IN THE MATTER OF

BERTOLLI USA, INC.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-3396. Complaint, Aug. 17, 1992--Decision, Aug. 17, 1992

This consent order prohibits, among other things, a New Jersey -- based company from misrepresenting the validity, results, conclusions or interpretations of any test or study; and from representing that olive oil or any other edible oil produces any health benefits, such as reducing blood pressure and blood sugar, unless the respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

Appearances

For the Commission: *Nancy S. Warder* and *Joel Winston.*

For the respondent: *Eugene I. Lambert, Covington & Burling*, Washington, D.C.

COMPLAINT

The Federal Trade Commission, having reason to believe that Bertolli USA, Inc. ("Bertolli" or "respondent"), a corporation, has violated provisions of the Federal Trade Commission Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, alleges:

PARAGRAPH 1. Bertolli is a Delaware corporation with its offices and principal place of business at 1 Harmon Plaza, P.O. Box 2617, Secaucus, New Jersey.

PAR. 2. Bertolli has advertised, offered for sale, sold, and distributed Bertolli Olive Oil Classico, Bertolli Extra Virgin Olive Oil, and Bertolli Extra Light Olive Oil (collectively referred to as "Bertolli Olive Oil") and other "foods" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

PAR. 3. Bertolli has disseminated or caused to be disseminated advertisements for Bertolli Olive Oil. These advertisements have been disseminated by various means in or affecting commerce, including magazines distributed across state lines, for the purpose of inducing the purchase of Bertolli Olive Oil by members of the public.

PAR. 4. The acts or practices of Bertolli alleged in this complaint have been in or affecting commerce.

PAR. 5. Respondent has disseminated or caused to be disseminated advertisements for Bertolli Olive Oil, including but not necessarily limited to, the advertisements attached hereto as Exhibits A, B, and C. The headlines of Exhibits A and B contain the following statements:

Last week, [or in Exhibit B, "On February 2,"] medical science confirmed olive oil can lower cholesterol, blood pressure and blood sugar. For people who use Bertolli, this was old news. (Emphasis added).

The headline of Exhibit C contains the following statements:

For years, Bertolli has said olive oil can lower your cholesterol, blood pressure and blood sugar. Last week, medical science said we were right. (Emphasis added).

All three advertisements also contain the following statements:

The February 2, 1990 issue of The Journal of the American Medical Association reported that monounsaturated oils like olive oil are healthier than other oils, margarine or butter.

The study, conducted in Italy, showed people who had the most olive oil in their diet had the lowest levels of blood cholesterol, blood pressure and blood sugar.

These findings support prior research in the United States that found monounsaturated oils, such as olive oil, can actually reduce the cholesterol, known as LDL, that is bad for you.

Yet they protect the cholesterol, known as HDL, that is good for you.

That's something corn oil, sunflower oil, vegetable oil, margarine and butter can't do.

All of this information simply confirms what we at Bertolli have known for generations. Bertolli olive oil is healthier.

PAR. 6. The respondent has disseminated or caused to be disseminated advertisements for Bertolli Olive Oil, including but not necessarily limited to, the advertisement attached hereto as Exhibit D, which contains the following statements:

Because Bertolli Olive Oil is healthier for your heart than other oils, butter or margarine. It can actually lower cholesterol, blood pressure and blood sugar.

PAR. 7. The study reported in the February 2, 1990, issue of The Journal of the American Medical Association to which the advertisements attached as Exhibits A, B, C, and D refer is by Trevisan and others titled Consumption of Olive Oil, Butter, and Vegetable Oils and Coronary Heart Disease Risk Factors ("Trevisan Article").

PAR. 8. Through the use of the statements set forth in paragraph five, and others not specifically set forth herein, respondent has represented, directly or by implication, that medical science has established that:

(a) Eating olive oil lowers blood pressure; and
(b) Eating olive oil lowers blood sugar.

PAR. 9. In truth and in fact, medical science has not established that:

(a) Eating olive oil lowers blood pressure; and
(b) Eating olive oil lowers blood sugar.

Therefore, the representations set forth in paragraph eight were and are false and misleading.

PAR. 10. Through the use of the statements in paragraphs five and six and others not specifically set forth herein, respondent has represented, directly or by implication, that:

(a) Eating olive oil lowers cholesterol more than other cooking oils used in the home;
(b) Eating olive oil lowers blood pressure;
(c) Eating olive oil lowers blood sugar; and

(d) Bertolli olive oil is healthier for the heart than other cooking oils used in the home.

PAR. 11. Through the use of the statements in paragraphs five and six and others not specifically set forth herein, respondent has represented, directly or by implication, that at the time it made the representations set forth in paragraph ten respondent possessed and relied upon a reasonable basis, consisting of competent and reliable scientific research, for such representations.

PAR. 12. In truth and in fact, at the time the representations were made, respondent did not possess and rely upon a reasonable basis, consisting of competent and reliable scientific research, for the representations set forth in paragraph ten. Therefore, the representations set forth in paragraph eleven were and are false and misleading.

PAR. 13. Through the use of the statements set forth in paragraph five, and others not specifically set forth herein, respondent has represented, directly or by implication, that the Trevisan Article reports that olive oil is healthier than other oils.

PAR. 14. In truth and in fact, the Trevisan Article does not report that olive oil is healthier than other oils. The Trevisan Article reports its findings in qualified terms and states that both polyunsaturated and monounsaturated fats may be associated with a lower coronary risk profile and that further studies are needed to confirm its findings. Therefore, the representation set forth in paragraph thirteen was and is false and misleading.

PAR. 15. Through the use of the statements set forth in paragraph five, and others not specifically set forth herein, respondent has represented, directly or by implication, that the findings of the Trevisan Article support prior research that found monounsaturated oils, such as olive oil, reduce LDL cholesterol and protect HDL cholesterol.

PAR. 16. In truth and in fact, the findings of the Trevisan Article do not support prior research that found monounsaturated oils, such as olive oil, reduce LDL cholesterol and protect HDL cholesterol. The Trevisan Article did not report any measures of either LDL or HDL cholesterol, and its findings do not pertain directly to the effects of olive oil on either LDL or HDL cholesterol. Therefore, the

representation set forth in paragraph fifteen was and is false and misleading.

PAR. 17. Through the use of the statements set forth in paragraph five, and others not specifically set forth herein, respondent has represented, directly or by implication, that the Trevisan Article reports that study participants who had the most olive oil in their diets had the lowest levels of blood cholesterol.

PAR. 18. In truth and in fact, the Trevisan Article does not report that study participants who had the most olive oil in their diets had the lowest levels of blood cholesterol. The Trevisan Article reports that the study participants who had the most polyunsaturated fat in their diets had the lowest levels of blood cholesterol. Therefore, the representation set forth in paragraph seventeen was and is false and misleading.

PAR. 19. The dissemination by respondent of the aforesaid false and misleading representations as alleged in this complaint constitutes unfair or deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act.

EXHIBIT A

EXHIBIT A

Last week, medical science confirmed olive oil can lowe1 cholesterol, blood pressure and blood sugar. For people who use Bertolli, this was old news.

The February 2, 1990 issue of The Journal of The American Medical Association reported that monounsaturated oils like olive oil are healthier than other oils, margarine or butter.

The study, conducted in Italy, showed people who had the most olive oil in their diet had the lowest levels of blood

research in the United States that found monounsaturated oils, such as olive oil, can actually reduce the cholesterol, known as LDL, that is bad for you.

Yet they protect the cholesterol, known as HDL, that is good for you.

That's something corn oil, sunflower oil, vegetable oil, margarine and

firms what we at Bertolli have known for generations.

Bertolli olive oil is healthier.

And, although the American Medical Association failed to mention it, you should know Bertolli is also delicious.

For more information about the health benefits of olive oil, write to the

EXHIBIT B

On February 2, medical science confirmed olive oil can lower cholesterol, blood pressure and blood sugar. For people who use Bertolli, this was old news.

The February 2, 1990 issue of The Journal of The American Medical Association reported that monounsaturated oils like olive oil are healthier than other oils, margarine or butter.

The study, conducted in Italy, showed people who had the most olive oil in their diet had the lowest levels of blood cholesterol, blood pressure and blood sugar.

These findings support prior research in the United States that found monounsaturated oils, such as olive oil, can actually reduce the cholesterol, known as LDL, that is bad for you.

Yet they protect the cholesterol, known as HDL, that is good for you.

That's something corn oil, sunflower oil, vegetable oil, margarine and butter can't do.

All of this information simply confirms what we have known for generatic

Bertolli olive oil is

And, although th Medical Association faile tion it, you should know also delicious.

For more inform the health benefits of oliv to the Bertolli Nutrition (P.O. Box 2617Y, Secaucus 07096-2617.

BERTOLLI

Eat well. Live long. Be happy.™

EXHIBIT B

EXHIBIT C

For years, Bertolli has said olive oil can lower your cholesterol, blood pressure and blood sugar. Last week, medical science said we were right.

The February 2, 1990 issue of The Journal of The American Medical Association reported that monounsaturated oils like olive oil are healthier than other oils, margarine or butter.

The study, conducted in Italy, showed people who had the most olive oil in their diet had the lowest levels of blood cholesterol, blood pressure and blood sugar.

These findings support prior research in the United States that found monounsaturated oils, such as olive oil, can actually reduce the cholesterol, known as LDL, that is bad for you.

Yet they protect the cholesterol, known as HDL, that is good for you.

That's something corn oil, sunflower oil, vegetable oil, margarine and butter can't do.

All of this information simply confirms what we at Bertolli have known for generations.

Bertolli olive oil is healthier.

And, although the American Medical Association failed to mention it, you should know Bertolli is also delicious.

For more information about the health benefits of olive oil, write to the Bertolli Nutrition Center, P.O. Box 2617Y, Secaucus, NJ 07096-2617.

BERTOLLI

Eat well. Live long. Be happy.

EXHIBIT C

EXHIBIT D

When it comes to affairs of the heart, no one knows more than Bertolli.

It's February 14. Everyone's thinking about hearts today.

At Bertolli, however, we're thinking about hearts every day of the year.

Because Bertolli olive oil is healthier for your heart than other oils, butter or margarine. It can actually lower cholesterol, blood pressure and blood sugar.

So, to keep the ones you love as healthy as they can be, cut out the 50¢ coupon and start cooking with Bertolli olive oil.

If you've never cooked with Bertolli – or you'd like to try some new ways to use our olive oil – mail the recipe book coupon to us.

We'll send you a collection of Bertolli recipes. Along with our heartfelt thanks.

And one more thing. Happy Valentine's Day.

BERTOLLI
Eat well. Live long. Be happy.

FREE! The Bertolli Light and Healthy Recipe Booklet.
Over 30 easy-to-fix recipes that are low in cholesterol and high in flavor. Facts on olive oil, cholesterol and healthful eating, too. A $2.95 value yours for just a little money, saving coupons for Bertolli olive oils.

Send your $2.00 check or money order (for postage and handling) to Bertolli Recipes, P.O. Box 408, Park Ridge, NJ 07656.

Name_____

Address_____

City_____ State_____ Zip_____

Please allow 6-8 weeks for delivery. Offer good while supplies last.

Homemakers Coupon Expires 4/30/90

SAVE 50¢

on any flavor of Bertolli olive oil 8.5 oz. or larger (not valid on trial size).

To Dealer: We will reimburse you for the face value plus 8¢ handling when you redeem this coupon at retail on the purchase of the item specified. Any other use constitutes fraud. Coupon void if taxed, prohibited or restricted by law. Cash value 1/100¢. Limit one coupon per purchase. To redeem this coupon, send to Bertolli USA, P.O. Box 4357, Clinton, Iowa 52734.

110516

BERTOLLI
Eat well. Live long. Be happy.

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and respondent having been furnished thereafter with a copy of a draft of complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondent with violation of the Federal Trade Commission Act; and

The respondent, its attorneys, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by respondent 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 respondent that the law has been violated as alleged in such complaint, and waivers and other provisions as required by the Commission's Rules.

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondent has violated the said Act, 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 Bertolli USA, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at: 1 Harmon Plaza, P.O. Box 2617, Secaucus, New Jersey.

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

ORDER

For purposes of this order the "*Trevisan Article*" means the study by Trevisan and others reported in the February 2, 1990, issue of the Journal of the American Medical Association titled Consumption of Olive Oil, Butter, and Vegetable Oils and Coronary Heart Disease Risk Factors.

I.

It is ordered, That respondent Bertolli USA, Inc., a corporation, its successors and assigns, and its officers, representatives, agents and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of any food product in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing, directly or by implication, contrary to fact, that medical science has established that:

A. Eating olive oil lowers blood pressure; or
B. Eating olive oil lowers blood sugar.

II.

It is further ordered, That respondent Bertolli USA, Inc., a corporation, its successors and assigns, and its officers, representatives, agents and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of any food product in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

A. Representing that the Trevisan Article reports that olive oil is healthier than other oils;

B. Representing that the findings of the Trevisan Article support prior research that found that monounsaturated oils, such as olive oil, reduce LDL cholesterol and protect HDL cholesterol; or

C. Representing that the Trevisan Article reports that study participants who had the most olive oil in their diets had the lowest levels of blood cholesterol.

III.

It is further ordered, That respondent Bertolli USA, Inc., a corporation, its successors and assigns, and its officers, representatives, agents and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of any food product in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing, directly or by implication, that:

A. Eating olive oil lowers cholesterol more than other cooking oils used in the home;

B. Eating olive oil lowers blood pressure or lowers blood sugar;

C. Bertolli olive oil is healthier for the heart than other cooking oils used in the home;

D. Any edible oil has the relative or absolute ability to cause or contribute to any health attribute or benefit; or

E. Any edible oil has a favorable impact on any physiologic function or risk factor for a disease, or any other health benefit;

unless at the time of making such representation respondent possesses and relies upon a reasonable basis consisting of competent and reliable scientific evidence that substantiates the representation; *provided, however,* that any such representation that is specifically permitted in labeling for such food product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990 will be deemed to have a reasonable basis as required by this paragraph. For any test, analysis, research, study, or other evidence to be "competent and reliable" for purposes of this order, such test, analysis, research, study, or other evidence must be conducted and evaluated in an objective manner by persons qualified to do so, using procedures

generally accepted by others in the profession or science to yield accurate and reliable results.

IV.

It is further ordered, That respondent Bertolli USA, Inc., a corporation, its successors and assigns, and its officers, representatives, agents and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of any food product in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from misrepresenting in any manner, directly or by implication, the contents, validity, conclusions, interpretations, purpose, or results of any study, test, or other scientific data.

V.

It is further ordered, That respondent Bertolli USA, Inc., its successors and assigns, shall, for three (3) years after the date of the last dissemination of the representation to which they pertain, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

A. All materials relied upon to substantiate any representation covered by this order;

B. All studies in scientific journals or other test reports that are referred to in any representation covered by this order; and

C. All test reports, studies, surveys, or other materials in its possession or control that contradict, qualify or call into question such representation or the basis upon which respondent relied for such representation.

VI.

It is further ordered, That respondent Bertolli USA, Inc., shall, within thirty (30) days after service upon it of this order, distribute a copy of the order to each of its operating divisions, to each of its

managerial employees, and to each of its officers, agents, representatives or employees engaged in the preparation or placement of advertising or other materials covered by this order and shall secure from each such person a signed statement acknowledging receipt of this order.

VII.

It is further ordered, That respondent Bertolli USA, Inc., shall notify the Commission at least thirty (30) days prior to any proposed change such as the 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.

VIII.

It is further ordered, That respondent Bertolli USA, Inc., shall, within sixty (60) days after service upon it of this order and at such other times as the Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which it has complied with the requirements of this order.

IN THE MATTER OF

CAMPBELL SOUP COMPANY

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF SECS. 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket 9223. Complaint, January 25, 1989--Decision, August 18, 1992

This consent order requires, among other things, a New Jersey-based company to disclose in future advertisements that directly or by implication mention heart disease -- in connection with soups containing significant amounts of sodium -- both the sodium content of a serving of such soup and the recommended maximum daily limit on sodium intake. Respondent also is prohibited from representing a connection between any soup and a reduction in the risk of heart disease, unless such representations are substantiated by competent and reliable scientific or medical evidence.

Appearances

For the Commission: *Lee Peeler* and *Nancy S. Warden.*

For the respondent: *S. William Livingston, Sandra L. Spear* and *Eugene I. Lambert, Covington & Burling*, Washington, D.C.

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended, and by virtue of the authority vested in it by said Act the Federal Trade Commission, having reason to believe that Campbell Soup Company, a corporation, ("Campbell" or "respondent") has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, alleges:

PARAGRAPH 1. Campbell is a New Jersey corporation, with its offices and principal place of business located at Campbell Place, Camden, New Jersey.

PAR. 2. Campbell produces, advertises, offers for sale, sells, and distributes canned soup products, which are foods as the term "food" is defined in Section 15 (b) of the Federal Trade Commission Act.

PAR. 3. Advertisements for Campbell's canned soup products have been disseminated by various means in or affecting commerce, including magazines distributed across state lines for the purpose of inducing the purchase of Campbell's soups by members of the public.

PAR. 4. The acts and practices alleged in this complaint constitute the maintenance of a substantial course of trade in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act.

PAR. 5. In the course and conduct of its business, and for the purpose of promoting the sale and distribution of its soups, respondent, as part of its "Soup is Good Food" advertising campaign, has disseminated, or caused the dissemination of, in a variety of national magazines an advertisement entitled "What's at the bottom of a bowl of Campbell's soup?," a copy of which is attached as Exhibit A.

PAR. 6. The advertisement described in paragraph five above contains the following statements, with emphasis in the original:

Did you know that most of Campbell's Soups are low in fat and cholesterol? For example, a serving of regular Chicken Noodle, or new Special Request with one-third less salt, is low in fat and has just 15 milligrams of cholesterol. And that's especially good to know, because research tells us that a diet low in fat and cholesterol may help reduce the risk of some forms of heart disease.

PAR. 7. In the advertisement described in paragraph five above, respondent has represented, and now represents, either directly or by implication, that:

a. Most of Campbell's soups are low in fat and cholesterol and, as part of a diet low in fat and cholesterol, may help reduce the risk of some forms of heart disease.

b. Campbell's Chicken Noodle is low in fat and has just 15 milligrams of cholesterol and, as part of a diet low in fat and cholesterol, may help reduce the risk of some forms of heart disease.

PAR. 8. In the advertisement described in paragraph five above respondent has failed to disclose that Campbell's soups are high in sodium and that diets high in sodium may increase the risk of heart disease. In light of the representations made these facts would be material to consumers in deciding to purchase Campbell's soups and the failure to disclose these facts is deceptive.

PAR. 9. In the advertisement described in paragraph five above, respondent has represented, and now represents, either directly or by implication, that most of its soups make a positive contribution to a diet that reduces the risk of heart disease.

PAR. 10. In the advertisement described in paragraph five above respondent represented and now represents that it possessed and relied on a reasonable basis for the representation set forth in paragraph nine at the time such representation was made.

PAR. 11. In truth and in fact, respondent did not possess and rely upon a reasonable basis for the representation set forth in paragraph nine at the time such representation was made. Therefore, the representation set forth in paragraph ten was and is false, misleading, or deceptive.

PAR. 12. Respondent's dissemination of the false and misleading representations as alleged in this complaint constitutes unfair or deceptive acts or practices in or affecting commerce in violation of Sections 5 (a) and 12 of the Federal Trade Commission Act.

Commissioner Machol not participating.

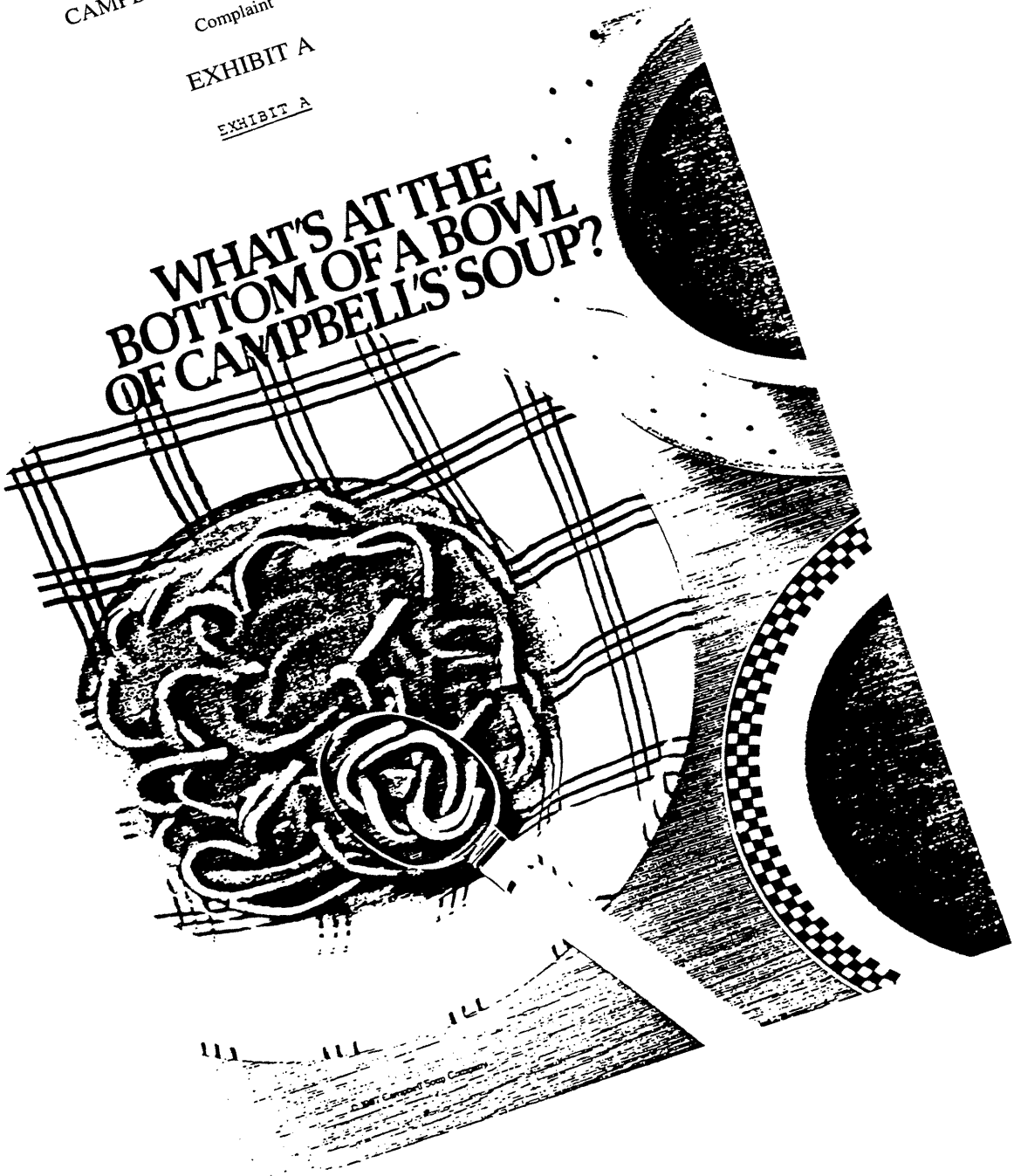
CAMPBELL SOUP COMPANY

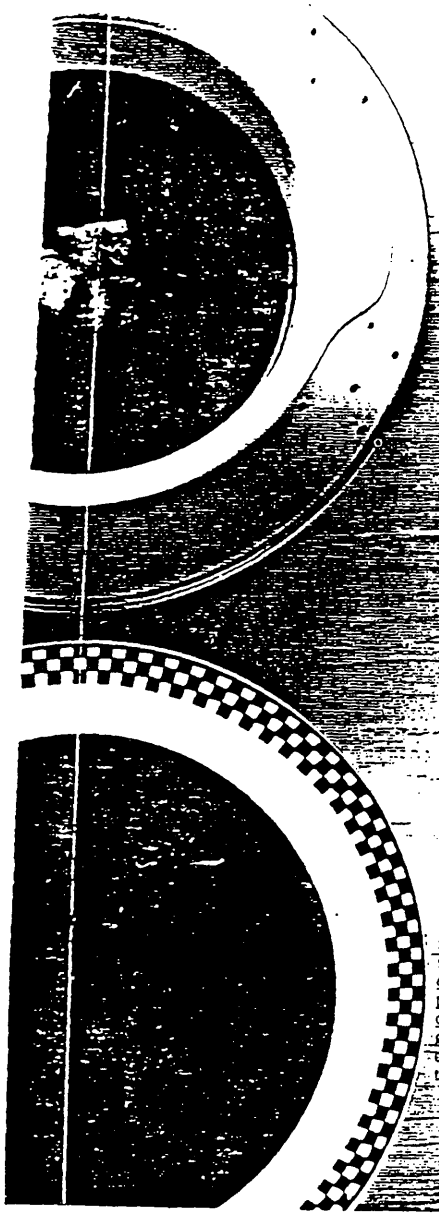
Complaint

EXHIBIT A

EXHIBIT A

788





There's a lot that's good for you at the bottom of a bowl of Campbell's Soup. And since eating right is just as important as exercise when it comes to looking and feeling better, why not stir up a bowl today?

FIBER.

When most people think of fiber, they automatically think of bran cereal. But you can also think of soup. Because some Campbell's Soups are a delicious source of fiber. In fact, a serving of one of our Bean or Pea Soups has as much fiber as a serving of many bran cereals. They're low in fat, too. Which is good news, since the National Cancer Institute says that a diet high in fiber and low in fat may help reduce the risk of some kinds of cancer.

LOW FAT and LOW CHOLESTEROL.

Did you know that most of Campbell's Soups are low in fat and cholesterol? For example, a serving of regular Chicken Noodle, or new Special Request, with one-third less salt, is low in fat and has just 15 milligrams of cholesterol. And that's especially good to know, because research tells us that a diet low in fat and cholesterol may help reduce the risk of some forms of heart disease.

CALCIUM.

When you prepare a can of Campbell's Tomato, Cream of Mushroom or Cream of Celery Soup with a full can of milk, you have more than just a delicious cream soup. You have a delicious source of calcium. In fact, one serving provides you with 10% of your daily requirement. And that's good for your body. Because calcium helps keep your bones and teeth strong.

AT THE BOTTOM OF IT ALL SOUP IS GOOD FOOD.

000636

DECISION AND ORDER

The Commission having heretofore issued its complaint charging the respondent named in the caption hereof with violation of Sections 5 and 12 of the Federal Trade Commission Act, as amended, and the respondent having been served with a copy of that complaint, together with a notice of contemplated relief; and

The respondent, its attorney, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondent of all the jurisdictional facts set forth in the complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondent 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 Secretary of the Commission having thereafter withdrawn this matter from adjudication in accordance with Section 3.25(c) of its Rules; and

The Commission having considered the matter 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 3.25(f) of its Rules, the Commission hereby makes the following jurisdictional findings and enters the following order:

1. Respondent Campbell Soup Company is a corporation organized, existing and doing business under and by virtue of the laws of the State of New Jersey, with its office and principal place of business located at Campbell Place, in the City of Camden, State of New Jersey.

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

ORDER

DEFINITIONS

For purposes of Part I, the term "*sodium disclosure amount*" shall mean:

1. 500 milligrams of sodium per eight ounce serving prior to the effective date of final regulations of the Food and Drug Administration implementing Section 403(r)(1) of the Federal Food, Drug, and Cosmetic Act, as amended by the Nutrition Labeling and Education Act of 1990; or

2. The disqualifying nutrient level of sodium per serving size or per 100 grams upon the effective date of final regulations of the Food and Drug Administration implementing Section 403(r)(1) of the Federal Food Drug and Cosmetic Act, as amended by the Nutrition Labeling and Education Act of 1990.

For purposes of Part I, the term "*recommended maximum daily limit of sodium intake*" shall mean:

i. The daily reference value or other daily intake limit established in an effective final regulation of the Food and Drug Administration; or

ii. In the absence of such a regulation, the daily intake limit of sodium advised by any one of the following three organizations: the National Academy of Sciences; the Surgeon General of the Public Health Service; and the American Heart Association.

I.

It is ordered, That Campbell Soup Company, a corporation, ("Campbell" or "respondent") its successors and assigns, its officers, agents, representatives and employees, directly or through any corporate or other device, in connection with the advertising, offering for sale, sale or distribution of any soup that contains more than the sodium disclosure amount, as defined above, in "commerce" as defined in the Federal Trade Commission Act, do forthwith cease and

desist in any advertisement that directly or by implication mentions heart disease in connection with the soup from failing to notify consumers of:

A. The sodium content of a serving of such soup in terms of the number of milligrams; and

B. The recommended maximum daily limit of sodium intake in terms of number of milligrams and the recommending organization.

For purposes of this Part, the statements required by subparagraphs A and B must appear in close proximity. In the event that the Food and Drug Administration does not have a final effective regulation as described in subparagraph (i) above and none of the three named organizations named in subparagraph (ii) above advises that daily sodium intake be limited to a specific maximum amount, subparagraph B of this Part shall not apply. *Provided, however*, that this Part shall not be deemed to apply to any representation approved for labeling (a) by applicable final regulations of the Food and Drug Administration implementing Section 403(r)(1) of the Federal Food, Drug, and Cosmetic Act, as amended by the Nutrition Labeling and Education Act of 1990, or (b) by the United States Department of Agriculture pursuant to, if applicable, Section 7 of the Federal Meat Inspection Act, as amended, or Section 8 of the Poultry Products Inspection Act, as amended.

II.

It is further ordered, That respondent in connection with the advertising, offering for sale, sale, or distribution of any soup in or affecting commerce, as the term "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing directly or by implication that there is a connection between soup or its composition and a reduction in the risk of heart disease, unless at the time of the dissemination of any such representation, respondent produces and relies upon a reasonable basis for the connection represented, consisting of competent and reliable scientific or medical evidence. *Provided, however*, that any such representation approved for labeling of any such soup (a) by

applicable final regulations of the Food and Drug Administration implementing Section 403(r)(1) of the Federal Food, Drug, and Cosmetic Act, as amended by the Nutrition Labeling and Education Act of 1990, or (b) by the United States Department of Agriculture pursuant to, if applicable, Section 7 of the Federal Meat Inspection Act, as amended, or Section 8 of the Poultry Products Inspection Act, as amended, will be deemed to have a reasonable basis as required by this Part.

III.

It is further ordered, That respondent shall distribute a copy of this order to each of its operating divisions and officers, agents, representatives, or employees engaged in the preparation and placement of advertisements or other such sale materials for any soup product.

IV.

It is further ordered, That respondent shall notify the Commission at least thirty (30) days prior to the effective date of any proposed change in the corporation which may affect compliance obligations arising out of this order, such as its dissolution, assignment, or sale, resulting in the emergence of a successor corporation, or the creation or dissolution of subsidiaries engaged in the advertising, offering for sale, sale or distribution of any soup product.

V.

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

SEPARATE STATEMENT OF COMMISSIONER MARY L. AZCUENAGA

I have voted to accept the settlement with the Campbell Soup Company and to issue the final consent order as modified from the version proposed for public comment. Although I would have preferred that the order, which applies to the advertising and marketing of soup, apply to a broader range of products, I accept the limitation to soup in the interest of settling the case. The proposed order may not apply expressly to Campbell food products other than soup, but it puts Campbell on notice that the Commission might consider claims similar to those challenged in this case deceptive for other food products as well. In other respects, the order has been improved to help cure the deception alleged in the Commission's complaint without unnecessarily restricting the communication of truthful information.

Although we do not have conclusive evidence on the question, the comments we received on the order as originally proposed lend weight to the view that when the order triggers a disclosure requirement regarding sodium content in soup, simply disclosing the number of milligrams of sodium the soup contains might not provide enough information for consumers to put the claim in context from a dietary standpoint. We have now added a requirement that when the sodium content disclosure is triggered by the order, Campbell must also disclose the recommended maximum daily sodium intake. This requirement is appropriate because it will provide consumers with the information necessary to decide if the sodium content of the soup is consistent with their dietary goals, yet it is not unnecessarily pejorative and should not discourage truthful and useful fat and cholesterol claims. I also support the other changes in the order because they have been made to promote consistency with the Nutrition Labeling and Education Act as currently read by the Food and Drug Administration.

IN THE MATTER OF

NME HOSPITALS, INC.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-3397. Complaint, Aug. 24, 1992--Decision, Aug. 24, 1992

This consent order prohibits, among other things, the California-based hospital chain from misrepresenting the comparative efficacy, permanence, or likely complications of any reconstructive surgical procedure, and requires that the respondent base future claims about the efficacy, permanence, or likely complications of any surgical procedure used in the treatment of bowel-related diseases on competent and reliable scientific evidence that substantiates any such representation.

Appearances

For the Commission: *Michael A. Katz* and *Matthew Daynard.*

For the respondent: *John A. Meyers*, in-house counsel, Santa Monica, CA.

COMPLAINT

The Federal Trade Commission, having reason to believe that NME Hospitals, Inc., d/b/a Continent Ostomy Center ("NME Hospitals"), a corporation, hereinafter referred to as respondent or proposed respondent, has violated Section 5(a) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. 45(a), and that an action by it is in the public interest, issues this complaint and alleges that:

PARAGRAPH 1. Respondent NME Hospitals is a Delaware corporation with its principal office and place of business located at 2700 Colorado Avenue, Santa Monica, California. NME Hospitals owns and operates numerous hospitals, the following five of which contain individual Continent Ostomy Centers:

1. Century City Hospital, 2070 Century Park East, Los Angeles, California.

2. RHD Memorial Center, 7 Medical Parkway, Dallas, Texas.

3. Lutheran Medical Center, 2639 Miami Street, St. Louis, Missouri.

4. Palms of Pasadena Hospital, 1501 Pasadena Avenue South, St. Petersburg, Florida.

5. San Ramon Regional Medical Center, 6001 Norris Canyon Road, San Ramon, California.

PAR. 2. Respondent is engaged in offering for sale and the sale of services in connection with the treatment of ulcerative colitis and other bowel-related diseases. The services are made available to the public under the trade name, "Continent Ostomy Center."

PAR. 3. Since at least 1989, NME Hospitals has placed, or caused to be placed, advertisements in various periodicals that are in general circulation to the public, has mailed promotional materials to potential patients and has provided on site promotional materials regarding services offered by the Continent Ostomy Center.

PAR. 4. The acts and practices of respondent alleged in this complaint have been and are in or affecting commerce, as "commerce" is defined in the FTC Act.

PAR. 5. Respondent has disseminated or caused to be disseminated advertisements and promotional materials in the offering for sale of services in connection with the treatment of ulcerative colitis and other bowel-related diseases, including, but not necessarily limited to, the attached Exhibits A through D. These advertisements and promotional materials contain one or more of the following statements:

1. "The Barnett procedure is recognized as the most successful alternative to the conventional ileostomy." (Exhibit A)

2. "[The Barnett ileostomy has] [n]o slippage or leakage." (Exhibit B)

3. "Generally [with an ileoanal anastomosis] there is over a 50% chance that patients will require additional surgery." (Exhibit C)

4. "Indeed, our initial experience with the Kock pouch was attended by an operative revision rate of 40%." (Exhibit D)

5. "A review of 71 consecutive cases where [the Barnett] technique was employed revealed a valve slippage incidence of 2.8% and overall revision rate of 7%." (Exhibit D)

6. "[With the Barnett ileostomy] [t]he incidence of valve slippage has been reduced to approximately 3%." (Exhibit D)

7. "[With the Barnett ileostomy] [t]he necessity for reoperation has progressively declined." (Exhibit D)

PAR. 6. By and through the use of the statements referred to in paragraph five, and others of similar import and meaning not specifically set forth herein, respondent has represented, directly or by implication, that:

1. Respondent's surgical procedure -- the Barnett ileostomy -- for the treatment of ulcerative colitis and other bowel-related diseases is superior to other surgical procedures used as alternatives to a conventional ileostomy.

2. No patients who have received a Barnett ileostomy have experienced slippage or leakage problems.

3. For patients who receive an ileoanal anastomosis, there is over a 50 percent chance that they will need corrective surgery.

4. Respondent's clinical experience shows that the incidence of valve slippage and reoperation for the Barnett ileostomy is substantially less than that for the Kock procedure.

PAR 7. In truth and in fact:

1. Respondent's surgical procedure--the Barnett ileostomy--for the treatment of ulcerative colitis and other bowel-related diseases is not superior to other surgical procedures used as alternatives to a conventional ileostomy.

2. Some patients who have received a Barnett ileostomy have experienced slippage and leakage problems.

3. For patients who receive an ileoanal anastomosis, there is significantly less than a 50 percent chance that they will need corrective surgery.

4. Respondent's clinical experience does not show that the incidence of valve slippage and reoperation for the Barnett ileostomy is substantially less than that for the Kock procedure.

Therefore, the representations as set forth in paragraph six were and are false and misleading.

PAR. 8. Through the use of the statements in paragraph five, and others not specifically set forth herein of similar import and meaning, respondent has represented, directly or by implication, that at the time respondent made the representations set forth in paragraph six, respondent possessed and relied upon a reasonable basis for such representations.

PAR. 9. In truth and in fact, at the time respondent made the representations set forth in paragraph six, respondent did not possess and rely upon a reasonable basis for such representations. Therefore, the representation set forth in paragraph eight was and is false and misleading.

PAR. 10. The acts and practices of respondent alleged in this complaint constitute deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the FTC Act, 15 U.S.C. 45(a).

EXHIBIT A

CONTINENT OSTOMY CENTER

AT PALMS OF PASADENA HOSPITAL

April 26, 1990

Mr. Ros Percy
30-70 34th St, 3-B
Astoria, NY 11103

Dear Mr. Percy:

Enclosed is information on the BCIR, the appliance-free ileostomy.

Due to tremendous success of the Barnett Continent Ileostomy, our experience has taken us beyond the original cases written about in the enclosed materials. Now, over 500 patients are experiencing an improved quality of life with the Barnett procedure. Today, several distinguished surgeons perform the Barnett procedure at Continent Ostomy Centers throughout the United States. Dr. Barnett has assumed the responsibility of the National Medical Directorship of these centers.

The Barnett procedure is recognized as the most successful alternative to the conventional ileostomy. In a recent article in the Journal of the American College of Surgeons, it was stated that 98% of the patients that converted to the Barnett procedure "had experienced a significant improvement in the quality of their lives." In the last year, Barnett was honored for his continent ileostomy with awards of recognition from the American College of Surgeons, United Ostany Association, Southern Medical Association, and the National Foundation for Ileitis and Colitis.

The Continent Ostomy Centers are dedicated to providing inflammatory bowel disease patients information about this renowned procedure for surgical treatment. If, after reviewing the enclosed information, you have any questions or comments, please feel free to call us at 1-800-262-5051.

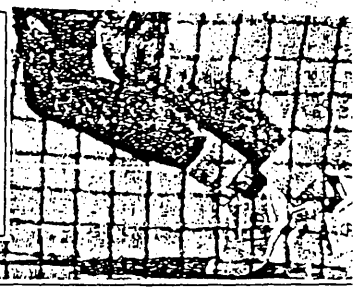
Sincerely,

Melanie Krapf
Counselor

Enclosures

EXHIBIT B

EXHIBIT B



"I wouldn't have played tennis before my Barnett ileostomy."

A few years ago, I had the Brooke ileostomy.

You know what that means. I had to wear an external pouch. It was difficult. Unsightly. Cumbersome. And at certain personal moments, more embarrassing than I could ever tell you.

I felt cut off from the rest of the world. I couldn't wear the clothes I wanted, or play sports the way I wanted. And, of course, it was nearly impossible to have the kind of personal relationships I wanted. The problems were mortifying—the terrible appearance, leakage and odors. I had never known that kind of depression before.

At The Century City Hospital Continent Ostomy Center, I learned about a new operation called the Barnett ileostomy. It completely replaced my earlier Brooke ileostomy. It can even replace the Kock Pouch, with its leakage and valve slippage problems.

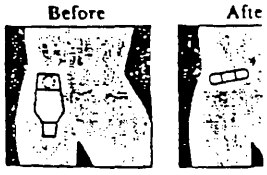
Now I have a new internal pouch using essentially my own body. No external pouch. No slippage or leakage. No odor. All I wear now is a small Band-Aid.® N to hide, because there is practically nothing t

It's changed my life so drastically I feel as I've been reborn. I wear what I want and c I want. And you won't believe what it's done personal life!

Find out about the new Barnett Continei tomy. It will change your life. Forever.

LOS ANGELES TIMES

Before Afte



THE CONTINENT OSTOMY CEI

Century City Hospital

2070 Century Park East

EXHIBIT C

EXHIBIT C

Alternative Procedures After Coloproctectomy

JEFFREY W. CLARKE, B.A., M.A., Ostomy Center Administrator

ABSTRACT: After removal of the colon, surgical options include: the conventional ileostomy, the ileoanal anastomosis, and the continent intestinal reservoir. Patients should be informed of their options and be allowed to make a knowledgeable decision. The conventional ileostomy is a comparatively elementary procedure which insures removal of the disease. A 18% rate of re-operation is associated with the conventional ileostomy. The ileoanal anastomosis is an unpredictable procedure. Approximately 43% of these patients remain incontinent. Its re-operative rate is about 50%. Recent technical improvements with the continent intestinal reservoir have made it a viable option. It insures removal of the disease. A 7% re-operative rate is identified with the continent intestinal reservoir.

INTRODUCTION

In patients with bowel disease such as ulcerative colitis, Crohn's colitis, or familial polyposis three possible alternatives exist for treatment after removal of the diseased colon. They are: the conventional ileostomy, the ileoanal anastomosis (with or without a pouch), and the continent intestinal reservoir. Each procedure has its benefits and disadvantages. The operation which is best for one patient may not be suitable for another.[1]

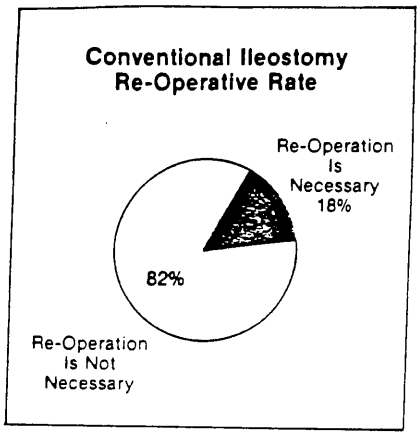
Thus, individual evaluation of each procedure allows one to choose the appropriate procedure on a case by case basis.

THE CONVENTIONAL ILEOSTOMY

Until recently proctocolectomy with the conventional ileostomy was the preferred procedure for patients with inflammatory bowel disease.[2,3] The procedure involves removal of the entire colon and rectum and construction of a protruding stoma on the abdominal wall. An external appliance is then needed to collect fecal discharge.

The Conventional Ileostomy (With Appliance)

The major advantage of the conventional ileostomy is that it is a comparatively elementary procedure which is readily available from a multiplicity of surgeons. Also, with this method usually all of the disease can be completely removed. A patient with a conventional ileostomy loos control of his feces and is reliant upon an extern appliance; this is considered a major disadvanta because of the various physical and psychologic problems associated with it.[4]



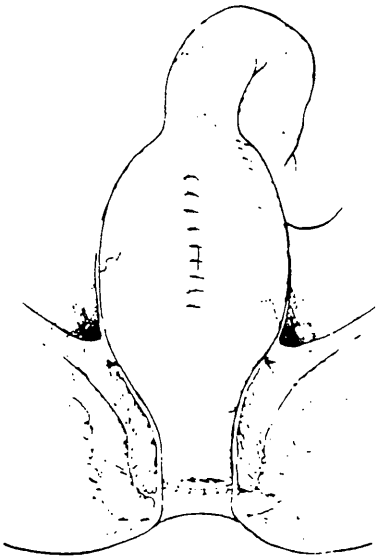
One indication of a successful procedure is the necessity for additional operations. Some individuals are under the misconception that the conventional ileostomy is without problems when in fact a substantial amount of these patients require additional surgery. The conventional ileostomy necessitates additional operations in approximately 18% of patients.[5]

THE ILEOANAL ANASTOMOSIS

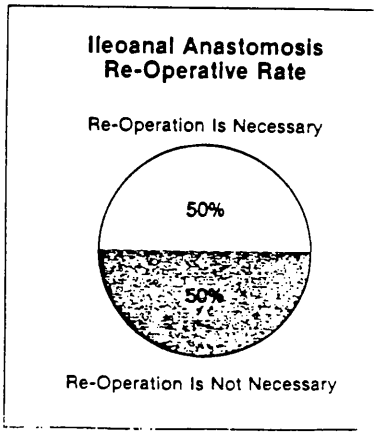
A person must approach the ileoanal anastomosis very carefully because the results are unpredictable.[6] The surgery consists of removal of the colon with preservation of the rectum's outer wall. A temporary conventional ileostomy is created and then, if the blood supply permits, the ileum is attached (preferably with an ileal pouch) to the anus. Weeks later, during a second surgery the conventional ileostomy is removed. Thus, patients without a rectum, patients with rectal cancer, perianal fistulas, poor sphincter function, or occupations that prohibit very frequent visits to the toilet are not candidates for this procedure.[7] Patients with Crohn's disease are not candidates for this procedure.[8]

The obvious advantage to this procedure is that continence may be restored and somewhat normal defecation is permitted. Unfortunately, 43% of these patients experience incontinence.[9] The continent patients initially have averaged about

The Ileoanal Anastomosis



ten (10) fecal discharges per twenty four h period.[10] After about a year, they report five nine (5-9) stools per day.[11] Thus, medicatio required to slow the intestine and to rel perianal and anal pain. Because the outer rectu



retained there is always an increased chance for *reoccurrence* of the disease.[12] Also, because of nerve damage due to this surgery urinary incontinence and sexual dysfunction (impotence) are more common.[13, 14]

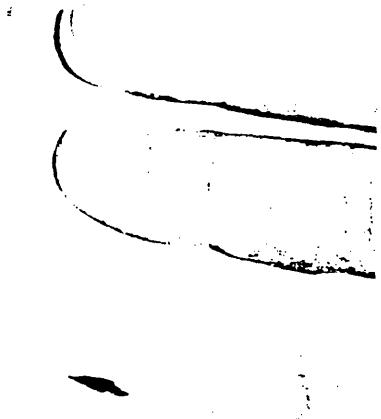
Re-operations are fairly common with the ileoanal anastomosis. Although results vary considerably, none are exceptional. Generally there is over a 50% chance that patients will require additional surgery.[15] However, because of the appeal of defecation from the anus some patients may acquiesce to these poor results and should be informed of this procedure.

THE CONTINENT INTESTINAL RESERVOIR

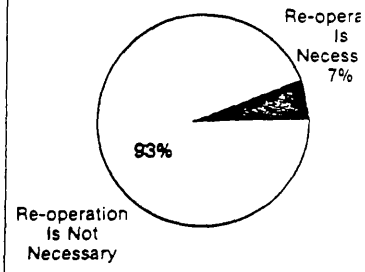
Recent technical advancements have made the continent intestinal reservoir a plausible procedure for most patients that must undergo a coloproctectomy.[16, 17] Additionally, this procedure enables patients with a conventional ileostomy the possibility to convert to a continent arrangement. Most authorities on the continent intestinal reservoir recognize that a select group of Crohn's patients are candidates for this procedure.[18] The procedure involves the removal of the c and rectum and the formation of a self se internal ileal pouch (preferably with an isop altic valve and intestinal collar). A flush sto placed just above the pubis.

The advantages to this procedure are aesthetic and psychological benefits of the ile procedure without the physiological diffic Continence is restored. The disease is rem and medication is no longer required.[21] To re the stool the patient induces a 30 Fr. intu catheter into the stoma about two or three per day.[22]

The Continent Intestinal Reservoir



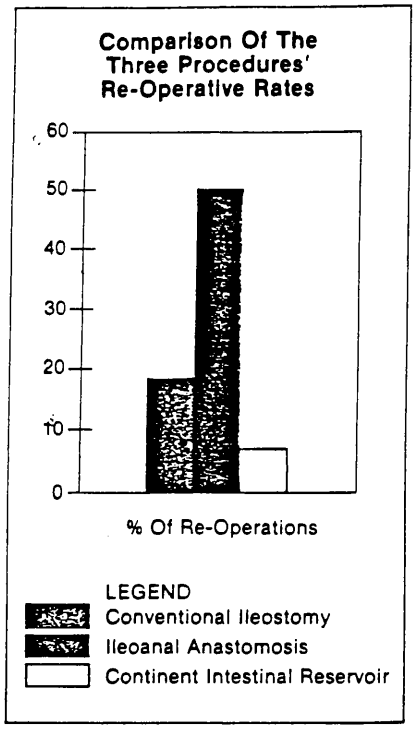
Continent Intestinal Reservoi Re-Operative Rate



The re-operative rate for this proced about 7%.[23, 24] The re-operations may be intensive than those associated with conventional ileostomy. This procedure is a ing because of its wide spectrum of candidat re-operative rate and continent design; patients should also be informed of alternative.

SUMMARY

In conclusion, if it is necessary to undergo surgery for the removal of the colon, alternatives to the conventional ileostomy are available. Factors such as the extent and type of the disease, rectal musculature, social and professional life-styles may eliminate some of the alternatives. Thus, patients should be informed of their options and be allowed to make a knowledgeable decision.



Jeffrey W. Clarke is the Administrator of the Continent Ostomy Center at Palms of Pasadena Hospital in St. Petersburg, Florida. The Center acts as a gastroenterologic educational institution and specializes in the treatment of bowel disease. Author of numerous papers, Clarke is an active member of both the United Ostomy Association and the National Foundation of Ileitis and Colitis.

Notes

1. Lavery, IC. "Alternative Procedures" Ostomy Quarterly 24, 16-18
2. Brooke BN. "The Management of an Ileostomy" Lancet 195 102-104
3. Emblem R., et al. "Operative Treatment of Ulcerative Co Conventional Proctectomy with Brook Ileostomy verses Muc Proctectomy with Ileoanal Anastomosis" Scand J Gastroen 1988, 23, 493-500
4. Barnett WO. "Current Experiences with the Continent Intes Reservoir" Surgery, Gynecology and Obstetrics, 1989, 168
5. Dozios, RR. Alternatives to Conventional Ileostomy. Book Medical Publishers, Inc 1985, 42
6. Cohen, Z. "Current Status of the Continent Ileostomy" Can Journal of Surgery, 1987, 5, 358
7. Fazio, VW. "Complications and Function of the Con Ileostomy" World Journal of Surgery, 1988, 12, 148
8. Mortensen, N. "Spout or Pouch? Alternatives for patients ileostomies" British Medical Journal, 1988, 296, 154
9. Pemberton, et al. "Quality of Life After Brooke Ileostomy an Pouch-Anal Anastomosis" Annals of Surgery, 1989, 205
10. Emblem, R., et al "Operative Treatment of Ulcerative C Conventional Proctectomy with Brooke Ileostomy verses M Proctectomy with Ileoanal Anastomosis" Scand J Gastroe 1988, 23, 497
11. Pemberton, JH. et al. "Quality of Life After Brooke Ileostom Ileal Pouch-Anal Anastomosis" Annals of Surgery, 1985 620-628
12. Lavery, IC. "Alternative Procedures" Ostomy Quarterly 24, 85
13. Pemberton, JH. "Quality of Life After Brooke Ileostomy an Pouch-Anal Anastomosis" Annals of Surgery, 1989, 20
14. Dozios, R. Alternatives to Conventional Ileostomy Book Medical Publishers, Inc. 1985, 348
15. Emblem, R., et al. "Operative Treatment of Ulcerative C Conventional Proctectomy with Brooke Ileostomy verses M Proctectomy with Ileoanal Anastomosis" Scand J Gastro 1988, 23 493-500
16. Barnett WO. "Modified Techniques for Improving the Co Ileostomy" American Surg., 1984, 49, 66-69
17. Zane C. "Current Status of the Continent Ileostomy" Ca Journal of Surgery, 1987, 5, 30
18. Bloom, RJ. "A Reappraisal of the Kock Continent Ileost Patients with Crohn's Disease" Surgery, Gyn. and Ob 1986, 162, 105
19. Barnett, WO. "Continent Intestinal Reservoir" Southern M Journal, 1987, 10, 1265
20. Fazio, VW. "Complications and Functions of the Co Ileostomy at the Cleveland Clinic" World Journal of S 1988, 12, 152
21. Lavery, IC. "Alternative Procedures" Ostomy Quarterly 24, 16-18
22. Barnett, WO., "Continent Intestinal Reservoirs. Th Experience", currently unpublished, 1-8
23. Barnett, WO. "Current Experiences with the Continent I Reservoir" Surgery, Gyn. and Obstetrics, 1989, 168, 1
24. Cohen, Z. "Current Status of the Continent Ileostomy" C Journal of Surgery, 1987, 30, 358

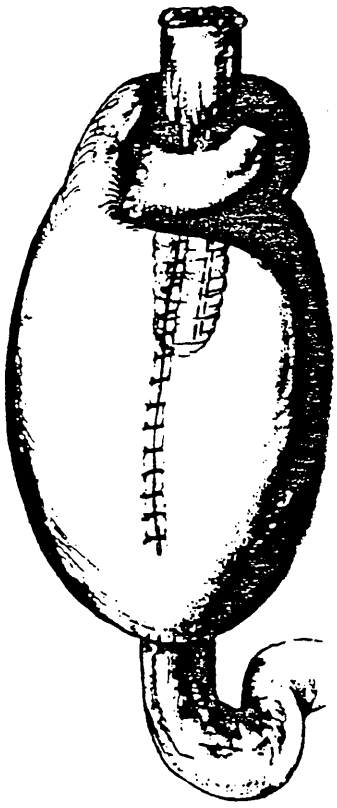
EXHIBIT D

EXHIBIT D

Continent Intestinal Reservoirs

A TEN YEAR EXPERIENCE

WILLIAM O. BARNETT, M.D., F.A.C.S.



CONTINENT OSTOMY CENTER

I. INTRODUCTION

II. CLINICAL MATERIAL - 351 CASES

III. EVOLUTION OF SURGICAL TECHNIQUES - BCIR I

IV. EVOLUTION OF SURGICAL TECHNIQUES - BCIR II

V. EVOLUTION OF SURGICAL TECHNIQUES - BCIR III

VI. CONCLUSIONS

I. INTRODUCTION

It was in 1969 that Dr. Niles Kock introduced the concept of the continent intestinal reservoir (CIR). Initial enthusiasm was high and many conventional ileostomy patients were thrilled by the prospect of a restored capacity to store intestinal waste and to control its discharge from the body. There is little question of the conclusion that a smoothly functioning CIR provides a better quality of life for most ileostomy patients. As experience with the procedure increased and larger series were reported, physicians became increasingly aware of the large number of CIR malfunctions requiring additional operative intervention. Valve slippage was probably the complication of greatest concern, being reported as 22% in one large series. Indeed, our initial experience with the Kock pouch was attended by an operative revision rate of 40%. Over the last 10 years we have maintained an effort to alter, correct and improve various technical details in CIR construction which held promise of improving results. An accumulated experience with 351 cases, all operated upon by a single surgeon, forms the basis of the subsequently detailed techniques, results and conclusions.

II. CLINICAL MATERIAL – 351 CASES

1. CONTINENT INTESTINAL RESERVOIR
A TEN YEAR EXPERIENCE

CIR TYPE	NO. CASES
KOCK	5
BCIR I	188
BCIR II	130
BCIR III	28
Total	351

2. SEX DISTRIBUTION

	NO. CASES
MALES	140 (40%)
FEMALES	211 (60%)
Total	351

3. AGE RANGE

AGE	NO. CASES
10 - 19	9
20 - 29	77
30 - 39	137
40 - 49	47
50 - 59	71
60 - 69	10
Total	351

4. CIR CONSTRUCTION

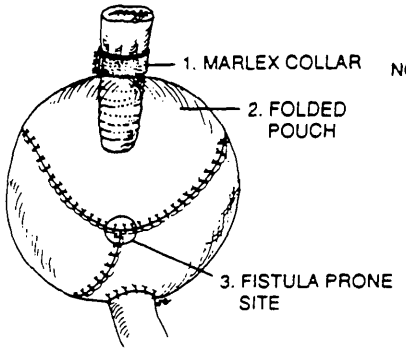
	NO. CASES
AT TIME OF COLOPROCTECTOMY	70 (20%)
CONVERTED FROM CONVENTIONAL ILEOSTOMY	281 (80%)
Total	351

5. INDICATIONS FOR COLOPROCTECTOMY

	NO. CASES
ULCERATIVE COLITIS	279 (79%)
FAMILIAL POLYPOSIS	30 (9%)
CROHN'S COLITIS	32 (10%)
OTHERS	10 (2%)
Total	351

III. EVOLUTION OF SURGICAL TECHNIQUES - BCIR I

BCIR I
1980-1986



RE OPERATIONS

NO. CASES	SLIPPED VALVE	POUCH AND VALVE PROBLEMS
170	3.5%	15%

DISADVANTAGES
1. VALVE FISTULA
2. POUCH FISTULA

In 1980 we began the use of a valve which incorporated an isoperistaltic direction, a Marlex collar, stapling of the valve and irritation of the serosal surface of the valve with the electrocautery. The valve slippage rate was reduced to 3.5% and the overall operative revision rate was 15%. Among the 26 cases requiring revision it was found that valve fistula, valve slippage and pouch fistula were responsible for 80% of these cases.

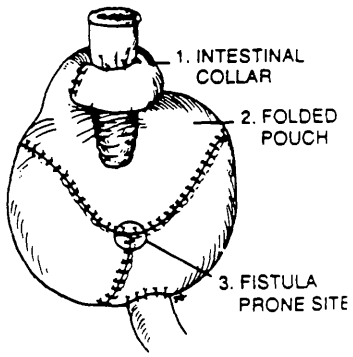
IV. EVOLUTION OF SURGICAL TECHNIQUES - BCIR II

BCIR II
1986-1988

RE OPERATIONS

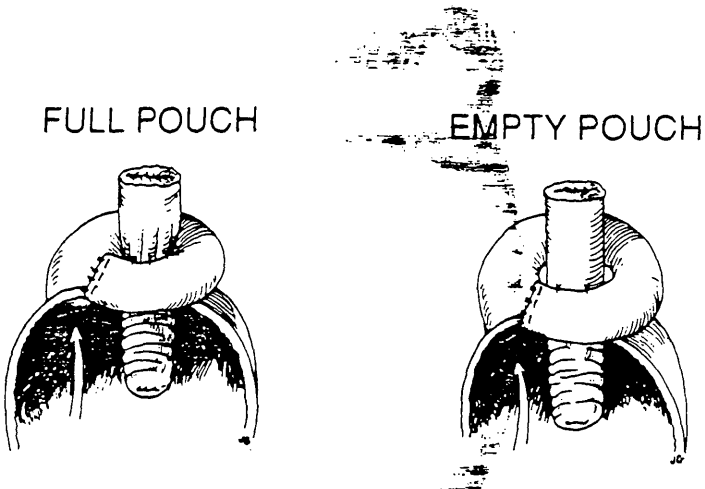
NO. CASES	SLIPPED VALVE	POUCH AND VALVE PROBLEMS
71	2.8%	7%

DISADVANTAGES
1. POUCH FISTULA



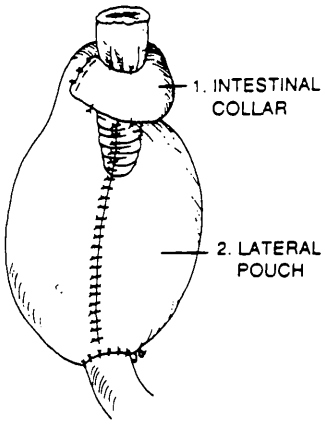
IV. EVOLUTION OF SURGICAL TECHNIQUES - BCIR II (cont'd.)

In order to eliminate valve erosion resulting from the Marlex collar we began using an intestinal collar in April of 1986. The intestinal collar provides a buttressing effect exerted against the mesenteric side of the valve where dessusception is usually initiated. This beneficial support is similar to that provided by the Marlex collar in lowering the incidence of valve slippage, but without the threat of erosion. In addition, the lumen of the intestinal collar communicates with the reservoir and allows gas and liquid to flow freely into the collar when pressure within the reservoir increases. Thus, the constricting action of the collar progressively increases as the tension within the reservoir rises. Fig (full pouch – empty pouch) The dynamics of these functions simulate the actions of the Nissen fundoplication in controlling reflux of gastric content into the esophagus. A review of 71 consecutive cases where this technique was employed revealed a valve slippage incidence of 2.8% and overall revision rate of 7%.



V. EVOLUTION OF SURGICAL TECHNIQUES - BCIR III

BCIR III



RE OPERATIONS

NO. CASES	SLIPPED VALVE	POUCH AND VALVE PROBLEMS
27	0%	3%

ADVANTAGES

1. NO VALVE EROSION FROM MARLEX
2. NO FISTULA PRONE SITE

The Kock pouch is characterized by the intersection of 3 suture lines at a point near the base of the valve. This is the usual site for pouch fistula formation, apparently because of poor healing at the suture line trifurcation. In January of 1988, we initiated the use of a lateral pouch which utilizes one straight suture line that completely encircles the pouch. The resulting pouch is longer and more narrow than the Kock pouch but has the same volume. Twenty seven such pouches have been fashioned over a 6 month period. One patient (3%) has required operative revision for valve malfunction. The follow up period is relatively short but results to date are encouraging.

VI. CONCLUSIONS

1. *The Continent Ileostomy was introduced by Kock in 1969 and represents a tremendous contribution to the quality of life for many ileostomy patients.*
2. *Storage capacity for intestinal waste and control of its discharge from the body are restored.*
3. *There is no need to wear a bag.*
4. *Skin problems are virtually non-existent.*
5. *There are no restrictions upon clothing (no bag bulge).*
6. *The ileal reservoir is emptied 2 to 3 times per 24 hours and this may be done with no difficulty in a public restroom.*
7. *The incidence of valve slippage has been reduced to approximately 3%.*
8. *Valve fistula has been controlled by the use of an intestinal collar rather than a Marlex collar.*
9. *Pouch fistula has been virtually eliminated by utilization of the lateral pouch.*
10. *The necessity for reoperation has progressively declined.*

CONTINENT OSTOMY CENTER
AT PALMS OF PASADENA HOSPITAL
1609 Pasadena Ave. South • 2A
St. Petersburg, FL 33707
1-800-282-5091
WILLIAM G. BARN TT, M.D., F.A.C.S., Director

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft of complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondent with violation of the Federal Trade Commission Act; and

The respondent, its attorney, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondent 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 respondent 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 respondent has violated the said Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such an 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 NME Hospitals, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 2700 Colorado Boulevard, Santa Monica, California.

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

ORDER

For purposes of this order, the following definition shall apply:

"*Competent and reliable scientific evidence*" shall mean tests, analysis, research, studies or other evidence conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted by others in the profession or science to yield accurate and reliable results.

I.

It is ordered, That respondent NME Hospitals, Inc., a corporation, its successors and assigns, and its officers, and respondent's agents, representatives, and employees, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, promotion, offering for sale or sale of services relating to the treatment of ulcerative colitis and other bowel-related diseases, do forthwith cease and desist from:

A. Representing in any manner, directly or by implication, that respondent's surgical procedure -- the Barnett ileostomy -- for the treatment of ulcerative colitis and other bowel-related diseases is superior to other surgical procedures used as alternatives to a conventional ileostomy, unless such is the case, or otherwise misrepresenting the efficacy of the Barnett ileostomy as compared to any other surgical procedure used in the treatment of bowel-related diseases.

B. Misrepresenting in any manner, directly or by implication, that patients who had received a Barnett ileostomy have not experienced slippage or leakage problems, or otherwise misrepresenting complications following the Barnett ileostomy procedure, or any other surgical procedure used in the treatment of bowel-related diseases.

C. Representing in any manner, directly or by implication, that there is over a 50 percent chance that patients who receive an ileoanal anastomosis will need corrective surgery, or otherwise misrepre-

senting the need for corrective surgery for any procedure used in the treatment of bowel-related diseases.

D. Misrepresenting in any manner, directly or by implication, that respondent's clinical experience shows that the incidence of valve slippage and reoperation for the Barnett ileostomy is substantially less than that for the surgical procedure commonly referred to as the "Kock procedure," or otherwise misrepresenting its clinical experience with complications following any other surgical procedure used in the treatment of bowel-related diseases.

E. Making any representation, directly or by implication, about the efficacy, permanence, or likely complications of any surgical procedure used in the treatment of bowel-related diseases unless, at the time of making any such representation, respondent possesses and relies upon competent and reliable scientific evidence that substantiates any such representation.

II.

It is ordered, That respondent NME Hospitals, Inc., a corporation, its successors and assigns, and its officers, and respondent's agents, representatives, and employees, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, promotion, offering for sale or sale of services relating to "reconstructive surgery," cease and desist from misrepresenting, directly or by implication, the efficacy, permanence, or likely complications of any of respondent's "reconstructive surgical procedures" as compared to the efficacy, permanence, or likely complications of any other surgical procedure. For purposes of this order provision, "reconstructive surgery" or "reconstructive surgical procedures" are those surgical procedures listed on Attachment A which is appended to this order.

III.

It is further ordered, That respondent shall maintain for a period of five (5) years after the date the representation was last made, and make available to the Federal Trade Commission upon request for inspection and copying, all materials possessed and relied upon to

substantiate any representation covered by this order, and all test reports, studies, or information in their possession or control that contradict, qualify or call into question any such representation.

IV.

It is further ordered, That, for a period of five (5) years after the date of entry of this order, respondent shall notify the Commission at least thirty (30) days prior to any proposed change in 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 respondent which may affect compliance obligations arising out of this order.

V.

It is further ordered, That respondent NME Hospitals, Inc., a corporation, and its successors or assigns, shall forthwith distribute a copy of this order to each of its officers, agents, representatives, independent contractors and employees who are engaged in the preparation and placement of advertisements or promotional materials, who communicate with patients or prospective patients, or who have any responsibilities with respect to the subject matter of this order; and, for a period of five (5) years from the date of entry of this order distribute same to all of respondent's future officers, agents, representatives, independent contractors and employees having said responsibilities.

VI.

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

ATTACHMENT A

RECONSTRUCTIVE SURGICAL PROCEDURES

ICD-9-CM PROCEDURE CODES	PROCEDURE
	NERVOUS SYSTEM
0204	BONE GRAFT TO SKULL
0205	INSERTION OF SKULL PLATE
0212	REPAIR OF CEREBAL MENINGES (INCLUDES GRAFT)
022	VENTRICULOSTOMY (INCLUDES VALVE/SHUNT INSERTION)
0231	VENTRICULAR SHUNT TO STRUCTURE IN HEAD AND NECK
0232	VENTRICULAR SHUNT TO CIRCULATORY SYSTEM
0233	VENTRICULAR SHUNT TO THORACIC CAVITY
0234	VENTRICULAR SHUNT TO ABDOMINAL CAVITY AND ORGANS
0235	VENTRICULAR SHUNT TO URINARY SYSTEM
0239	OPERATION TO ESTABLISH DRAINAGE OF VENTRICLE
0242	REPLACEMENT OF VENTRICULAR SHUNT
0293	IMPLANTATION OF INTRACRANIAL NEUROSTIMULATOR
0294	INSERTION/REPLACEMENT OF SKULL TONGS/HALO TRACTION DEVICE
0371	SPINAL SUBARACHNOID-PERITONEAL SHUNT
0372	SPINAL SUBARACHNOID-URETERAL SHUNT
0379	SHUNT OF SPINAL THECA
0390	INSERTION OF CATHETER INTO SPINAL CANAL FOR INFUSION OF THERAPEUTIC/PALLIATIVE SUBSTANCES
0393	INSERTION OR REPLACEMENT OF SPINAL NEUROSTIMULATOR
0395	SPINAL BLOOD PATCH
045	CRANIAL/PERIPHERAL NERVE GRAFT
0492	IMPLANTATION/REPLACEMENT OF PERIPHERAL NEUROSTIMULATOR
	ENDOCRINE SYSTEM
0694	THYROID TISSUE REIMPLANTATION
0695	PERATHYROID TISSUE REIMPLANTATION
0745	REIMPLANTATION OF ADRENAL TISSUE
0794	TRANSPLANTATION OF THYMUS
	EYE
0861	RECONSTRUCTION OF EYELID WITH SKIN FLAP/GRAFT
0862	RECONSTRUCTION OF EYELID WITH MUCOUS MEMBRANE FLAP/GRAFT
0863	RECONSTRUCTION OF EYELID WITH HAIR FOLLICLE GRAFT

0869	RECONSTRUCTION OF EYELID WITH FLAP/GRAFT
0944	INTUBATION OF NASOLACRIMAL DUCT
0983	CONJUNCTIVORHINDSTOMY WITH INSERTION OF TUBE/STENT
1041	REPAIR OF SYMBLEPHARON WITH FREE GRAFT
1042	RECONSTRUCTION OF CONJUNCTIVAL CUL-DE-SAC WITH FREE GRAFT
1044	FREE GRAFT TO CONJUNCTIVA
1132	EXCISION OF PTERYGIUM WITH CORNEAL GRAFT
1153	REPAIR OF CORNEAL LACERATION/WOUND WITH CONJUNCTIVAL FLAP
1160	CORNEAL TRANSPLANT, NOT OTHERWISE SPECIFIED
1162	LAMELLAR KERATOPLASTY
1164	PENETRATING KERATOPLASTY
1169	CORNEAL TRANSPLANT
1172	KERATOPHAKIA
1173	KERATOPROSTHESIS
1176	EPIKERATOPHAKIA
1285	REPAIR OF SCLERAL STAPHYLOMA WITH GRAFT
1287	SCLERAL REINFORCEMENT WITH GRAFT
1292	INJECTION INTO ANTERIOR CHAMBER
1371	INSERTION OF INTRAOCULAR LENS PROSTHESIS AT TIME OF CATARACT EXTRACTION (ONE-STAGE)
1370	INSERTION OF PSEUDOPHAKOS, UNSPECIFIED
1372	SECONDARY INSERTION OF INTRAOCULAR LENS PROSTHESIS
1441	SCLERAL BUCKLING WITH IMPLANT
1449	SCLERAL BUCKLING (with vitrectomy)
1475	INJECTION OF VITREOUS SUBSTITUTE
1631	REMOVAL OF OCULAR CONTENTS WITH SYNCHRONOUS IMPLANT
1641	EYEBALL ENUCLEATION WITH SYNCHRONOUS IMPLANT INTO TENON'S CAPSULE; ATTACHMENT OF MUSCLES
1642	EYEBALL ENUCLEATION WITH SYNCHRONOUS IMPLANT
1661	SECONDARY INSERTION OF OCULAR IMPLANT
1662	REVISION & REINSERTION OF OCULAR IMPLANT
1663	REVISION OF ENCULEATION SOCKET WITH GRAFT
1665	SECONDARY GRAFT TO EXENTERATION CAVITY

EAR

186	RECONSTRUCTION OF EXTERNAL AUDITORY CANAL
1871	CONSTRUCTION OF AURICLE OF EAR
1911	STAPEDECTOMY WITH INCUS REPLACEMENT
1921	REVISION OF STAPEDECTOMY WITH INCUS REPLACEMENT
1952	TYPE II TYMPANOPLASTY
1953	TYPE III TYMPANOPLASTY
1954	TYPE IV TYMPANOPLASTY
1955	TYPE V TYMPANOPLASTY

2001	MYRINGOTOMY WITH INSERTION OF TUBE
2061	FENESTRATION OF INNER EAR (INITIAL)
2071	ENDOLYMPHATIC SHUNT
208	OPERATIONS ON EUSTACHIAN TUBE (INCLUDES INSERTION OF CATHETER OR TUBE)
2095	IMPLANTATION OF ELECTROMAGNETIC HEARING DEVICE
2096	IMPLANTATION OF COCHLEAR PROSTHETIC DEVICE, NOT OTHERWISE SPECIFIED
2097	IMPLANTATION OR REPLACEMENT OF COCHLEAR PROSTHETIC DEVICE, SINGLE CHANNEL
2098	IMPLANTATION OR REPLACEMENT OF COCHLEAR PROSTHETIC DEVICE, MULTIPLE CHANNEL

NOSE, MOUTH, PHARYNX (1)

2107	CONTROL OF EPISTAXIS BY EXCISION OF NASAL MUCOSA & SKIN GRAFT OF SEPTUM/LATERAL NASAL WALL
2185	AUGMENTATION RHINOPLASTY
242	GINIVOPLASTY
245	ALVEOLOPLASTY
247	APPLICATION OF ORTHODONTIC APPLIANCE
2755	FULL-THICKNESS SKIN GRAFT TO LIP & MOUTH
2756	SKIN GRAFT TO LIP & MOUTH

(1) Excludes dental procedures

RESPIRATORY SYSTEM

3175	RECONSTRUCTION OF TRACHEA & CONSTRUCTION OF ARTIFICIAL LARYNX
3193	REPLACEMENT OF LARYNGEAL/TRACHEAL STENT
3485	IMPLANTATION OF DIAPHRAGMATIC PACEMAKER,

CARDIOVASCULAR (2)

3520	REPLACEMENT OF UNSPECIFIED HEART VALVE
3521	REPLACEMENT OF AORTIC VALVE WITH TISSUE GRAFT
3522	REPLACEMENT OF AORTIC VALVE
3523	REPLACEMENT OF MITRAL VALVE WITH TISSUE GRAFT
3524	REPLACEMENT OF MITRAL VALVE
3525	REPLACEMENT OF PULMONARY VALVE WITH TISSUE GRAFT
3526	REPLACEMENT OF PULMONARY VALVE
3527	REPLACEMENT OF TRICUSPID VALVE WITH TISSUE GRAFT
3528	REPLACEMENT OF TRICUSPID VALVE
3550	REPAIR OF UNSPECIFIED SEPTAL DEFECT OF HEART WITH PROSTHESIS

3551	REPAIR OF ATRIAL SEPTAL DEFECT WITH PROSTHESIS, OPEN TECHNIQUE
3552	REPAIR OF ATRIAL SEPTAT DEFECT WITH PROSTHESIS, CLOSED TECHNIQUE
3553	REPAIR OF VENTRICULAR SEPTAL DEFECT WITH PROSTHESIS
3554	REPAIR OF ENDOCARDIAL CUSHION DEFECT WITH PROSTHESIS
3560	REPAIR OF UNSPECIFIED SEPTAL DEFECT OF HEART WITH TISSUE GRAFT
3561	REPAIR OF ATRIAL SEPTAL DEFECT WITH TISSUE GRAFT
3562	REPAIR OF VENTRICULAR SEPTAL DEFECT WITH TISSUE GRAFT
3563	REPAIR OF ENDOCRAREAL CUSHION DEFECT WITH TISSUE GRAFT
3595	REVISION OF CORRECTIVE PROCEDURE ON HEART (INCLUDES REPLACEMENT OF HEART VALVE)
3603	OPEN CHEST CORONARY ANGIOPLASTY (WITH PATCH GRAFT)
3610	AORTOCORONARY BYPASS FOR HEART REVASCULARIZATION, NOT OTHERWISE SPECIFIED
3611	AORTOCORONRRY BYPASS OF ONE CORONARY ARTERY
3612	AORTOCORONARY BYPASS OF TWO CORONARY ARTERIES
3613	AORTOCORONARY BYPASS OF THREE CORONARY ARTERIES
3614	AORTOCORONARY BYPASS OF FOUR OR MORE CORONARY ARTERIES
3615	SINGLE INTERNAL MAMMARY-CORONARY ARTERY BYPASS
3616	DOUBLE INTERNAL MAMMARY-CORONARY ARTERY BYPASS
3619	OTHER BYPASS ANASTOMOSIS FOR HEART REVASCULARIZATION
362	HEART REVASCULARIZATION BY ARTERIAL IMPLANT
375	HEART TRANSPLANTATION
3761	IMPLANT OF PULSATION BALLOON
3762	IMPLANT OF HEART ASSIST SYSTEM
3763	REPLACEMENT AND REPAIR OF HEART ASSIST SYSTEM
3770	INITIAL INSERTION OF PACEMAKER LEAD (ELECTRODE), UNSPECIFIED
3771	INITIAL INSERTION OF TRANSVENOUS LEAD (ELECTRODE) INTO VENTRICLE
3772	INITIAL INSERTION OF TRANSVENOUS LEADS (ELECTRODES) INTO ATRIUM AND VENTRICLE
3773	INITIAL INSERTION OF TRANS VENOUS LEAD (ELECTRODE) INTO ATRIUM
3774	INSERTION OF REPLACEMENT OF EPICARDIAL LEAD (ELECTRODE) INTO EPICARDIUM
3776	REPLACEMENT OF TRANS VENOUS ATRIAL/VENTRICULAR LEAD(S) (ELECTRODE)
3778	INSERTION OF TEMPORARY TRANSVENOUS PACEMAKER SYSTEM

3780	INSERTION OF PERMANENT PACEMAKER, INITIAL OR REPLACEMENT, TYPE OF DEVICE UNSPECIFIED
3781	INITIAL INSERTION OF SINGLE-CHAMBER DEVICE, NOT SPECIFIED AS RATE RESPONSIVE (TO PHYSIOLOGIC STIMULI)
3782	INITIAL INSERTION OF SINGLE-CHAMBER DEVICE, RATE RESPONSIVE
3783	INITIAL INSERTION OF DUAL-CHAMBER DEVICE
3785	REPLACEMENT OF ANY TYPE OF PACEMAKER DEVICE WITH SINGLE-CHAMBER DEVICE, NOT SPECIFIED AS RATE RESPONSIVE
3786	REPLACEMENT OF ANY TYPE OF PACEMAKER DEVICE WITH SINGLE-CHAMBER DEVICE, RATE RESPONSIVE
3787	REPLACEMENT OF ANY TYPE PACEMAKER DEVICE WITH DUAL-CHAMBER DEVICE
3794	IMPLANTATION/REPLACEMENT OF AUTOMATIC CARDIOVERTER/DEFIBRILLATOR, TOTAL SYSTEM (AICD)
3795	IMPLANTATION OF AUTOMATIC CARDIOVERTER/DEFIBRILLATOR LEAD(S) ONLY
3796	IMPLANTATION OF AUTOMATIC CARDIOVERTER/DEFIBRILLATOR PULSE GENERATOR ONLY
3797	REPLACEMENT OF AUTOMATIC CARDIOVERTER/DEFIBRILLATOR LEAD(S) ONLY
3798	REPLACEMENT OF AUTOMATIC CARDIOVERTER/DEFIBRILLATOR PULSE GENERATOR ONLY
3840	RESECTION OF VESSEL WITH REPLACEMENT, UNSPECIFIED SITE
3841	RESECTION OF VESSEL WITH REPLACEMENT, INTRACRANIAL VESSEL
3842	RESECTION OF VESSEL WITH REPLACEMENT, VESSEL OF HEAD & NECK
3843	RESECTION OF VESSEL WITH REPLACEMENT, UPPER LIMB VESSEL
3844	RESECTION OF VESSEL WITH REPLACEMENT, ABDOMINAL AORTA
3845	RESECTION OF VESSEL WITH REPLACEMENT, THORACIC VESSEL (AORTA)
3846	RESECTION OF VESSEL WITH REPLACEMENT, ABDOMINAL ARTERY
3847	RESECTION OF VESSEL WITH REPLACEMENT, ABDOMINAL VEIN
3848	RESECTION OF VESSEL WITH REPLACEMENT, LOWER LIMB ARTERY
3849	RESECTION OF VESSEL WITH REPLACEMENT, LOWER LIMB VEIN
387	INTERRUPTION OF THE VENA CAVA (INCLUDES WITH IMPLANT OR SIEVE)
3895	VENOUS CATHETERIZATION FOR RENAL DIALYSIS

3956 REPAIR OF BLOOD VESSEL WITH TISSUE PATCH GRAFT
3957 REPAIR OF BLOOD VESSEL WITH SYNTHETIC PATCH GRAFT
3958 REPAIR OF BLOOD VESSEL WITH UNSPECIFIED TYPE OF PATCH GRAFT
3964 INTRAOPERATIVE CARDIAC PACEMAKER
398 OPERATIONS OF CARTOD BODY AND OTHER VASCULAR BODIES
3993 INSERTION OF VESSEL-TO-VESSEL CANNULA

(2) Does not include specialized pediatric cardiovascular procedures (not performed at any hospital owned by NME Hospitals, Inc.)

HEMIC/LYMPHATIC SYSTEM

4061 CANNULATION OF THORACIC DUCT
4100 BONE MARROW TRANSPLANT, NOT OTHERWISE SPECIFIED
4101 AUTOLOGOUS BONE MARROW TRANSPLANT
4102 ALLOGENEIC BONE MARROW TRANSPLANT WITH PURGING
4103 ALLOGENEIC PONE MARROW TRANSPLANT WITHOUT PURGING
4194 TRANSPLANTATION OF SPLEEN

DIGESTIVE SYSTEM (3)

4281 INSERTION - PERMANENT TUBE INTO ESOPHAGUS
4287 GRAFT OF ESOPHAGUS
4311 PERCUTANEOUS (ENDOSCOPIC) GASTROSTOMY (PEG)
4493 INSERTION OF GASTRIC BUBBLE (BALLOON)
4522 CONTINENT ILEOSTOMY
4532 PERCUTAEOUS (ENDOSCOPIC) JEJUNOSTOMY (PEJ)
4610 COLOSTOMY, UNSPECIFIED
4612 PERMANENT MAGNETIC COLOSTOMY
4613 PERMANENT COLOSTOMY
4620 ILEOSTOMY, UNSPECIFIED
4621 TEMPORARY ILEOSTOMY
4992 INSERTION OF SUBCUTANEOUS ELECTRICAL ANAL STIMULATOR
5051 AUXILIARY LIVER TRANSPLANT
5059 LIVER TRANSPLANT
5143 INSERTION OF CHOLEDO CHOHEPATIC TUBE FOR DECOMPRESSION
5186 ENDOSCOPIC INSERTION OF NASOBILIARY DRAINAGE TUBE
5187 ENDOSCOPIC INSERTION OF STENT (TUBE) INTO BILE DUCT
5280 PANCREATIC TRANSPLANT, UNSPECIFIED
5281 REIMPLANTATION OF PANCREATIC TISSUE
5282 HOMOTRANSPLANT OF PANCREAS
5283 HETEROTRANSPLANT OF PANCREAS

5292	CANJULATION OF PANCREATIC DUCT
5297	ENDOSCOPIC INSERTION OF NASOPANCREATIC DRAINAGE TUBE
5303	UNILATERAL REPAIR OF DIRECT INGUINAL HERNIA WITH GRAFT/PROSTHESIS
5304	UNILATERAL REPAIR OF INDIRECT INGUINAL HERHIA WITH GRAFT/PROSTHESIS
5305	UNILATERAL REPAIR OF INGUINAL HERNIA WITH GRAFT/PROSTHESIS, UNSPECIFIED
5314	BILATERAL REPAIR OF DIRECT INGUINAL HERNIA WITH GRAFT/PROSTHESIS
5315	BILATERAL REPAIR OF INDIRECT INGUINAL HERHIA WITH GRAFT/PROSTHESIS
5316	BILATERAL REPAIR OF INGUINAL HERNIA, DIRECT&INDIRECT, WITH GRAFT/PROSTHESIS
5317	BILATERAL REPAIR OF INGUINAL HERNIA, WITH GRAFT/PROSTHESIS, UNSPECIFIED
5321	UNILATERAL REPAIR OF FEMORAL HERHIA WITH GRAFT/PROSTHESIS
5331	BILATERAL REPAIR OF FEMORAL HERHIA WITH GRAFT/PROSTHESIS
5341	REPAIR UMBILICAL HERNIA WITH PROSTHESIS
5361	INCISIONAL HERNIA REPAIR WITH PROSTHESIS
5369	REPAIR OF HERNIA OF ANTERIOR ABDOMINAL WALL WITH GRAFT/PROSTHESIS

(3) Excludes bilroths, bypasses, and anastomoses

URINARY SYSTEM

5561	RENAL AUTOTRANSPLANTATION
5569	KIDNEY TRANSPLANTATION
5597	IMPLANTATION/REPLACEMENT OF MECHANICAL KIDNEY
5692	IMPLANTATION OF ELECTRONIC URETERAL STIMULATOR
5693	REPLACEMENT OF ELECTRONIC URETERAL STIMULATOR
5794	INSERTION OF INDWELLING URINARY CATHETER
5795	REPLACEMENT OF INDWELLING URINARY CATHETER
5796	IMPLANTATION OF ELECTRONIC BLADDER STIMULATOR
5797	REPLACEMENT OF ELECTRONIC BLADDER STIMULATOR
5893	IMPLANTATION OF ARTIFICIAL URINARY SPHINCTER (AUS)
598	URETERAL CATHETERIZATION
5993	REPLACEMENT OF URETEROSTOMY TUBE
5994	REPLACEMENT OF CYSTOSTOMY TUBE

MALE GENITAL ORGANS

627	INSERTION OF TESTICULAR PROSTHESIS

6395 INSERTION OF VALVE IN VAS DEFERENS
6443 CONSTRUCTION OF PENIS
6494 FITTING OF EXTERNAL PROSTHESIS OF PENIS
6495 INSERTION OR REPLACEMENT OF INTERNAL NON-INFLATABLE PROSTHESIS OF PENIS
6497 INSERTION OR REPLACEMENT OF INTERNAL INFLATABLE PROSTHESIS OF PENIS

FEMALE GENITAL ORGANS

6693 IMPLANTATION/REPLACEMENT OF PROSTHESIS OF FALLOPIAN TUBE
697 INSERTION OF INTRAUTERINE CONTRACEPTIVE DEVICE
6991 INSERTION OF THERAPEUTIC DEVICE INTO UTERUS
6992 ARTIFICIAL INSEMINATION (INCLUDES INVITRO FERTILIZATION)

MUSCULOSKELETAL

7691 BONE GRAFT TO FACIAL BONE
7692 INSERTION SYNTHETIC IMPLANT IN FACIAL BONE
7800 BONE GRAFT TO UNSPECIFIED BONE
7801 BONE GRAFT TO SCAPULA/CLAVICLE/THORAX (RIBS/STERNUM)
7802 BONE GRAFT TO HUMERUS
7803 BONE GRAFT TO RADIUS/ULNA
7804 BONE GRAFT TO CARPALS/METACARPALS
7805 BONE GRAFT TO FEMUR
7806 BONE GRAFT TO PATELLA
7807 BONE GRAFT TO TIBIA/FIBULA
7808 BONE GRAFT TO TARSALS/METATARSALS
7809 BONE GRAFT TO SPECIFIED BONE, EXCEPT FACIAL BONE
7810 APPLICATION OF EXTERNAL FIXATION DEVICE, UNSPECIFIED BONE
7811 APPLICATION OF EXTERNAL FIXATION DEVICE, SCAPULA/CLAVICLE/THORAX (RIBS/STERNUM)
7812 APPLICATION OF EXTERNAL FIXATION DEVICE HUMERUS
7813 APPLICATION OF EXTERNAL FIXATION DEVICE, RADIUS/ULNA
7814 APPLICATION OF EXTERNAL FIXATION DEVICE, CARPALS/METACARPALS
7815 APPLICATION OF EXTERNAL FIXATION DEVICE, FEMUR
7816 APPLICATION OF EXTERNAL FIXATION DEVICE, PATELLA
7817 APPLICATION OF EXTERNAL FIXATION DEVICE, TIBIA/FIBULA
7818 APPLICATION OF EXTERNAL FIXATION DEVICE, TARSALS/METATARSALS
7819 APPLICATION OF EXTERNAL FIXATION DEVICE
7830 LIMB LENGTHENING, UNSPECIFIED BONE

7832	LIMB LENGTHENING, HUMERUS
7833	LIMB LENGTHENING, RADIUS/ULNA
7834	LIMB LENGTHENING, CARPALS/METACARPALS
7835	LIMB LENGTHENING, FEMUR
7837	LIMB LENGTHENING, TIBIA/FIBULA
7838	LIMB LENGTHENING, TARSALS/METATARSALS
7839	LIMB LENGTHENING
7850	INTERNAL FIXATION OF BONE WITHOUT FRACTURE REDUCTION, UNSPECIFIED SITE
7851	INTERNAL FIXATION OF BONE WITHOUT FRACTURE REDUCTION, SCAPULA/CLAVICLE/THORAX (RIBS/STERNUM)
7852	INTERNAL FIXATION OF BONE WITHOUT FRACTURE REDUCTION, HUMERUS
7853	INTERNAL FIXATION OF BONE WITHOUT FRACTURE REDUCTION, RADIUS/ULNA
7854	INTERNAL FIXATION OF BONE WITHOUT FRACTURE REDUCTION, CARPALS/METACARPALS
7855	INTERNAL FIXATION OF BONE WITHOUT FRACTURE REDUCTION, FEMUR
7856	INTERNAL FIXATION OF BONE WITHOUT FRACTURE REDUCTION, PATELLA
7857	INTERNAL FIXATION OF BONE WITHOUT FRACTURE REDUCTION, TIBIA/FIBULA
7858	INTERNAL FIXATION OF BONE WITHOUT FRACTURE REDUCTION, TARSALS/METATARSALS
7859	INTERNAL FIXATION OF BONE WITHOUT FRACTURE REDUCTION, SPECIFIC BONE, EXCEPT FACIAL BONE
7890	INSERTION OF BONE GROWTH STIMULATOR INTO UNSPECIED BONE
7891	INSERTION OF BONE GROWTH STIMULATOR INTO SCAPULA/CLAVICLE/THORAX (RIBS/STERNUM)
7892	INSERTION OF BONE GROWTH STIMULATOR INTO HUMERUS
7893	INSERTION OF BONE GROWTH STIMULATOR INTO RADIUS/ULNA
7894	INSERTION OF BONE GROWTH STIMULATOR INTO CARPALS/METACARPALS
7895	INSERTION OF BONE GROWTH STIMULATOR INTO FEMUR
7896	INSERTION OF BONE GROWTH STIMULATOR INTO PATELLA
7897	INSERTION OF BONE GROWTH STIMULATOR INTO TIBIA/FIBULA
7898	INSERTION OF BONE GROWTH STIMULATOR INTO TARSALS/METATARSALS
7899	INSERTION OF BONE GROWTH STIMULATOR INTO SPECIFIED BONE, EXCEPT FACIAL BONE
7910	CLOSED REDUCTION OF FRACTURE WITH INTERNAL FIXATION OF UNSPECIFIED SITE

7911	CLOSED REDUCTION OF FRACTURE WITH INTERNAL FIXATION OF HUMERUS
7912	CLOSED REDUCTION OF FRACTURE WITH INTERNAL FIXATION OF RADIUS/ULNA
7913	CLOSED REDUCTION OF FRACTURE WITH INTERNAL FIXATION OF CARPALS/METACARPALS
7914	CLOSED REDUCTION OF FRACTURE WITH INTERNAL FIXATION OF PHALANGES OF HAND
7915	CLOSED REDUCTION OF FRACTURE WITH INTERNAL FIXATION OF FEMUR
7916	CLOSED REDUCTION OF FRACTURE WITH INTERNAL FIXATION OF TIBIA/FIBULA
7917	CLOSED REDUCTION OF FRACTURE WITH INTERNAL FIXATION OF TARSALS/METATARSALS
7918	CLOSED REDUCTION OF FRACTURE WITH INTERNAL FIXATION OF PHALANGES OF FOOT
7919	CLOSED REDUCTION OF FRACTURE WITH INTERNAL FIXATION OF SPECIFIED BONE
7930	OPEN REDUCTION OF FRACTURE WITH INTERNAL FIXATION OF UNSPECIFIED SITE
7931	OPEN REDUCTION OF FRACTURE WITH INTERNAL FIXATION OF HUMERUS
7932	OPEN REDUCTION OF FRACTURE WITH INTERNAL FIXATION OF RADIUS/ULNA
7934	OPEN REDUCTION OF FRACTURE WITH INTERNAL FIXATION OF PHALANGES OF HAND
7935	OPEN REDUCTION OF FRACTURE WITH INTERNAL FIXATION OF FEMUR
7936	OPEN REDUCTION OF FRACTURE WITH INTERNAL FIXATION OF TIBIA/FIBULA
7937	OPEN REDUCTION OF FRACTURE WITH INTERNAL FIXATION OF TARSALS/METATARSALS
7938	OPEN REDUCTION OF FRACTURE WITH INTERNAL FIXATION OF PHALANGES OF FOOT
7939	OPEN REDUCTION OF FRACTURE WITH INTERNAL FIXATION OF SPECIFIED BONE
8100	SPINAL FUSION, UNSPECIFIED
8101	ATLAS-AXIS SPINAL FUSION
8102	CERVICAL FUSION, ANTERIOR TECHNIQUE
8103	CERVICAL FUSION, POSTERIOR TECHNIQUE
8104	DORSAL/DORSOLUMBAR FUSION, ANTERIOR TECHNIQUE
8105	DORSAL/DORSOLUMBAR FUSION, POSTERIOR TECHNIQUE
8106	LUMBAR/LUMBOSACRAL FUSION, ANTERIOR TECHNIQUE
8107	LUMBAR/LUMBOSACRAL FUSION, LATERAL TRANSVERSE PROCESS TECHNIQUE
8108	LUMBAR/LUMBOSACRAL FUSION, POSTERIOR TECHNIQUE
8109	REFUSION OF SPINE, ANY LEVEL OR TECHNIQUE

8111	ANKLE FUSION
8112	TRIPLE ARTHRODESIS
8113	SUBTALAR FUSION
8114	MIDTARSAL FUSION
8115	TARSO/METATARSAL FUSION
8116	METATARSOPHALANGEAL FUSION
8117	FUSION OF FOOT
8120	ARTHRODESIS OF UNSPECIFIC JOINT
8121	ARTHRODESIS OF HIP
8122	ARTHRODESIS OF KNEE
8123	ARTHRODESIS OF SHOULDER
8124	ARTHRODESIS OF ELBOW
8125	CARPORADIAL FUSION
8126	METACARPOCARPAL FUSION
8127	METACARPOPHALANGEAL FUSION
8128	INTERPHALANGEAL FUSION
8129	ARTHRODESIS OF SPECIFIED JOINT
8151	TOTAL HIP REPLACEMENT
8152	PARTIAL HIP REPLACEMENT
8154	TOTAL KNEE REPLACEMENT
8156	TOTAL ANKLE REPLACEMENT
8157	REPLACEMENT OF JOINT OF FOOT & TOE
8171	ARTHROPLASTY OF METACARPALANGEAL & INTERPHALANGEAL JOINT WITH IMPLANT
8173	TOTAL WRIST REPLACEMENT
8174	ARTHROPLASTY OF CARPOCARPAL OR CARPOMETACARFAL JOINT WITH IMPLANT
8180	TOTAL SHOULDER REPLACEMENT
8181	PARTIAL SHOULDER REPLACEMENT
8184	TOTAL ELBOW REPLACEMENT
8261	SURGICAL CONSTRUCTION OF THUMB FROM PORTION OF INDEX FINGER
8269	RECONSTRUCTION OF THUMB
8272	PLASTIC OPERATION ON HAND WITH GRAFT OF MUSCLE OR FASCIA
8279	PLASTIC OPERATION ON HAND WITH GRAFT OR IMPLANT
8375	TENDON TRANSFER/TRANSPLANT
8377	MUSCLE TRANSFER/TRANSPLANT
8381	TENDON GRAFT
8382	MUSCLE/FASCIA GRAFT
8392	INSERTION/REPLACEMENT OF SKELETAL MUSCLE STIMULATOR
8440	IMPLANTATION/FITTING OF PROSTHETIC LIMB DEVICE, UNSPECIFIED
8441	FITTING OF PROSTHESIS OF UPPER ARM & SHOULDER
8442	FITTING OF PROSTHESIS OF LOWER ARM & HAND
8443	FITTING OF PROSTHESIS OF ARM, UNSPECIFIED

8444 IMPLANTATION OF PROSTHETIC DEVICE OF ARM
8445 FITTING OF PROSTHESIS ABOVE KNEE
8446 FITTING OF PROSTHESIS BELOW KNEE
8447 FITTING OF PROSTHESIS OF LEG, UNSPECIFIED
8448 IMPLANTATION OF PROSTHETIC DEVICE OF LEG

SKIN

8533 UNILATERAL SUBCUTANEOUS MAMMECTOMY WITH SYNCHRONOUS IMPLANT
8535 BILATERAL SUBCUTANEOUS MAMMECTOMY WITH SYNCHRONOUS IMPLANT
8550 AUGMENTATION MAMMOPLASTY, UNSPECIFIED
8551 UNILATERAL INJECTION INTO BREAST FOR AUGMENTATION
8552 BILATERAL INJECTION INTO BREAST FOR AUGMENTATION
8553 UNILATERAL BREAST IMPLANT (for Augmentation)
8554 BILATERAL BREAST IMPLANT (for Augmentation)
8570 TOTAL RECONSTRUCTION OF BREAST
8582 SPLIT-THICKNESS GRAFT TO BREAST
8583 FULL-THICKNESS GRAFT TO BREAST
8584 PEDICLE GRAFT TO BREAST
8585 MUSCLE FLAP GRAFT TO BREAST
8595 INSERTION OF BREAST TISSUE EXPANDER
8606 INSERTION OF TOTALLY IMPLANTABLE INFUSION PUMP
8607 INSERTION OF TOTALLY IMPLANTABLE VASCULAR ACCESS DEVICE (VAD)
8660 FREE SKIN GRAFT, UNSPECIFIED
8661 FULL-THICKNESS SKIN GRAFT TO HAND
8662 SKIN GRAFT TO HAND
8663 FULL-THICKNESS SKIN GRAFT
8664 HAIR TRANSPLANT
8665 HETEROGRAFT TO SKIN
8666 HOMOGRAFT TO SKIN
8669 SKIN GRAFT
8670 PEDICLE FLAP/GRAFT, UNSPECIFIED
8671 CUTTING & PREPARATION OF PEDICLE FLAP/GRAFT
8672 ADVANCEMENT OF PEDICLE GRAFT
8673 ATTACHMENT OF PEDICLE FLAP/GRAFT TO HAND
8674 ATTACHMENT OF PEDICLE FLAP/GRAFT
8693 INSERTION OF TISSUE EXPANDER

IN THE MATTER OF

THE WINNING COMBINATION, INC., ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF SECS. 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-3398. Complaint, Aug. 24, 1992--Decision, Aug. 24, 1992

This consent order prohibits, among other things, a California corporation and its officer from misrepresenting the efficacy of Essential Factors with Oxy-Energizer, a food supplement, or any similar product; from making certain representations unless they possess competent and reliable scientific evidence to substantiate the representations; and from representing that any such product has been accepted by the U.S. Government as effective for relieving fatigue or providing extra energy.

Appearances

For the Commission: *Michael Milgrom* and *Brinley H. Williams.*
For the respondents: *Pro se.*

COMPLAINT

The Federal Trade Commission, having reason to believe that The Winning Combination, Inc., a corporation, and Andrew Lessman, individually and as an officer of said corporation ("respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, alleges:

PARAGRAPH 1. Respondent The Winning Combination, Inc., is a corporation organized, existing and doing business under and by virtue of the laws of the State of California, with its office or principal place of business located at 1661 19th Street, Santa Monica, California.

Respondent Andrew Lessman is an officer of the corporate respondent named herein. He formulates, directs and controls the acts and practices of said corporate respondent, including the acts and

practices hereinafter set forth. His address is the same as that of said corporation.

PAR. 2. Respondents have advertised, offered for sale, sold or distributed food products, including Essential Factors with Oxy-Energizer (hereinafter referred to as "Essential Factors"), intended for human consumption.

PAR. 3. The acts and practices of respondents alleged in this complaint have been in or affecting commerce as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

PAR. 4. Respondents have disseminated or caused to be disseminated advertisements for Essential Factors, which is a "food" or "drug" within the meaning of Section 12 of the Federal Trade Commission Act, 15 U.S.C. 52. These advertisements have been disseminated by various means in or affecting commerce for the purpose of inducing the purchase of such product by members of the public.

PAR. 5. Respondents' advertisements include, but are not necessarily limited to the attached Exhibit A. These advertisements contain the following statements:

(A) Can you really get extra energy from a vitamin? This US-patented formula says yes. Oxy-Energizer™ is the first nutritional supplement ever to be granted a US patent. Supported by over 300 independent clinical trials, this anti-fatigue formula consistently demonstrates increases in stamina, endurance, recovery time, and cardiovascular function-results that simply can't be duplicated by any other nutritional supplement.

(B) The proof of patent #3,009,858. Oxy-Energizer contains a trade-secret blend of potassium, magnesium, and aspartic acid. People who take the formula feel more energetic throughout the day, especially at normal tired periods in mid-afternoon and early morning. Double-blind swimming, running, and aerobics studies consistently show improvements in stamina and endurance for subjects who regularly take the active ingredients in Oxy-Energizer. Taken daily, the formula can help you accomplish more at the office because you're not fighting tiredness. After work, you have more energy to enjoy sports or a late evening out. You may even feel less need for sleep (most test subjects do).

(C) People who take Essential Factors with Oxy-Energizer regularly report feeling more energetic. They spend extra productive hours at the desk, and still have energy for competitive sports.

(D) You only have about 16 waking hours each day to work, play, dine, make love.... Call today to order the formula triathletes, aerobics instructors, and top executives choose for extra energy and start living every hour to its fullest.

PAR. 6. Through the use of the statements contained in the advertisements referred to in paragraph five, including but not necessarily limited to the advertisement attached hereto as Exhibit A, respondents have represented, directly or by implication, that:

(A) Competent and reliable scientific tests have established that Essential Factors prevents fatigue and tiredness;

(B) Competent and reliable scientific tests have established that Essential Factors provides energy, stamina and endurance beyond its caloric value; and

(C) The United States Government has accepted the active ingredient in Essential Factors as effective for relieving fatigue and providing extra energy.

PAR. 7. In truth and in fact:

(A) It has not been established by competent and reliable scientific tests that Essential Factors prevents fatigue and tiredness;

(B) It has not been established by competent and reliable scientific tests that Essential Factors provides energy, stamina or endurance beyond its caloric value; and

(C) The United States Government has not accepted the active ingredient in Essential Factors to be effective for relieving fatigue and providing extra energy.

Therefore, the representations set forth in paragraph six were and are false and misleading.

PAR. 8. Through the use of the statements referred to in paragraph five, and others in advertisements and promotional materials not specifically set forth herein, respondents have represented, directly or by implication, that:

(A) Consumption of Essential Factors can prevent fatigue and tiredness; and

(B) Consumption of Essential Factors provides energy beyond its caloric value.

PAR. 9. Through the use of the statements set forth in paragraph five, and others not specifically set forth herein, respondents have represented, directly or by implication, that at the time they made the representations set forth in paragraph eight, respondents possessed and relied upon a reasonable basis, consisting of competent and reliable scientific evidence, for each such representation.

PAR. 10. In truth and in fact, at the time respondents made the representations set forth in paragraph eight, they did not possess and rely upon a reasonable basis, consisting of competent and reliable scientific evidence, for making each such representation. Therefore, respondents' representation as set forth in paragraph nine was and is false and misleading.

PAR. 11. The acts and practices of respondents as alleged in this complaint, and the placement in the hands of others of the means and instrumentalities by and through which others may have used said acts and practices, constitute unfair or deceptive acts or practices in or affecting commerce, and the dissemination of false advertisements, in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

EXHIBIT A

C-3398

New

Can you really get extra energy from a vitamin?

This US-patented formula says yes.

Oxy-Energizer™ is the first nutritional supplement ever to be granted a US patent. Supported by over 300 independent clinical trials, this anti-fatigue formula consistently demonstrates increases in stamina, endurance, recovery time, and cardiovascular function—results that simply can't be duplicated by any other nutritional supplement.

Once provided only to professional athletes like Kathy Smith (see box), Essential Factors™ with the patented Oxy-Energizer is now available through The Sharper Image. This formula contains all the vitamins and minerals you require, in the specific amounts and proportions recommended for maximum effectiveness.

People who take Essential Factors with Oxy-Energizer regularly report feeling more energetic. They spend extra productive hours at the desk— and still have energy for competitive sports.

The proof of patent #3,009,858.

Oxy-Energizer contains a trade-secret blend of potassium, magnesium, and aspartic acid. People who take the formula feel more energetic throughout the day, especially at normal tired periods in mid-afternoon and early morning.

Double-blind swimming, running, and aerobics studies consistently show improvements in stamina and endurance for subjects who regularly take the active ingredients in Oxy-Energizer. Taken daily, the formula can help you accomplish more at the office because you're not fighting tiredness. After work, you have more energy to enjoy sports or a late evening out. You may even feel less need for sleep (most test subjects do).

In a class beyond any ordinary vitamin.

Because vitamins and minerals amplify the effects of Oxy-Energizer, the manufacturer combines the energy formula with the most potent nutritional supplement you can buy. Essential Factors is the only supplement derived completely from hypoallergenic, contaminant-free, natural sources—the rarest and most expensive ingredients available. The vitamin C, for example, comes from calcium ascorbate (which doesn't cause stomach discomfort like commonly used ascorbic acid). The formula contains all the lipotropics, or "fat burners," which help you metabolize body fat. Powerful anti-oxidants such as germanium sesquioxide, beta-carotene, and selenium are also added to help support the immune system.

Nutrients are absorbed, not flushed away.

Vitamins and minerals can only be absorbed in the first part of the digestive system, just past the stomach. In order to be utilized, a supplement must fully dissolve quickly prior to leaving this small area.

Most multi-vitamins are made by "glueing" together and compressing bits of nutrient matter. Researchers and radiologists consistently observe that these tablets *do not dissolve in time to be absorbed*. The binders, cellulose, and glazes prevent your body from breaking down the tablets. And the sudden flash of heat produced in the 50,000 psi tableting process actually destroys many nutrients —the same way overcooking leaches nutrition from food.

Essential Factors with Oxy-Energizer begins with the freshest ingredients, purchased in small amounts (not bulk materials that lose potency while they sit in warehouses). Ingredients are micro-granulated™ into an extra-fine pH-balanced powder and inserted into capsules in a 100% heat-free process. The gelatin capsule dissolves quickly in the stomach to immediately release the nutrients at the exact time for maximum absorption (it also makes them easier to swallow than tablets).

Even the pharmaceutical-quality packaging is unique. In the final step of production, nine filled capsules are immediately sealed in each Perma-fresh packet. Made of space-age foil mylar, these packages are impervious to light, moisture, and oxygen—forces which break down potency. Packets are then sealed in an airtight plastic container for an extra measure of protection. Each capsule you take is as fresh as on the day it was produced.

Your daily energizer.

Simply take one packet a day, preferably with breakfast or lunch. The convenient foil packets slip easily into your briefcase, purse, or overnight bag—so you never forget to take your vitamins. The two-month supply (60 packets) works out to about $1.25 per day—about the price of coffee and a doughnut. Or order the 120-day supply (great for couples) and save even more.

This formula contains no milk, soy, yeast, sodium, starch, fats, oils, emulsifiers, waxes, allergens, animal products, artificial flavors or colors, or preservatives. *It is the only additive-free complete nutritional supplement you can buy.*

You only have about 16 waking hours each day to work, play, dine, make love .... Call today to order the formula triathletes, aerobics instructors, and top executives choose for extra energy—and start living every hour to its fullest.

■ **Essential Factors with Oxy-Energizer**
60-day Supply
#JWY600 $79 (4.00)
120-day Supply
#JWY601 $149 (5.50)

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 Cleveland 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; 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 Act, 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 The Winning Combination, Inc., is a corporation organized, existing and doing business under and by virtue of the laws of the State of California, with its office and principal place of business located at 1661 19th Street, Santa Monica, California.

Respondent Andrew Lessman is an officer of the corporate respondent named herein. He formulates, directs and controls the acts and practices of said corporate respondent, including the acts and practices hereinafter set forth. 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 respondent, and the proceeding is in the public interest.

ORDER

I.

It is ordered, That respondents The Winning Combination, Inc., a corporation, and Andrew Lessman, individually and as an officer of said corporation, their successors and assigns, and their officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of the food supplement Essential Factors with Oxy-Energizer, or any other product of similar composition, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from misrepresenting, directly or by implication:

A. That consumption of such product has been scientifically proven to prevent fatigue and tiredness;

B. That consumption of such product has been scientifically proven to provide energy, stamina or endurance beyond its caloric value; and

C. That such product has been accepted by the United States Government, or any agency or division thereof, as effective for relieving fatigue or providing extra energy.

II.

It is further ordered, That respondents The Winning Combination, Inc., a corporation, and Andrew Lessman, individually and as an officer of said corporation, their successors and assigns, and their officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of the food supplement Essential Factors with Oxy-Energizer or any other health-

related service or product in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from misrepresenting the existence, contents, validity, results, conclusions or interpretations of any test or study.

III.

It is further ordered, That respondents The Winning Combination, Inc., a corporation, and Andrew Lessman, individually and as an officer of said corporation, their successors and assigns, and their officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of any product in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing, directly or by implication, that:

A. Consumption of such product prevents fatigue and tiredness; or

B. Consumption of such product provides energy beyond its caloric value;

unless, at the time such representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation. For purposes of the order for any test, analysis, research, study or other evidence to be "competent and reliable," the test, analysis, research, study, or other evidence shall be conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the relevant profession to yield accurate and reliable results.

IV.

It is further ordered, That respondent The Winning Combination, Inc., a corporation, shall distribute a copy of this order to each of its operating divisions and to each officer and other person responsible for the preparation or review of advertising materials at the time this order becomes effective.

V.

It is further ordered, That, for a period of five (5) years from the date that any representation covered by this order is last disseminated, respondents The Winning Combination, Inc., a corporation, and Andrew Lessman, individually and as an officer of said corporation, shall maintain and, upon request, make available to the Commission for inspection and copying, all advertising, promotional and/or sales materials containing any representation covered in this order and all materials relied upon to substantiate such representation, and all test reports, studies, surveys, demonstrations or other evidence in respondents' possession or control that contradict, qualify or call into question either the representation or the basis upon which respondents relied in making the representation.

VI.

It is further ordered, That respondent Andrew Lessman shall promptly notify the Commission of the discontinuance of his present business or employment and of his affiliation with a new business or employment. In addition, for a period of ten (10) years from the service date of this order, he shall promptly notify the Commission of each affiliation with a new business or employment whose activities relate to the manufacture, sale or distribution of food or drug products, or of his affiliation with a new business or employment in which his own duties and responsibilities relate to the manufacture, advertising, offering for sale, sale or distribution of food or drug products. Each such notice shall include the respondent's new business address and a statement of the nature of the business or employment in which respondent is newly engaged, as well as a description of respondent's duties and responsibilities in connection with the business or employment. The expiration of the notice provision of this paragraph shall not affect any other obligation arising under this order.

VII.

It is further ordered, That respondent The Winning Combination, Inc., a corporation, shall:

A. Notify the Commission at least thirty (30) days prior to the effective date of 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 this order; and

B. Require, as a condition precedent to the closing of the sale or other disposition of 50 percent of the stock or assets of The Winning Combination, Inc., that the acquiring party file with the Commission, prior to the closing of such sale or other disposition, a written agreement to be bound by the provisions of this order.

VIII.

It is further ordered, That respondents The Winning Combination, Inc., and Andrew Lessman shall, within one hundred twenty (120) days after service 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, including, but not limited to, the names and addresses of all recipients of materials distributed pursuant to Part IV of this order.

IN THE MATTER OF

AUTOMATIC DATA PROCESSING, INC., ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-3399. Complaint, Aug. 27, 1992--Decision, Aug. 27, 1992

This consent order prohibits, among other things, a New Jersey-based company that sells computer software programs and its subsidiary from making misrepresentations concerning the advantages of financing purchases, and from selling or licensing software or printed materials the firm knows or should know are likely to be used to misrepresent comparative costs.

Appearances

For the Commission: *John F. Lefevre.*

For the respondents: *Resa T. Drasin*, in-house counsel, Roseland, N.J.

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, 15 U.S.C. 41 *et seq.* and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that Automatic Data Processing, Inc., a corporation, and ADP, Inc., a 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 public interest, hereby issues its complaint stating as follows:

PARAGRAPH 1. Respondents Automatic Data Processing, Inc., and ADP, Inc., are corporations organized, existing and doing business under and by virtue of the laws of the State of Delaware. Respondents have their principal office and place of business at One ADP Boulevard, Roseland, N.J.

Respondent Automatic Data Processing, Inc., dominates and controls the acts and practices of its wholly-owned subsidiary, ADP, Inc.

PAR. 2. Respondents are now engaged in, and for some time in the past have engaged in the business of computer software and hardware licensing, sales, and service, including the provision of computer software for use by motor vehicle dealers in providing financing and insurance services to consumers.

PAR. 3. Respondents maintain, and have maintained, a substantial course of business, including the acts and practices as hereinafter set forth, that are in or affect commerce as "commerce" is defined in the Federal Trade Commission Act.

PAR. 4. Respondents offer for license or sale and sell or license a package of computer software programs entitled "ADP Onsite Plus Finance & Insurance," designed to assist automobile dealers in completing finance and insurance contracts, disclosures, and other forms and in promoting the sale of finance and insurance services. The software allows the user to select from a menu of computer screens, each of which can be used to produce contracts, disclosures, or other forms or printouts.

PAR. 5. Respondents have included in their ADP Onsite Plus Finance & Insurance computer software package a screen entitled "Cash Comparison." The screen allows an automobile dealer to provide computer printouts to consumers. Typical and illustrative of such printouts, but not all-inclusive thereof, is the following:

****
========== CASH COMPARISON==========
17 SEP 1989

1) AMOUNT FINANCED..... $6,469.31
2) CONTRACT TERM.....36
3) APR 13%
4) SAVINGS AMOUNT.....$6,469.31
5) SAVINGS RATE 7.5%

YEAR	TOT. PMTS	TOT.INT. PD	PRIN. BAL	PRINCIPLE[1]	INT.	BALANCE
1	$ 434.14	$172.14	$6,203.51	$6,469.31	$100.47	$6,569.78
2	$2,628.84	$693.83	$4,268.29	$6,569.78	$510.03	$7,079.81
3	$2,628.84	$426.73	$2,066.18	$7,079.81	$549.62	$7,629.43
4	$2,190.70	$124.52	$ 0.00	$7,629.43	$490.48	$8,119.91
TOTAL	$7,882.52	$1,417.22	$ 0.00	$6,469.31	$1,650.60	$8,119.91

NET DIFFERENCE (INTEREST EARNED-INTEREST PAID) = $233.39
NET MONTHLY DIFFERENCE = $6.48

PAR. 6. In conjunction with the promotion of their software package, respondents have made the following statements in writing to prospective customers, such as automobile dealers, concerning the meaning of the Cash Comparison printout shown in paragraph five above. Typical and illustrative of such statements, but not necessarily all-inclusive thereof, is the following: "Calculates and prints document detailing savings possible by financing vehicle versus paying cash."

PAR. 7. Through the use of the statements referred to in paragraphs five and six and others in advertisements and promotional materials not specifically set forth herein, respondents have represented, directly or by implication, that:

(a) Customers of automobile dealers will save money by financing or arranging for financing rather than paying cash even when the interest rate for the financing higher than the rate the customers would receive on the funds to be used to make the cash payment;

(b) The number shown as "NET DIFFERENCE" on such printouts is an amount that a consumer would save by financing or arranging for financing through respondents' clients rather than redeeming a certificate of deposit and paying cash; and

(c) Such printouts are a valid comparison of the cost of financing or arranging for financing through respondents' clients rather than redeeming a certificate of deposit and paying cash.

[1] *Sic.*

PAR. 8. In truth and in fact,

(a) Customers of automobile dealers will not save money by financing or arranging for financing rather than paying cash when the interest for the financing is higher than the rate the customers would receive on the funds to be used to make the cash payment;

(b) The number shown as "NET DIFFERENCE" on such printouts is not an amount that a consumer would save by financing or arranging for financing through respondents' clients rather than redeeming a certificate of deposit and paying cash; and

(c) Such printouts are not a valid comparison of the cost of financing or arranging for financing through respondents' clients rather than redeeming a certificate of deposit and paying cash. A valid comparison of the cost of financing rather than paying cash would, in most if not all cases, show that it is to the customer's advantage to pay cash rather than finance.

Therefore, the representations set forth in paragraph seven above were, and are, false and misleading.

PAR. 9. Respondents' dissemination of the false and misleading representations as alleged in this complaint, and placement in the hands of others of the means and instrumentalities by and through which others may have used said false and misleading representations, constitute an unfair or deceptive act or practice in or affecting commerce in violation of Section 5(a) of 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 a complaint which the Bureau of Consumer Protection 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; and

The respondents, their attorney, 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 Act, 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, and having duly considered the comments filed thereafter by interested persons pursuant to Section 2.34 of its Rules, 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. Respondents Automatic Data Processing, Inc., and ADP, Inc., are corporations organized, existing and doing business under and by virtue of the laws of the State of Delaware, with their principal office and place of business located at One ADP Boulevard, in the City of Roseland, State of New Jersey. Respondent Automatic Data Processing, Inc., dominates and controls the acts and practices of its wholly-owned subsidiary, ADP, Inc.

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

I.

It is ordered, That respondents Automatic Data Processing, Inc., a corporation, ADP, Inc., a corporation, and their successors and assigns, agents, representatives, and employees, directly or through any corporation, partnership, unincorporated association, division, or

other device, in connection with the licensing, sales, and service of computer software and hardware, do forthwith cease and desist from:

(1) Representing in any manner, directly or by implication, that a consumer can save money by financing rather than paying cash for a purchase, when the interest rate for the financing is higher than the rate the consumer would receive on the funds to be used to make the cash payment;

(2) Misrepresenting in any manner, directly or by implication, through the use of terms such as "cash comparison," "net difference," or other terms used in any computer printout or other statement, that the printout or other statement accurately describes the amount (if any) that the consumer can save by financing or arranging for financing through respondents' clients rather than by paying cash for a purchase;

(3) Misrepresenting in any other manner, directly or by implication, the comparative cost to a consumer of financing a purchase as opposed to paying cash for it; and

(4) Selling, licensing, continuing to license or otherwise providing software or printed materials to any person when respondents know or should know that the software or printed materials are likely to be used to misrepresent in any manner, directly or by implication, the comparative cost to a consumer of financing a purchase as opposed to paying cash for it.

II.

It is further ordered, That respondents shall, in conjunction with their next Routine Release of their "Onsite Plus Finance & Insurance" computer software (the "Software"), but in any case within ninety (90) days of the date of service of this order, notify, through a letter in the form set out in Attachment A, all purchasers or licensees of the Software that:

(1) Respondents have entered into a consent agreement with the Federal Trade Commission to cease and desist from the use of the "Cash Comparison" screen and printout in the Software, and they will no longer be available as part of the software package;

(2) Because use of such screen and printout may mislead consumers, the purchaser or licensee should immediately discontinue such use.

For purposes of this paragraph, the term "Routine Release" means an update of respondents' computer software package, containing improvements, additions, and/or corrections, that is or may be periodically provided to purchasers and licensees of respondents' software and which such purchasers and licensees are contractually obligated to install on their computer systems.

III.

It is further ordered, That respondents shall maintain for at least three (3) years and, upon request, make available to the Federal Trade Commission for inspection and copying, documentation of their compliance with this order.

IV.

It is further ordered, That respondents shall notify the Federal Trade Commission at least thirty (30) days prior to any proposed change in respondents 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 corporations that may affect compliance obligations arising out of this order.

V.

It is further ordered, That 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.

ATTACHMENT A

Dear Client:

Automatic Data Processing, Inc., and its subsidiary, ADP, Inc. (collectively referred to as "ADP"), have entered into a consent agreement with the Federal Trade Commission (FTC) to stop providing, selling, licensing or otherwise supplying you with the "Cash Comparison" screen and printout in our Onsite Plus Finance & Insurance software. According to the FTC, use of the screen and printout conveys the erroneous impression that a consumer will save money by financing or arranging for financing rather than paying cash. The FTC alleges that, because the consumer will not save money by financing, this representation is false and misleading and a violation of the Federal Trade Commission Act. The FTC has not otherwise challenged the software.

As of (date), ADP updated its Onsite Plus Finance & Insurance software and removed the "Cash Comparison" screen and printout from this software package. As you know, your licensing agreement with ADP requires you to promptly install all such updates. Therefore, you are not authorized to use the "Cash Comparison" and continued use of the "Cash Comparison" will be a violation of your license. Because the screen and printout may be misleading to consumers, you should immediately stop using them. You should also be aware that the FTC has taken the position that the use of any such comparison, whether manually created or computer generated, may be deceptive and misleading and a violation of federal law.

Sincerely yours,
[ ]
* * *

IN THE MATTER OF

PATRICIA WEXLER, M.D.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF SECS. 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-3400. Complaint, Aug. 31, 1992--Decision Aug. 31, 1992

This consent order prohibits, among other things, a New York doctor from misrepresenting the efficiency of Omexin, a hair loss treatment, or any similar treatment concerning the curtailment of hair loss or the promotion of hair growth, and from making certain representations unless she possesses competent and reliable scientific evidence to substantiate such representations. The respondent also is prohibited from disseminating or assisting with the dissemination of a program-length advertisement regarding baldness.

Appearances

For the Commission: *Lesley A. Fair, Lisa B. Kopchik* and *Michael J. Bloom.*

For the respondent: *Mary D. Dorman*, New York, N.Y.

COMPLAINT

The Federal Trade Commission, having reason to believe that Patricia Wexler, M.D., hereinafter sometimes referred to as respondent, has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, alleges:

PARAGRAPH 1. Respondent Patricia Wexler, M.D. ("Wexler") is or was at relevant times herein a medical doctor licensed to practice by the State of New York, with a specialty in dermatology. Dr. Wexler's business address is 568 Broadway, New York, New York. Dr. Wexler has aided in the promotion of the Omexin System for Hair ("Omexin"), a purported treatment for hair loss, by providing an endorsement of the product on the program-length television

advertisement entitled "Can You Beat Baldness?" The advertisements in which respondent Wexler appears depict her as possessing an expertise in dermatology and hair loss superior to that generally acquired by ordinary individuals. Respondent has received compensation for the use of her endorsements in advertisements for Omexin.

PAR. 2. Omexin is a "food," "drug," "device," or "cosmetic," within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

PAR. 3. The acts and practices of respondent alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. 44.

PAR. 4. Respondent has made statements as an expert endorser in advertisements for Omexin, including but not necessarily limited to the attached Exhibit A. The aforesaid advertisements contain the following statements:

1. Dr. Wexler: "We have patients in both a double-blind study and using what we consider to be a very active ingredient, and what we've seen is that patients are ceasing to lose their hair very quickly within starting Omexin and then within a short time after, they start seeing new hair appear. It's not just fuzz, we're seeing actual pigmented terminal hair, which is very exciting for the patient as well as the doctor." [Exhibit A, p. 10]

2. Dr. Wexler: "I'd say 9 out of 10 patients that I've put on the active ingredient stopped losing hair and that alone is an exciting statement. I think that Omexin is going to be a wonderful treatment for people who are starting to lose hair, who are seeing changes in their hair and who start to use it early, and they can prevent further loss as well as possibly gain new hair. I think it's going to be a great benefit to both men and women with thinning hair." [Exhibit A, p. 11]

3. Dr. Wexler: "Omexin is the first product that I can say with enthusiasm can stop hair loss and promote growth." [Exhibit A, p. 20]

PAR. 5. Through the use of the statements contained in the advertisements referred to in paragraph four, including but not necessarily limited to the advertisement attached as Exhibit A, respondent has represented, directly or by implication, that:

A. Omexin contains an ingredient that curtails hair loss for a large majority of balding men and women.

B. Omexin contains an ingredient that promotes the growth of significant numbers of new, pigmented terminal hairs where hair has previously been lost for a significant number of balding men and women.

C. Omexin contains an ingredient that has been scientifically proven to curtail hair loss for a large majority of balding men and women.

D. Omexin contains an ingredient that has been scientifically proven to promote the growth of significant numbers of new, pigmented terminal hairs where hair has previously been lost for a significant number of balding men and women.

PAR. 6. In truth and in fact:

A. Omexin does not contain an ingredient that curtails hair loss for a large majority of balding men and women.

B. Omexin does not contain an ingredient that promotes the growth of significant numbers of new, pigmented terminal hairs where hair has previously been lost for a significant number of balding men and women.

C. Omexin does not contain an ingredient that has been scientifically proven to curtail hair loss for a large majority of balding men and women.

D. Omexin does not contain an ingredient that has been scientifically proven to promote the growth of significant numbers of new, pigmented terminal hairs where hair has previously been lost for a significant number of balding men and women.

Therefore, the representations set forth in paragraph five were, and are, false and misleading, and respondent knew or should have known that said representations were, and are, false and misleading.

PAR. 7. Through the use of the statements contained in the advertisements and promotional materials referred to in paragraph four, including but not necessarily limited to the advertisement attached as Exhibit A, respondent has represented, directly or by implication, that at the time she made the representations set forth in paragraph five, she possessed and relied upon a reasonable basis for such representations, consisting of an actual exercise of her

represented expertise in the treatment of hair loss, in the form of an examination or testing of Omexin at least as extensive as an expert in that field would normally conduct in order to support the conclusions presented in the endorsement.

PAR. 8. In truth and in fact, at the time she made the representations set forth in paragraph five, respondent did not possess and rely upon a reasonable basis for such representations. Therefore, respondent's representation as set forth in paragraph seven was, and is, false and misleading.

PAR. 9. The acts and practices of respondent as alleged in this complaint constitute unfair or deceptive acts or practices and the making of false advertisements in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

EXHIBIT A

CAN YOU BEAT BALDNESS? LOOKING CLOSER
As Recorded 7/7/88

Roberta Morgan (VO)
(OVER SHOTS OF BALD MEN IN STREET)

To just be told your hair is falling out, and there's nothing wrong with you, and there's nothing we can do about it, is about the most distressing news you could receive.

Brian Cristiano (VO)
(OVER SHOTS OF BALD MEN)

You say, Oh my God, is that going to happen to me too? My brother went bald; my father is completely bald.

Cut to Brian (OC)

So you kind of know what's happening, but you don't want it to happen.

(IMAGE FREEZES) SUPER - IT DOESN'T HAVE TO HAPPEN!

Announcer (VO)

Maybe it doesn't have to happen.

Joe Baldwin (SOT)

Since I started using the Omexin, it stopped falling out and started growing back.

Alex Jimenez (SOT)

This used to be a bald spot back here and it's almost completely covered up now.

Jonathan Avner (SOT)

With the Omexin, it started growing hairs below my hairline. In effect, starting to drop the hairline.

Roberta Morgan (SOT)

I had a tremendous amount of loss through here and in here. I do feel I'm well on the road to recovery now, thanks to the Omexin.

(IMAGE FREEZES)

(DISSOLVE TO 20 SEC. TEASER SPOT)

(ANNOUNCER VO; SUPER CRAWL OF HIS WORDS)

ANNCR (VO)

The following program will give you news of a product unlike anything else available anywhere for stopping hair loss and actually reversing balding by growing new hair. How is this product different? It works, while the others don't! This program presents the facts. We are repeating this broadcast in response to viewer demand.

(SPLIT SCREENS OF USERS; MUSIC STARTS)

Joe Campanella (VO)

(OVER SPLIT SCREENS - SUPER: CAN YOU BEAT BALDNESS?)

Can anything really stop hair loss and grow hair back? Is Omexin as effective as people are saying it is? We'll discover the facts about beating baldness.

(PROGRAM LOGO ANIMATES) (DISSOLVE TO HOST IN STUDIO)

Joe Campanella

Welcome to "Looking Closer." I'm Joseph Campanella. Our show will be exploring some of the innovations, ideas and trends in the news and on our minds. One thing that's very much on our minds and very dear to our hearts is our hair. One-half of all men can expect substantial baldness or hair thinning as they grow older, and many will start losing their hair while still young -- as early as their teenage years. Even though it's called male pattern baldness, many women will lose much of their hair as well. The good news is that you may not have to be resigned to the inevitable anymore. In early 1987, news of the discovery of a substance that reportedly would stop hair loss and grow hair back on balding heads with unprecedented success emerged from the laboratories of an innovative young medical firm. Wall Street insiders were among the first to get wind of this scientific breakthrough. The company went public, and Wall Street responded! News of this new product began to filter through to the press. That product is called Omexin, and it's the subject of our show today.

Is Omexin the breakthrough it's being heralded to be? Does it really work? We're going to look for solid proof of the answers to those questions.

To help us, we've assembled a distinguished panel of highly-qualified experts on hair loss, all of whom are familiar with this new product.

(CU DR. VICTOR ON LARGE SCREEN ON WALL OPPOSITE HOST)

First, Dr. Steven Victor is a dermatologist and hair loss specialist in New York who has been testing Omexin.

(CU DR. WEXLER ON LARGE SCREEN. DR. VICTOR IS SEEN ON ONE OF THE SMALL SCREENS)

Dr. Patricia Wexler, a board-certified specialist in internal medicine as well as dermatology, has been conducting a controlled study and clinical trials of Omexin.

Joe Campanella

Doctors, thank you for being here. I'll have questions for you shortly. And please feel free to jump into the conversation at any time. The definitive book on baldness and its cure is aptly named "The Bald Book." The author is Walter Klenhard, and he rounds out our panel of experts.

(CU WALTER KLENHARD ON LARGE SCREEN;
REST OF PANEL ON SMALL SCREENS)

Walter, why did your write "The Bald Book?"

Walter

Well, I think the answer to that question should be obvious. I wanted to put some hair on my head.

Joe Campanella

You present a lot of facts in your book. Where do those facts come from?

Walter

Well, I was interested in the subject like I think all bald people are, and I spent 4 years researching the subject to write the book, "The Bald Book." I went across the country. I talked to everybody involved in the hair industry, from people selling treatments to research scientists busy in the laboratories trying to find a cure for baldness, people selling hairpieces to doctors who do transplants and the result of that research was the book, "The Bald Book."

Joe Campanella

Thank you, Walter.

And finally, we invited John Hylan, the President of the Omexin Research Center, to join us. While hardly impartial--he does, after all, represent the manufacturer--he's here as well to answer our questions.

(CU JOHN HYLAN ON LARGE SCREEN;
REST OF PANEL ON SMALL SCREENS)

So that's our distinguished panel; I'll be seeking answers from them to some tough questions about baldness and Omexin shortly. But first, let's take a brief look at the problem. It hurts to lose your hair at a young age.

Cristiano (SOT)

I started losing my hair when I was eighteen. Which was ...it's kind of scary, you know? Losing your hair is bad enough, but at a young age it's even worse.

Weissberg (SOT)

I'm not sick, I have no health problems, I have no reason to fell I'm an old man. But then when I look in the mirror, I'm under 40, why should I feel I'm, ...I look over 40, when I'm under 35?

Maldanado (SOT)

Embarrassed, to say the least. I felt very embarrassed about it. Very embarrassed. I think it's one of the worst things for a man to have to happen to him, is to lose his hair.

Joe Baldwin (SOT)

When my hair started thinning in high school, I started wondering. Am I going to look like my father when he graduated high school in the fifties? Because he was already bald by then.

Walter (SOT)

Our image of male attractiveness always is a man with hair. The movie star that gets the girl has hair, the guy without hair gets to play Mr. Whipple.

Avner (SOT)

It is devastating to you, whether you're a man or a woman, it is devastating.

Roberta Morgan (SOT)

When I would come and see Dr. Wexler, I would probably spend a good half of every visit crying. I would swear I wasn't going to but my eyes would just start to fill up and ...it's just very deep pain to me.

Joe Campanella

Now, we're not saying that baldness is necessarily bad, or something to be ashamed of, but it certainly seems that given the choice, most balding people would prefer to keep the hair they've got and would be delighted to get back the hair they've lost. The search for a cure is as old as history. In ancient Egypt, they laid pigeon droppings on their scalps. Even Hippocrates, the father of medicine, had his own recipe for a cure. And ever since, there's been a steady stream of treatments, potions and contraption swearing they'll invigorate the scalp, prevent baldness and make what's gone today, hair tomorrow. Baldness is still a growth industry. They're busy trying to beat it all over the globe. But the sad truth is that virtually everything being sold for baldness, even today, just doesn't seem to work. Walter Klenhard, let's get right to the bottom line. Is there anything out there that really works?

Walter

Up until Minoxydil you cannot say there was anything out there that could grow hair on a bald head. I just didn't find anything that convinced me that it would work and I wanted to find something. I mean, I looked at everything out there and I looked at it objectively. Nothing I could find really offered a viable treatment for people suffering from male pattern hair loss.

Joe Campanella

Are you saying there's something else legitimate of the market?

Walter

Now there's another product called Omexin. I've spoken to some doctors who are conducting the first trials for this right now and they said the results they're getting are very promising.

Joe Campanella

What does "promising" mean? Is Omexin really a breakthrough?

Walter

If the results that the doctors are seeing now, the ones I've spoken to, conducting theses studies, hold true (and there's no reason to think that they won't), then I think you could safely say that Omexin will be the next breakthrough after Minoxydil.

Joe Campanella

John Hylan. I think I first heard about Omexin in the Wall Street Journal quite some time ago. And I've also seen it mentioned in articles in Playboy and Omni. Why hasn't Omexin been available?

Hylan

(SUPER: JOHN HYLAN, PRESIDENT, OMEXIN RESEARCH CENTER)

Well, Mr. Campanella ...

Joe Campanella

Please ...it's Joe.

Hylan

Ok ...Joe ...We wanted to research Omexin's effectiveness thoroughly first --it takes time to do valid research, you know.

Campanella

And now?

Hylan

Well, our research is still going on --but ...it has gone far enough to show that Omexin works. We know now that Omexin really does stop hair loss and does grow hair back, so we decided not to wait any longer, and we are now making Omexin available to the public.

Campanella

What's the hurry?

Hylan

If you were losing your hair, Joe, you wouldn't ask that question!

Campanella

We're going to take a closer look at your research and see just what is does show in a minute. But first, John, tell us --how does Omexin work?

Hylan

There's a widely-held theory that loss of blood supply to the affected hair follicles is a factor in male-pattern baldness. Now we discovered and patented a safe, natural formula --Omexin, that in laboratory tests, actually increased the blood supply in fertile chicken eggs. So we got the idea to test it for baldness, and it worked! No, we don't know if that's the reason Omexin grows hair, but we sure do know that it does.

Campanella

And you can prove that?

Hylan

Absolutely! To prove that Omexin really works, we've done thorough, extensive testing using medically sound methods and applying the highest scientific standards.

Campanella

Excuse me, John, give us an example.

Hylan

Omexin's now being tested in a double-blind study being conducted by a major university Medical Center Hair Clinic, which is, in fact, the same clinic that conducted the testing on Minoxydil.

Campanella

What do you mean by "double-blind" study?

Hylan

It's a particularly stringent kind of scientifically valid controlled test.

Campanella

Dr. Victor, what kind of testing are you now conducting with Omexin?

Dr. Victor

We have several tests on Omexin. We have what we call an open study where we have about 450 men and women who range in age from 18 actually up to 83, who apply the product regularly. Now what we see in that group is that 90 percent of our patients will tell us they stopped losing hair, some within a week, some within a month.

Dr. Victor (VO)

(NURSE AND PATIENT IN EXAMINING ROOM)

Then, on the other side of the coin, we have very controlled scientific studies. We have 2 groups. We actually take the men who are bald. We tattoo theirs scalp and we have them apply the Omexin in the balding area every day, twice a day. Now, every month they come back and we count the numbers of hairs that grow in the area where we tattooed their scalp.

Nurse

I already see an increase in the hairs.

Patient

Substantial ... Or ...

Nurse

Well, it seems to be. The hair seems to be a lot thicker now.

Dr. Victor (VO)

(DR. VICTOR JOINS NURSE AND PATIENT)

We can actually see if there's an increase in hair growth, hair falling out, new hair, vellous hair, new thick hair, terminal hairs.

Dr. Victor (OC)

So far, the studies have shown that these men are growing new hair.

Campanella

What are your initial impressions of Omexin?

Victor

I think in Omexin, we have for men and women a new safe product that they can apply that will stop the hair from falling out, and in a fair number of patients, probably up to 70%, will start growing some new hair.

Campanella

I must say, the test volunteers we've spoken with seem to agree.

Jim Conte

I started using the Omexin and I started to notice results right away. The results I've seen is that I have grown hair and that I have stopped losing hair.

Joe Baldwin

Omexin stopped my hair from falling out, and it started it to growing back to the way it used to be.

Tony Maldonado

I'm going to tell you something. I'm very excited about it. If I can have this much hair grow back, I'm very excited. Because there was nothing there. Literally nothing there.

Weissberg's Barber

This entire part of Steven's hair had been bald. Since I've been taking care of him for a long period of time, within the period of 6 months, this entire section grew in. I have never seen this in my experience and I've been in this business an awful long time.

Campanella

Dr. Wexler, what about your research?

Dr. Wexler

We have patients in both a double-blind study and using what we consider to be a very active ingredient, and what we've seen is that patients are ceasing to lose their hair very quickly within starting Omexin and then within a short time after, they start seeing new hair appear. It's not just a fuzz, we're seeing actual pigmented terminal hair, which is very exciting for the patient as well as the doctor.

Campanella

Really.

Dr. Wexler

They're really excited. These are people who had given up on growing back hair or stopping their loss. And patients on Omexin are excited about the program (sic) they've made.

Campanella

Give us an example

Dr. Wexler

Okay. I have a patient, Roberta, who came to the office 6 months ago with a dramatic thinning of her hair. You could see her scalp through her dark hair and she was very devastated by it.

(CUT TO DR. WEXLER EXAMING ROBERTA)

Roberta

...hairline was receding...

Dr. Wexler (SOT)

Okay, we're going to do what we usually do, which is just try to pull on a few of the hairs to see how many are coming out.

Roberta

It feels much healthier; the hair feels much better.

Dr. Wexler

I'm not getting any, which is a very good sign.

Roberta

That's wonderful. I think we got about 10 in the beginning.

Dr. Wexler

We used to get a clump every time we pulled.

Dr. Wexler

And within 2 months of being on Omexin, her hair stopped falling out and now that she's been on it for 6 months, she has her entire head of hair back and she's really happy and very confident about herself now.

Campanella

And what are your initial impressions of Omexin?

Wexler

I'd say 9 out of 10 patients that I've put on the active ingredient stopped losing hair and that alone is an exciting statement. I think that Omexin is going to be a wonderful treatment for people who are starting to lose hair, who are seeing changes in their hair and who start to use it early, and they can prevent further loss as well as possibly gain new hair. I think it's going to be a great benefit to both men and women with thinning hair.

Campanella

You know, I'm getting the point here: Omexin really does grow hair. Dr. Victor, how quickly does Omexin work?

Dr. Victor

In Omexin, we've seen results as far as hair stop falling out as early as a week but we've seen that basically, the majority of patients get a good result within 3 weeks.

Campanella

Wow! Dr. Wexler, what about your patients?

Dr. Wexler

Typically, the patients who I've given Omexin to, who are responding quickly --and within 1 month there is a change in their hair pattern. It's either less loss or new growth or both but it's a quick response.

Campanella

Thank you, Doctors. You've been very helpful...and very convincing. It sure sounds like proof to me.

Hylan

Actually, Joe, what you've heard is a group of truly expert doctors reporting on their own extensive observations of their patients. That, by itself, doesn't constitute scientific proof. But from our double-blind study, we have that proof, as well. Our study proves that Omexin stops hair loss and grows hair.

Campanella

Our experts and I will be back, after this.

Maldonado

It took 2 months for this to grow back. And I can honestly say there was nothing there to begin with. But now I have hair from using the product. And I am very, very happy and very pleased with it.

Cristiano

Look at all the hair I grew right here. The crown area -- this was so thin and it grew back. It's so much better. Even my girlfriend -- who's a hair stylist --said that it's like so much healthier hair, that's it's unbelievable. I'm very happy with it.

Weissberg

I've been using Omexin for about 8 to 9 months and I saw results after the first 2 weeks but I really started to see results after 4 weeks. I literally saw new hairs growing where there was a bald spot.

Roberta

I just wanted to say that I think the Omexin is a blessing. I mean, for people like me, it was a godsend and I haven't used anything but that. And it alone, on its own,

has brought back my hair and that has brought back a great deal of happiness to me, to my life, and I'm thrilled with it.

LOOKING CLOSER LOGO

VIDEO: Stark B+W title: (pop on) The Question: (pop on)
What Can You Do About Thinning Hair?
AUDIO: The question: What Can You Do About Thinning Hair?
VIDEO: Stark B+W title: The Answer:
(Answers Pop On, Then... Fade Out) A Hairpiece??
AUDIO: A Hairpiece?
VIDEO: Stark B+W title: Hair Transplants??
AUDIO: Hair Transplants?
VIDEO: Stark B+W title: Drugs??
AUDIO: Drugs?... No, these answers aren't practical for most men - they're expensive, and can be painful or aesthetically unpleasant.
VIDEO: Stark B+W title: The Answer: (Answer Pops On, Then Fades Out) Over-The-Counter Preparations?
AUDIO: What about...over-the-counter preparations? The sad fact is, they just don't work! But now... there's a new answer!
VIDEO: Stark B+W title: (snap on) OMEXIN
VIDEO: Dissolve through to... Omexin product.

The answer is Omexin... newly discovered at the cutting edge of science, completely safe, yet powerfully effective...

VIDEO: dissolve to...Multi-image screen of testifiers, research shots, and graphics from the show.

Omexin has been scrupulously tested by dermatologists, and clinicians, and by thousands of grateful individuals. The test results and the personal stories speak for themselves.

VIDEO: Cut back to...Omexin product.

The bottom line may be the most powerful statement in the history of thinning hair - it's just two words:

VIDEO: Wipe on bold title - OMEXIN WORKS!

Omexin Works!

VIDEO: Pull out from Omexin product to the three-part system.

The Answer couldn't have been simpler. The Omexin System is based on the Omexin Active Treatment, a fine white cream which you simply massage into the affected areas daily. You'll also use the carefully formulated, gentle Omexin Shampoo and Omexin Conditioner. The total System helps care for your hair, insuring maximum benefits from the treatment and keeping your hair looking better than ever before.

VIDEO: Dissolve on 800#.

To start using Omexin couldn't be a simpler decision to make,

VIDEO: Fade on Super: Unconditional 30-Day Money Back Guarantee.

because Omexin is backed with an absolutely unconditional 30 day money-back guarantee. Omexin works for the vast majority of people, but if you're

not satisfied with your results, for any reason, you get your money back. No question asked. It's that simple.

VIDEO: Hold on 800#. Dissolve on Info Panel.

And getting the Omexin System couldn't be simpler, either,. Just dial the toll free number on your screen. Your first 30 day supply of Omexin, the revolutionary, scientific solution to the hair-loss problem is just $49.95. Complete! Call now: 1-800-777-7777. Please have your credit card number ready. Sorry, no COD's.

VIDEO: Omexin P.O. Box 9010 Southampton, N.Y. 11968

Or, send Check or Money order for just $49.95 plus $4.00 for shipping and handling to this address. Call now: 1-800-777-7777.

VIDEO: Back to Omexin product. Super: It works. Omexin. The Answer. It Works.

Campanella

Welcome back. I'm Joesph Campanella and if you've just joined us today on "Looking Closer," we are talking about a new product called Omexin, which has just been made available for sale to the public. It reportedly has stopped the balding process in a high percentage of test subjects and even re-grown healthy new hair for a large number of men and women of all ages. But is that news? What about all the other products on TV that are claiming to grow hair? Is Omexin any differnt or any better? I'm going to ask all four of our experts to respond. Polysorbate products like Helsinki Forumla, for instance, have gotten a lot of attention lately. Walter Klenhard, do they grow hair?

Walter

Well, polysorbate products have had a great deal of popularity in recent years. I spent a lot of time investigating them, and I could really find no eveidence to support their claims as being an effective treatment for male pattern hair loss. There's a number of names: there's the Helsinki Formula, Pantron I; there's New Generation and others. I couldn't find anybody who had grown a decent head of hair using this stuff. And, in fact, some of the studies that have been done -- one at the University of California -- concluded that it was not an effective treatment for male pattern hair loss.

Dr. Wexler

They talk about penetration of the hair shaft and the hair follicle. But really, what they're doing, is they're adding a coating to the hair that makes the hair look thicker, but it's not growing hair. And it's not preventing hair loss. There's no data to support that.

Dr. Victor

We found that over the years, all the patients who try them for months or for years -- that I've seen in the practice -- did not have any hair loss that stopped. Didn't grow any new hair. And actually were disappointed in the products.

Walter

None of the doctors I've talked to either say that there's anything in the product that would help prevent hair loss.

Hylan

They simply don't work. And the sad part is that people are spending hard-earned mony for these products.

Campanella

What about their theory that baldness is cured (sic) by an oily scalp, which clogs the hair follicles?

Walter

The theory that male pattern baldness is caused by clogged hair follicies, really doesn't hold any water. That suggest that oil and pollution and general dirt and grime combine together to clog up the follicies on your scalp, and the hair can't grow. All you have to do is go down to any downtown area of any major city, and take a look at all the bums and winos down there who probably shampoo their hair once a year, if that, and they're not bald. They've got full heads of hair. These follicles aren't clogged -- why would these become clogged? The fact that a hair transplant is effective, that you can take a follicle from here and put it on the top will grow. It doesn't become clogged again. So, clogged follicles and dirt and dust and stuff on the scalp really isn't a cause for hair loss.

Campanella

Thank you, Walter, and thank you, doctors. Well, if Omexin does truly stop hair loss and start hair growing again, and if it's true, as our experts say, that the other advertised products don't really work, I'd say it looks like we may have some real news here. John Hylan, where can our viewers find Omexin?

Hylan

They don't have to find it; they just call our toll-free number [ALT: We'll send them an initial 30-day supply. Thereafter, we'll send a fresh 60-day supply automatically, every other month. They'll never have to worry about running out of the product. And of course, they can cancel anytime.]

Campanella

What if Omexin doesn't work for someone?

Hylan

Joe, that's an important point and I'm really glad you asked that question. We haven't forgotten that the flip side of "Omexin works for the vast majority of people" is that it doesn't work for a few. But we don't want consumers to risk anything: we assume that risk. So, Omexin is backed by an unconditional 30-day money-back guarantee. Our customers have to be completely satisfied --and they can define satisfaction any way they want. If they're not satisfied, they simply call our toll-free number and get their money back. It's absolutely risk-free.

Campanella

One final concern: Just how safe is Omexin?

Hylan

Extensive safety testing has been done, much of it by Eli Lilly & Company, a giant pharmaceutical firm. And the tests have established that Omexin has no side effects. There are no adverse reactions. It's a proven fact. Omexin is safe.

Campanella

I'd like to ask each of the experts for their final comments about Omexin.

Dr. Victor

Up until now, all over the counter products and all the products sold on TV haven't really worked. Now, Omexin is a product that can stop hair loss and grow hair for a vast majoriy of people.

Dr. Wexler

Omexin is the first product that I can say with enthusiasm can stop hair loss and promote growth.

Dr. Victor

What is particularly good about Omexin, for a man or a woman in their early 30's or 20's, with just beginning to thin. If they start using the product religiously, they can stop the hair from falling out. And they can retain the hair they have and remain that way for the rest of their lives.

Walter

Well, anytime a treatment like a treatment like Omexin comes along, where legitimate doctors and scientists are conducting trials; they're using it, they're reporting positive results-- this is very good news. It's very exciting news.

Hylan

This is certain. For the vast majority of people, Omexin stops hair loss. And the most of them are going to grow their hair back.

Wexler

As a doctor, being able to give Omexin means that I can now tell patients who were going to go bald, that they no longer have to do that, and that they can now use a product that can stop their hair loss.

Dr. Victor

I think in Omexin we have, for men and women, a new safe product they can apply that will stop the hair from falling out and in a fair number of patients, probably up to 70% will start growing some new hair. When I say new hair, my concept of new hair is hair you can look in the mirror and actually see. If you can't see it, it's not new hair to me.

Campanella

Is Omexin the baldness breakthrough that will enable you to beat fate and overcome your genes? We've heard and seen a lot of solid evidence in this program. It has come from highly qualified doctors and experts, and from serious, thoughtful people who had a problem and got some real help. There are hundreds of test subjects who are growing hair today where there was none before. And that's a fact. The experts we heard from today have convinced me that Omexin really does work, and may just be the best thing currently available to maintain the head of hair you already have, and bring back the hair you've lost. Omexin just might be worth trying, with that money back guarantee, you've got nothing to lose, I guess. --

Except your hair, of course, if you prefer to just let nature have its way. And if that's your choice, well, it's not what's on your head, it's what's in it. I'm Joseph Campanella. Thanks for looking closer with me.

Cheryl Yellin

I noticed a tremendous change in his self-confidence. That was the first thing.

Hairdresser

He developed a lot more hair all back here, you know, in the front rather than in the back, you can see that still, all this hair is new growth as well.

Weissberg

Within the first two weeks of using Omexin, my hair stopped falling out.

Avner

I have experienced some real hair growth with Omexin.

Roberta Morgan

Since using the Omexin, it's not only fuller, it's prettier. It's shinier, it's bouncier. It feels a lot better.

Tony Maldanado

You see something growing, something is happening, it really is. I can honestly say I'm very happy about it, and I know all my hair's going to grow back. All of it.

PROGRAM LOGO

VIDEO: Stark B+W title: (pop on) The Question: (pop on) What Can You Do About Thinning Hair?
AUDIO: The question: What Can you do About Thinning Hair?
VIDEO: Stark B+W title: The Answer: (Answers Pop On, Then... Fade Out) A Hairpiece??
AUDIO: A Hairpiece?
VIDEO: Stark B+W title: Hair Transplants??
AUDIO: Hair Transplants?
VIDEO: Stark B+W title: Drugs??
AUDIO: Drugs?... No, these answers aren't practical for most men - they're expensive, and can be painful or aesthetically unpleasant.
VIDEO: Stark B+W title: The Answer: (Answer Pops On, Then Fades Out) Over-The-Counter Preparations?
AUDIO: What about... over-the-counter preparations? The sad fact is, they <u>just don't work</u>! But now... there's a <u>new</u> answer!
VIDEO: Stark: B+W title: (snap on) OMEXIN
VIDEO: Dissolve through to... Omexin product.

The answer is Omexin... newly discovered at the cutting edge of sceince, completely safe, yet powerfully effective...

VIDEO: Dissolve to... Mutli-image screen of testifiers, research shows, and graphics from the show.

Omexin has been scrupulously tested by dermatologists, and clinicians, and by thousands of grateful individuals. The test results and the personal stories speak for themselves.

VIDEO: Cut back to... Omexin Product.

The bottom line may be the most powerful statement in the history of thinning hair - it's just two words:

VIDEO: Wipe on bold title - OMEXIN WORKS!

Omexin Works!

VIDEO: Pull out from Omexin product to the three-part system.

The Answer couldn't have been simpler. The Omexin system is based on the Omexin Active Treatment, a fine white cream which you simply massage into the affected areas daily. You'll also use the carefully formulated, gentle Omexin Shampoo and Omexin Conditioner. The total System helps care for your hair, insuring maximum benefits the treatment and keeping your hair looking better than ever before.

VIDEO: Dissolve on 800#.

To start using Omexin couldn't be a simpler decision to make,

VIDEO: Fade on Super: Unconditional 30-Day Money Back Guarantee.

because Omexin is backed with an absolutely unconditional money-back guarantee. Omexin works for the vast majority of people, but if you're not satisfied with your results, for any reason, you get your money back. No question asked. It's that simple.

VIDEO: Hold on 800#. Dissolve on Info Panel

And getting the Omexin System couldn't be simpler, either. Just dial the toll free number now on your screen.

Your first 30 day supply of Omexin, the revolutionary, scientific solution to the hair-loss problem is just $49.95, complete! Call now: 1-800-777-7777. Please have your credit card number ready. Sorry, no COD's.

VIDEO: Omexin P.O. Box 9010 Southampton, N.Y. 11968

Or, send Check or Money Order for just $49.95 plus $4.00 shipping and handling to this address. Call now: 1-800-777-7777.

VIDEO: Back to Omexin product. Super: It Works.

Omexin. The Answer. It Works.

DECISION AND ORDER

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

The respondent, her attorney, 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 the complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by the respondent that the law has been violated as alleged in such complaints and waivers and other provisions as required by the Commission Rules; and

The Commission having thereafter considered the matter and having determined that it has reason to believe that the respondent has violated said Act, 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 Patricia Wexler, M.D. ("Wexler") is or was at relevant times herein a medical doctor licensed to practice the State of New York, with a specialty in dermatology. Dr. Wexler's business address is 568 Broadway, New York, New York. After January 1, 1992, Dr. Wexler expects her new business address to be 461 Park Avenue South, New York, New York.

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

ORDER

I.

It is ordered, That respondent Patricia Wexler, M.D., and respondent's agents, representatives and employees, directly or through any partnership, corporation, subsidiary, division or other device, in connection with the endorsing, advertising, packaging, labeling, promotion, offering for sale, sale or distribution of any product or service in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from selling, broadcasting or otherwise disseminating, or assisting others to sell, broadcast or otherwise disseminate, in part or in whole, the program-length television advertisement for Omexin described and identified in the complaint as "Can You Beat Baldness?"

II.

It is further ordered, That respondent Patricia Wexler, M.D., and respondent's agents, representatives and employees, directly or through any partnership, corporation, subsidiary, division or other device, do forthwith cease and desist from:

A. Representing, directly or by implication, in connection with the endorsing, advertising, packaging, labeling, promotion, offering for sale, sale or distribution of Omexin or any other substantially similar hair loss treatment product or service, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, that:

1. Such product or service contains an ingredient that can or will curtail hair loss;
2. Such product or service contains an ingredient that can or will promote the growth of new, pigmented terminal hair where hair has already been lost;
3. Such product or service contains an ingredient that has been scientifically proven to curtail hair loss;

4. Such product, or service contains an ingredient that has been scientifically proven to promote the growth of new, pigmented terminal hair where hair has already been lost;

5. Such product or service can or will prevent, cure, relieve, reduce, or reverse hair loss;

6. Such product or service is an effective remedy for hair loss in a large majority of cases; or

7. Any test or study establishes that such product prevents, cures, relieves, reduces, or reverses hair loss.

For purposes of this order a "substantially similar hair loss treatment product or service" shall be defined as any product or service that is advertised or intended for sale over-the-counter to treat, cure or curtail hair loss and which contains omentum or any extract thereof.

B. Representing, directly or by implication, in connection with the endorsing, advertising, packaging, labeling, promotion, offering for sale, sale or distribution of any other product or service in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, that:

1. The use of the product or service can or will prevent, cure, relieve, reduce, or reverse loss of hair;

2. The use of the product or service can or will promote the growth of new hair where hair has already been lost;

3. The product or service is an effective remedy for hair loss in a substantial number of cases; or

4. Any test or study establishes that the product or service prevents, cures, relieves, reduces, or reverses hair loss,

unless the representation is true and, at the time of making the representation, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation. For the purposes of this order, "competent and reliable scientific evidence" shall mean tests, analyses research, studies, or other evidence that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession or science to yield accurate and reliable results. *Provided that*, for any representation made by respondent as an expert endorser, respondent must possess and rely upon competent

and reliable scientific evidence, and an actual exercise of respondent's represented expertise, in the form of an examination or testing of the products or services at least as extensive as an expert in that field would normally conduct in order to support the conclusions presented in the representation.

III.

It is further ordered, That respondent Patricia Wexler, M.D., and respondent's agents, representatives and employees, directly or through any partnership, corporation, subsidiary, division or other device, in connection with the endorsing, advertising, packaging, labeling, promotion, offering for sale, sale or distribution of any product or service in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from misrepresenting, in any manner, directly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test or study.

IV.

It is further ordered, That respondent Patricia Wexler, M.D., and respondent's agents, representatives and employees, directly or through any partnership, corporation, subsidiary, division or other device, in connection with the endorsing, advertising, packaging, labeling, promotion, offering for sale, sale or distribution of any food, drug, device, or cosmetic, as those terms are defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. 55, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from making any representation, directly or by implication, regarding the performance, benefits, efficiency or safety of, any such product unless at the time of making the representation respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation. *Provided that*, for any representation made by respondent as an expert endorser, respondent must possess and rely upon competent and reliable scientific evidence, and an actual exercise of respondent's represented expertise, in the form of an examination or testing of the products or services at least as extensive

as an expert in that field would normally conduct in order to support the conclusions presented in the representation.

V.

It is further ordered, That respondent Patricia Wexler M.D., shall, for three (3) years after the date of the last dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission or its staff for inspection and copying:

A. All materials that were relied upon by respondent to substantiate any such representation;

B. All test reports, studies, or other materials in her possession or control that contradict, qualify, or call into question such representation.

VI.

It is further ordered, That Patricia Wexler, M.D., shall, for a period of six (6) years from the date of service of this order, promptly notify the Commission of the discontinuance of her present business or employment and of her affiliation with a new business or employment whose activities include, or in which her own duties and responsibilities involve, the advertising, endorsing, promotion, offering for sale, sale, or distribution of any food, drug, device, or cosmetic, as those terms are defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. 55. For each such new affiliation, the notice shall include the name and address of the new business or employment a statement of the nature of the new business or employment, and a description of respondent's duties and responsibilities in connection with the new business or employment.

VII.

It is further ordered, That Patricia Wexler, M.D., shall, within sixty (60) days after service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which she has complied with this order.

IN THE MATTER OF

BELAGE PLASTIC SURGERY CENTER, P.C., ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-3401. Complaint, Sept. 8, 1992--Decision, Sept. 8, 1992

This consent order prohibits, among other things, a Virginia-based plastic surgery center and its founder from misrepresenting the likelihood of risks or scarring, the length of the recovery period, the amount of pain, or the need for pain medication, following plastic or cosmetic surgery. In addition, the order requires a risk disclosure any time the respondents state that cosmetic or plastic surgery procedures are safe.

Appearances

For the Commission: *Michael C. McCarey* and *Renate Kinscheck.*

For the respondents: *Lewis Rose* and *Michael Eaton, Arent, Fox, Kintner, Plotkin & Kahn*, Washington, D.C.

COMPLAINT

The Federal Trade Commission, having reason to believe that BelAge Plastic Surgery Center, P.C., a corporation, (hereinafter "BelAge") and George F. Miller, Jr., M.D., individually, and as an officer of BelAge ("respondents") have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, alleges:

PARAGRAPH 1. (a) Respondent BelAge Plastic Surgery Center, P.C., is a Virginia corporation. Its offices and principal place of business are at 4900 Seminary Road, Alexandria, VA. (b) Respondent George F. Miller, Jr., M.D., is an individual medical doctor who founded BelAge, and is an officer and director of the corporate respondent. He directs, controls, and formulates the acts

and practices of the corporate respondent, including the acts and practices alleged in this complaint. Dr. Miller's business address is 4900 Seminary Road, Alexandria, VA. (c) The aforementioned respondents cooperate and act together in carrying out the acts and practices alleged in this complaint.

PAR. 2. Respondents advertise, offer for sale, and sell and provide surgery services to the public and have done so at all times material to this complaint. Dr. Miller is an otolaryngologist, specializing in head and neck surgery and facial plastic surgery. Dr. Miller, through BelAge, associates with other doctors who are trained to perform plastic surgery of other parts of the body. In the spring of 1989, respondents, along with other plastic surgeons, were offered a preexisting cosmetic surgery marketing campaign which included suggested broadcast and newspaper advertisements and a brochure entitled "Everything You've Always Wanted To Know About Plastic Surgery." Respondents purchased the campaign and, after some modifications, disseminated the brochure (hereinafter "brochure").

PAR. 3. The acts and practices of respondents alleged in this complaint are and have been in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act.

COUNT I.

PAR. 4. The brochure contains the statement that breast lift surgery "leaves minimal, barely visible scars." (p. 14).

PAR. 5. By and through the use of the statement referred to in the preceding paragraph, respondents falsely represent, and have represented, directly or by implication, that breast lift surgery is unlikely to result in permanent and conspicuous scars.

PAR. 6. In truth and in fact, breast lift surgery is likely to result in permanent and conspicuous scars.

COUNT II.

PAR. 7. The brochure contains the following statements:

(a) "recovery [following face lift operations] is surprisingly quick and usually pain-free. There is some bruising, stitches, and bandages you'll have to put up with but

it doesn't take long. Some patients are back to their normal schedules within a week looking younger and feeling younger too." (p. 6).

(b) "after an easy week of recovery [after breast reduction surgery] . . . you can be back at work." (p. 14).

PAR. 8. By and through the use of the statements referred to in the preceding paragraph, respondents falsely represent, and have represented, directly, or by implication, that the recovery period following face lift and breast reduction is likely to be very short.

PAR. 9. In truth and in fact, the recovery period following face lift and breast reduction is not likely to be very short.

COUNT III.

PAR. 10. The brochure contains the statement that if a patient has "an oversized, protruding chin .... surgery of the chin can correct it quickly, easily and permanently." (p. 9).

PAR. 11. By and through the use of the statement referred to in the preceding paragraph, respondents falsely represent, and have represented, directly, or by implication, that a protruding chin or jaw can usually be corrected through surgery which involves a very short recovery time.

PAR. 12. In truth and in fact, a protruding chin or jaw can not usually be corrected through surgery which involves a very short recovery time.

COUNT IV.

PAR. 13. The brochure contains the following statements:

(a) "Recovery [following surgery to correct protruding ears] is . . . painless. Many patients require no pain medication . . . .(p. 9).

(b) "And post-op discomfort [following breast augmentation] is so mild it can usually be handled with Tylenol." (p. 14).

(c) "... an easy week of recovery (usually Tylenol is all that's needed for post-op discomfort) [following breast reduction]." (p. 14).

PAR. 14. By and through the use of the statements referred to in the preceding paragraph, respondents falsely represent, and have

represented, directly, or by implication, that, following otoplasty (surgery to correct protruding ears), breast augmentation and breast reduction, most patients will experience no pain or only mild discomfort, and are not likely to require narcotic pain medication to relieve pain.

PAR. 15. In truth and in fact, following otoplasty (surgery to correct protruding ears), breast augmentation and breast reduction, most patients are unlikely to experience no pain or only mild discomfort, and are likely to require narcotic pain medication to relieve pain.

COUNT V.

PAR. 16. By and through the use of the statement that "[n)or do implants interfere with mammography...." (p. 13), respondents falsely represent, and have represented, directly or by implication, that silicone breast implants do not interfere with mammography.

PAR. 17. In truth and in fact, silicone breast implants can interfere with mammography.

COUNT VI.

PAR. 18. By and through the combined use of numerous statements in the brochure referring to the safety of various plastic surgery operations, including, but not limited to, statements that "[today's plastic surgery has gotten so safe..." (p. 4), "[today's breast reduction procedures are safe..." (p. 14), and "... anyone's breasts can be easily and safely changed in almost any manner" (p. 12), respondents represent, and have represented, directly, or by implication, that plastic surgery is safe. Respondents have failed to disclose that such, surgery entails serious adverse risks. In light of respondents representations that such surgery is safe, such failure to disclose is a deceptive practice.

PAR. 19. By and through the aforesaid acts and practices, respondents engage, and have engaged, in unfair or deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the FTC Act, 15 U.S.C. 45(a).

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 complaint, which the Bureau of Consumer Protection 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, and

The respondents, their attorneys, 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 Act, and that a 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 BelAge Plastic Surgery Center, P.C., is a corporation organized, existing and doing business under and by virtue of the laws of the State of Virginia, with its office and principal place of business at 4900 Seminary Road, Alexandria, Virginia.

2. Respondent George F. Miller, Jr., M.D., is an individual medical doctor who founded BelAge Plastic Surgery Center, P.C., and is an officer and director of the corporate respondent. He directs, controls and formulates the acts and practices of BelAge Plastic Surgery Center, including the acts and practices alleged in the complaint herein. His business address is 4900 Seminary Road, Alexandria, Virginia.

3. 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

DEFINITIONS

For purposes of this order, the following definitions shall apply:

1. "*Advertising, offering for sale or promotion*" does not include any statement made by respondents or their representatives, agents or employees to a patient after the patient has agreed to purchase the procedure represented.

2. *"Recovery period"* means the period between when a typical patient of respondents has had the surgery represented and when such patient actually returns to a normal schedule, including social activities and full-time employment, but excluding strenuous exercise.

3. In order for a disclosure to be made "*prominently*" it must be in the same typeface and color contrast as the representation which triggers the disclosure.

4. "*Typical*" or *"typically"* means in the majority of instances or the majority of patients.

I.

It is ordered, That respondents BelAge Plastic Surgery Center, P.C., a Virginia corporation, its successors and assigns, and its officers, and George F. Miller, Jr., M.D., 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 advertising, offering for sale or promotion of any cosmetic or plastic surgical procedure, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from, directly or by implication:

A. Representing that the results from any cosmetic or plastic surgical procedure can be achieved easily, simply or quickly or that the recovery period following any surgical procedure is quick, easy, or simple, when the recovery period is likely to be more than five days, unless the length of the recovery period is clearly and prominently disclosed in close proximity to such representation.

B. Making any representation as to when patients can resume a normal schedule or return to work or making any other representation regarding recovery experience, which does not describe the recovery experience of a typical patient of respondents, unless one of the following is clearly and conspicuously disclosed in close proximity to such representation: (1) the recovery experience of a typical patient of respondents, or (2) that patients will experience the represented recovery experience only under limited or atypical circumstances.

C. Representing that following breast augmentation, breast reduction, or any other cosmetic or plastic surgical procedure for which patients typically take narcotic pain medications during the post-operative period, patients are likely to experience no pain, or only mild discomfort, or are unlikely to require narcotic pain medication; provided, however, that this paragraph shall not apply if respondents can demonstrate that their patients typically do not take narcotic pain medication during the post-operative period for the procedure in question;

D. Representing that any cosmetic or plastic surgery procedure which entails serious adverse risks is safe unless respondents clearly and prominently disclose that such procedure entails adverse risks. For purposes of this order, the following disclosure shall be deemed adequate to satisfy this disclosure requirement:

Of course, plastic surgery, like any surgery, has risks. Your surgeon will discuss the risks with you in detail.

The disclosure required by this paragraph shall be made either (1) in close proximity to such representation or (2) in the case of a written representation, on the same page as the representation, in which case the disclosure must be boxed and isolated from all other material, and be in the same typeface and color contrast as the largest and most noticeable representation on that page which triggers the disclosure.

E. Misrepresenting the likelihood of serious adverse risks associated with any plastic or cosmetic surgical procedure or device implanted through any such procedure;

F. Misrepresenting the likelihood of permanent, extensive or conspicuous scars resulting from breast reduction, breast lift or abdominoplasty, or any other cosmetic or plastic surgical procedure which typically results in permanent and conspicuous scars;

G. Misrepresenting the length of the recovery period following any cosmetic or plastic surgical procedure; *provided, however*, that nothing in this order shall prevent respondents from making any truthful representation as to when a typical patient of respondents returns to work;

H. Representing, contrary to fact, that little or no pain or discomfort is typically experienced as a result of undergoing any cosmetic or plastic surgical procedure;

I. Misrepresenting the need for pain medication or the type of pain medication that is likely to be needed to relieve pain following any cosmetic or plastic surgical procedure; *provided however*, that nothing in this order shall prevent respondents from making any truthful representation regarding the pain medication taken by a typical patient of respondents.

II.

It is further ordered, That respondents shall notify the Commission at least thirty (30) days prior to the effective date of 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, the filing of a bankruptcy petition, or any other change in the corporation(s) which may affect compliance obligations arising out of the order.

III.

It is further ordered, That respondents and their successors or assigns, shall distribute a copy of this order to each of their officers, agents, representatives, independent contractors and employees who are engaged in the preparation and placement of advertisements or

promotional materials, who communicate with patients or potential patients, who perform surgical services or who have any responsibilities with respect to the subject matter of this order.

IV.

It is further ordered, That, for a period of ten years from the date of entry of this order, the individual respondent named herein shall promptly notify the Commission of the discontinuance of his present business or employment and of his affiliation with a new business or employment, with each such notice to include the respondent's new business address and a statement of the nature of the business or employment in which the respondent is newly engaged as well as a description of respondent's duties and responsibilities in connection with the business or employment.

V.

It is further ordered, That respondents shall maintain for a period of three years from the date the document is created or used, whichever is later, documents demonstrating the manner and form of respondents' compliance with this order. *It is further ordered*, That such documents shall be made available to the Commission or its staff for inspection and copying within thirty (30) days of receipt of a request for an inspection.

VI.

It is further ordered, That respondents and their successors or assigns, shall, within sixty (60) days after service 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.