IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**CONSENT DECREE**
	)	
JASON PHARMACEUTICALS, INC., a Maryland corporation, and a subsidiary of Medifast, Inc.,	)	
	)	**CIV. ACTION NO.** 12-1476
Defendant.	)	
	)	

WHEREAS: Plaintiff, the United States of America, has commenced this action by filing the Complaint herein; Defendant Jason Pharmaceuticals, Inc. has waived service of the Summons and Complaint; the parties have been represented by the attorneys whose names appear hereafter; and the parties have agreed to settlement of this action upon the following terms and conditions, without adjudication of any issue of fact or law and without Defendant admitting liability for any of the matters alleged in the Complaint;

THEREFORE, on the joint motion of Plaintiff and Defendant, it is hereby ORDERED, ADJUDGED, and DECREED as follows:

FINDINGS

1. This Court has jurisdiction over the subject matter and of the parties pursuant to 28 U.S.C. §§ 1331, 1337(a), 1345, and 1355, and 15 U.S.C. §§ 45(*l*), 53(b), and 56(a).

2. Venue is proper in the District of Columbia under 15 U.S.C. § 53(b) and under 28 U.S.C. §§ 1391(b-c) and § 1395(a).

3. The activities of Defendant are in or affecting commerce as defined in Section 4 of the

Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 44.

4. The Complaint states a claim upon which relief may be granted against Defendant under Sections 5(a), 5(*l*), 12, 13(b), and 16(a) of the FTC Act, 15 U.S.C. §§ 45(a), 45(*l*), 52, 53(b), and 56(a), without trial or final adjudication of any issue of fact or law. By entering into this Consent Decree, Defendant does not admit or deny any of the allegations set forth in the Complaint, other than jurisdictional facts, to which Defendant is stipulating only as to this action. The parties agree that this Consent Decree settles allegations in the Complaint of violations of a prior consent order, entered in FTC Docket No. 3392.

5. Defendant has entered into this Consent Decree freely and without coercion. Defendant further acknowledges that it has read the provisions of this Consent Decree and is prepared to abide by them.

6. Plaintiff and Defendant hereby waive all rights to appeal or otherwise challenge or contest the validity of this Consent Decree.

7. This Consent Decree reflects the negotiated agreement of the parties.

8. Plaintiff and Defendant stipulate and agree that the entry of this Consent Decree shall constitute a full, complete, and final settlement of this action.

9. Defendant has agreed that this Consent Decree does not entitle Defendant to seek or obtain attorneys' fees as a prevailing party under the Equal Access to Justice Act, 28 U.S.C. § 2412, and Defendant further waives any rights to attorneys' fees that may arise under said provision of law.

10. Entry of this Consent Decree is in the public interest.

DEFINITIONS

For purposes of this Consent Decree, the following definitions shall apply:

1. **"Adequate and well-controlled human clinical study"** means a human clinical study conducted by persons qualified by training and experience to conduct such a study. Such study shall utilize a food-based, reduced energy diet plan as a control and be of at least sixteen weeks duration, provided that, for substantiation of a representation relating to weight maintenance, the study shall be of at least fifty-two weeks duration total, including the active weight loss period. Such study shall be of sufficient size, based on procedures generally used by experts in the field, to yield reliable and statistically significant results at the ninety-five percent confidence level and include an appropriate intent to treat analysis. Participants shall be randomly assigned to a treatment and a control group.

2. **"Advertising"** means any written or verbal statement, illustration, or depiction that is designed to effect a sale or create interest in the purchasing of goods or services, whether it appears in a brochure, newspaper, magazine, pamphlet, leaflet, circular, mailer, book insert, free standing insert, newsletter, catalogue, poster, chart, billboard, public transit card, point of purchase display, packaging, package insert, label, film, slide, radio, television or cable television, audio program transmitted over a telephone system, program-length commercial ("infomercial"), Internet website (including metatags), or in any other medium, wherever located.

3. **"Commerce"** means as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

4. **"Corporate Defendant"** means Jason Pharmaceuticals, Inc., a subsidiary of Medifast, Inc.; and its successors and assigns.

5. **"Covered Program"** means any low calorie meal replacement program manufactured or

distributed by the Corporate Defendant designed to lower the user's total caloric intake, including The Medifast 5 & 1 Plan.

6. **"Defendant"** means the Corporate Defendant.

7. **"Endorsement"** has the meaning set forth in the Commission's Guides Concerning the Use of Endorsements and Testimonials in Advertising, 16 C.F.R. § 255.0(b).

8. **"Testimonial"** has the same meaning as "endorsement," as endorsement is defined in the Commission's Guides Concerning the Use of Endorsements and Testimonials in Advertising, 16 C.F.R. § 255.0(b). The two terms shall be treated identically in this Consent Decree, pursuant to 16 C.F.R. § 255.0(c).

9. **"Weight loss product, program, or service"** means any product, program, or service that is advertised, marketed, promoted, offered for sale, distributed, or sold with express or implied representations that the product, program, or service will or may cause weight loss, reduction or elimination of fat, reduction of dress or other clothing size, slimming, or calorie deficit, or will or may prevent weight gain in a user of the product, program, or service.

10. The term **"including"** in this Consent Decree means "including without limitation."

11. The terms **"and"** and **"or"** in this Consent Decree shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.

I.

CIVIL PENALTY

IT IS ORDERED that

A. Defendant shall pay to Plaintiff a civil penalty, pursuant to Section 5(*l*) of the Federal Trade Commission Act, 15 U.S.C. § 45(*l*), in the amount of $3,700,000 (Three Million and Seven Hundred Thousand Dollars).

B. Defendant shall make the payment required by Section I.A within seven (7) days of the date of entry of this Consent Decree, by transferring the sum of (Three Million and Seven Hundred Thousand Dollars) ($3,700,000) in the form of an electronic fund transfer or certified or cashier's check made payable to the Treasurer of the United States. The check or written confirmation of the electronic fund transfer shall be delivered in accordance with procedures specified by the Office of Consumer Protection Litigation, Civil Division, U.S. Department of Justice, Washington, DC 20530.

C. In the event of any default in payment required to be made under this Consent Decree, the entire unpaid penalty, together with interest from the date of default to the date of payment, as computed pursuant to 28 U.S.C. § 1961, shall immediately become due and payable.

D. In accordance with 31 U.S.C. § 7701, Defendant is hereby required, unless it has done so already, to furnish to Plaintiff and the Commission its taxpayer identifying number. Such number may be used for purposes of collecting and reporting on any delinquent amount arising out of Defendant's relationship with the government.

II.

PROHIBITED UNSUBSTANTIATED REPRESENTATIONS CONCERNING AMOUNT OF WEIGHT LOSS AND WEIGHT MAINTENANCE

IT IS FURTHER ORDERED that Defendant and its officers, agents, representatives, and employees, and all persons in active concert or participation with any one or more of them who receive actual notice of this Consent Decree by personal service or otherwise, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Program, in or affecting commerce, are hereby permanently enjoined from making any representation, or assisting others in making any representation, in any manner, directly or indirectly, expressly or by implication, including through endorsements or a trade name, that:

A. Members of the public who use the program can generally expect to achieve the results represented by an endorser of such program; or

B. Such program enables users to lose any particular amount of weight, or that users maintain weight loss;

unless the representation is non-misleading, and, at the time of making such representation, Defendant possesses and relies upon competent and reliable scientific evidence that substantiates that the representation is true. For purposes of this Section, competent and reliable scientific evidence shall consist of at least one Adequate and well-controlled human clinical study of the Covered Program that conforms to acceptable designs and protocols, or a study of the Covered Program satisfying all of the criteria set forth in Appendix A, and whose results, when considered

in light of the entire body of relevant scientific evidence, are sufficient to substantiate that the representation is true.

III.

PROHIBITED UNSUBSTANTIATED REPRESENTATIONS REGARDING HEALTH OR SAFETY CLAIMS

IT IS FURTHER ORDERED that Defendant and its officers, agents, representatives, and employees, and all persons in active concert or participation with any one or more of them who receive actual notice of this Consent Decree by personal service or otherwise, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Program, in or affecting commerce, are hereby permanently enjoined from making any representation, other than representations covered under Section II of this Order, in any manner, directly or indirectly, expressly or by implication, including through endorsements or a trade name, or assisting others in making any representation, about the health benefits, safety, or side effects of such program, unless the representation is non-misleading, and, at the time of making such representation, Defendant 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 Section, competent and reliable scientific evidence means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results.

IV.

OTHER INJUNCTIVE RELIEF

IT IS FURTHER ORDERED that Defendant and its officers, agents, representatives, and employees, and all persons in active concert or participation with any one or more of them who receive actual notice of this Consent Decree by personal service or otherwise, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any weight loss product, program, or service, are hereby permanently enjoined from misrepresenting that any doctor, health professional, or endorser recommends the weight loss product, program, service, drug, or dietary supplement.

V.

FOOD AND DRUG ADMINISTRATION

IT IS FURTHER ORDERED that nothing in this Consent Decree prohibits the Defendant from making:

A. Any representation for any drug that is permitted or required in the 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. Any representation for any product that is specifically permitted or required in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

VI.

CONSENT DECREE ACKNOWLEDGMENTS

IT IS FURTHER ORDERED that Defendant obtain acknowledgments of receipt of this Consent Decree:

A. Defendant, within 7 days of entry of this Consent Decree, must submit to the Commission an acknowledgment of receipt of this Consent Decree sworn under penalty of perjury.

B. For 5 years after entry of this Consent Decree, Defendant must deliver a copy of this Consent Decree to: (1) all principals, officers, and directors; (2) all managers, employees, agents, and representatives who participate in conduct related to the subject matter of the Consent Decree; and (3) any business entity resulting from any change in structure as set forth in the Section titled Compliance Reporting. Delivery must occur within 7 days of entry of this Consent Decree for current personnel. To all others, delivery must occur before they assume their responsibilities.

C. From each individual or entity to which Defendant delivered a copy of this Consent Decree, Defendant must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Consent Decree.

VII.

COMPLIANCE REPORTING

IT IS FURTHER ORDERED that Defendant make timely submissions to the Commission:

A. One year after entry of this Consent Decree, Defendant must submit a compliance

report, sworn under penalty of perjury.

Defendant must: (a) designate at least one telephone number and an email, physical, and postal address as points of contact, which representatives of the Commission and Plaintiff may use to communicate with Defendant; (b) identify all of Defendant's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses; (c) describe the activities of each business, including the products and services offered, and the means of advertising, marketing, and sales; (d) describe in detail whether and how Defendant is in compliance with each Section of this Consent Decree; and (e) provide a copy of each Consent Decree Acknowledgment obtained pursuant to this Consent Decree, unless previously submitted to the Commission.

B. For twenty (20) years following entry of this Consent Decree, Defendant must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following:

Defendant must report any change in: (a) any designated point of contact; or (b) the structure of the Defendant or any entity that Defendant has any ownership interest in or directly or indirectly controls that may affect compliance obligations arising under this Consent Decree, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Consent Decree.

C. Defendant must submit to the Commission notice of the filing of any bankruptcy petition, insolvency proceeding, or any similar proceeding by or against Defendant within 14 days of its filing.

D. Any submission to the Commission required by this Consent Decree to be sworn

under penalty of perjury must be true and accurate and comply with 18 U.S.C. § 1746, such as by concluding: "I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on:_____" and supplying the date, signatory's full name, title (if applicable), and signature.

E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Consent Decree must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: United States of America v. Jason Pharmaceuticals, Inc.

VIII.

RECORDKEEPING

IT IS FURTHER ORDERED that Defendant must create certain records for twenty (20) years after entry of the Consent Decree, and to retain each such record for 5 years. Specifically, Defendant must maintain the following records:

A. Accounting records showing the revenues from all goods or services sold, all costs incurred in generating those revenues, and the resulting net profit or loss;

B. Personnel records showing, for each person providing services related to any marketing or substantiation of any advertising claim, whether as an employee or otherwise, that person's last known: name, addresses, and telephone numbers; job title or position; dates of service; and, if applicable, the reason for termination;

C. Complaints and refund requests, whether received directly or indirectly, such as

through a third party, and any response;

D. All records necessary to demonstrate full compliance with each provision of this Consent Decree, including all submissions to the Commission and copies of all substantiation materials; and

E. A copy or template of each different advertisement or other marketing material.

IX.

COMPLIANCE MONITORING

IT IS FURTHER ORDERED that, for the purpose of monitoring Defendant's compliance with this Consent Decree, including any failure to make the payment required under Section I.A:

A. Within 14 days of receipt of a written request from a representative of the Commission or Plaintiff, Defendant must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury; appear for depositions; and produce documents, for inspection and copying. The Commission and Plaintiff are also authorized to obtain discovery, without further leave of court, using any of the procedures prescribed by Federal Rules of Civil Procedure 29, 30 (including telephonic depositions), 31, 33, 34, 36, 45, and 69.

B. For matters concerning this Consent Decree, the Commission and Plaintiff are authorized to communicate directly with Defendant. Defendant must permit representatives of the Commission and Plaintiff to interview any employee or other person affiliated with Defendant who has agreed to such an interview. The person interviewed may have counsel present.

C. The Commission and Plaintiff may use all other lawful means, including posing, through its representatives, as consumers, suppliers, or other individuals or entities, to Defendant or any individual or entity affiliated with Defendant, without the necessity of identification or prior notice. Nothing in this Consent Decree limits the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.

X.

RETENTION OF JURISDICTION

IT IS FURTHER ORDERED that this Court retains jurisdiction of this matter for purposes of construction, modification, and enforcement of this Consent Decree.

JUDGMENT IS THEREFORE ENTERED in favor of Plaintiff and against Defendant, pursuant to all the terms and conditions recited above.

SO ORDERED this 17 day of Sept, 201_.

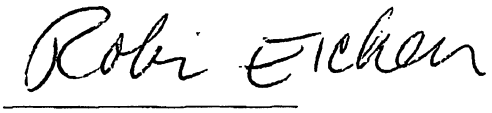
UNITED STATES DISTRICT JUDGE

The parties, by their respective counsel, consent to the terms and conditions of the Consent Decree as set forth above and consent to the entry thereof.

FOR THE FEDERAL TRADE COMMISSION:

WILLARD K. TOM
General Counsel

WILLIAM H. EFRON
Regional Director



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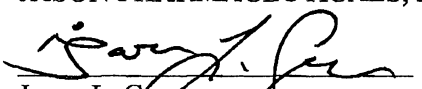
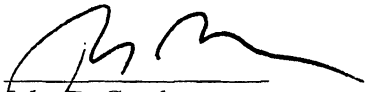
FOR THE DEFENDANTS:

JASON PHARMACEUTICALS, INC.



Jason L. Groves
Executive Vice President and
General Counsel



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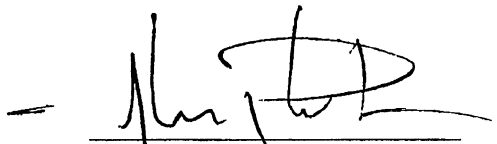

ALAN PHELPS
Consumer Protection Branch
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Appendix A

1. Consistent with the requirements set forth below, the protocol for the study shall:
   a. Identify primary and secondary outcome measurements;
   b. Describe how the sample size was determined, including an appropriate power analysis, provided that, in determining sample size, a confidence level of at least 95% shall be used;
   c. Describe how specific subjects were selected to ensure that the study used an appropriate representative sample;
   d. Identify the data points to be analyzed;
   e. Specify procedures for identifying and collecting subject data; and
   f. Specify the statistical procedures used to assess the impacts on the relevant data points of the proposed intervention.

2. The study shall be conducted by persons qualified by training and experience to conduct such a study and utilize procedures and statistical techniques generally accepted by experts in conducting weight-loss or weight-maintenance studies.

3. The study shall be based on a randomly selected representative sample of
   a. all participants who have entered the program, where the representation relates to such persons, provided, however, the required sample may exclude those participants who dropped out of the program within two weeks of their entrance or who were unable to complete the program due to change of residence or medical reasons, such as pregnancy; or
   b. all participants who have completed a particular phase of the program or the entire program, where the representation only relates to those persons and the representation conveys the portion of such participants to all participants who have entered the program.

4. Except for the exclusions specified in 3(a) above, all participants who have entered the program, or, for studies covered under 3(b), all participants who have completed a particular phase of the program, must have an equal opportunity to be selected to be included in the sample.

5. In studies covered by 3(a) above, in the event that a subject drops out of the program after two weeks for a reason other than a change of residence or medical reason, as specified above, but before the completion of the study, the subject's last recorded weight shall be used as that subject's ending weight for purposes of analysis, provided that, if other procedures and statistical techniques become generally accepted by the experts in the field to account for drop outs in an analysis of a random sample as described above, then such procedures may be utilized in lieu of those set forth in this paragraph.

6. If the representation relates to weight loss, the study shall cover a period of at least 16

weeks.

7. If the representation relates to weight maintenance, the study shall cover a period of at least fifty-two weeks.

8. Data for the study shall be selected using procedures that insure, to the maximum extent possible, that the data collected is accurate and reliable. Self-reported data on the primary and secondary outcome measurements shall not be utilized except for measurements that can only be self-reported, such as lack of satiety, hunger, or energy.