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

| In the Matter of |)) |
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| 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. |))) |

DOCKET NO. C-3750

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondents named in the caption hereof, and respondent William Pelzer, Jr., 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

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

1. Respondent William Pelzer, Jr., 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 address is at P.O. Box 269006, in the City of San Diego, 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 Pelzer, Jr., individually and as a former officer of IMT and EHI.

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 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.

II.

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 I 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, at 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.

III.

Nothing in this order shall prohibit respondent from making any representation for any drug that is permitted in labeling for any 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.

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.

V.

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 and 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.

VI.

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, for a period of five (5) years thereafter, to future personnel within thirty (30) days after the person assumes such position or responsibilities.

VII.

IT IS FURTHER ORDERED that respondent shall, for a period of ten (10) 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 labeling, 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.

VIII.

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

IX.

This order will terminate on June 16, 2017, or twenty years from the most recent date that the United States or the Federal Trade 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.

<u>Provided, further</u>, 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