

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-3751
LTD., and EFFECTIVE HEALTH, INC.,	)	
corporations, and	)	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 respondents Interactive Medical Technologies, Ltd. ("IMT") and Effective Health, Inc. ("EHI") 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

Respondents IMT and EHI, their attorney, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by respondents IMT and EHI 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 these respondents 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 respondents IMT and EHI have violated the said Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of sixty (60) days, now in further conformity with the procedure prescribed in § 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent Interactive Medical Technologies, Ltd., is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 2139 Pontius Avenue, in the City of Los Angeles, State of California.
2. Respondent Effective Health, Inc., is a corporation organized, existing and doing business under and by virtue of the laws of the State of California, with its office and principal place of business located at 2139 Pontius Avenue, in the City of Los Angeles, State of California.
3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondents, and the proceeding is in the public interest.

#### ORDER

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, "respondents" shall mean Interactive Medical Technologies, Ltd., and Effective Health, Inc., corporations, their successors and assigns and their officers, agents, representatives and employees.
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 respondents, 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 weight loss, fat reduction or cholesterol reduction 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, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that respondents, 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 weight loss, fat reduction or cholesterol reduction product or program or any food, drug or dietary supplement, as "food" and "drug" are defined in Section 15 of the Federal Trade Commission Act, 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, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

III.

IT IS FURTHER ORDERED that respondents, 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 weight loss, fat reduction or cholesterol reduction product or program or any food, drug or dietary supplement, as "food" and "drug" are defined in Section 15 of the Federal Trade Commission Act, 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 respondents, 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 weight loss, fat reduction or cholesterol reduction product or program or any food, drug or dietary supplement, as "food" and "drug" are defined in Section 15 of the Federal Trade Commission Act, 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, unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

#### V.

IT IS FURTHER ORDERED that respondents shall not provide means and instrumentalities or substantial assistance or support to any person or entity who respondents know 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 SeQuester or 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 respondents, 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 respondents are 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 respondents know 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 respondents IMT and EHI, corporations, their 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 thirty-five thousand dollars (\$35,000). This payment shall be made in the following manner:

A. By certified or cashier’s check made payable to the Federal Trade Commission, in three installments, the first payment of eleven thousand dollars (\$11,000) to be made no later than the date that this order becomes final; the second payment of eleven thousand dollars (\$11,000) to be made no later than the first day of the sixth month thereafter; and the third payment of thirteen thousand dollars (\$13,000) to be made no later than 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 respondents’ indebtedness to the Commission, within seven (7) days of the date that this order becomes final, respondents 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-four thousand dollars (\$24,000) or more in excess of all other perfected security interests, as security for the payments required to be made by respondents in Part VII(A) of this order. The respondents 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 respondents 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 VII(A) of this order.

D. The funds paid by respondents, 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. Respondents relinquish 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. Respondents 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 respondents, respondents acknowledge that the funds are not part of the debtor's estate, nor does the estate have any claim or interest therein.

## VIII.

Nothing in this order shall prohibit respondents 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.

## IX.

Nothing in this order shall prohibit respondents 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.

X.

IT IS FURTHER ORDERED that respondents 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 their 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.

XI.

IT IS FURTHER ORDERED that respondents IMT and EHI 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. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of this order and, for a period of five (5) years thereafter, to future personnel within thirty (30) days after the person assumes such position or responsibilities.

XII.

IT IS FURTHER ORDERED that respondents shall notify the Commission at least thirty (30) days prior to any change in the corporations that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or change in corporate name or address. Provided, however, that, with respect to any proposed change in the corporation about which respondents learn less than thirty (30) days prior to the date such action is to take place, respondents shall notify the Commission as soon as is practicable after obtaining such knowledge. 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.

### XIII.

IT IS FURTHER ORDERED that respondents 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 they have complied with this order.

### XIV.

This order will terminate on June 16, 2017, or twenty 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.]