower courts have upheld the validity of these regulations, and it is not disputed that

(*Continued*)

not prevent or cure colds or sore throats or ameliorate cold symptoms. Accordingly, respondent has violated the Federal Trade Commission Act.

IV. *The Prior Proceeding*

In 1940 the Commission issued a complaint challenging cold and sore throat claims for Listerine which it later dismissed "* * * without prejudice to the right of the Commission to institute further proceedings should future facts so warrant." 38 F.T.C. 730 (1944). Respondent argues that the complaint in the present proceeding must be dismissed because complaint counsel have not come forward with "future facts." Respondent has misconstrued the 1944 order. In previously expressing our position on this question, *Warner-Lambert Company*, 82 F.T.C. 749, 752 (1973), we stated:

> The future facts which would warrant a new proceeding are those upon which the Commission's decision to issue a complaint are based and, as we have previously held, respondent is precluded from inquiring into our mental processes leading up to that decision. *In the Matter of the Seeburg Corporation*, 70 FTC 1818.

Respondent also contends that the Commission relied upon the Reddish Study in dismissing the 1944 complaint, and therefore the ALJ's findings relating to the deficiencies in the Reddish Study "constitute an impermissable [sic] relitigation of matters long ago settled." (RB 67.) Although in his separate statement Chairman Freer said that the Reddish tests

> * * * afford some basis for the respondent's conclusion that the use of Listerine in practice actually mitigates or shortens colds and their complications,

the Commission's order belies respondent's assertion that the validity of the Reddish tests was settled in the prior action. Had it been of the

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they express well-established principles of scientific investigation." *Weinberger* v. *Hynson, Westcott & Dunning*, 412 U.S. 609, 619 (1973). As is discussed in the Appendix, respondent did not take adequate precautions to minimize bias on the part of either the subjects or the investigators in its clinical tests of Listerine. Thus, respondent has not satisfied even the substantial evidence standard.

Respondent also contends that (RB at 39): "* * * in the case of old (pre-1938), well-established drugs such as Listerine Antiseptic, Congress further concluded that their history of consumer acceptance was in itself substantial evidence of efficacy and established for those drugs a presumption of efficacy and an exemption from the preclearance procedures established in the 1962 Drug Amendments." 21 U.S.C. §321(p); *see*, *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, *supra* at 614.

Neither §321(p) nor the cited case suggest that a "history of consumer acceptance was in itself substantial evidence of efficacy" or that old drugs are presumed to be efficacious. On the contrary, Congress viewed this grandfather clause merely as a "transitional" provision for implementing the 1962 Drug Industry Act (S. Rep. No. 1744, 87th Cong., 2nd Sess., Part II at 7-8 1962). FDA was given the statutory mandate "to review all marketed drugs for their therapeutic efficacy, whether or not previously approved * * *" *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 614 and, as the Supreme Court has noted, "[i]n May 1972 FDA adopted a procedure for determining whether particular OTC products, not covered by NDA's are safe products, not ineffective, and not misbranded." *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 650 (1973). Thus, no presumption of efficacy arises from the fact that Listerine has been on the market since 1879.

view that the Reddish tests proved that Listerine was effective for the treatment of colds, the Commission presumably would have dismissed the complaint with prejudice. Instead, it dismissed the complaint "without prejudice to the right of the Commission to institute further proceedings should future facts so warrant."[19] The dismissal of a Federal Trade Commission action "without prejudice" does not work an estoppel to a future determination of the merits of that action. *Hastings Mfg. Co.* v. *FTC*, 153 F.2d 253 (6th Cir. 1946), *cert. denied*, 328 U.S. 853 (1946).

V. *The Remedy*

A. Corrective Advertising

The ALJ imposed on respondent the duty to engage in corrective advertising. Specifically, for two years respondent shall not disseminate any advertisement for Listerine unless the advertisement clearly and conspicuously states: Contrary to prior advertising of Listerine, Listerine will not prevent or cure colds or sore throats, and Listerine will not be beneficial in the treatment of cold symptoms or sore throats.

1. Authority to Issue a Corrective Advertising Order

The Commission has previously noted its authority to issue corrective advertising orders.[20] It also has ordered affirmative relief to dispel the lingering effects of misrepresentations[21] and has accepted numerous consent orders which require corrective advertising.[22] In concluding that the Commission's statutory mandate encompasses the

[19] In explaining his reason for so doing Chairman Freer said:

In my opinion the issues raised by paragraphs 3, 4 and 5 of the complaint involve in their determination the adoption of one of two opposing medical or scientific opinions in respect to which our decision would settle only the legal right of the respondent to continue to make the challenged representations and not the underlying controversy. Should we so resolve those issues (both as to interpretations of the advertisements and as to the medical or scientific opinions) as to require an order to cease and desist, the respondent can, and no doubt will, appeal. In that appeal, however, the door will be closed to any weighing of the evidence by the court, since "the findings of the Commission as to the facts, if supported by evidence, shall be conclusive." Should we, on the other hand, so resolve the several issues of interpretation of language and of medical or scientific opinion in such a manner as to dictate an outright dismissal of the complaint, the respondent might, and probably would, raise the defense of *res adjudicata* to any proceeding which the Government might decide to institute at some future time when and if the medical profession learns more about and reaches a greater degree of unanimity concerning the cause of and cure for dandruff, bad breath and colds or sore throats.

Hence, while not unmindful of the forcefulness of the arguments on the one hand for an order to cease and desist and on the other for outright dismissal, I feel that a *dismissal without prejudice* is warranted by the probability (almost certainty) that neither an order to cease and desist nor an outright dismissal would settle with finality or help greatly in the final settlement of the *underlying medical and scientific controversies*, although either disposition would be interpreted as having settled these matters once and for all. 38 F.T.C. at 741-42.

[20] *Firestone Tire & Rubber Company*, 81 F.T.C. 393, 464-74 (1972) *aff'd.* 481 F.2d 246 (6th Cir.), *cert. denied*, 414 U.S. 1112 (1973); *ITT Continental Baking Company, Inc.*, Dkt. 8860 (Oct. 19, 1973 [83 F.T.C. 865]) at 31-32, appeal docketed No. 75-4141, 2d Cir., July 11, 1975; *Campbell Soup Company, et al.*, 77 F.T.C. 664, 668 (1970).

[21] *Travel King, Inc.*, Dkt. No. 8949 (Sept. 30, 1975 [86 F.T.C. 715]).

[22] Matsushita Electric of Hawaii, Inc., 78 F.T.C. 353 (1971); *Sugar Information, Inc.*, 81 F.T.C. 711 (1972); *ITT Continental Baking Co., Inc.*, 79 F.T.C. 248 (1971); *Ocean Spray Cranberries, Inc.*, 80 F.T.C. 975 (1972); *Shangri-La*

(*Continued*)

authority to order corrective advertising, we have been mindful of the wide latitude courts have afforded the Commission in fashioning appropriate relief.[23] Illustrative of this wide latitude are orders requiring divestiture, *L. G. Balfour Co.* v. *FTC*, 442 F.2d 1 (7th Cir. 1971); ordering compulsory licensing of a patent on a reasonable royalty basis, *Charles Pfizer & Co., Inc.* v. *FTC*, 401 F.2d 574 (6th Cir. 1968), *cert. denied*, 394 U.S. 920 (1969); limiting the purchases of certain products between respondents, *Luria Bros. & Co., Inc.* v. *FTC*, 389 F.2d 847 (3d Cir. 1968), *cert. denied*, 393 U.S. 829 (1968); and requiring affirmative disclosures in advertisements and on products, *J. B. Williams Company* v. *FTC*, 381 F.2d 884 (6th Cir. 1967), *Keele Hair & Scalp Specialists, Inc.* v. *FTC*, 275 F.2d 18 (5th Cir., 1960), *Ward Laboratories, Inc.* v. *FTC*, 276 F.2d 952 (2nd Cir. 1960), *cert. denied*, 364 U.S. 827 (1960), *Waltham Precision Instrument Co.* v. *FTC*, 327 F.2d 427 (7th Cir. 1964), *cert. denied*, 377 U.S. 992 (1964).

Simply stated, the common thread linking these cases is the principle that the Commission has authority to order the relief necessary to adequately protect the public from the effects of a law violation. Thus, if a deceptive advertisement has played a substantial role in creating or reinforcing in the public's mind a false and material belief which lives on after the false advertising ceases, there is clear and continuing injury to competition and to the consuming public as consumers continue to make purchasing decisions based on the false belief. Since this injury cannot be averted by merely requiring respondent to cease

Industries 81 F.T.C. 596 (1972); *Pay Less Drug Stores Northwest, Inc.* 82 F.T.C. 1473 (1973); *Boise Tire Co.*, C-2425 (July 16, 1973); *Lens Craft Research and Development Co. et al.*, D. 8950 (Sept. 4, 1974[84 F.T.C. 355]); *Wasem's Inc.*, C-2524 (July 23, 1974[84 F.T.C. 209]).

[23] We said in *Firestone*, 81 F.T.C. at 467-68:

The courts have repeatedly recognized that to deal with the ever expanding scope of unfair and deceptive practices, the Commission must be permitted wide latitude in fashioning effective relief, In *Jacob Siegel Co.* v. *FTC*, 327 U.S. 608, 612-13 (1946) the Court stated:

The Commission is the expert body to determine what remedy is necessary to eliminate the unfair and deceptive trade practices which have been disclosed. It has wide latitude for judgment and the courts will not interfere except where the remedy selected has no reasonable relation to the unlawful practices found to exist.

Again in *FTC* v. *Ruberoid Co.*, 343 U.S. 470, 473 (1952) the Supreme Court reiterated this view:

Congress placed the primary responsibility for fashioning such orders upon the Commission, and Congress expected the Commission to exercise a special competence in formulating remedies to deal with problems in the general sphere of competitive practices. (Footnote omitted.)

The court pointed out that if the Commission is to carry out the objectives envisioned by Congress "it cannot be required to confine its road block to the narrow lane the transgressor has traveled," but must be able "to close all roads to the prohibited goal." *Ruberoid, supra* at 473.

Such wide latitude in determining remedy has been deemed necessary so that the Commission can effectively carry out the statutory policy of the Federal Trade Commission Act to protect consumers and maintain competitive vigor in the marketplace. As the Ninth Circuit stated in *Carter Products, Inc.* v. *FTC*, 268 F.2d 461, 498 (9th Cir. 1959):

Shaping a remedy is essentially an administrative function. Congress has entrusted the Commission with the responsibility of selecting *the means* of achieving a statutory policy—the relation of remedy to policy is peculiarly a matter for administrative competence.

The Seventh Circuit recently reflected this same view in *L. G. Balfour Co.* v. *FTC*, 442 F.2d 1,24 (7th Cir. 1971):

The Commission must be accorded latitude in forming its orders for "the Commission alone is empowered to develop that enforcement policy best calculated to achieve the ends contemplated by Congress and to allocate its available funds and personnel in such a way as to execute its policy efficiently and economically." *Moog Industries, Inc.* v. *FTC*, 355 U.S. 411, 413, 78 S. Ct. 377, 379, 2 L. Ed. 2d 370 (1958)."

disseminating the advertisement, we may appropriately order respondent to take affirmative action designed to terminate the otherwise continuing ill effects of the advertisement.

Respondent claims that *Heater* v. *FTC*, 503 F.2d 321 (9th Cir. 1974), rejected the proposition set forth in *Firestone* that the Commission has authority to terminate continuing injury to the public.[24] Respondent has misread *Heater*. In that case the court simply held that the Commission lacked authority to order a respondent to refund to customers monies obtained from them through deceptive practices. Neither the holding in *Heater* nor the court's rationale support respondent's assertion that the Commission lacks authority to order corrective advertising. In fact, the *Heater* court explicitly distinguished the Commission's order in that case from a corrective advertising order:

> Our holding denies retroactive impact to a Commission decision, at least insofar as private rights and liabilities are involved * * *
>
> We recognize that divestiture and corrective advertising orders support the Commission's position that it has power, in order to remedy the continuing effects of violations of the Act, to order acts imposing economic costs properly attributed to conduct occurring before the conduct is declared illegal. Moreover, we recognize that there is no economic difference in the impact of those orders and a restitution order—in each case the offender loses the benefits of money expended in reliance on the legality of conduct later found illegal. Nevertheless, the two cases must be treated differently because Congress, out of reasonable fair notice consideration, chose to leave the cure of private injuries caused by violations of the Act to whatever common-law remedies existed. 503 F.2d 321, 324-25 n. 13.

We thus conclude that *Heater* is no authority for the contention that the Commission lacks authority to issue a corrective advertising order to dispel the continuing effects which a deceptive advertisement has on the consuming public.

Moreover, the continued sale of a product under false pretenses is itself a violation of the FTC Act,[25] which, in the case of lingering false beliefs created by discontinued advertisements, can be remedied only by dispelling the false belief.

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[24] In considering the Commission's authority to issue an order designed to terminate the continuing effects of a deceptive advertisement, the Commission said in *Firestone:*

> ANA and respondent contend that a corrective advertising order is retrospective and therefore unlawful because it seeks to dissipate the effects of illegal conduct. In our view, however, such an order is quite obviously not retrospective if its purpose and effect is to terminate *continuing* injury to the public. This continuing injury may be in the form of lingering effects which a misrepresentation may have on consumers' minds or in the form of a lessening of competitive vigor in the marketplace due to the deceptive practices. Under such circumstances, the appropriate relief is that which will terminate the continuing injury to the public. 81 F.T.C. at 470.

[25] *J. B. Williams Company* v. *FTC*, 381 F.2d 884 (6th Cir. 1967); *Keele Hair & Scalp Specialists, Inc.* v. *FTC*, 275 F.2d 18 (5th Cir. 1960); *Ward Laboratories, Inc.* v. *FTC*, 276 F.2d 952 (2nd Cir. 1960); *Waltham Precision Instrument Co.* v. *FTC*, 327 F.2d 427 (7th Cir. 1964), *cert. denied*, 377 U.S. 992 (1964).

2. Applying the Corrective Advertising Standard to the Case at Hand

The record demonstrates that respondent's deceptive advertisements have created false beliefs which are likely to continue to exist and influence consumer decisions to purchase Listerine.

Consumer Beliefs. Market research reports, known as "Product Q" reports,[26] which were commissioned by respondent over a seven-year period at a cost of over $100,000, demonstrate that the majority of those surveyed believe that Listerine is effective for colds and sore throats. Specifically, the percentage of those persons surveyed who rated Listerine as "one of the best" in the category "effective for colds and sore throats" rose from 43 percent in 1963 to 59 percent in 1971, averaging 53.8 percent for the entire period. This figure includes the entire population surveyed, Listerine users as well as nonusers. 53.8 percent is itself a substantial portion of the survey population, but that figure probably understates the percentage who believes Listerine has some effect on colds and sore throats because it includes only those who believe that Listerine is "one of the best" mouthwashes for that characteristic. It does not include responders who rated Listerine as "very good," "good" or "fair" for the category "effective for colds and sore throats." (IDF 236.)

Although the data for the precoded category "effective for colds and sore throats" was not refined into more specific beliefs, the ALJ concluded that this category encompasses prevention, amelioration and cure claims. (IDF 230.) On the one hand respondent takes issue with the ALJ's interpretation, but on the other hand, it appears to argue, in support of its amelioration and partial prevention claims, that consumers perceive Listerine to be an effective remedy. (RB 74-75.) More important, the record adequately supports the conclusion that "effective for colds and sore throats" includes prevention and amelioration beliefs. (Tr. 1553.) However, on the basis of the record before it, the Commission is unconvinced as to cure beliefs. We thus find that a substantial portion of the consumer public holds prevention and amelioration beliefs but we can draw no conclusion about cure beliefs.

Effect of Listerine Advertisements on Consumer Beliefs. Respondent has advertised Listerine to consumers as a cold remedy since 1921. Not only have Listerine packages and labels contained cold efficacy messages, but also respondent has spent large sums to advertise Listerine on television and in print media as effective for colds and sore throats. (IDF 219-220.) Common sense indicates that this extensive cold efficacy advertising campaign (including labels and packages) has

[26] For discussion of the nature of Product Q reports see IDF 222-227.

contributed substantially to Listerine cold and sore throat efficacy beliefs and that current advertising performs the dual functions of maintaining beliefs created by prior advertisements and creating beliefs in consumers entering the market.

Record evidence supports what common sense suggests:

(1) Dr. Peter Rossi, a witness for complaint counsel, testified that (Tr. 1451):

> Indeed, the evidence here is consistent with the idea that it is the advertising of Listerine as registered in the memories of consumers which produces the distinctive patterning of the brand image for that brand; and, indeed, the advertising for Micrin does the same thing for Micrin, but certainly it is clear that the advertising for Listerine does its job for that brand.

(2) Dr. Alvin A. Achenbaum, a witness for respondent, stated (Tr. 3439-40):

> * * * insofar as the users of a brand are concerned that advertising for a well-established product like Listerine — that probably the advertising has the effect of reminding people of information or their belief or about the brand so that at the time at which they make a purchase — that hopefully that brand will come to their mind as opposed to perhaps some other brand which is out there trying to advertise and have some effect upon their point of view as well. So I would say that, in that sense in the life cycle, it has a reminding effect.
>
> Now, there are always new people coming into the market. I mean, people grow up and form households who are not users, and, to some degree, the advertising could affect their belief structure.

See also testimony of Dr. Frank Bass. (Tr. 1607-12, 1617-21.)

(3) The benefit of spending vast sums on cold efficacy advertising has not escaped respondent's notice. A Product Q report commissioned by respondent stated:

> Listerine continues to be first on most measures and it continues to grow while Scope remains a distant second; its performance relatively static. However, despite this one sided picture, comparable numbers of respondents claim to recall "a lot" of advertising for each brand. With this dimension constant and Listerine well ahead of Scope on everything else, it would appear that *the quality of Listerine's advertising and/or its media plan are making a vital contribution to the brand's success.*
>
> *Also, there is a very close relationship between Listerine advertising registration and the brand's image.* (Emphasis added) CX 65E-F.

Moreover, a letter from respondent to the J. Walter Thompson Co. stated that a cold efficacy commercial, "* * * helped generate all-time high brand shares." (CX 109A.)

(4) Apparently, Listerine's three leading competitors were not advertised as colds remedies. (Tr. 1595, RB 85.) The Product Q data reveals that over 60 percent of responders in 1967 and 1968 believed

Listerine was effective for colds and sore throats, whereas fewer than 20 percent attributed that quality to Listerine's three leading competitors."[27] (CX 802-11.) Although this empirical data showing a three-fold differential in belief levels does not prove that Listerine cold efficacy advertising substantially affected consumer beliefs, it is consistent with the aforesaid views expressed by experts and respondent.

Respondent argues that consumer beliefs result from actual experience with the product rather than from the advertising. We have previously concluded that Listerine has no efficacy for colds and sore throats. We further noted that a cold is a self-limiting malady, and therefore a cold sufferer may wrongly attribute the termination of the cold episode to Listerine. In fact, the only source of consumer "satisfaction" is the placebo effect. Although the placebo effect probably causes some Listerine users to think the mouthwash works, the record does not establish it as the exclusive or even major source of the belief.

Respondent further incorrectly contends that a corrective advertising order cannot properly be issued unless the Commission finds that advertising was the sole source of the belief. We have previously ordered affirmative relief to correct a false impression created merely "in part through respondent's own efforts." *Waltham Instrument Co.*, 61 F.T.C. 1027, 1049 (1962) *aff'd.* 327 F.2d 427 (7th Cir. 1964), *cert. denied*, 377 U.S. 992 (1964). To the extent that dicta in *Sun Oil*, Dkt. 8889 (Aug. 19, 1974 [84 F.T.C. 247]), an unappealed initial decision adopted by the Commission, could be construed as supporting a sole-source standard, that opinion does not reflect the views of this Commission. The Commission's mandate is to eliminate the effects of false advertising, and a sole-source standard would effectively bury a remedy which is vital to the achievement of that goal.

Persistence of the False Beliefs. The record demonstrates that long after Listerine cold efficacy advertising ceased, a substantial proportion of the public would continue to believe in Listerine's efficacy for the treatment and prevention of colds and sore throats. Dr. Bass testified that cold efficacy belief levels would continue at the 1971 rate (59 percent) for about two years after colds advertising ceased and would remain high even *after* five years. (Tr. 1560-61, 1611.) It is Dr. Bass' view that consumer beliefs tend to continue once they are created and that after a belief is created it lasts much longer than the memory of the copy points of the ads that created the belief. (Tr. 1556-57.) Dr.

[27] In commenting on the low scores of Listerine's competitors, Dr. Bass said "and I would expect that there would be levels of belief for these other brands of about the level that we observe in the absence of advertising." Tr. 1595. He suggested that the low percentages which the other mouthwashes registered in the absence of colds advertising could have resulted from color, image of antiseptic properties and perhaps word of mouth. Tr. 1596.

Rossi concluded that the stability of Listerine's image is quite impressive, and that in the absence of colds advertising consumer beliefs would decline at *no greater* a rate than 5 percent a year. (Tr. 1433, 1469-72.) At that maximum rate of decline, belief levels would still register over 30 percent ten years after the advertising ceased. Moreover, the Product Q data reveals that consumer beliefs about Listerine's effectiveness against colds and sore throats were practically the same during the portions of the year when respondent engaged in colds advertising as during the rest of the year. (CX 159D.)

As was previously discussed (*supra*, Part II), the record shows that respondent's advertisements and labels made the challenged claims at least as late as 1972. Thus, we conclude that a substantial proportion of the consuming public will retain the beliefs in issue well into the 1980's.

Materiality of the False Beliefs. The ALJ found that "[t]he belief that Listerine is effective for colds and sore throats is a determining factor in a significant number of consumers' decisions to purchase Listerine." (IDF 244(a).) The testimony of Dr. Rossi supports this conclusion (Tr. 1455, 1460) as does empirical evidence. According to Product Q data, 37.5 percent of those interviewed over a seven-year period said that "effective for colds and sore throats" was "extremely important" in their selection of a mouthwash. (CX 159A.) This tabulation did *not* include those for whom "effective for colds and sore throats," was "very important," "somewhat important," or "fairly important." Thus, although 37.5 percent is in itself substantial, it probably does not fully reflect the extent to which cold efficacy beliefs affect purchasing decisions.

3. The Nature of the Corrective Advertising Order

In view of the foregoing findings that respondent's advertisements substantially contributed to the development and maintenance of the belief that Listerine is effective for the prevention and treatment of colds and sore throats, that a substantial portion of the population will continue to hold this belief well into the 1980's and that this belief plays a material role in purchasing decisions (thereby injuring both consumers and competition), we conclude that an order merely requiring cessation of the deceptive advertising would not afford the public adequate protection. The lingering false belief must be dispelled, a task which requires corrective advertising.[28]

The ALJ's order, which requires respondent to include a corrective message in all advertising for two years, may not accomplish this task.

[28] The ALJ justified the corrective advertising order on the additional ground that future representations of Listerine as a germ killer would automatically remind the public of false colds claims (IDF 248). We need not consider at this time this additional rationale.

If respondent chose not to advertise during the two-year period (or to do a miniscule amount of advertising) the corrective message would not adequately reach the public and the false beliefs would live on. To avert this possibility we shall order respondent to include the corrective message[29] in all Listerine advertising until it has expended an amount on such advertising equal to its average annual Listerine advertising budget for the ten-year period of April 1962 to March 1972 (as set forth in CX 44). A corrective advertising campaign of this scope should adequately dispel the lingering beliefs.

In this proceeding we cannot determine in advance with computer-like precision the minimum amount of corrective advertising which will dispel the otherwise continuing beliefs at issue. However, in ordering the relief which the public interest requires, it is the duty of a tribunal to exercise its best judgment to predict the relief which is essential. As the Supreme Court has recognized, the fashioning of appropriate affirmative relief necessarily "* * * involves predictions and assumptions concerning future economic and business events." *Ford Motor Company* v. *United States*, 405 U.S. 562, 578, (1972).[30] We see no reason why different considerations should apply when drafting a corrective advertising order.

4. Other Objections to a Corrective Advertising Order

Respondent contends that a corrective advertising order would raise First Amendment questions. However, it has not disputed the commercial nature of its advertisements. As we noted in *Firestone*,[31] courts have repeatedly held that regulation of false commercial advertising is constitutional. In *Pittsburgh Press Co.* v. *Pittsburgh Commission on Human Relations*, 413 U.S. 376, 389 (1973), the Supreme Court articulated a balancing test which must be applied to the regulation of truthful commercial speech:

> Any First Amendment interest which might be served by advertising an ordinary commercial proposal and which might arguably outweigh the governmental interest supporting the regulation is altogether absent when the commercial activity itself is illegal and the restriction on advertising is incidental to a valid limitation on economic activity.

Assuming that the same considerations apply when mandating

[29] Since the record does not demonstrate that consumers hold cure beliefs, we have modified the message to read: Contrary to prior advertising, Listerine will not help prevent colds or sore throats or lessen their severity.

[30] The Court upheld a lower court's determination that to restore and encourage competition, Ford must, *inter alia*, be enjoined from manufacturing spark plugs for ten years, be ordered for five years to buy one half its spark plug requirements from the divested plant under the "Autolite" name and refrain from using its own name on spark plugs during that five-year period, and be ordered for ten years to sell to its dealers at prices not less than the minimum suggested jobbers' selling price.

[31] 81 F.T.C. at 471-72.

commercial speech as when proscribing it, we conclude that the corrective advertising order in this case is a valid limitation on economic activity because it is designed to dispel the continuing effects of illegal commercial activity.[32]

Respondent also claims that a corrective advertising order is a punitive measure because it may adversely affect the product's consumer franchise as a breath freshener. The corrective advertising order that we are issuing is intended solely to dissipate the effects of respondent's deceptive representations. In dispelling these beliefs, respondent may impair a portion of its breath-freshener franchise, but the fact that the remedy may have some harsh consequences does not render it punitive. As the Commission said in *Firestone*, 81 F.T.C. at 469:

> The fact that the remedy may be deemed by the court to have severe consequences to the respondent does not in itself render the order punitive if the order is also deemed a "needed public precaution." *All-State Industries of North Carolina, Inc.* v. *FTC*, 423 F.2d 423, 425 (4th Cir.), *cert. denied*, 400 U.S. 828 (1970).

B. Objections to Part II of the ALJ's Order

Part II of the ALJ's order requires respondent to cease representing that Listerine *or any other mouthwash product* is effective for colds. Respondent objects to the inclusion of other mouthwashes on the ground that the complaint challenges solely the efficacy of Listerine.

Respondent has spent a considerable sum advertising Listerine as a cold remedy for decades. Presumably, it found this representation to be profitable. Respondent thus has an incentive to formulate a new mouthwash which it could advertise as a cold remedy. In view of our conclusion that the act of gargling does not deliver a mouthwash to the critical areas of the body, we question whether any mouthwash would be effective for colds or sore throats. Thus, by limiting the order to Listerine we would set the stage for a replay of the instant proceeding, the only difference being the name of the mouthwash. To avert this prospect we must, in the exercise of our fencing-in authority, include all mouthwashes within the coverage of Part II of the order. *See FTC* v. *Colgate-Palmolive Co.*, 380 U.S. 374, 394-95 (1965).

Of course, if respondent were to develop a mouthwash which was effective for colds or sore throats, it could petition to modify the order, as provided by Section 3.72 of the Commission's rules.

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[32] *See also Bigelow* v. *Virginia*, 95 S. Ct. 2222, 2235 (1975) where the Court again noted the distinction between advertising related to activities the state may legitimately regulate (including fraudulent or deceptive advertising (2235-36)) and advertising not so related.

APPENDIX

The ALJ determined that the following exhibits do not support respondent's efficacy claims. After a thorough review of each exhibit, we concur in the ALJ's conclusion that they lack probative value, but as explained below, in some instances we have a different reason for finding that a particular exhibit has no value.

1. *RX 40-43:* We agree with IDF 134-142 (the last citation to Dr. Knight's testimony in IDF 142 should be "Knight 1982").

2. *RX 44:* We agree with IDF 198.

3. *RX 46:* As described in IDF 145, the procedures used in the tests discussed in RX 46 render those tests useless in this proceeding.

4. *RX 47:* This is a report of a test in which the drug was administered to test rabbits. In addition to the reasons advanced by the ALJ for according little value to this test (IDF 174-176) we emphasize the following:

Dr. Carson stated that studies in animals are simply preliminary studies and that clinical tests are necessary to draw conclusions about the effect of a drug in man (Tr. 3576). Moreover, the probative value of the test is further reduced by the dissimilarity between the method by which the drug was administered to the rabbits and the method by which Listerine is administered to humans. Furthermore, even assuming *arguendo* that this test demonstrated that ingredients of Listerine can have a decongestant effect, Dr. Carson did not satisfactorily establish that an effective dose of these ingredients would reach the critical areas of the respiratory tract (Tr. 3572-73).

5. *RX 48:* The systemic administration of the drug renders the test valueless. We note, however, that since we place no value in RX 47, we need not reach the ALJ's conclusion that RX 47 contradicts RX 48. (IDF 178.)

6. *RX 50:* We agree with IDF 173.

7. *RX 53:* We agree with IDF 149.

8. *RX 55:* We agree with IDF 150.

9. *RX 56:* This was an in vitro test conducted in hamster cheek tissue. Assuming *arguendo* that hamster cheek tissue closely resembles tissues in the human nasopharynx, this test has little value because, as the ALJ noted, the amount of ingredients retained was not quantified. (IDF 151.)

10. *RX 57:* See opinion at 15 [pp. 1494-1495 herein].

11. *RX 60, 61, 63 and 64:* We agree with IDF 153.

12. *RX 65-68:* We agree with the ALJ that the tests discussed in these exhibits deserve little weight in this proceeding. RX 67, a document to which Dr. Ritchie, the coauthor fully subscribes (Tr. 2404)

stated, in essence, that the results of the tests described in RX 65, 66, 67 and 68 are not statistically significant:

> Severe colds are usually those in which the viral stage of about three days duration is succeeded by a more prolonged bacterial stage, believed to be due to the multiplication of the native nasopharyngeal bacteria. Such colds can be prevented by a six-months course of autogenous bacterial vaccines given beforehand, or they can be aborted and rendered innocuous by early antibiotic treatment. The evidence submitted, although strong, does not reach statistical significance.

These tests, therefore, have little probative value. Respondent argues that the above reference to the statistical insignificance of the tests does not encompass so-called "subsequent tests" described in RX 66. However, RX 66 was printed in 1958. RX 67, which was published in 1969 (Tr. 2389), was offered into evidence as a summary of Ritchie's views over the period 1958-1969. Thus, we cannot see how the test discussed in RX 66 could be regarded as a "subsequent" test which Dr. Ritchie somehow failed to consider in making the assessment in RX 67 that "the evidence * * * does not reach statistical significance."

We also accord these tests little weight because the record does not show that the results obtained with a bacteriostatic substance (which purportedly maintains the bacteria population at a reduced level) carry over to a bactericidal substance, particularly since bactericides do not prevent the bacteria from growing back to their previous strength or greater. *See* IDF 154.

13. *RX 69-71:* We agree with ALJ at IDF 199-201.

14. *RX 73:* The ALJ's finding (IDF 205) that the machine did not measure the quantities of any ingredient is sufficient reason to accord this test little weight, and therefore, we need not reach other reasons he offered for finding the exhibit valueless.

15. *RX 75:* We agree with IDF 207-209. In IDF 208 the ALJ noted the prospect that the panelists may have exercised bias in favor of Listerine. Although the panelists may have been biased, we need not reach this issue because the test has little probative value for the other reasons discussed at IDF 207-209.

16. *RX 97:* We agree with IDF 168-172.

17. *RX 108:* In 1935, Dr. Oscar B. Hunter performed tests which he claimed showed that gargling is an adequate mechanism for bathing the crypts of the tonsils with Listerine. *See* RX 108 p-r, z-z26. However, he also testified that Listerine would not get into *all* of the crevices of the mouth, RX 108 z-96. We have resolved this apparent inconsistency in his testimony in favor of his assertion that Listerine would not reach all the crevices because this is the view which is consistent with the testimony of experts for both sides in this proceeding, *e.g.*, Seal Tr. 554; McNamara, Tr. 2342.

Clinical Studies of Listerine

Respondent contends that two clinical studies, the St. Barnabas and Reddish studies, demonstrate the efficacy of Listerine for colds and sore throats. After a careful review, we must conclude that the design and execution of these tests heavily biases the results in favor of Listerine, and therefore, the results cannot support respondent's efficacy claim.

1. *The St. Barnabas Test*

Students in an elementary school and a high school were randomly selected to participate in this study which spanned four years (the high school was dropped at the end of the third year). During the first two years, the participating students were assigned either to the treatment group, which gargled with Listerine twice a day, or to a control group which used no mouthwash at all. (RX 81, Tr. 2789-90.) During the last two years the control group gargled with water colored to resemble Listerine's amber hue, (Baron Tr. 2746-47). Since it did not have Listerine's taste or odor, the ALJ concluded that this amber-colored water was not a true placebo, IDF 87, and that the absence of a true placebo biased the test results in favor of the tested agent, Listerine. We agree with this conclusion. As the ALJ noted:

> People who are given medication for an ailment frequently feel better because they think they should, even though the product has no therapeutic value. There are very few people who are not susceptible to this phenomenon (Seal 562, 566; Proctor 659; Rammelkamp 785). As Dr. Proctor testified, "Even with severe pain you can substitute sugar for morphine and about 30 percent of the people will be relieved of their pain." (Tr. 659.) And as Dr. Rammelkamp explained, "[Y]ou see paralysis even stopped where you just give an injection of salt water." (Tr. 783.) This is known as the placebo effect. The placebo effect is always present when medication is taken (Shirkey 2635). (IDF 81.)

In order to determine whether the product has efficacy, the bias of the placebo effect should be removed. This bias can be neutralized by "blinding" the participants, *i.e.*, dispensing to the control group a placebo which simulates in taste, smell and appearance the product being tested. This practice of blinding the control group through the use of a placebo is a generally-accepted procedure today. (*See* Knight 2051; Bogarty 3072-73, 3117; Shirkey 2655-56; Jawetz 3698-99, 3838-39; Wehrle 4011; Lasagna 4126, 4131). Use of an adequate placebo becomes even more important where the evaluation of symptoms involves subjective judgments (Wehrle 4038). The record demonstrates that a cold is a self-limiting infection, and evaluation of cold symptoms tends to be quite subjective (Gwaltney 407; Hornick 476, 497, 499; Seal 549).

We are not requiring in this case that the placebo duplicate the taste,

smell, texture, color, etc. of the tested product. There may well be degrees of simulation short of duplication which would neutralize the placebo effect.[1] However, the use of caramel-colored water was patently inadequate.

Respondent urges that the absence of a true placebo can be counterbalanced by factors which tend to reduce the impact of the placebo effect, such as conducting the study over a long period of time, permitting the use of concomitant medication, and maintaining the "blindness" of the examining physician—precautions which respondent claims were taken in the St. Barnabas study. Perhaps in some drug studies other factors could compensate for the absence of a placebo but so many uncertainties permeate the St. Barnabas test that we cannot place any reliance in it. For example, it is unclear whether the examiner was properly blinded. We note that blinding the examiner is not merely a device for counterbalancing the absence of a proper placebo; it is essential that a properly administered test avoid bias on the part of the investigator. Whatever bias he may consciously or subconsciously possess can be neutralized by preventing him from knowing which subjects used the purported medication and which received no medication. In this sense, the examiner is "blinded." The ALJ aptly summarized the necessity for properly "blinding" the examiner (at IDF 83):

> Another bias that must be avoided is that of the investigator who is recording the results as narrated to him by the subjects or as observed by him when he conducts his examination. Every investigator has his own biases. It is important that the investigator not know whether the subjects are taking the test agent or are in the control group. Otherwise, he will subconsciously try to give his employer the answers the employer wants (Gwaltney 407; Haggie 1794; Knight 2051; Lamm 2934, 2937; Sadusk 3206; Carson 3589, 3601; Jawetz 3698-3701; Wehrle 3995, 4013-15, 4037-39; Lasagna 4126, 4133-34; CX 162G-I). As Dr. Knight reported to respondent (CX 162G-H):
>
> > * * * In the absence of double blind controls, however, there is no way to exclude the possibility of some bias. There is a tendency of both patients and experimentalists to see a favorable effect of medication in any experiment.

As respondent's statistical expert testified (Lamm 2934):

> * * * [T]he important thing in this type of study is that your investigator be blind.

And, as one of respondent's expert medical witnesses testified (Sadusk 3228):

[1] Dr. Vernon Knight, a witness for respondent, identified an alternative which may have proved adequate: A new study would have to be of the "double blind" type. This might be arranged by completely avoiding the use of the word "Listerine." Listerine colored another color or conceivably flavored slightly differently as well could be compared with a colored, flavored, 25% alcohol solution. A third group could be given a non-alcoholic, non-germicidal solution of a different color and flavor. CX 162 at 8.

> If the doctor knew [which subject that came to him was a control and which was a test]—and this would indicate that the doctor was dishonest because he would actually ask each person—the experiment, of course, would not be valid.

The ALJ concluded that the examiner, Dr. Benjamin W. Nitzberg, was not properly "blinded" because the test protocol required that the children gargle at 9:00 a.m., and he began examining them at 10 a.m. Although Dr. Nitzberg denied that he knew which children were in the test group (Tr. 2790, 2800) or that he smelled Listerine on the student's breath except on rare occasions (*i.e.*, three or four children in six months, Tr. 2803), the ALJ concluded that Dr. Nitzberg must have detected the odor of Listerine on the students' breath because other witnesses for respondent testified, on the basis of their own experiences with Listerine, that Listerine can be smelled on the breath for 1 1/2 to 2 hours after gargling. IDF 99.

The record offers support for the ALJ's concern. It establishes that Dr. Nitzberg knew that the test was being conducted for Warner-Lambert, that it involved Listerine and that the data would be used to determine the effect on colds of gargling with Listerine daily, Tr. 2829. Thus, if he knew which children used Listerine, he might have biased the results in favor of Listerine. The students gargled at 9:00 a.m. (CX 51D, RX 81D); Dr. Nitzberg arrived at 10:00 a.m. (Tr. 2811, 2826) and left within an hour during the first two years of the study and within one and one-half hours during the last two years (Tr. 2811). Therefore, many students were examined one to two hours after gargling. Two physicians who testified for respondent stated that, on the basis of their own experience with Listerine, it can be detected on the breath for 1 1/2 to 2 hours after gargling. (Sadusk Tr. 3216, 3229-30; Krantz 1879, 1901). *See also* Carache at 3840. On the other hand, another witness for respondent testified that a laboratory instrument could not detect some ingredients of Listerine in a human subject's nasal cavity twenty minutes after the subject gargled (Tr. 2486, 2505). However, he also testified that the instrument leaked large amounts of the volatile materials (Tr. 2498), and that after the instrument failed to detect the ingredients, they were identified by smell (Tr. 2505). Considering this evidence as a whole, we are led to conclude that by virtue of respondent's own witnesses, it is uncertain whether Dr. Nitzberg was properly "blinded."

Three additional infirmities heighten our concern about the study's probative value. Students were instructed to report to the medical examiner, usually Dr. Nitzberg, at the first sign of a cold. The medical examiner would evaluate and record the overall severity of the cold plus the severity of fourteen cold-related symptoms (only eight during the first two years of the study). The student returned to the examiner each day for the duration of the cold episode, and the physician

examined and questioned the student about each symptom, recording the severity of the symptoms on the same sheet that he used the previous day (a rating scale of 0-4 was used during the first two years and 0-7 for the last two). Dr. Nitzberg allotted himself only 1 1/2 to 2 minutes to examine and question each child (Tr. 2820). This procedure detracts from the probative value of the test in three respects. First, by using the same score sheet day after day Dr. Nitzberg would know how he evaluated a child's symptoms the previous day (Tr. 2822-23). As the ALJ found, Dr. Nitzberg's knowledge of what he had done previously would tend to bias his scores, and therefore he would not make an independent judgment each day. IDF 101. Second, given the number of symptoms which Dr. Nitzberg had to evaluate and the fine gradations he had to make in his evaluation, we question whether he spent an adequate amount of time on each subject. In addition to asking each child for historical data on every item on the report form, he would "examine the upper respiratory tract, the eyes, the ears, the nose and the throat, the sinuses by palpitation and the neck for cervical adenopathy" Tr. 2791. During the last two years of the study the examiner checked for six additional symptoms (Tr. 2798-99). On Mondays he often had to fill in the form for Saturday and Sunday. (*See also* Tr. 2816-2819). Third, even if Dr. Nitzberg had been properly blinded the scores he recorded could have been biased to the extent the scores were based upon the non-blinded child's subjective evaluation. (*See Lamm* Tr. 2937).

All of the foregoing defects have the cumulative effect of rendering the St. Barnabas study unreliable for evaluating the efficacy of Listerine. In view of this conclusion, we find it unnecessary to consider the parties' disagreement over the meaning of the results.

2. *The Reddish Cold Tests*

During the winters of 1932 to 1942 respondent conducted tests, mainly using its own employees, to determine whether Listerine has the ability to fight colds. These tests, which respondent claimed established Listerine's efficacy against colds and sore throats, have such grave deficiencies in design and execution that their results are meaningless. Of foremost concern, no placebo was used. (During some winters control groups gargled with a saline solution or tap water. These liquids cannot qualify as adequate placebos.) Moreover, employees were allowed to choose which group they preferred, thereby further biasing the results because those who thought that gargling was an effective method for fighting a cold would most likely join the test group. In addition, the ALJ found that the investigators themselves had predetermined beliefs that Listerine was good for

colds. Finally, the investigators were not provided with a uniform definition of a "cold." Common colds last no longer than 10 days, yet illnesses lasting up to 69 days were counted as "colds" in the Reddish study. Even respondent's own expert, Dr. Knight, said that "present opinion would hold that satisfactory evidence for efficacy is no longer provided by these early studies." IDF 124, CX 162G-H.

Respondent does not address these infirmities in the Reddish tests. Instead, it contends that the Commission relied upon these tests in dismissing the 1944 complaint, and therefore the ALJ's finding of deficiencies in the Reddish tests is "an impermissable [sic] relitigation of matters long ago settled." RB 67. This issue is discussed in Section IV herein.

FINAL ORDER

This matter having been heard by the Commission upon respondent's appeal from the initial decision; and

The Commission having considered the oral arguments of counsel, their briefs, and the whole record; and

The Commission, for reasons stated in the accompanying opinion, having denied the appeal; accordingly

It is ordered, That, except to the extent that it is inconsistent with the Commission's opinion, the initial decision of the administrative law judge be, and it hereby is, adopted together with the opinion accompanying this order as the Commission's final findings of fact and conclusions of law in this matter;

It is further ordered, That the following order be, and it hereby is, entered:

PART I

It is ordered, That respondent Warner-Lambert Company, a corporation, its successors and assigns and respondent's officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the labeling, advertising, offering for sale, sale or distribution of Listerine or any other nonprescription drug product in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

1. Representing, directly or by implication, that any such product will cure colds or sore throats;

2. Representing, directly or by implication, that any such product will prevent colds or sore throats;

3. Representing, directly or by implication, that users of any such product will have fewer colds than nonusers.

PART II

It is further ordered, That respondent Warner-Lambert Company, a corporation, its successors and assigns and respondent's officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the labeling, advertising, offering for sale, sale, or distribution of Listerine or any other mouthwash product in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

1. Representing, directly or by implication, that any such product is a treatment for, or will lessen the severity of, colds or sore throats;

2. Representing that any such product will have any significant beneficial effect on the symptoms of sore throats or any beneficial effect on symptoms of colds;

3. Representing that the ability of any such product to kill germs is of medical significance in the treatment of colds or sore throats or the symptoms of colds or sore throats.

PART III

It is further ordered, That respondent Warner-Lambert Company, a corporation, its successors and assigns, and respondent's officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, do forthwith cease and desist from disseminating or causing the dissemination of any advertisements for the product Listerine Antiseptic unless it is clearly and conspicuously disclosed in each such advertisement in the exact language below that:

Contrary to prior advertising, Listerine will not help prevent colds or sore throats or lessen their severity.

In print advertisements, the disclosure shall be displayed in type size which is at least the same size as that in which the principal portion of the text of the advertisement appears and shall be separated from the text so that it can be readily noticed. In television advertisements, the disclosure shall be presented simultaneously in both the audio and visual portions. During the audio portion of the disclosure in television and radio advertisements, no other sounds, including music, shall occur. Each such disclosure shall be presented in the language, *e.g.*, English, Spanish, principally employed in the advertisement.

The aforesaid duty to disclose the corrective statement shall continue until respondent has expended on Listerine advertising a sum equal to the average annual Listerine advertising budget for the period of April 1962 to March 1972.

PART IV

It is further ordered, That the allegations of Paragraphs Nine and Ten of the complaint be, and they hereby are, *dismissed.*

PART V

It is further ordered, That respondent shall forthwith distribute a copy of this order to each of its operating divisions.

It is further ordered, That respondent notify the Commission at least thirty (30) days prior to any proposed change in its structure such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in the corporation which may affect compliance obligations arising out of this order.

It is further ordered, That respondent shall, within sixty (60) days after the effective date of this order, file with the Commission a written report, setting forth in detail the manner and form of its compliance with this order.

IN THE MATTER OF

MAGNETIC VIDEO CORPORATION, ET AL.

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

Docket C-2767. Complaint, Dec. 12, 1975 — Decision, Dec. 12, 1975

Consent order requiring a Farmington Hills, Mich., manufacturer and distributor of various tape products, including compilations of hits and sound alike recordings, among other things to cease using any advertisement or promotional material which misrepresents that any tape product has been recorded by the original artist(s). Further, respondents must either disclose the name of the actual recording artist or print a warning advising prospective purchasers that the product "is not an original artist recording."

Appearances

For the Commission: *Paul K. Trause.*

For the respondents: *Charles Tathem, Merrill, Tathem & Rosati*, Detroit, Mich.

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 Magnetic Video Corporation, a corporation, and Andre Blay, individually and as an officer of said corporation, hereinafter sometimes 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. For the purposes of this proceeding, the following definitions shall apply:

Original Artist: The original artist is the person who originally recorded and made popular the song(s) or album in question, or with whom the public generally identifies the song(s) in question.

Sound Alike Recording: A sound alike recording is a recording of a hit song(s) or a hit album recorded by one other than the original artist and performed in the style and manner of the original artist.

Compilation of Hits: A compilation of hits is a tape product featuring a variety of songs originally recorded and made popular by various artists.

Tape Products: Tape products include tape cartridges or tape cassettes; or, insofar as Magnetic Video Corporation produces or distributes them, phonograph records.

PAR. 2. Respondent Magnetic Video Corporation is a corporation organized, existing, and doing business under and by virtue of the Laws of the State of Michigan, with its office and principal place of business located at 24380 Indoplex Circle, Farmington Hills, Mich.

Respondent Andre Blay is an individual and an officer of the corporate respondent. He formulates, directs, and controls the acts and practices of the corporate respondent, including the acts and practices hereinafter set forth. His address is the same as that of the corporate respondent.

PAR. 3. Respondents are now, and for some time last past have been, engaged in the manufacture and distribution of various tape products, including compilations of hits and sound alike recordings.

PAR. 4. In the course and conduct of their business as aforesaid, respondents now cause, and for sometime last past have caused, their products when sold to be shipped from their place of business located in the State of Michigan to purchasers thereof located in various other