IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

FEDERAL TRADE COMMISSION,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
NATIONAL UROLOGICAL GROUP, INC., et al.	)	
	)	
	)	**1:04-CV-3294-CAP**
Defendants.	)	
	)	
	)	

FINAL JUDGMENT AND PERMANENT INJUNCTION AGAINST NATIONAL UROLOGICAL GROUP, INC., HI-TECH PHARMACEUTICALS, INC., JARED WHEAT, THOMASZ HOLDA, AND STEPHEN SMITH

This matter comes before the Court on complaint of Plaintiff, Federal Trade Commission ("FTC" or "Commission"), against Defendants National Urological Group, Inc. d/b/a Warner Laboratories, Inc. ("NUG"), National Institute for Clinical Weight Loss, Inc. ("NICWL"), Hi-Tech Pharmaceuticals, Inc. ("Hi-Tech"), Jared Wheat ("Wheat"), Thomasz Holda ("Holda"), Michael Howell ("Howell"), Stephen Smith ("Smith"), and Terrill Mark Wright, M.D ("Wright"). On November 10, 2004, the Commission filed a Complaint for a permanent injunction and other equitable relief in this matter pursuant to Sections 5(a) and

12 of the Federal Trade Commission Act ("FTC Act"), 15U.S.C. §§ 45(a) and 52. The FTC charged Defendants NUG, NICWL, Hi-Tech, Wheat, Holda, Howell, Smith, and Wright with engaging in deceptive acts or practices in connection with the marketing and sale of dietary supplement products, in violation of Section 5 of the FTC Act, 15 U.S.C. § 45. On June 1, 2005, this Court entered a Stipulated Final Order For Permanent Injunction and Settlement of Claims For Monetary Relief against Defendant Howell.

The Commission filed a motion for summary judgment along with the entry of a separate set of Findings of Fact and Conclusions of Law. On June 4, 2008, the court granted the FTC's motion for summary judgment against NUG, NICWL, Hi-Tech, Wheat, Holda, Smith, and Wright as to monetary relief, and against the same defendants, with the exception of dissolved corporation NICWL, as to injunctive relief. Accordingly, it is hereby **ORDERED, ADJUDGED, AND DECREED**:

FINDINGS

1. This Court has jurisdiction of the subject matter of this case and the parties hereto pursuant to 28 U.S.C. § § 1331, 1337(a) and 1345 and 1355, and 15 U.S.C. §§ 45(a), 53(b), and 57b.

2. Venue in the Northern District of Georgia is proper as to all parties under 15 U.S.C. § 53(b) and 28 U.S.C. § 1391(b) and (c).

3. On June 4, 2008, the court granted the FTC's motion for summary judgment against NUG, NICWL, Hi-Tech, Wheat, Holda, Smith, and Wright as to monetary relief, and against the same defendants, with the exception of dissolved corporation NICWL, as to injunctive relief.

4. The activities of Defendants NUG, NICWL, Hi-Tech, Wheat, Holda, Howell, Smith, and Wright are in or affecting commerce, as defined in the FTC Act, 15 U.S.C. § 44.

5. The Complaint states a claim upon which relief may be granted against Defendants NUG, NICWL, Hi-Tech, Wheat, Holda, Howell, Smith, and Wright under Sections 5(a) and 12 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. §§ 45(a) and 52.

6. This is a final order with respect to Corporate Defendants NUG, NICWL, and Hi-Tech, and Individual Defendants Wheat, Holda, and Smith.

7. This Final Order is in addition to, and not in lieu of, any other civil or criminal remedies that may be provided by law.

8. Entry of this Final Order is in the public interest.

DEFINITIONS

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

1. Unless otherwise specified, "Defendants" shall mean National Urological Group, Inc. d/b/a Warner Laboratories, Inc., Hi-Tech Pharmaceuticals, Inc., Jared Wheat, Thomasz Holda, and Stephen Smith; "Corporate Defendants" shall mean National Urological Group, Inc. d/b/a Warner Laboratories, Inc. and Hi-Tech Pharmaceuticals, Inc.; "Individual Defendants" shall mean Jared Wheat, Thomasz Holda, and Stephen Smith.

2. "Advertising" or "Advertisement" 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, letter, catalogue, poster, chart, billboard, public transit card, point of purchase display, packaging, package insert, label, film,

3. “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.

4. “Clear(ly) and Prominent(ly)” shall mean as follows:

   A. In an advertisement communicated through an electronic medium (such as television, video, radio, and interactive media such as the Internet, online services and software), the disclosure shall be presented simultaneously in both the audio and visual portions of the advertisement. *Provided, however*, that in any advertisement presented solely through visual or audio means, the disclosure may be made through the same means in which the ad is presented. *Provided, further*, that in any advertisement communicated through interactive media which is presented predominantly through visual or audio means, the disclosure may be made through the same means in which the ad is predominantly presented. The audio disclosure shall be delivered in a volume and cadence sufficient for

an ordinary consumer to hear and comprehend it. The visual disclosure shall be of a size and shade, with a degree of contrast to the background against which it appears, and shall appear on the screen for a duration and in a location, sufficiently noticeable for an ordinary consumer to read and comprehend it.

B. In a print advertisement, promotional material, or instructional manual, the disclosure shall be in a type size and location sufficiently noticeable for an ordinary consumer to read and comprehend it, in print that contrasts with the background against which it appears.

C. On a product label, the disclosure shall be in a type size and location sufficiently noticeable for an ordinary consumer to read and comprehend it and in print that contrasts with the background against which it appears. *Provided, however,* if a disclosure on a bottle label or package label is made in a location other than the principal display panel, the bottle label or package label shall (i) include the statement, "**See important safety warning(s) on [insert disclosure location]**," in a type size and location on the principal

display panel sufficiently noticeable for an ordinary consumer to read and comprehend it and in print that contrasts with the background against which it appears; *and* (ii) place the disclosure on the bottle label and, if applicable, the package label, within a border that is a color or shade that contrasts with the background against which it appears. *Provided further*, that in a multi-page insert, the disclosure shall appear on the cover page or first page.

D. In the case of advertisements disseminated by means of an interactive electronic medium, such as software, the Internet, or online services, "in close proximity" means on the same Web page, online service page, or other electronic page, and proximate to the triggering representation, and does not include disclosures accessed

5. “Product label” shall mean any label or other written, printed or graphic matter upon any product or accompanying any product, including package labels, bottle labels, and package inserts.

6. “Weight Loss Product” shall mean any product, program, or service designed, used, or marketed to prevent weight gain or produce weight loss, reduce or eliminate fat, slim, or increase caloric deficit in a user of the product, program, or service.

7. “Erectile Dysfunction Product” shall mean any product, program, or service designed, used, or marketed to affect erectile function or impotence in users of the product, program, or service.

8. “Thermalean” shall mean any product containing sida cordifolia, kola nut, citrus aurantium, cassia nomame, green tea extract, and 5-HTP that is manufactured, supplied, distributed, offered for sale, sold, marketed, advertised, or promoted by Defendants under the name Thermalean.

9. “Lipodrene” shall mean any product containing sida cordifolia, citrus aurantium, caffeine, coleus forskohlii, naringen, green tea, ginseng, and l-caritine that is manufactured, supplied, distributed, offered for sale, sold,

marketed, advertised, or promoted by Defendants under the name Lipodrene.

10. "Spontane-ES" shall mean any product containing xanthoparmelia scabrosa extract, cnidium monnier extract, yohimbine extract, epimedium extract, gingko biloba extract, mucuna pruriens extract, and l-arginine that is manufactured, supplied, distributed, offered for sale, sold, marketed, advertised, or promoted by Defendants under the name Spontane or Spontane-ES.

11. "Covered product or service" shall mean any health-related service or program, weight loss product, erectile dysfunction product, dietary supplement, food, drug, or device.

12. "Yohimbine" shall mean a source of yohimbine, including, 8 -E noc0d4, odtracty,a-re2T5

by Defendants through a website on the Internet or through any other medium.

15. "Endorsement" shall mean as defined in 16 C.F.R. § 255.0(b).

16. The term "including" in this Order means "without limitation."

17. 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.

18. "Food" and "drug" shall mean as defined in Section 15 of the FTC Act, 15 U.S.C. § 55.

ORDER

I.
PROHIBITED FALSE CLAIMS FOR WEIGHT LOSS PRODUCTS

IT IS HEREBY ORDERED that Defendants, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and their officers, agents, servants, representatives, employees, and all persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Thermalean, Lipodrene, or any other weight loss product, is

permanently restrained and enjoined from misrepresenting, in any manner, expressly or by implication, including through the use of endorsements, that:

a. Such product is clinically proven to be or is an effective treatment for obesity;

b. Such product is clinically proven to cause or causes rapid and substantial weight loss;

c. Such product causes substantial weight loss, including as much as 125 pounds;

d. Such product is clinically proven to enable or enables users to lose 19% of their total body weight, lose 20-35% of abdominal fat, reduce their overall fat by 40-70%, decrease their stored fat by 300%, or increase their metabolic rate by 50% or more;

e. Such product is clinically proven to inhibit the absorption of fat, suppress appetite, or increase metabolism without dangerous side effects;

f. Such product inhibits the absorption of fat, suppresses appetite, or increases metabolism without dangerous side effects;

g. Such product is clinically proven to be or is safe;

h. Such product is clinically proven to have or has virtually no side effects.

g. Such product is equivalent or superior to any drug that the Food and Drug Administration has approved for sale in the United States for the purpose of treating obesity or causing weight loss;

unless the representation, including any such representation made through the use of endorsements, is true and non-misleading, and, at the time the representation is made, Defendants possess and rely upon competent and reliable scientific evidence that substantiates the representation.

III.
PROHIBITED FALSE CLAIMS FOR ERECTILE DYSFUNCTION PRODUCTS

IT IS FURTHER ORDERED that Defendants, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and their officers, agents, servants, representatives, employees, and all persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Spontane-ES or any other substantially similar product containing one or more of the active ingredients in Spontane-ES, in or affecting commerce, is permanently restrained and enjoined from misrepresenting, in any manner, expressly or by implication, including through the use of endorsements, that:

a. Such product is clinically proven to be effective in treating erectile dysfunction in any specified percentage or proportion of users;

b. Such product is clinically proven to be effective in treating men with erectile dysfunction; or

c. Such product is clinically proven to cause no harmful side effects.

IV.
PROHIBITED UNSUBSTANTIATED CLAIMS FOR ERECTILE DYSFUNCTION PRODUCTS

IT IS FURTHER ORDERED that Defendants, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and their officers, agents, servants, representatives, employees, and all persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any erectile dysfunction product, are hereby permanently restrained and enjoined from making any representation, in any manner, expressly or by implication, including through the use of endorsements, that:

a. Such product is effective in treating erectile dysfunction in any specified percentage or proportion of users; or

b. Such product is safe;

unless, the representation, including any such representation made through the use of endorsements, is true and non-misleading, and, at the time the representation is made, Defendants possess and rely upon competent and reliable scientific evidence that substantiates the representation.

V.
MISREPRESENTATION OF TESTS OR STUDIES

IT IS FURTHER ORDERED that Defendants, directly or through any partnership, corporation, subsidiary, division, trade name, or other device, and their officers, agents, servants, representatives, employees, and all persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product or service, in or affecting commerce, shall not misrepresent, in any manner, directly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test or study.

VI.
WARNING OF HEALTH RISKS OF YOHIMBINE

IT IS FURTHER ORDERED that, in any advertisement, promotional material, or product label for any covered product or program containing

yohimbine that contains any representation about the efficacy, benefits, performance, safety, or side effects of such product, and during any discussion relating to the use of such product communicated via electronic mail or any telephone line, Defendants, their officers, agents, servants, representatives, and employees shall make clearly and prominently, the following disclosure:

> **WARNING:** This product can raise blood pressure and interfere with other drugs you may be taking. Talk to your doctor about this product.

VII.
OTHER PROHIBITED CLAIMS

IT IS FURTHER ORDERED that Defendants, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and their officers, agents, servants, representatives, employees, and all persons or entities in active concert or participation with them who receive actual notice of this Order, by personal service or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product or service, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of endorsements, about the health benefits, absolute or comparative benefits, performance, safety, or efficacy of such product or service

unless, at the time the representation is made, Defendants possess and rely upon competent and reliable scientific evidence that substantiates the representation.

VIII.
NONDISCLOSURE OF MAILING LISTS

IT IS FURTHER ORDERED that Defendants and their officers, agents, servants, employees, and attorneys, and all other persons or entities in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, are permanently restrained and enjoined from selling, renting, leasing, transferring, or otherwise disclosing the name, address, telephone number, credit card number, bank account number, e-mail address, or other identifying information of any person who paid any money to any Defendant named in this Action for Thermalean, Lipodrene, or Spontane-ES or shipping and handling therefor, at any time prior to entry of this order. *Provided, however,* that Defendants may disclose such identifying information to a law enforcement agency or as required by any law, regulation, or court order.

IX.

related to the practices of the Defendants and NICWL, as alleged in the Complaint. Any funds not used for such equitable relief shall be deposited to the United States Treasury as disgorgement. Defendants and NICWL shall have no right to challenge the Commission's choice of remedies under this Paragraph or the manner of distribution chosen by the Commission. No portion of any payments under the judgment herein shall be deemed a payment of any fine, penalty, or punitive assessment.

E. In accordance with 31 U.S.C. § 7701, Defendants and NICWL are hereby required, unless they have done so already, to furnish to the Commission their respective taxpayer identifying numbers (social security numbers or employer identification numbers), which shall be used for the purposes of collecting and reporting on any delinquent amount arising out of the relationship of the Defendants and NICWL with the government.

X.
COMPLIANCE MONITORING

IT IS FURTHER ORDERED that, for the purpose of monitoring and investigating compliance with any provision of this Order,

A. Within ten (10) days of receipt of written notice from a representative of the Commission, NUG, Hi-Tech, Wheat, Holda, and Smith each shall submit additional written reports, sworn to under penalty of perjury; produce documents for inspection and copying; appear for deposition; and/or provide entry during normal business hours to any business location in such Defendant's possession or direct or indirect control to inspect the business operation;

B. In addition, the Commission is authorized to monitor compliance with this Order by all other lawful means, including but not limited to the following:

1. obtaining discovery from any person, without further leave of court, using the procedures prescribed by Fed. R. Civ. P. 30, 31, 33, 34, 36, and 45; and

2. posing as consumers and suppliers to: NUG, Hi-Tech, Wheat, Holda, or Smith, employees of NUG, Hi-Tech, Wheat, Holda, or Smith, or any other entity managed or controlled in whole or in part by NUG, Hi-Tech, Wheat, Holda, or Smith, without the necessity of identification or prior notice; and

C. NUG, Hi-Tech, Wheat, Holda, and Smith shall permit representatives of the Commission to interview any employer, consultant, independent contractor, representative, agent, or employee who has agreed to such an interview, relating in any way to any conduct subject to this Order. The person interviewed may have counsel present.

Provided, however, that nothing in this Order shall limit 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, to obtain any documentary material, tangible things, testimony, or information relevant to unfair or deceptive acts or practices in or affecting commerce (within the meaning of 15 U.S.C. § 45(a)(1)).

XI.
COMPLIANCE REPORTING BY DEFENDANTS

IT IS FURTHER ORDERED that, in order that compliance with the provisions of this Order may be monitored:

A. For a period of five (5) years from the date of entry of this Order,

1. Each Individual Defendant shall notify the Commission of the following:

a. Any changes in residence, mailing addresses, and telephone numbers of Individual Defendant, within ten (10) days of the date of such change;

b. Any changes in employment status (including self-employment) of Individual Defendant, and any change in the ownership of the Individual Defendant in any business entity, within ten (10) days of the date of such change. Such notice shall include the name and address of each business that the Individual Defendant is affiliated with, employed by, creates or forms, or performs services for; a statement of the nature of the business; and a statement of the Individual Defendant's

duties and responsibilities in connection with the business or employment; and

c. Any changes in the Individual Defendant's name or use of any aliases or fictitious names; and

2. The Individual Defendants and Corporate Defendants shall notify the Commission of any changes in corporate structure that Corporate Defendant(s) or any business entity that an Individual Defendant(s) directly or indirectly control(s), or has an ownership interest in, 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 filing of a bankruptcy petition; or a change in the corporate name or address, at least thirty (30) days prior to such change, *provided* that, with respect to any proposed change in the corporation about which Defendant(s) learn less than thirty (30) days prior

2. For all Defendants:

a. A copy of each acknowledgment of receipt of this Order, obtained pursuant to Paragraph XIII; and

b. Any other changes required to be reported under Paragraph A of this Section.

C. For the purposes of this Order, Defendants, unless otherwise directed by the Commission's authorized representatives, mail all written notifications to the Commission to:

Associate Director for Enforcement
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580
Attn: FTC v. National Urological Group, Inc., et. al. (N.D. Ga.)
Civil Action No. 1:04-CV-3294

D. For purposes of the compliance reporting and monitoring required by this Order, the Commission is authorized to communicate directly with Defendants.

XII.
RECORD KEEPING PROVISIONS

IT IS FURTHER ORDERED that, for a period of eight (8) years from the date of entry of this Order, Corporate Defendants and Individual Defendants and

any business where (1) an Individual Defendant is the majority owner or an officer or director of the business, or directly or indirectly manages or controls the business, or where (2) the business engages, or assists others engaged in, the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any weight loss product, erectile dysfunction product, or covered product, program, or service, and an Individual Defendant's agents, employees, officers, corporations, successors, and assigns, and those persons in active concert or participation with the Individual Defendant who receive actual notice of this Order by personal service or otherwise, are hereby restrained and enjoined from failing to create and retain the following records:

A. Accounting records that reflect the cost of goods or services sold, revenues generated, and the disbursement of such revenues;

B. Personnel records accurately reflecting: the name, address, and telephone number of each person employed in any capacity by such business, including as an independent contractor; that person's job title or position; the date upon which the person commenced work; and the date and reason for the person's termination, if applicable;

C. Customer files containing the names, addresses, phone numbers, dollar amounts paid, quantity of items or services purchased, and description of items or services purchased, to the extent such information is obtained in the ordinary course of business;

D. Complaints and refund requests (whether received directly, indirectly or through any third party) and any responses to those complaints or requests;

E. Copies of all sales scripts, training materials, advertisements, Web sites, or other marketing materials for any weight loss product, erectile dysfunction product, or any covered product, program, or service;

F. All records and documents necessary to demonstrate full compliance with each provision of this Order, including but not limited to, copies of acknowledgments of receipt of this Order and all reports submitted to the FTC pursuant to this Order.

G. All materials that were relied upon in making any representations contained in the materials identified in Paragraph E of this Section, including all documents evidencing or referring to the accuracy of

any claim therein or to the efficacy of any weight loss product, erectile dysfunction product, or any covered product, program, or service, including, but not limited to, all tests, reports, studies, demonstrations, or other evidence that confirm, contradict, qualify,

XIII.
DISTRIBUTION OF ORDER BY DEFENDANTS

IT IS FURTHER ORDERED that, for a period of five (5) years from the date of entry of this Order, Defendants shall deliver copies of the Order as directed below:

A. **Corporate Defendant**: Each Corporate Defendant must deliver a

representatives of that business who engage in conduct related to the subject matter of the Order. For current personnel, delivery shall be within (5) days of service of this Order upon Individual Defendant. For new personnel, delivery shall occur prior to their assuming their responsibilities.

C. **Individual Defendant As Employee or Non-Control Person**: For any business where each Individual Defendant is not a controlling person of a business but otherwise engages in conduct related to the subject matter of this Order, each Individual Defendant must deliver a copy of this Order to all principals and managers of such business before engaging in such conduct.

D. The Corporate and Individual Defendants each must secure a signed and dated statement acknowledging receipt of the Order, within thirty (30) days of delivery, from all persons receiving a copy of the Order pursuant to this Part.

XIV.
ACKNOWLEDGMENT OF RECEIPT OF ORDER

IT IS FURTHER ORDERED that each Defendant, within five (5) business days of receipt of this Order as entered by the Court, must submit to the

Commission a truthful sworn statement, in the form of Attachment A to this Order, acknowledging receipt of this Order.

XV.
RETENTION OF JURISDICTION

IT IS FURTHER ORDERED that this Court shall retain jurisdiction of this matter for purposes of construction, modification, and enforcement of this Order.

SO ORDERED, this 16th day of December, 2008.

/s/ Charles A. Pannell, Jr.
HON. CHARLES A. PANNELL, JR.
United States District Judge