# UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF GEORGIA ATLANTA DIVISION

#### FEDERAL TRADE COMMISSION,

Plaintiff,

v.

AMERICAN UROLOGICAL CORPORATION, a Texas corporation; INSTITUTE OF SEXUAL RESEARCH, INC., a Texas corporation; INSTITUTE OF SEXUAL RESEARCH, LTD., a North Carolina corporation; THE CLINIC FOR NATURAL SOLUTIONS, INC., a Texas corporation; OLD WELL CORPORATION, a Texas corporation; OLD WELL CORPORATION, a North Carolina corporation; and DAVID A. BRADY, individually and as an officer and director of American Urological Corporation, Institute of Sexual Research, Inc., Institute of Sexual Research, Ltd., The Clinic for Natural Solutions, Inc., and Old Well Corporation (Texas and North Carolina);

Defendants.

Civil Action No.

## [Proposed] EX PARTE TEMPORARY RESTRAINING ORDER WITH ASSET FREEZE AND ORDER FOR DEFENDANTS TO SHOW CAUSE

Plaintiff Federal Trade Commission ("FTC" or "Commission"), having moved for an ex parte temporary restraining order with an asset freeze, an accounting, expedited asset discovery, and an order permitting immediate access to defendants' business premises, pursuant to Fed. R. Civ. P. 65(b), and the Court having considered the pleadings and exhibits filed in support of said Motion, finds:

- 1. That this Court has jurisdiction over the subject matter of this case, and that there is good cause to believe it will have jurisdiction over all the parties hereto;
- 2. That there is good cause to believe that defendants have violated Sections 5(a) and 12 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45(a), and that the Commission is therefore likely to prevail on the merits of this action;
- 3. That there is good cause to believe that immediate and irreparable damage to the Court's ability to grant effective final relief for consumers in the form of monetary redress will occur from the transfer, disposition or concealment by defendants of their assets or business records unless defendants are immediately restrained and enjoined by Order of this Court, and that in accordance with Fed. R. Civ. P. 65(b), the interests of justice therefore require that the Commission's Motion be heard ex parte without prior notice to defendants;
- 4. That, weighing the equities and considering the Commission's likelihood of ultimate success, a temporary restraining order with an asset freeze, accounting, expedited asset discovery, and an order permitting immediate access to defendants' records, is in the public interest; and
- 5. That no security is required of any agency of the United States for issuance of a restraining order. Fed. R. Civ. P. 65(c).

#### IT IS THEREFORE ORDERED AS FOLLOWS:

#### **DEFINITIONS**

I.

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

- 1. "Impotence treatment products" shall refer to any product that is promoted, offered for sale, or sold with express or implied representations that the product will or may treat, reverse, eliminate, or ameliorate impotence. "Impotence treatment products" shall specifically include, but not be limited to, "Alprostaglandin®," "Celldenaphil-pc," "Renak-pc," "Oral Phentalomil®," "Prosta-Gen," "Testosterone-21," "Väegra," "Urophil," "VasoGenitine," and any substantially similar products.
- 2. "Impotence" shall refer to the inability of a man to attain an erection of sufficient rigidity and/or duration to permit him to engage in sexual intercourse. "Sexual dysfunction" and "erectile dysfunction" shall have the same meaning as "impotence."
- 3. "Participating associates" shall refer to defendants' agents, employees, officers, independent contractors, attorneys, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise.
- 4. "Defendants" shall refer to the following:
  - A. American Urological Corporation (herein "AUC"), and its successors or assigns;
  - B. Institute of Sexual Research, Inc. (herein "ISR Inc."), also doing business as American Urological Clinic, Carnegie Research Institute, and New England Institute for Impotence and Prostate Care, and its successors or assigns;
  - C. Institute of Sexual Research, Ltd. (herein "ISR Ltd."), and its successors or assigns;
  - D. The Clinic for Natural Solutions, Inc. (herein "CNS"), also doing business as United States Academy of Urological Sciences and National Institute for Urological Health, and its successors or assigns;
  - E. Old Well Corporation, a Texas corporation (herein "Old Well (Texas)"), and its successors or assigns;
  - F. Old Well Corporation, a North Carolina corporation (herein "Old Well (North Carolina)"), and its successors or assigns;
  - G. David A. Brady (herein "Brady"), an individual whose social security number is and
  - H. any combination of the foregoing.
- 5. "Documents" shall refer to written, typed, printed, transcribed, or computer-stored material, however produced or recorded.

#### PROHIBITED MISREPRESENTATIONS

- IT IS HEREBY ORDERED that defendants and their participating associates, directly or indirectly, or acting through any corporation, entity, or person under their control, are hereby restrained and enjoined from making, or assisting others in making, directly or by implication, any material false or misleading oral or written statement or representation in connection with any impotence treatment product, including but not limited to:
  - 1. Representing, directly or by implication, that the American Urological Corporation; Institute of Sexual Research, Inc.; American Urological Clinic; Carnegie Research Institute; New England Institute for Impotence and Prostate Care; Institute of Sexual Research, Ltd.; The Clinic for Natural Solutions, Inc.; United States Academy of Urological Sciences; or National Institute for Urological Health (herein "defendants' entities") is a bona fide medical enterprise, including the use of any of the following statements or depictions in any literature prepared or disseminated by defendants' entities:
    - A. Displaying the caduceus or any other medical symbol in such a manner as to state or imply that defendants' entities are medical enterprises;
    - B. Displaying photographs of persons wearing attire customarily worn by medical personnel in such a manner as to state or imply that defendants' entities employ, or are affiliated with, medical doctors or other medical personnel;
    - C. Displaying photographs of buildings in such a manner as to state or imply that defendants' entities maintain facilities in these buildings, unless such is the case;
    - D. Using the name of any bona fide academic or scientific organization, or of any individual with medical or scientific training, in such a manner as to state or imply that such organization or individual is affiliated with, or otherwise endorses or supports, defendants' entities or any impotence product sold by defendants' entities, unless such is the case;
    - E. Using the name of any fictitious individual or medical organization in such a manner as to state or imply that such individual or organization is affiliated with, or otherwise endorses or supports, defendants' entities or any impotence treatment product sold by defendants' entities;
    - F. Using the name of, or excerpts from, any bona fide publication in such a manner as to state or imply that such publication discusses, endorses or supports defendants' entities or any impotence treatment product sold by defendants' entities, unless such is the case:
    - G. Using the name of, or excerpts from, any fictitious publication in such a manner as to state or imply that such publication is a bona fide publication that endorses or supports defendants' entities or any impotence treatment product sold by defendants' entities;

- H. Displaying any chart, graph, press release, mission statement, or other depiction or statement that states or implies that defendants' entities have conducted, or participated in the conduct of, bona fide scientific research; and
- I. Otherwise misrepresenting the medical or scientific nature or affiliations of any entity engaged in the promotion, offering for sale, or sale of any impotence treatment product.
- 2. Representing, directly or by implication, that Alprostaglandin®, Celldenaphil-pc, Renak-pc, Oral Phentalomil®, Prosta-Gen©, Testosterone-21, Väegra, Urophil, or VasoGenitine, or any ingredient contained in them, is effective in eliminating impotence in 68 percent or more of impotent men, or otherwise misrepresenting the efficacy of any impotence treatment product; 3. Representing, directly or by implication, that Alprostaglandin®,
- Celldenaphil-pc, Renak-pc, Oral Phentalomil®, Prosta-Gen©, Testosterone-21, Väegra, Urophil, or VasoGenitine, or any ingredient contained in them, has been scientifically proven to be effective in eliminating impotence in 68 percent or more of impotent men, or otherwise misrepresenting the nature or extent of scientific evidence regarding any impotence treatment product;
- 4. Making any representation, in any manner, directly or by implication, regarding the efficacy of any impotence treatment product unless, at the time of making such representation, defendants possess and rely upon competent and reliable scientific evidence that substantiates the representation. "Competent and reliable scientific evidence" means at least two adequate and well-controlled, double-blinded clinical studies conforming to acceptable designs and protocols, using procedures generally accepted by professionals in the relevant area to yield accurate and reliable results. Such studies shall be conducted by different persons, independently of each other, who are qualified by training and experience to conduct such testing.
- 5. Displaying the registered trademark symbol ® following the name Alprostaglandin, Oral Phentalomil, or any impotence treatment product unless, at the time such trademark symbol is displayed, the United States Trademark Office has issued a trademark for such product name;
- 6. Falsely representing, directly or by implication, through the use of product names such as Alprostaglandin, Oral Phentalomil, and Testosterone-21, or through any other means, that any impotence treatment product contains any ingredient that is not, in fact, present in that product;
- 7. Falsely representing, directly or by implication, that the United States Food and Drug Administration has reviewed and/or approved a product or ingredient as effective or safe for treating any disease; and
- 8. Misrepresenting, or failing to disclose, any other fact material to a consumer's decision to purchase any impotence treatment product.

#### **RECORD KEEPING PROVISIONS**

III.

IT IS FURTHER ORDERED that defendants and their participating associates are hereby restrained and enjoined from:

A. Failing to make and keep books and records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of

defendants; and

B. Destroying, altering, transferring, concealing, or otherwise disposing of, in any manner, any books, records, or other financial or business documents of any kind, including electronically stored data.

#### ASSET FREEZE AND ACCOUNTING PROVISIONS

#### IV.

IT IS FURTHER ORDERED that defendants and their participating associates are hereby restrained and enjoined, until further order of this Court, from:

- A. Transferring, encumbering, concealing, selling, incurring charges or cash advances on any credit card, or otherwise disposing of any funds, property, mail, or assets of any kind, wherever located, that are (a) owned or controlled by any defendant, in whole or in part; (b) in the actual or constructive possession of any defendant; (c) held by an agent of any defendant as a retainer for the agent's provision of services to any defendant; or
- (d) owned, controlled by, or in the actual or constructive possession of, or otherwise held for the benefit of, any entity directly or indirectly owned, managed, or controlled by any defendant. The assets referenced above in this subparagraph shall also include, but are not limited to, any assets held by, for, or under the name of any defendant at any bank or other financial institution of any kind, including, but not limited to, NationsBank account number 4770453647; and B. Transferring any funds or other assets subject to this Order for attorney's fees, living expenses, business expenses or any other purpose, until the Court, on application, has approved such an expenditure, or until the Commission has stipulated in writing to such an expenditure.

The assets affected by Paragraph IV of this Order shall include both existing assets and assets acquired after the effective date of this Order; provided, however, that the asset freeze shall not apply to any monies earned by defendant Brady after the effective date of this Order as salaries or wages from any source other than from defendants AUC, ISR Inc., ISR Ltd., CNS, Old Well (Texas), Old Well (North Carolina), or their successors or assigns. V.

IT IS FURTHER ORDERED that, within five (5) days (including non-business days) of receiving service of this Order, each defendant shall prepare and deliver to counsel for the FTC a complete schedule, verified under oath, identifying:

- A. The nature, location, source, and dollar value, estimated if necessary, of all the tangible and intangible assets and property of the defendant, or of any business entity that the defendant owns, manages or controls, regardless of location, status or form; and
- B. For all payments, transfers or assignments of assets worth \$1,000 or more, excluding ordinary business expenses, that the defendant made since September 1, 1997:
  - (1) the amount transferred or assigned; (2) the name of each transferee or assignee; (3) the date of the assignment or transfer; and (4) the type and amount of consideration paid for the item transferred or assigned.

IT IS FURTHER ORDERED, pending determination of the FTC's request for a preliminary injunction, that any financial institution, business entity, or person that (1) holds accounts, property, mail, or any other asset owned, managed, or controlled by, or held for the benefit of, any defendant, and (2) is served with a copy of this Order, shall hold and retain within its control and prohibit any disposal of any such assets, except in accordance with any further order of the Court or for specific transfers authorized in writing by counsel for the FTC. The assets affected by this Paragraph shall include all assets frozen pursuant to Paragraph IV of this Order.

#### VII.

IT IS FURTHER ORDERED that within four (4) business days of the date of service of this Order on any financial institution, other business entity, or person that currently maintains or has custody or control of any account or other asset of any defendant, or that at any time since September 1, 1997, maintained or had custody or control of any such account or other asset, such entity or person shall provide to counsel for the FTC and the account holder a statement setting forth:

- A. The identification of each account or asset titled in the name, or held on behalf of or for the benefit of any defendant, individually or jointly; and
- B. The balance of each such account, or a description and appraisal of the fair market value of each such asset, as of the close of business on the day on which this Order is served.

#### **EXPEDITED ASSET DISCOVERY**

#### VIII.

IT IS FURTHER ORDERED that the FTC is granted leave, at any time after service of this Order and pursuant to Fed. R. Civ. P. 30(a), 34, and 45, to take depositions for the purpose of discovering the nature, location, status, and extent of defendants' assets and the location of documents reflecting defendants' business transactions, and to demand the production of documents reflecting defendants' business transactions relating to the nature, status, and extent of defendants' assets. Seventy-two (72) hours' notice shall be deemed sufficient for any such deposition and five (5) days' notice shall be deemed sufficient for the production of any such documents. The provisions of this Paragraph shall apply both to parties to this case and non-parties.

#### IMMEDIATE ACCESS TO DEFENDANTS' BUSINESS PREMISES

#### IX.

IT IS FURTHER ORDERED that the FTC's representatives, employees, agents and assistants shall be granted immediate access to any offices, mail drops, storage facilities, and all other locations used by defendants' businesses. This right of access shall continue from day to day, excluding Sundays, during regular business hours, and shall include access to such offices or premises for the purpose of inspecting, indexing, and copying, and if necessary, removing from present locations for the sole purpose of copying:

- A. All documents referring or relating to any aspect any impotence treatment product promoted, offered for sale, or sold by any defendant, including but not limited to:
  - 1. All promotional materials, sales scripts, advertisements, and training manuals;

- 2. All documents referring or relating to the preparation, printing, and distribution of any promotional materials, sales scripts, advertisements, and training manuals;
- 3. All correspondence with customers and prospective customers, and customer files, including all customer complaints;
- 4. All correspondence and all documents referring or relating to contracts or other business arrangements between defendants and any business entity;
- 5. All documents referring or relating to any scientific research, evidence, tests, studies, or literature of any kind concerning any impotence treatment product;
- 7. All documents referring or relating to the efficacy of any impotence treatment product;
- 8. All documents referring or relating to the use of the registered trademark symbol ® in connection with any name;
- 9. All documents referring or relating to the use of any photograph or name of any person or entity in any promotional materials:
- 10. All documents referring or relating to defendants' affiliation or correspondence with any medical or scientific organization;
- 11. All documents referring or relating to the development, manufacturing, contents, ingredients, labeling, and fulfillment of any impotence treatment product; and
- 12. All documents referring or relating to the shipping, distribution and sale of any impotence treatment product.
- B. All accounting ledgers or records, checkbooks, bank statements, cancelled checks, deposit slips, or other financial documents of: any defendant; any of defendants' affiliates or subsidiaries; or any business owned, controlled or managed by any defendant;
- C. The contents of any safe deposit boxes and any storage facilities under defendants' custody, control, or possession;
- D. All documents identifying or otherwise referring or relating to employees of, or independent contractors retained by, defendants;
- E. All documents referring or relating to the location or the disposition of the proceeds of any business owned, controlled or managed by defendants, or in which defendants have a beneficial interest; and
- F. All documents referring or relating to assets owned, wholly or in part, controlled by, or in the possession of: (a) defendants; (b) any of defendants' affiliates or subsidiaries, or any entity doing business in any defendant's name; or (c) any entity owned, controlled, or managed by defendants.

Defendants and all participating associates shall provide the FTC with any necessary means of access to these documents including, without limitation, keys and

combinations to locks, and computer access codes. The defendants and all participating associates to the extent they are not in possession of documents described in this Paragraph (and that are not subject to recognized judicial privileges), regardless of the location of any such documents, nevertheless shall provide the FTC immediately with any information they possess regarding the location of these documents, including without limitation the names, telephone numbers, and addresses of any individuals who they have reason to believe might possess, or have further knowledge as to the location of, these documents.

#### NOTICE TO EMPLOYEES

X.

IT IS FURTHER ORDERED that defendants shall immediately provide a copy of this Order to each of their corporations, subsidiaries, affiliates, and participating associates. Within twenty-one (21) calendar days following service of this Order by the FTC, defendants shall serve on the FTC an affidavit identifying the names, titles, addresses, and telephone numbers of the persons and entities that defendants have served with a copy of this Order in compliance with this provision.

#### **EXPIRATION OF THIS ORDER**

XI.

IT IS FURTHER ORDERED that the Temporary Restraining Order granted herein shall expire on \_\_\_\_\_\_\_, 1998, at 11:59 PM, unless within such time the Order, for good cause shown, is extended, or unless, as to any defendant, the defendant consents that it should be extended for a longer period of time.

#### CORRESPONDENCE WITH PLAINTIFF

XII.

For the purposes of this Order, all correspondence and pleadings to the Commission shall be addressed to:

Sondra L. Mills, Esq. Federal Trade Commission c/o Atlanta Regional Office Suite 5M35, Midrise Bldg. 60 Forsyth Street, S.W. Atlanta, GA 30303 (404) 656-1390 (voice) (404)656-1379 (facsimile)

#### SERVICE OF THIS ORDER

#### XIII.

IT IS FURTHER ORDERED that, pursuant to Federal Rule of Civil Procedure 4(c)(2), copies of this Order and the initial pleadings and papers filed in this matter may be served by employees of the FTC, by employees of any other law enforcement agency, and by agents of any process servers retained by the Federal Trade Commission, upon any defendant, any of defendants' participating associates, any of defendants' business premises, any financial institution, or any person or entity that may be in possession of

any assets, property, or property rights of defendants.

### RETENTION OF JURISDICTION

XIV.

IT IS FURTHER ORDERED	that this	Court	shall	retain	jurisdiction	of this	matter	for all
purposes.								

ourposes.	
IT IS SO ORDERED.	
UNITED STATES DISTRICT JUDGE	
Issued at,m.	
Dated:, 1998	