

UNITED STATES OF AMERICA  
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS:

Robert Pitofsky, Chairman  
Mary L. Azcuenaga  
Janet D. Steiger  
Roscoe B. Starek, III  
Christine A. Varney

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In the Matter of	)	
	)	
INTERACTIVE MEDICAL TECHNOLOGIES,	)	DOCKET NO. C-3749
LTD., and EFFECTIVE HEALTH, INC.,	)	
corporations,	)	DECISION AND ORDER
	)	
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.	)	
	)	

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The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondents named in the caption hereof, and respondent William E. Shell, M.D., having been furnished thereafter with a copy of a draft of complaint which the Seattle 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 respondent, his 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 the respondent that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true, 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 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 § 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent William E. Shell, M.D. was an officer of Interactive Medical Technologies, Ltd., and Effective Health, Inc. He formulated, directed and controlled the policies, acts and practices of said corporations. His home address is at 3048 Nicada Drive, in the City of Los Angeles, State of 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

IT IS ORDERED that 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 on June 16, 2017, 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.

By the Commission.

Donald S. Clark  
Secretary

ISSUED: June 16, 1997

[Confidential Appendix A redacted.]