# UNITED STATES OF AMERICA BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS:	Edith Ramirez, Chairwoman Julie Brill Maureen K. Ohlhausen Joshua D. Wright Terrell McSweeny		
T. A. M. M. M. C.			
In the Matter of		)	DOCKET NO. C-4492
JOHN MATTHEW DW	YER III,	)	
a/k/a Matthew Dwyer,	,	)	DECISION AND ORDER
individual	ly.	)	
	•	)	

The Federal Trade Commission ("Commission") having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge the respondent with violation of the Federal Trade Commission Act, 15 U.S.C. § 45 *et seq.*; and

The respondent and counsel for the Commission having thereafter executed an agreement containing a consent order ("consent agreement"), which includes: a statement by the respondent that he neither admits nor denies any of the allegations in the draft complaint, except as specifically stated in the consent agreement, and only for purposes of this action, admits the facts necessary to establish jurisdiction; 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 Federal Trade Commission Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such consent agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34, now in further conformity with the procedure prescribed in Commission Rule 2.34, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

- 1. Respondent John Matthew Dwyer III, a/k/a Matthew Dwyer ("Dwyer"), is the co-founder of HealthyLife Sciences, LLC, a Georgia limited liability company. He was the company's chief executive officer until September 2011 and company co-owner until 2013. Individually, or in concert with others, he formulated, directed, controlled, or participated in the policies, acts, or practices of the company.
- 2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and this proceeding is in the public interest.

# **ORDER**

### **DEFINITIONS**

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

- 1. Unless otherwise specified, "respondent" means John Matthew Dwyer III.
- 2. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
- 3. "Covered Product" shall mean any Dietary Supplement, Food, or Drug.
- 4. "Dietary Supplement" means:
  - a. Any product labeled as a dietary supplement or otherwise represented as a dietary supplement; or
  - b. Any pill, tablet, capsule, powder, softgel, gelcap, liquid, or other similar form containing one or more ingredients that is a vitamin, mineral, herb or other botanical, amino acid, probiotic, or other dietary substance for use by humans to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any ingredient described above, that is intended to be ingested, and is not represented to be used as a conventional food or as a sole item of a meal or the diet.
- 5. "Food" and "Drug" mean as defined in Section 15 of the FTC Act, 15 U.S.C. § 55.
- 6. "Reliably Reported," for a human clinical test or study ("test"), means a report of the test has been published in a peer-reviewed journal, and such published report provides sufficient information about the test for experts in the relevant field to assess the reliability of the results.
- 7. The term "including" in this Order shall mean "without limitation."
- 8. The terms "and" and "or" in this Order shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.

**IT IS ORDERED** that respondent is permanently restrained and enjoined from manufacturing, labeling, advertising, marketing, promoting, offering for sale, selling, or distributing, or assisting others in manufacturing, labeling, advertising, marketing, promoting, offering for sale, selling, or distributing, any weight-loss product or program.

II.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, licensee, affiliate, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, shall not make any representation, other than representations covered under Part I of this Order, in any manner, expressly or by implication, including through the use of product name, endorsement, depiction, illustration, trademark, or trade name, about the health benefits, performance, or efficacy of any Covered Product, unless the representation is non-misleading, and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

For purposes of this Part, competent and reliable scientific evidence means tests, analyses, research, or studies (1) that have been conducted and evaluated in an objective manner by qualified persons; (2) that are generally accepted in the profession to yield accurate and reliable results; and (3) as to which, when they are human clinical tests or studies, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as described in Part V must be available for inspection and production to the Commission.

# III.

**IT IS FURTHER ORDERED** that respondent, directly or through any corporation, partnership, subsidiary, division, licensee, affiliate, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication:

- A. The existence, contents, validity, results, conclusions, or interpretations of any test, study, or research; or
- B. That the efficacy of such product has been clinically or scientifically proven.

## IT IS FURTHER ORDERED that:

- A. 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, or under any new drug application approved by the Food and Drug Administration; and
- B. Nothing in this Order shall prohibit respondent from making any representation for any product specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990 or permitted under Sections 303-304 of the Food and Drug Administration Modernization Act of 1997.

V.

IT IS FURTHER ORDERED that, with regard to any human clinical test or study ("test") upon which respondent relies to substantiate any claim covered by this Order, respondent shall secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of the test, including, but not necessarily limited to:

- A. All protocols and protocol amendments, reports, articles, write-ups, or other accounts of the results of the test, and drafts of such documents reviewed by the test sponsor or any other person not employed by the research entity;
- B. All documents referring or relating to recruitment; randomization; instructions, including oral instructions, to participants; and participant compliance;
- C. Documents sufficient to identify all test participants, including any participants who did not complete the test, and all communications with any participants relating to the test; all raw data collected from participants enrolled in the test, including any participants who did not complete the test; source documents for such data; any data dictionaries; and any case report forms;
- D. All documents referring or relating to any statistical analysis of any test data, including, but not limited to, any pretest analysis, intent-to-treat analysis, or between-group analysis performed on any test data; and
- E. All documents referring or relating to the sponsorship of the test, including all communications and contracts between any sponsor and the test's researchers.

*Provided, however*, the preceding preservation requirement shall not apply to a Reliably Reported test, unless the test was conducted, controlled, or sponsored, in whole or in part (1) by respondent, or by any person or entity affiliated with or acting on behalf of respondent,

including, agents, representatives, and employees, or by any other person or entity in active concert or participation with respondent ("respondent's affiliates"), (2) by the supplier or manufacturer of the product at issue, or (3) by a supplier to respondent, to respondent's affiliates, or to the product's manufacturer of any ingredient contained in such product.

For any test conducted, controlled, or sponsored, in whole or in part, by respondent, or by any business for which respondent is the majority owner, or directly or indirectly controls, respondent or such business must establish and maintain reasonable procedures to protect the confidentiality, security, and integrity of any personal information collected from or about participants. These procedures shall be documented in writing and shall contain administrative, technical, and physical safeguards appropriate to such business's size and complexity, the nature and scope of such business's activities, and the sensitivity of the personal information collected from or about the participants.

# VI.

**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 reasonable notice make available to the Federal Trade 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.

### VII.

IT IS FURTHER ORDERED that respondent shall deliver a copy of this Order to all current and future principals, officers, directors, and other employees having managerial 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. Delivery shall occur to current personnel within thirty (30) days after date of service of this Order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

### VIII.

**IT IS FURTHER ORDERED** that respondent, for a period of seven (7) years after the date of issuance of this Order, shall notify the Commission of the discontinuance of his current business or employment, or of his affiliation with any new business or employment, within 14 days of such change occurring. The notice shall include respondent's new business address and telephone number and a description of the nature of the 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, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

### IX.

**IT IS FURTHER ORDERED** that respondent, within sixty (60) days after the date of service of this Order, shall file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of his compliance with this Order. Within ten (10) days of receipt of written notice from a representative of the Commission, respondent shall submit additional true and accurate reports.

X.

This Order will terminate on October 22, 2034, 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 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

SEAL:

ISSUED: October 22, 2014