In the Matter of John Matthew Dwyer III, a/k/a Matthew Dwyer

ANALYSIS OF PROPOSED CONSENT ORDER TO AID PUBLIC COMMENT
File No. 122 3287

The Federal Trade Commission ("FTC" or "Commission") has accepted, subject to final approval, an agreement containing a consent order from John Matthew Dwyer III, a/k/a Matthew Dwyer ("Dwyer").

The proposed consent order ("proposed order") has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

This matter involves advertising for HealthyLife Sciences, LLC's Healthe Trim line of weight loss dietary supplements ("Healthe Trim"). The complaint alleges that Dwyer, a co-founder of HealthyLife Sciences, LLC, and former chief executive officer and spokesman for Healthe Trim, violated Sections 5(a) and 12 of the Federal Trade Commission Act by making false or unsubstantiated representations that Healthe Trim would cause rapid and substantial weight loss, including as much as 35, 130, and 165 pounds. Dwyer also claimed that users would lose weight without dieting, and that Healthe Trim would burn fat, increase metabolism, and suppress appetite. The complaint also alleges that Dwyer violated Sections 5(a) and 12 by falsely representing that Healthe Trim is clinically proven to cause weight loss.

The proposed order includes injunctive relief that prohibits these alleged violations and fences in similar and related violations. For purposes of the order, "Covered Product" means any dietary supplement, food, or drug.

Part I of the proposed order bans Dwyer from manufacturing, marketing, or distributing any weight-loss product or program, or assisting others in any of the foregoing.

Part II of the proposed order prohibits any representation about the health benefits, performance, or efficacy of any Covered Product, unless it is non-misleading and supported by 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 is defined as tests, analyses, research, or studies that have been conducted by qualified persons in an objective manner and are generally accepted in the profession to yield accurate and reliable results. When that evidence consists of human clinical tests or studies, Dwyer must maintain all underlying or supporting data and documents that experts in the field generally would accept as relevant to an assessment of such testing.

Part III of the proposed order prohibits Dwyer from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research in

connection with the manufacturing, labeling, advertising, promotion, offering for sale, and sale or distribution of any Covered Product.

Part IV provides a safe harbor for representations permitted under any tentative final or final standard promulgated by the Food and Drug Administration ("FDA"), any new drug application approved by the FDA, or FDA regulations pursuant to the Nutrition Labeling and Education Act of 1990 or the FDA Modernization Act of 1997.

Triggered when the human clinical testing requirement in Part II applies, **Part V** of the proposed order requires Dwyer to 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, such as protocols, instructions, participant-specific data, statistical analyses, and contracts with the test's researchers. There is an exception for a "Reliably Reported" test, defined as a test published in a peer-reviewed journal that was not conducted, controlled, or sponsored by Dwyer, his affiliates, or others in the manufacturing or supply chain. Also, the published report must provide sufficient information about the test for experts in the relevant field to assess the reliability of the results.

Parts VI through IX of the proposed order require Dwyer to: deliver a copy of the order to principals, officers, directors, and other employees having responsibilities with respect to the subject matter of the order; notify the Commission of changes in employment that might affect compliance obligations under the order; and file compliance reports with the Commission.

Part X provides that the order will terminate after twenty (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the complaint or proposed order, or to modify the proposed order's terms in any way.