

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MINNESOTA**

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IN RE:	:	MDL DOCKET NO. 1724
VIAGRA PRODUCTS LIABILITY LITIGATION	:	Judge Paul A. Magnuson
_____	:	PRETRIAL ORDER NO. 1:
<b>This Order Relates To:</b>	:	<b>STIPULATED PROTECTIVE ORDER</b>
<b>ALL CASES</b>	:	

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**I. SCOPE OF ORDER**

1. This Order shall govern those actions transferred to this Court by the Judicial Panel on Multidistrict Litigation (“the Panel”) pursuant to its Transfer Order of January 26, 2006, any “tag-along” actions transferred to this Court by the Panel, and all related actions that have been or will be originally filed in, transferred to, or removed to this Court and assigned thereto.

2. Disclosure and discovery activity in this MDL proceeding are likely to involve production of confidential, proprietary, or private information for which special protection from public disclosure and from use for any purpose other than prosecuting this litigation would be warranted. Accordingly, the parties hereby stipulate to and petition the Court to enter the following Pretrial Order No. 1: Order Governing the Production of Confidential Information (“Protective Order” or “Order”)

3. This Protective Order shall govern all documents, the information contained therein, and all other information produced or disclosed during the MDL proceeding, including all copies, excerpts, summaries, or compilations thereof, whether revealed in a document, deposition, other testimony, discovery response or otherwise, by any party to the MDL proceeding (the “Supplying Party”) to any other party or parties (the “Receiving Party”). This Protective Order is binding upon the parties to the MDL proceeding, including their respective corporate parents, subsidiaries and affiliates and their respective attorneys, agents, experts, consultants, representatives, officers and employees and others as set forth in this Order. This

produced or disclosed in the MDL proceeding pursuant to this Protective Order, including those parties' respective corporate parents, subsidiaries and affiliates and their respective attorneys, agents, experts, consultants, representatives, officers and employees and others as set forth in this Protective Order.

4. Third parties who so elect may avail themselves of, and agree to be bound by, the terms and conditions of this Protective Order and thereby become a Supplying Party for purposes of this Protective Order.

5. The entry of this Protective Order does not prevent any party from seeking a further order of this Court pursuant to Federal Rule of Civil Procedure 26(c).

6. Nothing herein shall be construed to affect in any manner the admissibility at trial or any other court proceeding of any document, testimony, or other evidence.

7. The parties acknowledge that this Order does not confer blanket protections on all disclosures or responses to discovery and that the protection it affords extends only to the limited information or items that are entitled under the applicable legal principles to treatment as confidential.

## **II. DESIGNATION OF CONFIDENTIAL INFORMATION**

1. "Confidential Information" as used herein means any information that the Supplying Party believes in good faith constitutes, reflects, discloses, or contains information subject to protection under Federal Rule of Civil Procedure 26(c) or other applicable law, whether it is a document (electronic or otherwise), information contained in a document, information revealed during a deposition or other testimony, information revealed in an interrogatory response or information otherwise revealed. In designating material as "CONFIDENTIAL," the Supplying Party will make such designation only as to that material that it in good faith believes to be entitled to confidential treatment under applicable law or would disclose the parties' private financial information, private competitive information, trade secrets, confidential scientific information, personal or medical information or other kinds of sensitive information which a party deems confidential.

2. Specific documents and discovery responses produced by the Supplying Party shall, if appropriate, be designated as "CONFIDENTIAL" by marking the pages of the document that contain Confidential Information as follows: "CONFIDENTIAL" or "CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER." Except as provided in paragraphs 14 and 28, documents that do not bear the foregoing designation are not Confidential Information as that term is used in this Order.

3. To the extent that matter stored or recorded in the form of electronic or magnetic media (including information, files, databases or programs stored on any digital or analog machine-readable device, computers, Internet sites, discs, networks or tapes) ("Computerized Material") is produced by any party in such form, the Supplying party may designate such matters as confidential by cover letter referring generally to such matter. Whenever any party to whom Computerized Material designated as confidential is produced reduces such material to hardcopy form, that party shall mark the hardcopy form with the "CONFIDENTIAL" designation.

4. In order to protect against unauthorized disclosure of Confidential Information, and to comply with all applicable state and federal laws and regulations, the Supplying Party may redact from produced documents, materials or other things, or portions thereof:

a. The names, addresses, Social Security or tax identification numbers and other personally identifying information of employees, patients, health care providers, and individuals in clinical studies or adverse event reports. However, other general identifying information, such as patient or health care provider numbers, shall not be redacted unless required by federal law;

b. Highly confidential trade secrets such as those related to the formulation of the product(s) allegedly taken by plaintiff(s) in the MDL proceeding; and

c. Any information relating to products other than Viagra®.

5. Pursuant to 21 C.F.R. §§ 314.430(e) & (f) and 20.63(f), the names of any person or persons reporting adverse experiences of patients and the names of any patients that are not redacted pursuant to Paragraph 11 shall be treated as confidential, regardless of whether the document containing such names is designated as Confidential Information. No such person shall

express written permission of the Supplying Party.

6. Any material produced or provided in the MDL proceeding for inspection is to be treated by the Receiving Party as Confidential Information pending the copying and delivery of any copies of same by the Supplying Party to the Receiving Party.

7. Information disclosed at a deposition taken in connection with the MDL proceeding may be designated as Confidential Information by: (a) designating testimony as confidential on the record during the taking of the deposition, and/or (b) designating the portions of the transcript that are confidential in a letter to be served on the court reporter and opposing counsel within thirty (30) calendar days of the Supplying Party's receipt of the transcript of a deposition. The court reporter will indicate the portions designated as confidential and segregate them as appropriate. Designations of transcripts will apply to audio, video, or other recordings of the testimony. The court reporter shall clearly mark any transcript released prior to the expiration of the 30-day period as "Confidential – Subject to Further Confidentiality Review." Such transcripts will be treated as Confidential Information until the expiration of the 30-day period.

8. A party in the MDL proceeding may designate as Confidential Information any document or information produced by or testimony given by any other person or entity that the party reasonably believes qualifies as such party's Confidential Information pursuant to this Protective Order. If any third party produces information that any party in good faith believes constitutes its Confidential Information, the party claiming confidentiality shall designate the information as such within thirty (30) days of its receipt of such information. Any party receiving information from a third party shall treat such information as confidential during this thirty (30) day period while all parties have an opportunity to review the information and determine whether it should be designated as confidential. Any party designating third party information as confidential shall have the same rights as a Supplying Party under this order with respect to such information.

### **III. PERMISSIBLE DISCLOSURE OF CONFIDENTIAL INFORMATION**

1. Subject to paragraphs 17 and 23, a Receiving Party may show and deliver Confidential Information only to the following persons:

- a. Counsel for the Receiving Party, including any in-house counsel, and the attorneys, paralegals, stenographic, and clerical staff employed by such counsel to whom it is reasonably necessary to disclose the Confidential Information for purposes of the litigation;
- b. With respect to any Confidential Information produced by any plaintiff or third party with respect to plaintiff, any employee or agent of the Receiving Party to whom it is reasonably necessary to disclose such information;
- c. Any plaintiff or claimant who has asserted or intends to assert a claim in the MDL proceedings;
- d. Any outside consultant or expert to whom it is reasonably necessary to disclose Confidential Information, whether formally retained or not, subject to paragraph 17, *infra*;
- e. Any witness for the purpose of conducting an examination of such witness during a trial or deposition; provided, however, that Confidential Information shall not lose its confidential or restricted status through such use;
- f. Any attorney for claimants in other pending litigation in the United States alleging personal injury arising from the alleged use or purchase of Viagra® (or attorneys for claimants in any other pending litigation as the parties may mutually agree or the Court directs) for use in this or such other action, provided that the proposed recipient is (i) already operating under a stipulated Protective Order or (ii) agrees to be bound by this Order and signs the "Acknowledgment and Agreement to Be Bound" ("Acknowledgment") described in paragraph 23;
- g. Stenographic employees and court reporters recording or transcribing testimony in the MDL proceeding; and
- h. The Court, any Special Master appointed by the Court, any state court conducting related proceedings, and any members of their staffs to whom it is necessary to disclose Confidential Information.

2. Before disclosing Confidential Information to any person who is, independent of this litigation, a current employee of, or a consultant to, a pharmaceutical company other than Pfizer Inc. that is marketing or has in development a phosphodiesterase type-5 inhibitor or other

ten (10) days' advance notice in writing to the counsel for the party who designated such information as confidential, stating the names and addresses of the person(s) to whom the disclosure will be made and the nature of his or her affiliation with a pharmaceutical company. If, within the 10-day period, the Supplying Party files a motion objecting to the proposed disclosure, then the party seeking disclosure may not disclose any Confidential Information to that person until ten days have elapsed after the appeal period from a Court order denying the motion. In making such motion, it shall be the Supplying Person's burden to demonstrate good cause for preventing such disclosure. Before disclosing Confidential Information to any person who is, independent of this litigation, a current employee of, or a consultant to, a pharmaceutical company other than Pfizer Inc. (whether or not such company is marketing or has in development a phosphodiesterase type-5 inhibitor or other treatment for erectile dysfunction), the party wishing to make such disclosure shall give counsel for the party who designated such information as confidential sufficient information concerning the proposed recipient that does not identify the proposed recipient but is sufficient to permit an informed decision to be made with respect to any potential objection, including at a minimum, the name of the pharmaceutical company and the nature of the person's relationship thereto. If there is no consent to the disclosure within ten (10) days, the party wishing to make the disclosure may submit the information to the Court for a determination of whether the disclosure may be made. The objecting party will have opportunities to request that the Court direct the party wishing to make disclosure to produce additional information about the proposed recipient and to submit any other papers and argument it feels necessary to allow the Court to make an informed decision. It shall be the burden of the party wishing to prevent such disclosure to demonstrate good cause for prohibiting disclosure. The party seeking disclosure may not disclose any Confidential Information to that person unless and until the Court has permitted such disclosure and ten days have elapsed after the appeal period from any such order. If the Court allows disclosure of the Confidential Information, the Information remains Confidential Information and the person shall be bound by this order.

3. Disclosure of Confidential Information beyond the terms of this Protective Order may be made only if the Supplying Party designating the material as confidential consents

orders such disclosure. The terms of this Order shall not apply to any publicly available information or documents.

#### **IV. USE OF CONFIDENTIAL INFORMATION**

1. Persons having knowledge of Confidential Information by virtue of their participation in the MDL proceedings, or by virtue of obtaining any documents or other Confidential Information produced or disclosed in the MDL proceedings pursuant to this Protective Order, shall use that Confidential Information only in connection with the MDL proceedings or a related action in which the Receiving Party is permitted by this Order to use Confidential Information.

2. Notwithstanding any other provisions hereof, nothing herein shall restrict any party's counsel from rendering advice to its clients with respect to the MDL proceedings or a related action in which the Receiving Party is permitted by this Order to use Confidential Information and, in the course thereof, relying upon Confidential Information, provided that in rendering such advice, counsel shall not disclose any other party's Confidential Information other than in a manner provided for in this Protective Order.

3. Nothing contained in this Protective Order shall preclude any party from using its own Confidential Information in any manner it sees fit, without prior consent of any party or the Court.

#### **V. PROTECTION OF CONFIDENTIAL INFORMATION**

1. Counsel shall take all reasonable and necessary steps to assure the security of any Confidential Information and will limit access to Confidential Information to those persons authorized by this Protective Order. In particular, if counsel for any party makes documents produced pursuant to this Order available via the Internet, such counsel shall take all reasonable and necessary steps to ensure that the Internet site is secure and may not be accessed by individuals who are not authorized to review Confidential Information and who have not executed the Acknowledgment described in paragraph 23 herein. At a minimum, any Internet site must require each individual user to have a distinct log-in and password. Upon request by

2. Prior to the disclosure of any Confidential Information to any person identified in paragraph 16(c)-(f), each putative recipient of Confidential Information shall be provided with a copy of this Protective Order, which he or she shall read. Upon reading this Protective Order, such person shall sign an Acknowledgment, in the form annexed hereto as Exhibit A, acknowledging that he or she has read this Protective Order and shall abide by its terms. These Acknowledgments are strictly confidential. Counsel for each party shall maintain the Acknowledgments without giving copies to the other side. The parties expressly agree, and it is hereby ordered that, except in the event of a violation of this Order, they will make no attempt to seek copies of the Acknowledgments or to determine the identities of the persons signing them. If the Court finds that any disclosure is necessary to investigate a violation of this Order, the disclosure will be limited to outside counsel only and outside counsel shall not disclose any information to their clients that could tend to identify any Acknowledgment signatory unless and until there is specific evidence that a particular signatory may have violated the Order, in which case limited disclosure may be made with respect to that signatory. Persons who come into contact with Confidential Information for clerical or administrative purposes, and who do not retain copies or extracts thereof, are not required to execute Acknowledgments but must comply with the terms of this Order.

3. Any party that is served with a subpoena or other notice compelling the production of discovery materials produced by another party must immediately give written notice of such subpoena or other notice to the original Supplying Party. Upon receiving such notice, the original Supplying Party shall bear the burden of opposing, if it deems appropriate, the subpoena on grounds of confidentiality.

4. All counsel shall at all times keep secure all notes, abstractions, or other work product derived from or containing Confidential Information; shall be obligated to maintain the confidentiality of such work product; and shall not disclose or reveal the contents of said notes, abstractions or other work product after the documents, materials, or other things, or portions thereof (and the information contained therein) and information are returned and surrendered.

5. If a Receiving Party learns of any authorized disclosure of Confidential Information, it shall immediately (a) inform the Supplying Party in writing of all pertinent facts relating to such disclosure, (b) make its best efforts to retrieve all copies of the Confidential Information, (c) inform the person or persons to whom unauthorized disclosures were made of all the terms of this Order, and (d) request such person or persons execute the Acknowledgment that is attached hereto as Exhibit A.

6. Within thirty (30) days of the conclusion of any attorney's last case in this proceeding (or such case in which the Receiving Party is permitted by this Order to use Confidential Information), including any appeals related thereto, at the written request and option of the Supplying Party, such attorney and any persons to whom he or she disclosed Confidential Information pursuant to this Order shall return and surrender any Confidential Information or copies thereof to the Supplying Party at the Supplying Party's expense. Such persons shall return or surrender any discovery materials produced by the Supplying Party and any and all copies (electronic or otherwise), summaries, notes, compilations, and memoranda related thereto; provided, however, that counsel may retain their privileged communications, work product, Acknowledgments pursuant to paragraph 23, and all court-filed documents even though they contain discovery materials produced by the Supplying Party, but such retained privileged communications and work product shall remain subject to the terms of this Protective Order. At the written request of the Supplying Party, any person or entity having custody or control of recordings, notes, memoranda, summaries or other written materials, and all copies thereof, relating to or containing discovery materials produced by the Supplying Party shall deliver to the Supplying Party an affidavit certifying that reasonable efforts have been made to assure that all such discovery materials produced by the Supplying Party and any copies thereof, any and all records notes, memoranda, summaries, or other written material regarding the discovery materials produced by the Supplying Party (except for privileged communications, work product and court-filed documents as stated above) have been delivered to the Supplying Party in accordance with the terms of this Protective Order.

1. Inadvertent production of any document or information without a designation of confidentiality will not be deemed to waive a later claim to its confidential nature or preclude the Supplying Party from designating said document or information as confidential at a later date. Any Supplying Party may designate as Confidential Information or withdraw a Confidential Information designation from any material that it has produced; provided, however, that such redesignation shall be effective only as of the date of such redesignation. Such redesignation shall be accomplished by notifying counsel for each party in writing of such redesignation. Upon receipt of any redesignation that designates material as confidential, the Receiving Party shall (i) treat such material in accordance with this Order; (ii) take reasonable steps to notify any persons known to have possession of any such material of such redesignation under this Protective Order; and (iii) promptly endeavor to procure all copies of such material from any persons known to have possession of such material who are not entitled to receipt under paragraph 16.

2. Unless a prompt challenge to a Supplying Party's confidentiality designation is necessary to avoid foreseeable substantial unfairness, unnecessary economic burdens, or a later significant disruption or delay of the litigation, a Receiving Party does not waive its right to challenge a confidentiality designation by electing not to mount a challenge promptly after the original designation is disclosed. A Receiving Party that elects to initiate a challenge to a Supplying Party's confidentiality designation must do so in good faith and must begin the process by conferring directly (in voice to voice dialogue; other forms of communication are not sufficient) with counsel for the Supplying Party. In conferring, the challenging party must explain the basis for its belief that the confidentiality designation was not proper and must give the Supplying Party an opportunity to review the designated material, to reconsider the circumstances, and, if no change in designation is offered, to explain the basis for the chosen designation. A Receiving Party may proceed to the next stage of the challenge process only if it has engaged in this meet and confer first. A Receiving Party that elects to press a challenge to a confidentiality designation after considering the justification offered by the Supplying Party may file and serve a motion that identifies the challenged material and sets forth in detail the basis for the challenge. Each such motion must be accompanied by a competent declaration that affirms

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that the movant has complied with the meet and confer requirements imposed in this paragraph and that sets forth with specificity the justification for the confidentiality designation that was given by the Supplying Party in the meet and confer dialogue. The burden of persuasion in any such challenge proceeding shall be on the Supplying Party. Until the Court rules on the challenge, all parties shall continue to afford the material in question the level of protection to which it is entitled under the Supplying Party's designation.

## **VII. FILING PAPERS IN COURT RECORDS**

1. Without written permission from counsel of record for the Supplying Party or a Court order secured after appropriate notice to all interested persons, a party may not file in the public record in the MDL proceedings any Confidential Information. Any Confidential Information that is filed with the Court, and any pleading, motion or other paper filed with the Court containing or disclosing any such Confidential Information shall be filed under seal and shall bear the legend:

“THIS DOCUMENT CONTAINS CONFIDENTIAL  
INFORMATION COVERED BY A PROTECTIVE  
ORDER OF THE COURT AND IS SUBMITTED  
UNDER SEAL PURSUANT TO THAT PROTECTIVE  
ORDER. THE CONFIDENTIAL CONTENTS OF THIS  
DOCUMENT MAY NOT BE DISCLOSED WITHOUT  
EXPRESS ORDER OF THE COURT.”

Said Confidential Information and/or other papers shall be kept under seal until further order of the Court; however, said Confidential Information and other papers filed under seal shall be available to the Court and counsel of record, and to all other persons entitled to receive the Confidential Information contained therein under the terms of this Order.

## **VIII. MISCELLANEOUS PROVISIONS**

1. The use of Confidential Information during any trial in the MDL proceeding will be addressed in a later agreement between the parties, or, if they cannot reach agreement, by further order of the Court.

2. It is expressly understood by and between the parties that in producing Confidential Information in this litigation, the parties shall be relying upon the terms and conditions of this Protective Order.

3. By written agreement of the parties, or upon motion and order of the Court, the terms of this Protective Order may be amended or modified. This Protective Order shall continue in force until amended or superseded by express order of the Court, and shall survive and remain in effect after the termination of this proceeding.

4. Notwithstanding any other provision in the order, nothing in this Order shall affect or modify Pfizer's ability to review plaintiffs' information and report such information to any applicable regulatory agencies.

Dated: June 27, 2006

By s/ Ronald S. Goldser

Ronald S. Goldser  
Randy Hopper  
ZIMMERMAN REED  
651 Nicollet Mall  
Suite 501  
Minneapolis, MN 55402  
612-341-0400

Plaintiffs' Liaison Counsel

Dated: June 27, 2006

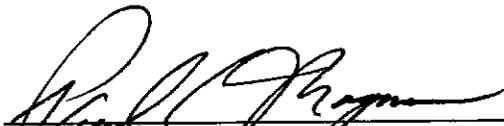
By s/ Stacey L. Drentlaw

William P. Studer  
OPPENHEIMER WOLFF & DONNELLY  
3300 Plaza VII  
45 S. Seventh Street  
Minneapolis, MN 55402  
612-607-7000

Defendant's Liaison Counsel

**PURSUANT TO STIPULATION, IT IS SO ORDERED.**

Dated: June 28, 2006

  
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HONORABLE PAUL A. MAGNUSON  
UNITED STATES SR. DISTRICT JUDGE