UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of	)	
	)	FILE NO. 942 3237
INTERACTIVE MEDICAL TECHNOLOGIES, LTD., and EFFECTIVE HEALTH, INC., corporations,	)	
	)	AGREEMENT CONTAINING CONSENT ORDER AS TO WILLIAM E. SHELL, M.D.
WILLIAM PELZER, JR., individually and as a former officer of Interactive Medical Technologies, Ltd., and Effective Health, Inc., and	)	
WILLIAM E. SHELL, M.D., individually and as a former officer of Interactive Medical Technologies, Ltd.	)	

The Federal Trade Commission ("Commission") has conducted an investigation of certain acts and practices of William E. Shell, M.D. ("proposed respondent"), individually and as an officer of Interactive Medical Technologies, Ltd. ("IMT"). Proposed respondent is willing to enter into an agreement containing a consent order resolving the allegations contained in the attached draft complaint. Therefore,

IT IS HEREBY AGREED by and between William E. Shell, M.D., individually and as a former officer of IMT, and counsel for the Commission that:

1. Proposed respondent William E. Shell, M.D. ("Shell") was chairman of the board of IMT from January 1990 through February 1996, and served as that company's chief financial officer from May 1993 through June 1994. Individually or in concert with others, he formulated, directed, controlled or participated in the acts and practices of IMT and its wholly owned subsidiary, Effective Health, Inc., including the acts and practices alleged in the attached complaint. His principal office or place of business is 2934 1/2 Beverly Glen Circle, Suite 209, Los Angeles, California 90077.

2. Proposed respondent admits all the jurisdictional facts set forth in the draft complaint.

3. Proposed respondent waives:

a. Any further procedural steps;

b. The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law; and

c. All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement.

4. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission, it, together with the draft complaint, will be placed on the public record for a period of sixty (60) days and information about it publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify proposed respondent, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision in disposition of the proceeding.

5. This agreement is for settlement purposes only and does not constitute an admission by proposed respondent that the law has been violated as alleged in the draft complaint, or that the facts as alleged in the draft complaint, other than the jurisdictional facts, are true.

6. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of Section 2.34 of the Commission's Rules, the Commission may, without further notice to proposed respondent, (1) issue its complaint corresponding in form and substance with the attached draft complaint and its decision containing the following order in disposition of the proceeding, and (2) make information about it public. When so entered, the order shall have the same force and effect and may be altered, modified, or set aside in the same manner and within the same time provided by statute for other orders. The order shall become final upon service. Delivery of the complaint and the decision and order to proposed respondent by any means specified in Section 4.4 of the Commission's Rules shall constitute service. Proposed respondent waives any right he may have to any other manner of service. The complaint may be used in construing the terms of the order. No agreement, understanding, representation, or interpretation not contained in the order or in the agreement may be used to vary or contradict the terms of the order.

7. Proposed respondent has read the draft complaint and consent order. He understands that he may be liable for civil penalties in the amount provided by law and other appropriate relief for each violation of the order after it becomes final.

ORDER

DEFINITIONS

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

1. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

2. Unless otherwise specified, "respondent" shall mean William E. Shell, M.D., individually and as a former officer of IMT.

3. "In or affecting commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

I.

IT IS ORDERED that respondent, directly or through any corporation, subsidiary, division or other device, in connection with the labeling, advertising, promotion, offering for sale, sale or distribution of Lipitrol or any product or program marketed or sold under any name, in or affecting commerce, shall not represent, in any manner, expressly or by implication, that such product prevents or reduces the body's absorption of fat from consumed food or absorbs any amount of fat from consumed food unless the representation is true and, at the time it is made, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, subsidiary, division or other device, in connection with the labeling, advertising, promotion, offering for sale, sale or distribution of Lipitrol or any product or program, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, that any such product:

A. Provides any weight loss benefit;

B. Lowers blood cholesterol levels;

C. Reduces, or reduces the risks associated with, high cholesterol, including clogged arteries, high blood pressure, diabetes, breast cancer and heart disease; or

D. Can be used, beneficially and safely, in amounts or with frequency sufficient to cause diarrhea,

unless, at the time the representation is made, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

III.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, subsidiary, division or other device, in connection with the labeling, advertising, promotion, offering for sale, sale or distribution of Lipitrol or any product or program, in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, the existence, contents, validity, results, conclusions or interpretations of any test, study or research.

IV.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, subsidiary, division or other device, in connection with the labeling, advertising, promotion, offering for sale, sale or distribution of Lipitrol or any product or program, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, about the benefits, performance, efficacy or safety of any such product or program, unless, at the time the representation is made, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

V.

IT IS FURTHER ORDERED that respondent shall not provide means and instrumentalities or substantial assistance or support to any person or entity who respondent knows or should know is making any false or misleading benefits, performance, efficacy or safety claim, or any benefits, performance, efficacy or safety claim that is not substantiated by competent and reliable scientific evidence, in connection with the labeling, advertising, promotion, offering for sale, sale or distribution of any weight loss, fat reduction or cholesterol reduction product or program. "Assistance" includes, but is not limited to, providing:

A. Any tests, analyses, studies or research to determine the benefits, performance, efficacy or safety of any such product or program;

B. The licensing or other contractual rights to market any such product or program;

C. Any technical assistance; or

D. Any advertising, labeling or promotional materials.

VI.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, subsidiary, division or other device, when providing assistance, as "assistance" is defined in Part V of this order, to any person or entity that is engaged in the labeling, advertising, promotion, offering for sale, sale or distribution of any weight loss, fat reduction or cholesterol reduction product or program, shall:

A. Take reasonable steps sufficient to determine, commencing with the beginning of any business relationship, or with entry of this order if a relationship already exists, and continuing on a regular basis throughout the relationship, whether any labeling, advertising, promotion, offering for sale, sale or distribution of any such product or program by any person to whom respondent is or will be providing assistance involves any false or misleading benefits, performance, efficacy or safety claim or any benefits, performance, efficacy or safety claim that is not substantiated by competent and reliable scientific evidence. Such steps shall include evaluating, on a basis independent of such person, the truthfulness of and substantiation for, representations made to consumers. For purposes of this order, evaluating includes, but is not limited to, reviewing all advertisements and promotional materials and all tests, reports, studies, surveys, demonstrations or other evidence that any such person relies upon in making any benefits, performance, efficacy or safety claims to consumers.

B. Immediately terminate any business relationship with any person who respondent knows or should know is making any false or misleading benefits, performance, efficacy or safety claim or any benefits, performance, efficacy or safety claim that is not substantiated by competent and reliable scientific evidence.

VII.

IT IS FURTHER ORDERED that:

A. Respondent, directly or through any corporation, subsidiary, division or other device, shall not:

1. Advertise, promote, offer for sale, sell or distribute Lipitrol or any weight loss, fat reduction or cholesterol reduction product composed of any combination of fiber and bile extract, unless he first obtains a performance bond in the principal amount of one million dollars ($1,000,000);

2. Hold any ownership interest, share or stock in, other than a passive investment, or serve as an officer, director or trustee of, any business entity engaged, in whole or in part, in the advertising, promotion, offering for sale, sale or distribution of Lipitrol or any weight loss, fat reduction or cholesterol reduction product composed of any combination of fiber and bile extract, unless he first obtains a performance bond for each such business entity or activity in the principal sum of one million dollars ($1,000,000);

3. Advertise, promote, offer for sale, sell or distribute any weight loss, fat reduction or cholesterol reduction product or program, not including the treatment of patients in connection with

his private medical practice, unless he first obtains a performance bond in the principal amount of two hundred and fifty thousand dollars ($250,000); or

4. Hold any ownership interest, share or stock in, other than a passive investment, or serve as an officer, director or trustee of, any business entity engaged, in whole or in part, in the advertising, promotion, offering for sale, sale or distribution of any weight loss, fat reduction or cholesterol reduction product or program, not including the treatment of patients in connection with his private medical practice, unless he first obtains a performance bond for each such business entity or activity in the principal sum of two hundred and fifty thousand dollars ($250,000).

B. Each such bond shall be deemed continuous and remain in full force and effect as long as respondent engages in or holds any ownership interest, share or stock in, or serves as an officer, director or trustee of, any business entity engaged, in whole or in part, in the advertising, promotion, offering for sale, sale or distribution of any product or program that is related to weight loss, fat reduction or cholesterol reduction and for at least three (3) years after respondent has ceased to engage in any such activity.

C. Each such bond shall cite this order as the subject matter of the bond, and shall provide surety thereunder against financial loss due, in whole or in part, to any violation of Sections 5 and 12 of the FTC Act, to any violation of the provisions of this order, or to any other cause attributable to respondent's engaging or participating in the advertising, promotion, offering for sale, sale or distribution of any product or program that is related to weight loss, fat reduction or cholesterol reduction.

D. Each such bond shall be an insurance agreement providing surety for financial loss issued by a surety company that holds a Federal Certificate of Authority As Acceptable Surety On Federal Bond and Reinsuring and that is admitted to conduct surety business in each state where the entity to be insured does business. Each such bond shall be in favor of both: (1) the Commission for the benefit of consumers injured due, in whole or in part, to any violation of Sections 5 and 12 of the Federal Trade Commission Act, to any violation of the provisions of this order, or to any other cause attributable to respondent's engaging or participating in the advertising, promotion, offering for sale, sale or distribution of any product or program that is related to weight loss, fat reduction or cholesterol reduction; and (b) any consumer so injured. Each such bond shall be executed in favor of the Commission or in favor of any injured consumer if the Commission or the consumer demonstrates, by a preponderance of the evidence, that respondent has violated any condition of the bond.

E. Respondent shall provide a copy of each such bond required by this Part to the Regional Director, Federal Trade Commission, 915 Second Avenue, Suite 2896, Seattle, Washington, 98174, at least ten (10) days before commencing any activity or business for which the bond is required.

F. Respondent may not disclose the existence of the performance bond to any consumer, or other purchaser or prospective purchaser, to whom a covered weight loss, fat reduction or cholesterol reduction product or program is advertised, promoted, offered for sale, sold, or distributed, without also disclosing at the same time and in a like manner that the performance bond is required by order of

the Commission in settlement of charges that respondent engaged in false and misleading representations.

G. The bond required by this Part shall be in addition to, and not in lieu of, any other bond required by law.

H. Proceedings instituted under this Part are in addition to, and not in lieu of, any other civil or criminal remedies as may be provided by law, including any other proceedings the Commission may initiate to enforce this order.

VIII.

IT IS FURTHER ORDERED that respondent, his successors and assigns, shall deposit into an escrow account, to be established by the Commission for the purpose of receiving payment due under this order ("escrow account"), the sum of twenty thousand dollars ($20,000). This payment shall be made in the following manner:

A. By certified or cashier's check made payable to the Federal Trade Commission, in four installments, the first payment of five thousand dollars ($5,000) to be made within 60 days after the date that this order becomes final; the second payment of five thousand dollars ($5,000) to be made no later than the first day of the fourth month thereafter; the third payment of five thousand dollars ($5,000) to be made no later than the first day of the eighth month thereafter; and the final payment of five thousand dollars ($5,000) to be made within one year from the date that this order becomes final. The checks shall be deliverable to Regional Director, Federal Trade Commission, 915 Second Avenue, Suite 2896, Seattle, Washington 98174.

B. In the event of any default in payment, which default continues for ten (10) days beyond the due date of payment, the entire amount due, together with interest, as computed pursuant to 28 U.S.C. § 1961 from the date of default to the date of payment, shall immediately become due and payable.

C. In order to secure payment of respondent's indebtedness to the Commission, within seven (7) days of the date that this order becomes final, respondent shall cause to be transferred to the Commission a security interest in the property described in Appendix A, which property has been determined by an independent appraisal to have a value of twenty thousand dollars ($20,000) or more in excess of all other perfected security interests, as security for the payments required to be made by respondent in Part VIII(A) of this order. The respondent shall, within seven (7) days of the date that this order becomes final, file all documents necessary to perfect and record the Commission's security interest in the property described in Appendix A, in conformity with appropriate state law. The respondent shall, within ten (10) days of the date that this order becomes final, furnish to counsel for the Commission complete documentation evidencing that the Commission's security interest in the property described in Appendix A has been correctly perfected and recorded. The Commission will release this security interest upon receipt of all payments required by Part VIII(A) of this order.

D. The funds paid by respondent, together with accrued interest, shall, in the discretion of the Commission, be used by the Commission to provide direct redress to purchasers of Lipitrol in connection with the acts or practices alleged in the complaint, and to pay any attendant costs of administration. If the Commission determines, in its sole discretion, that redress to purchasers of this product is wholly or partially impracticable or is otherwise unwarranted, any funds not so used shall be paid to the United States Treasury. Respondents shall be notified as to how the funds are distributed, but shall have no right to contest the manner of distribution chosen by the Commission. No portion of the payment as herein provided shall be deemed a payment of any fine, penalty or punitive assessment.

E. At any time after this order becomes final, the Commission may direct the escrow agent to transfer funds from the escrow account, including accrued interest, to the Commission to be distributed as herein provided. The Commission, or its representative, shall, in its sole discretion, select the escrow agent.

F. Respondent relinquishes all dominion, control and title to the funds paid into the escrow account, and all legal and equitable title to the funds vests in the Treasurer of the United States and in the designated consumers. Respondent shall make no claim to or demand for return of the funds, directly or indirectly, through counsel or otherwise; and in the event of bankruptcy of respondent, respondent acknowledges that the funds are not part of the debtor's estate, nor does the estate have any claim or interest therein.

IX.

Nothing in this order shall prohibit respondent from making any representation for any drug that is permitted in labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration ("FDA"), or under any new drug application approved by the FDA.

X.

Nothing in this order shall prohibit respondent from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the FDA pursuant to the Nutrition Labeling and Education Act of 1990.

XI.

IT IS FURTHER ORDERED that respondent shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Commission for inspection and copying:

A. All advertisements or promotional materials containing the representation;

B. All materials that were relied upon in disseminating the representation; and

C. All tests, reports, studies, surveys, demonstrations or other evidence in his possession or control that contradict, qualify or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

XII.

IT IS FURTHER ORDERED that respondent shall deliver a copy of this order to all current and future principals, officers, directors and managers, and to all current and future employees, agents and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondent shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

XIII.

IT IS FURTHER ORDERED that respondent shall, for a period of five (5) years after the date of issuance of this order, notify the Commission within thirty (30) days of his affiliation with any business or employment involving any activities related to the advertising, offering for sale, sale or distribution of any weight loss, fat reduction or cholesterol reduction product or program. The notice shall include respondent's new business address and telephone number, current home address, and a description of the nature of the business or employment, respondent's interest in the new business or employment and his duties and responsibilities. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580.

XIV.

IT IS FURTHER ORDERED that respondent shall, within sixty (60) days after the date of service of this order, and at other such times as the Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which he has complied with this order.

XV.

This order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

A. Any Part in this order that terminates in less than twenty (20) years;

B. This order's application to any respondent that is not named as a defendant in such complaint; and

C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

Signed this _____ day of _____, 199___

_____

WILLIAM E. SHELL, M.D., individually
and as a former officer and director of
Interactive Medical Technologies, Ltd.

_____

NADINE S. SAMTER
Counsel for the Federal Trade Commission

_____

PATRICIA A. HENSLEY
Counsel for the Federal Trade Commission

APPROVED:

_____

CHARLES A. HARWOOD
Regional Director
Seattle Regional Office

[Confidential Appendix A redacted.]

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of	)	
INTERACTIVE MEDICAL TECHNOLOGIES, LTD., and EFFECTIVE HEALTH, INC., corporations, and	)	DOCKET NO.
WILLIAM PELZER, JR., individually and as a former officer of Interactive Medical Technologies, Ltd., and Effective Health, Inc., and	)	
WILLIAM E. SHELL, M.D., individually and as a former officer of Interactive Medical Technologies, Ltd.	)	

COMPLAINT

The Federal Trade Commission ("Commission"), having reason to believe that Interactive Medical Technologies, Ltd., and Effective Health, Inc., corporations, and William Pelzer, Jr., individually and as a former officer of Interactive Medical Technologies, Ltd., and Effective Health, Inc., and William E. Shell, M.D., individually and as a former officer of Interactive Medical Technologies, Ltd. ("respondents"), have violated provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Interactive Medical Technologies, Ltd. ("IMT"), is a Delaware corporation with its principal office or place of business at 2139 Pontius Avenue, Los Angeles, California 90025.

2. Respondent Effective Health, Inc. ("EHI"), is a California corporation with its principal office or place of business at 2139 Pontius Avenue, Los Angeles, California 90025. EHI is a wholly owned subsidiary of IMT.

3. Respondent William Pelzer, Jr. ("Pelzer"), was chief executive officer and president of IMT and EHI from February 1993 to April 1995. Individually or in concert with others, he formulated, directed, controlled or participated in the acts and practices of IMT and EHI, including the acts and practices alleged in this complaint. His principal office or place of business is P.O. Box 269006, San Diego, California 92196.

4. Respondent William E. Shell, M.D. ("Shell") was chairman of the board of IMT from January 1990 through February 1996, and served as that company's chief financial officer from May 1993 through June 1994. Individually or in concert with others, he formulated, directed, controlled or participated in the acts and practices of IMT and EHI, including the acts and practices alleged in this complaint. His principal office or place of business is 2934 1/2 Beverly Glen Circle, Suite 209, Los Angeles, California 90077.

5. Respondents IMT, EHI and Shell have advertised, labeled, offered for sale, sold and distributed products to the public, including Lipitrol, an over-the-counter fat reduction and weight-loss tablet. Lipitrol is a "food" and/or "drug," within the meaning of Sections 12 and 15 of the Federal Trade Commission Act. Respondents have advertised, distributed and sold Lipitrol, a combination of fiber and ox bile extract, to the public through direct mail.

6. Respondents also have assisted others who have advertised, labeled, offered for sale, sold and distributed products to the public, including SeQuester, an over-the-counter fat reduction and weight-loss tablet. SeQuester is a "food" and/or "drug," within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

7. 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.

Lipitrol Fat Reduction and Weight-Loss Tablets

8. Respondents IMT, EHI and Shell have disseminated or have caused to be disseminated advertisements for Lipitrol, including but not necessarily limited to the attached Exhibits A through E. These advertisements contain the following statements:

A.

INTRODUCING

LIPITROL

a patented dietary supplement
that aids in your FIGHT against FAT
by assisting in weight and cholesterol reduction.

NO ANCIENT FORMULA NO MAGIC NO MECHANICAL GADGETS
NO SHOTS NO DRUGS NO WILD PROMISES NO PATCHES
NO SPECIAL FOOD TO PURCHASE NO SECRET INGREDIENTS NO WRAPS
NO SPECIAL TESTING MATERIALS NO POWDERS NO SURGERY
NO VERY LOW CALORIE DIETS NO GIMMICKS NO CURE-ALLS

NO MOOD ELEVATORS NO SUPER-SPEEDY WEIGHT LOSS NO HYPE
DOESN'T EVEN DISSOLVE CELLULITE
BUT IT DOES WORK
WHICH MAY SEEM LIKE A MIRACLE TO SOME PEOPLE

Effective Health knows of no other diet or weight loss program that is backed by scientific data and a recognized patent for "Dietary Fat Reduction."

Lipitrol contains natural ingredients consisting of Activated Fiber Complex (AFC). AFC forms an indigestible cellulose mesh containing molecules of bile. Bile is the part of the digestive system which enables the body to use and/or store fat. Fat droplets in stomach and intestines are naturally attracted to the AFC and when they adhere to the enmeshed bile molecules, they can then be carried through the intestinal tract and excreted rather than being absorbed for use or storage (sic). If stools are lighter in color, or yellowish, and if they frequently tend to float instead of sink in water, then the bile-bonded fat is now being excreted rather than absorbed. The only adverse effect from using LIPITROL is occasional diarrhea related to the excessive fat in the stools.

A major benefit of LIPITROL is that it imparts a feeling of satiety of fullness to the user (sic). A second, highly significant benefit is the fact that LIPITROL has been proven to lower blood cholesterol levels. Cholesterol is lowered as a result of the weight loss.

. . . .

Effective Health believes LIPITROL meets an urgent need in society, and does so in a healthy and genuine manner. LIPITROL is not an overnight solution to excess weight, but it offers sincere and dedicated users an option whereby they can lose weight and maintain the loss without doing violence to their lifestyles or drugging their systems.

You have nothing to LOSE but FAT itself!

(Exhibit A -- direct mail solicitation)

B. NOW THERE'S AN EFFECTIVE WAY TO HELP REDUCE FAT -- NOW THERE'S LIPITROL! -- DIETARY SUPPLEMENT

LIPITROL IS AN EFFECTIVE WEIGHT CONTROL PRODUCT

LIPITROL can help you control your weight by reducing FAT intake. No kidding! LIPITROL actually helps decrease the amount of FAT absorbed by your body. . . .

IT HELPS FAT PASS THROUGH THE BODY

LIPITROL'S fiber formula forms an indigestible cellulose mesh containing molecules of bile. Bile is part of the digestive system which enables the body to use and/or store FAT. FAT droplets in the stomach and intestines are naturally attracted to the "Fiber Complex." When the FAT adheres to the enmeshed bile molecules, the FAT can then be passed through the intestinal tract and is excreted rather than absorbed - Naturally and Comfortably. **NO DRUGS, NO CAFFEINE, NO DIURETICS - EVER!**

. . . .

CONTROL FAT WITH LIPITROL:

Keeping FAT under control is important to good health.

FAT makes you FAT. There are 9 calories in 1 gram of FAT - plus your body stores FAT directly. Get FAT out of your diet. FAT laden diets may contribute to a variety of health problems including high blood pressure, diabetes, breast cancer, and heart disease.

Our clinical studies have shown LIPITROL to absorb approximately 5.9 grams of FAT per tablet from the foods you

eat. Take hold of the FAT before the FAT takes hold of you. Use **LIPITROL** - Dietary Supplement DAILY!
. . . .

A NATURAL FOOD PRODUCT
. . . .

Remember, LIPITROL is not an overnight solution to excess weight, but offers you, the sincere and dedicated individual the option to reduce FAT absorption, lose weight, and maintain that loss, without doing harm to your body.

MORE ABOUT LIPITROL:

LIPITROL has been studied for over 7 years. One of the recent 4 week studies has indicated that diet and exercise will result in an average weight loss of about 2.1 lbs per month. With sensible eating, exercise and LIPITROL the average weight loss was 6.2 lbs per month -- with little or no FAT retention.

THE REAL ENEMY

Remember while excess "weight" is certainly a big concern, your real enemy is FAT. LIPITROL Fights FAT, and losing FAT takes time. Use LIPITROL for 60 days or more to see measurable results. LIPITROL helps remove a large portion of the FAT from the food you eat before it ends up on your body, or clogging your arteries.

You Have Nothing to LOSE, But Fat Itself!

(Exhibit B -- direct mail solicitation)

C. **Effective Health Inc. is pleased to announce the development of LIPITROL through fat sequestrant technology. Our specially formulated product, marketed as a dietary food supplement, assists in weight and cholesterol reduction.**

. . . .

When taken as directed, our tablet attracts fat from the food you eat and helps eliminate it from your body. Cholesterol reduction occurs subsequent to weight loss. Overdoses result in nothing more serious than self/limiting diarrhea (sic).

. . . .

LIPITROL has undergone independent open label trials. A technical brochure that substantiates the efficacy of LIPITROL is available upon request.

(Exhibit C -- direct mail solicitation)

D. . . . .

Q: Should I Increase My Dosage?

A: After two or three days, increase your dosage to 2 tablets prior to your largest and Fattiest meal of the day. If no diarrhea results from 2 tablets at your largest meal, you may choose to use 2 tablets prior to every meal. Some people will even use 3 LIPITROL or more prior to their Fattiest meal. If diarrhea occurs, this is a form of controllable diarrhea and not the same as diarrhea caused by food poisoning. It does not require medication or any treatment. It just means that there is too much FAT in your stool to allow a normal bowel movement. This actually is a condition we regard as Desirable as it means the FAT is leaving your body. Whether the normal dosage or the Maxi FAT strategy described below is appropriate for you depends upon how your body responds to lesser dosages, and upon the advice of your physician.

Q: How Can I Get Maximum FAT Removal?

A: Each LIPITROL tablet has the capability to remove approximately 6 grams of FAT (the actual figure is 5.9 grams) from the food you eat. By determining as accurately as possible, the number of grams of FAT you are consuming in your next meal, you can use that figure, divided by 6, and take the appropriate number of tablets to absorb that FAT -- this is what we call the Maxi-FAT strategy.

. . . .

Q: When Should I Begin To See Weight Loss and/or Size Loss?

A: One of our four week studies indicates that diet and exercise alone will result in an average weight loss of about 2.1 pounds per month. With diet and exercise plus LIPITROL the average weight loss in our study was 6.2 pounds per month.

. . . .

Q: NOTE: Please do not view your LIPITROL as an antidote for poor nutritional habits. Don't think that it is now o.k. to over indulge yourself and eat all the FAT-soaked food you want. NOT SO. You must realize that while some foods may be 40% or 50% FAT, the remaining 50% or 60% is not and still contains calories that won't be dealt with by taking LIPITROL.

. . . .

(Exhibit D -- product package insert)

E. . . . .

Each LIPITROL tablet has been shown to absorb approximately 5.9 grams of FAT, from the foods you eat.

. . . .

(Exhibit E -- product package label)

9. Through the means described in Paragraph 8, respondents IMT, EHI and Shell have represented, expressly or by implication, that:

A. Lipitrol prevents or significantly reduces the body's absorption of fat from consumed food.

B. Lipitrol absorbs approximately 5.9 grams of fat per tablet from consumed food.

C. Scientific research demonstrates that Lipitrol prevents or significantly reduces the body's absorption of fat from consumed food.

D. Scientific research demonstrates that Lipitrol absorbs approximately 5.9 grams of fat per tablet from consumed food.

E. Scientific research demonstrates that Lipitrol causes significant weight loss.

F. Scientific research demonstrates that Lipitrol lowers blood cholesterol levels.

10. In truth and in fact:

A. Lipitrol does not prevent or significantly reduce the body's absorption of fat from consumed food.

B. Lipitrol does not absorb approximately 5.9 grams of dietary fat per tablet from consumed food.

C. Scientific research does not demonstrate that Lipitrol prevents or significantly reduces the body's absorption of fat from consumed food.

D. Scientific research does not demonstrate that Lipitrol absorbs approximately 5.9 grams of fat per tablet from consumed food.

E. Scientific research does not demonstrate that Lipitrol causes significant weight loss.

F. Scientific research does not demonstrate that Lipitrol lowers blood cholesterol levels.

Therefore, the representations set forth in Paragraph 9 were, and are, false or misleading.

11. Through the means described in Paragraph 8, respondents IMT, EHI and Shell have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 9(A) and (B), at the time the representations were made.

12. In truth and in fact, respondents IMT, EHI and Shell did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 9(A) and (B), at the time the representations were made. Therefore, the representation set forth in Paragraph 11 was, and is, false or misleading.

13. Through the means described in Paragraph 8, respondents IMT, EHI and Shell have represented, expressly or by implication, that Lipitrol:

A. Causes significant weight loss.

B. Lowers blood cholesterol levels.

C. Reduces, or reduces the risks associated with, high cholesterol, including clogged arteries, high blood pressure, diabetes, breast cancer and heart disease.

D. Causes significantly greater weight loss than diet and exercise alone.

E. Is beneficial and safe when taken in amounts sufficient to cause diarrhea.

14. Through the means described in Paragraph 8, respondents IMT, EHI and Shell have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 13, at the time the representations were made.

15. In truth and in fact, respondents IMT, EHI and Shell did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 13, at the time the representations were made. Therefore, the representation set forth in Paragraph 14 was, and is, false or misleading.

SeQuester Fat Reduction and Weight-Loss Tablets

16. Since at least May 1994, KCD, Incorporated, its holding corporation, KCD Holdings, Inc., their former principal, Clark M. Holcomb, and current principal, Bonnie L. Richards (collectively, “KCD”), have advertised, distributed and sold an over-the-counter fat reduction and weight-loss product to the public through, among other means, newspaper and radio advertisements disseminated nationally. KCD has wholesaled this product to retail drug stores and other retailers for resale to the general public. The product, sold under the name "SeQuester," is a combination of fiber and ox bile extract, and is the same or substantially the same as Lipitrol.

17. IMT, through its subsidiary EHI, Pelzer and Shell (hereinafter "IMT respondents") have provided KCD with, among other things, exclusive rights to sell SeQuester, technical assistance and "know how," clinical studies purporting to show that SeQuester is an effective fat reduction and weight-loss product, and certain promotional materials and information. Under the licensing agreement between the IMT respondents and KCD, KCD was required to make royalty payments to the IMT respondents based on sales of SeQuester.

18. KCD has disseminated or has caused to be disseminated advertisements for SeQuester, including but not necessarily limited to the attached Exhibits F through J. These advertisements contain the following statements and depictions:

F.

THIS

IS WHAT
SEQUESTER
DOES TO
THE FAT
IN FOOD
YOU
EAT

Introducing SeQuester - the revolutionary tablet that “shrinks” the amount of dietary fat your body absorbs.

SeQuester is a lab-tested formula that neutralizes fat in the food you eat - safely and naturally - *before* it's absorbed, so it won't wind up on your body.

SeQuester's unique, patented ingredients bind fat molecules to vegetable fiber passing them gently and harmlessly through your digestive tract. It's like you never ate them at all. Shrink fat with SeQuester. Take advantage of introductory savings, and discover the safe, natural approach to fat reduction. It's in the diet section, today.

(Exhibit F - newspaper advertisement)

G. **THE FAT STOPS HERE**

Dietary fat is a prime cause of overweight, heart disease, high cholesterol, and other major health problems. So imagine a tablet that can “shrink” the amount of fat your body absorbs.

Imagine SeQuester. A revolutionary discovery that lets you “remove” fat from the food you eat before it's absorbed, so it won't wind up on your body. Or in your arteries.

SeQuester is a safe, natural, lab-tested formula, shown to be effective in lowering fat absorption. It's easy. Just take one or more SeQuester tablets 30 minutes before meals. Its unique, patented formula binds fat molecules to natural vegetable fiber (as illustrated), passing it gently and harmlessly through your digestive tract.

SeQuester is intended for use as part of a program of sensible nutrition and exercise. Unlike fad diets that are ineffective at best, unhealthy at worst, SeQuester contributes to a safe, gradual loss of body fat and weight significantly better than what you're likely to accomplish through dieting and exercise alone.

So get control of fat, before fat controls you. Take advantage of our introductory savings on SeQuester, and experience for yourself this patently superior approach to fat reduction. Look for SeQuester in the diet section, today.

(Exhibit G - newspaper advertisement)

H. For the holidays, don't cut it all out.

Just take SeQuester.

SEQUESTER REDUCES FAT FROM THE FOOD YOU EAT.

Don't look now, weight watchers, but the holidays are gaining on us. So many parties, so much good food, so hard to say, “no.” So consider your choices:

Either you can cut out all those rich, delicious foods that make life worthwhile.

Or you can cut out this coupon and introduce yourself to SeQuester - a revolutionary discovery that helps your body minimize fat retention from the food you eat.

With SeQuester, you can plan on enjoying reasonable portions of all those great holiday foods, confident that their entire fat content won't be showing up on your scale - or in your arteries - come January 1st.

SeQuester is a safe, natural dietary supplement. Its unique, patented formula helps bind fat molecules to natural vegetable fiber, so they pass gently and effortlessly through the digestive tract. Just take one or more tablets 30 minutes before meals.

This season, make SeQuester the centerpiece of all your holiday meals. You'll find it in better drugstores and supermarkets, everywhere.

NOTE: SeQuester is intended for use as part of a complete program of sensible nutrition and moderate exercise. By following this program, studies suggest that SeQuester contributes to a safe, gradual loss of body fat and weight significantly more successful than dieting and exercise alone.

(Exhibit H - newspaper advertisement)

I. . . . .

Q. SHOULD I INCREASE MY DOSAGE?

A: After two or three days, increase your dosage to 2 tablets prior to your largest and fattiest meal of the day. If no diarrhea results from 2 tablets at your largest meal, you may choose to use 2 tablets before every meal. Some people will even use 3 or more SeQuester tablets prior to their fattiest meal. If diarrhea occurs, it is controllable. It does not require medication or any treatment. It just means that there is too much fat in your stool to allow a normal bowel movement. This actually is a condition we regard as desirable as it means the fat is leaving your body. Whatever is appropriate for you depends upon how your body responds to lesser dosages, and upon the advice of your physician.

. . . .

(Exhibit I - product package insert)

J. **SeQuester**

Natural Nutritional Fat Sequestrant*

*SeQuester is a specially formulated patented product which, when used as directed, reduces fat and sugar from the foods you eat.

Tests have shown SeQuester effects metabolizable energy, thus increasing fecal energy (calorie) excretion and reduces hunger feelings without increasing total calorie intake.

(Exhibit J - product package)

19. Through the means described in Paragraph 18, KCD has represented, expressly or by implication, that:

A. SeQuester prevents or significantly reduces the body's absorption of fat from consumed food.

B. SeQuester significantly reduces the body's absorption of sugar from consumed food.

C. Scientific research demonstrates that SeQuester prevents or significantly reduces the body's absorption of fat from consumed food.

D. Scientific research demonstrates that SeQuester causes significant weight loss.

20. In truth and in fact:

A. SeQuester does not prevent or significantly reduce the body's absorption of fat from consumed food.

B. SeQuester does not significantly reduce the body's absorption of sugar from consumed food.

C. Scientific research does not demonstrate that SeQuester prevents or significantly reduces the body's absorption of fat from consumed food.

D. Scientific research does not demonstrate that SeQuester causes significant weight loss.

Therefore, the representations set forth in Paragraph 19 were and are, false or misleading.

21. Through the means described in Paragraph 18, KCD has represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 19(A) and (B), at the time the representations were made.

22. In truth and in fact, KCD did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 19(A) and (B), at the time the representations were made. Therefore, the representation set forth in Paragraph 21 was, and is, false or misleading.

23. Through the means described in Paragraph 18, KCD has represented, expressly or by implication, that:

A. SeQuester causes significant weight loss.

B. Use of SeQuester allows consumers to eat high-fat foods without gaining weight.

C. SeQuester causes significantly greater loss of weight and body fat than diet and exercise alone.

D. Use of SeQuester allows consumers to eat high-fat foods without increasing their risk of high cholesterol, clogged arteries, heart disease and other health problems associated with a high-fat diet.

E. SeQuester reduces the risk of high cholesterol, clogged arteries, heart disease, and other health problems associated with a high-fat diet.

F. Use of SeQuester in amounts sufficient to cause diarrhea is beneficial and safe.

24. Through the means described in Paragraph 18, KCD has represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 23, at the time the representations were made.

25. In truth and fact, KCD did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 23, at the time the representations were made. Therefore, the representation set forth in Paragraph 24 was, and is, false or misleading.

26. The IMT respondents knew or should have known that the advertisements referred to in Paragraph 18, including but not limited to the advertisements attached as Exhibits F through J, contained the false and misleading representations set forth in Paragraphs 19 through 25 above; but the IMT respondents nevertheless have provided services and promotional materials to assist KCD's marketing and sale of SeQuester, including but not limited to:

A. Studies purporting to show that SeQuester effectively reduces the body's absorption of fat from consumed food and causes significant weight loss;

B. The licensing rights to market and sell SeQuester to consumers;

C. Technical information regarding SeQuester; and

D. Various promotional materials and information.

27. Through the means described in Paragraph 26, the IMT respondents have provided means and instrumentalities and/or have provided substantial assistance to KCD in furtherance of the unfair or deceptive acts or practices alleged in Paragraphs 19 through 25, which the IMT respondents knew or should have known were unfair or deceptive.

28. The acts and practices of respondents 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.

THEREFORE, the Federal Trade Commission this _____ day of ___, 1997, has issued this complaint against respondents.

By the Commission.

Donald S. Clark
Secretary

SEAL:

[Exhibits A-J attached to paper copies of complaint, but not available in electronic form.]

ANALYSIS OF PROPOSED CONSENT ORDERS TO AID PUBLIC COMMENT

The Federal Trade Commission ("Commission") has accepted, subject to final approval, agreements to proposed consent orders from KCD, Incorporated ("KCD") and KCD Holdings, Inc. ("KCD Holdings"), their former officer, Clark M. Holcomb ("Holcomb"), and their current officer, Bonnie L. Richards ("Richards") (hereinafter "KCD respondents"), their advertising agency, Deerfield Corporation ("Deerfield"), and its owner, Gerald E. Hatto ("Hatto"). The KCD respondents market and sell an over-the-counter weight loss product, known as SeQuester, comprised of fiber and ox bile. The product advertisements have represented that the product reduces the body's absorption of fat and sugar from consumed food, thereby providing weight loss and cholesterol lowering benefits. Respondents Deerfield and Hatto assisted in the creation and dissemination of the SeQuester advertisements.

The Commission has also accepted, subject to final approval, agreements to proposed consent orders from Interactive Medical Technologies, Ltd. ("IMT"), its wholly owned subsidiary, Effective Health, Inc. ("EHI"), William Pelzer, Jr. ("Pelzer"), a former officer of IMT and EHI, and William E. Shell, M.D. ("Shell"), also a former officer of IMT (hereinafter "IMT respondents"). These respondents marketed and sold an over-the-counter weight loss product, known as Lipitrol, also comprised of fiber and ox bile. The Lipitrol product advertisements represented that the product reduced the body's absorption of fat from consumed food, thereby providing weight loss and cholesterol lowering benefits. The IMT respondents also provided means and instrumentalities or substantial assistance to the KCD respondents' marketing and sale of SeQuester.

The proposed consent orders have been placed on the public record for sixty (60) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreements and the comments received and will decide whether it should withdraw from the agreements and take other appropriate action or make final the proposed orders contained in the agreements.

The Proposed Complaints

The Commission's complaint against the KCD respondents, Deerfield and Hatto, charges these respondents with making false and unsubstantiated claims, in advertising and promotional materials, regarding the efficacy of SeQuester as a weight loss, fat reduction and cholesterol reduction product. Specifically, the complaint alleges that the KCD respondents falsely represented, expressly or by implication, that SeQuester prevents or significantly reduces the body's absorption of fat and sugar from consumed food. The complaint also charges that these respondents failed to possess and rely upon a reasonable basis for these representations. The complaint further alleges that these respondents made false and deceptive

representations that scientific research demonstrates that SeQuester prevents or significantly reduces the body's absorption of fat from consumed food and causes significant weight loss.

In addition, the complaint alleges that the KCD respondents have represented that SeQuester causes significant weight loss; allows consumers to eat high-fat foods without gaining weight; causes significantly greater weight loss than diet and exercise alone; allows consumers to eat high-fat foods without increasing their risk of high cholesterol, clogged arteries, heart disease and other health problems associated with a high-fat diet; reduces the risk of high cholesterol, clogged arteries, heart disease and other problems associated with a high-fat diet; and is beneficial and safe when used in amounts sufficient to cause diarrhea. The complaint charges that these respondents did not possess and rely upon a reasonable basis for these representations.

The complaint also alleges that Deerfield and Hatto have represented, expressly or by implication, that SeQuester causes significant weight loss; allows consumers to eat high-fat foods without gaining weight; allows consumers to eat high-fat foods without increasing their risk of high cholesterol, clogged arteries, heart disease and other health problems associated with a high-fat diet; prevents or significantly reduces the body's absorption of fat and sugar from consumed food; reduces the risk of high cholesterol, clogged arteries, heart disease and other problems associated with a high-fat diet; and significantly reduces the body's absorption of sugar from consumed food. The complaint charges that Deerfield and Hatto did not possess and rely upon a reasonable basis for these representations. The complaint further alleges that Deerfield and Hatto falsely represented that scientific research demonstrates that SeQuester prevents or significantly reduces the body's absorption of fat from consumed food and causes significant weight loss. The complaint also charges that respondents Deerfield and Hatto knew or should have known that these representations were false and misleading.

The Commission's complaint against the IMT respondents charges IMT, EHI and Shell, with making false and unsubstantiated advertising claims regarding the efficacy of Lipitrol as a weight loss, fat reduction and cholesterol reduction product. Specifically, the complaint alleges that IMT, EHI and Shell falsely represented, either expressly or by implication, that Lipitrol prevents or significantly reduces the body's absorption of fat from consumed food, and absorbs approximately 5.9 grams of fat per tablet from consumed food. The complaint also charges that respondents IMT, EHI and Shell failed to possess and rely upon a reasonable basis for these representations. The complaint further alleges that these respondents made false and deceptive representations that scientific research demonstrates that Lipitrol prevents or significantly reduces the body's absorption of fat from consumed food, absorbs approximately 5.9 grams of fat per tablet from consumed food, causes significant weight loss and lowers blood cholesterol levels.

In addition, the complaint alleges that respondents IMT, EHI and Shell have represented that Lipitrol causes significant weight loss; lowers blood cholesterol levels; reduces, or reduces the risks associated with, high cholesterol, including clogged arteries, high

blood pressure, diabetes, breast cancer and heart disease; causes significantly greater weight loss than diet and exercise alone; and is beneficial and safe when taken in amounts sufficient to cause diarrhea. The complaint charges that these respondents did not possess and rely upon a reasonable basis for these representations.

Respondent William Pelzer, Jr. is not included in the above-mentioned allegations because he had no involvement in the advertising, marketing or sale of Lipitrol.

In addition, the complaint charges that the IMT respondents, including respondent Pelzer, provided means and instrumentalities and/or substantial assistance to others who respondents knew or should have known were making false and deceptive or unsubstantiated claims for the product, sold under the name SeQuester. Specifically, the complaint alleges that the respondents licensed to KCD, its holding company, KCD Holdings, those companies' former principal, Holcomb, and current principal, Richards, the exclusive rights to market the product.

The complaint alleges that the IMT respondents knew or should have known that the KCD respondents made false and deceptive or unsubstantiated representations similar to those made for Lipitrol, in advertisements for SeQuester. The complaint charges that despite the fact that respondents knew or should have known that KCD was making the false and deceptive, and/or unsubstantiated representations in the marketing and sale of SeQuester, the IMT respondents nevertheless provided various services and promotional materials to the KCD respondents in furtherance of the KCD respondents' efforts to disseminate these false claims, including providing the KCD respondents with studies purporting to show that SeQuester effectively reduces the body's absorption of fat from consumed food and causes significant weight loss; the licensing rights to market and sell the product to consumers; technical information regarding the product; and various promotional materials and information for marketing the product.

The Proposed Orders

The Commission has accepted four separate consent orders in this matter. The proposed orders contain provisions designed to remedy the alleged violations. The proposed orders against respondents KCD Holdings, Inc., KCD, Incorporated and Bonnie L. Richards; IMT and EHI; and Shell provide for the payment of consumer redress in installments over a period of one year from the date the proposed orders become final. In the event that consumer redress is not feasible, the proposed orders provide that the funds will be deposited in the United States Treasury. In addition, the proposed order against respondent Shell requires him to post a performance bond of either $250,000 or $1,000,000, depending on the circumstances of his activities.

Proposed Consent Order with the KCD Respondents, Deerfield and Hatto

Part I of the proposed consent order against the KCD respondents, Deerfield and Hatto bars them from making representations that SeQuester or any product or program prevents or reduces the body's absorption of fat or sugar from consumed food unless the representation is true at the time it is made and is supported by competent and reliable scientific evidence.

Part II of the proposed consent order against the KCD respondents, Deerfield and Hatto prohibits them from representing that SeQuester or any product or program provides any weight loss benefit; causes greater loss of body fat than diet and exercise alone; allows consumers to eat high-fat foods without increasing their risk of high cholesterol, clogged arteries, heart disease or other health problems associated with a high-fat diet; or reduces, or reduces the risk of, high cholesterol, clogged arteries, heart disease and other health problems associated with a high-fat diet, unless respondents can substantiate these representations with competent and reliable scientific evidence.

Part III of the proposed consent order against the KCD respondents prevents them from representing that SeQuester or any product or program can be used beneficially and safely, in amounts or with frequency sufficient to cause diarrhea, unless, at the time the representation is made, they possess and rely upon competent and reliable scientific evidence that substantiates the representation, which when appropriate, must be competent and reliable scientific evidence.

Part IV of the proposed consent order against the KCD respondents, Deerfield and Hatto bars them from misrepresenting the existence, contents, validity, results, conclusions or interpretations of any test, study or research. Part V of the proposed consent order against the KCD respondents, Deerfield and Hatto prohibits them from making representations about the benefits, performance, efficacy or safety of SeQuester or any product or program unless competent and reliable evidence substantiates any such representation.

Part VI of the proposed consent order against the KCD respondents provides Deerfield and Hatto with a defense to Parts I, II and V of the order if they neither knew nor had reason to know of an inadequacy of substantiation for any representation covered by those parts of the order; and a defense to Part IV of the order if they neither knew nor had reason to know that the test, study or research did not prove, demonstrate or confirm any representation covered by that part of the order.

Part VII of the proposed order against the KCD respondents requires KCD, KCD Holdings and Richards to pay $150,000 in consumer redress, in thirteen installments over a period of one year. If consumer redress is impracticable, Part VII provides that these funds will be paid to the United States Treasury. Part VII(C) requires KCD, KCD Holdings and Richards to provide the Commission with a security interest in certain property to insure full payment of the $150,000 of consumer redress.

Parts VIII and IX of the proposed order against the KCD respondents, Deerfield and Hatto contain provisions permitting certain claims that are approved for labeling by the FDA, either under the Nutrition Labeling and Education Act, a tentative final or final monograph or under any new drug application approved by the FDA.

Parts X, XI, XII, XIII and XIV of the proposed order against the KCD respondents, Deerfield and Hatto contain compliance reporting provisions requiring respondents to: retain records that bear on their compliance with the order; distribute copies of the order to those persons having responsibility with respect to the subject matter of the order; notify the Commission of any changes in the structure of the corporate respondents that may affect their compliance obligations under the order, or any changes in the business affiliations of the individual respondents; and report to the Commission their compliance with the terms of the order.

Part XV of the proposed order against the KCD respondents, Deerfield and Hatto contains a provision automatically terminating the order twenty (20) years from the date that it becomes final.

Proposed Consent Order with IMT, EHI, Shell and Pelzer

Part I of the proposed consent order against respondents IMT and EHI bars them from making representations that Lipitrol or any weight loss, fat reduction or cholesterol reduction product or program prevents or reduces the body's absorption of fat from consumed food or absorbs any amount of fat from consumed food unless the representation is true and supported by competent and reliable scientific evidence. Part I of the proposed order against respondent Shell contains the same bar, but covers representations for Lipitrol or any product or program.

Part II of the proposed order against respondents IMT and EHI prohibits them from representing that Lipitrol or any weight loss, fat reduction or cholesterol reduction product or program, or any food, drug or dietary supplement, provides any weight loss benefit; lowers blood cholesterol levels; reduces, or reduces the risks associated with, high cholesterol, including clogged arteries, high blood pressure, diabetes, breast cancer and heart disease; or can be used, beneficially and safely, in amounts or with frequency sufficient to cause diarrhea, unless respondents can substantiate these representations with competent and reliable scientific evidence. Again, the same prohibition is contained in Part II of the proposed order against respondent Shell, but covers representations for Lipitrol or any product or program.

Part III of the proposed order against respondents IMT and EHI prohibits them from misrepresenting the existence, contents, validity, results, conclusions or interpretations of any test, study or research in connection with Lipitrol or any weight loss, fat reduction or cholesterol reduction product or program, or any food, drug or dietary supplement. Part IV of the proposed order prohibits respondents IMT and EHI from making representations about the

benefits, performance, efficacy or safety of Lipitrol or any weight loss, fat reduction or cholesterol reduction product or program, or any food, drug or dietary supplement unless competent and reliable scientific evidence substantiates any such representation. Parts III and IV of the proposed order against respondent Shell are the same except that the prohibitions apply to representations for Lipitrol or any product or program.

Part V of the proposed orders against respondents IMT, EHI and Shell, and Part I of the proposed order against respondent Pelzer, bars each of these respondents from providing means and instrumentalities or substantial assistance or support to any person or entity who they know or should know is making any false or misleading or unsubstantiated claim for any weight loss, fat reduction or cholesterol reduction product or program. The proposed orders define "assistance" to include providing: tests, analyses, studies or research to determine the benefits, performance, efficacy or safety of the product or program; licensing or other contractual rights to market any such product or program; technical assistance; or advertising, labeling or promotional materials for the marketing and sale of any such product or program.

Part VI of the proposed orders against respondents IMT, EHI and Shell, and Part II of the proposed order against respondent Pelzer, require these respondents to monitor business practices of certain parties to whom they provide assistance. To the extent that any such party is engaged in the marketing and sale of any weight loss, fat reduction or cholesterol reduction product or program, these respondents must make an effort to determine whether false or misleading or unsubstantiated claims are being made with respect to any such product or program. Specifically, these respondents must review all advertisements and promotional materials and all tests, reports, studies, surveys, demonstrations or other evidence that any such person relies upon in making any claims to consumers. In addition, these respondents are required to terminate their business relationship with any person whom they know or should know is making any false or misleading or unsubstantiated claims.

Part VII of the proposed order against respondents IMT and EHI requires them to pay $35,000 in consumer redress in three installments over a period of one year. If consumer redress is impracticable, Part VII provides that these funds will be paid into the United States Treasury. Part VII(C) requires IMT and EHI to provide the Commission with a security interest in certain property to insure full payment of the $35,000 of consumer redress.

Part VII(A)(1) and (2) of the proposed order against respondent Shell requires him to obtain a performance bond for $1,000,000 before he markets, sells or holds any ownership interest or official position in any business that advertises or sells Lipitrol or any other weight loss, fat reduction or cholesterol reduction product composed of fiber and bile extract. Part VII(A)(3) and (4) of the proposed order also requires respondent Shell to obtain a performance bond of $250,000 before he markets, sells or holds an ownership interest or official position in any business that advertises or sells any weight loss, fat reduction or cholesterol reduction product or program to consumers, other than his treatment of patients in connection with his private medical practice. Parts VII(B) through (F) require respondent Shell to provide a copy

of the bond to the FTC; prohibit him from disclosing the existence of the bond to any consumer; and describe the period during which the bond must remain effective, the bond's coverage, the bond's potential beneficiaries and certain other administrative requirements.

Part VIII of the proposed order against respondent Shell requires him to pay consumer redress in the amount of $20,000 in four installments over a period of one year. In the event that consumer redress is impracticable, this Part provides that these funds will be paid into the United States Treasury. Part VIII(C) requires Shell to provide the Commission with a security interest in certain property to insure full payment of the $20,000 of consumer redress.

Parts VIII and IX of the proposed order against respondents IMT and EHI, Parts IX and X of the proposed order against respondent Shell, and Parts III and IV of the proposed order against respondent Pelzer, contain provisions permitting certain claims that are approved for labels by the FDA, either under the Nutrition Labeling and Education Act, a tentative final or final monograph or under any new drug application approved by the FDA.

Parts X, XI, XII and XIII of the proposed order against respondents IMT and EHI, Parts XI, XII, XIII and XIV of the proposed order against respondent Shell, and Parts V, VI, VII and VIII of the proposed order against respondent Pelzer, contain compliance reporting provisions requiring these respondents to: retain all records that would bear on their compliance with the respective orders; notify the Commission of any changes in the structure of the corporate respondents that may affect their compliance obligations under the orders, or any changes in the business affiliations of the individual respondents relating to the advertising, offering for sale, sale or distribution of any weight loss, fat reduction or cholesterol reduction product or program; distribute copies of the orders to those persons having responsibility with respect to the subject matter of the respective orders; and report to the Commission their compliance with the terms of the respective orders.

Part XIV of the proposed order against respondents IMT and EHI, Part XV of the proposed order against respondent Shell, and Part IX of the proposed order against respondent Pelzer contain a provision automatically terminating the orders twenty (20) years from the date that they become final.

The purpose of this analysis is to facilitate public comment on the proposed orders. It is not intended to constitute an official interpretation of the agreements and proposed orders or to modify their terms in any way.