

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

IN RE: BEXTRA AND CELEBREX
MARKETING SALES PRACTICES AND
PRODUCT LIABILITY LITIGATION

CASE NO. M:05-CV-01699-CRB
MDL No. 1699

This Order Relates to:

ALL CASES.

**PRETRIAL ORDER NO. 3: STIPULATED
PROTECTIVE ORDER**

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 September 6, 2005, 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. 3: Stipulated Protective Order (“Protective Order” or “Order”).

1 3. This Protective Order shall govern all documents, the information
2 contained therein, and all other information produced or disclosed during the MDL proceeding,
3 including all copies, excerpts, summaries, or compilations thereof, whether revealed in a
4 document, deposition, other testimony, discovery response or otherwise, by any party to the MDL
5 proceeding (the "Supplying Party") to any other party or parties (the "Receiving Party"). This
6 Protective Order is binding upon the parties to the MDL proceeding, including their respective
7 corporate parents, subsidiaries and affiliates and their respective attorneys, agents, experts,
8 consultants, representatives, officers and employees and others as set forth in this Order. This
9 Order is also binding on any party who obtains any documents or other Confidential Information
10 produced or disclosed in the MDL proceeding pursuant to this Protective Order, including those
11 parties' respective corporate parents, subsidiaries and affiliates and their respective attorneys,
12 agents, experts, consultants, representatives, officers and employees and others as set forth in this
13 Protective Order.

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

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

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

21 7. The parties acknowledge that this Order does not confer blanket
22 protections on all disclosures or responses to discovery and that the protection it affords extends
23 only to the limited information or items that are entitled under the applicable legal principles to
24 treatment as confidential. The parties further acknowledge, as set forth in Paragraph 30 below,
25 that this Protective Order creates no entitlement to file confidential information under seal. Civil
26 Local Rule 79-5 sets forth the procedures that must be followed and reflects the standards that
27 will be applied when a party seeks permission from the Court to file material under seal.

28 /////

1 **II. DESIGNATION OF CONFIDENTIAL INFORMATION**

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

13 9. Specific documents and discovery responses produced by the Supplying
14 Party shall, if appropriate, be designated as “CONFIDENTIAL” by marking the pages of the
15 document that contain Confidential Information as follows: “CONFIDENTIAL” or
16 “CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER.” Except as provided in paragraphs
17 14 and 28, documents that do not bear the foregoing designation are not Confidential Information
18 as that term is used in this Order.

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

27 11. In order to protect against unauthorized disclosure of Confidential
28 Information, and to comply with all applicable state and federal laws and regulations, the

1 Supplying Party may redact from produced documents, materials or other things, or portions
2 thereof:

3 a. The names, addresses, Social Security or tax identification numbers
4 and other personally identifying information of employees, patients, health care providers, and
5 individuals in clinical studies or adverse event reports. However, other general identifying
6 information, such as patient or health care provider numbers, shall not be redacted unless required
7 by federal law. To the extent plaintiff(s)' names are contained in any of these documents, a copy
8 of the documents that have not had the plaintiff(s)' information redacted will be produced directly
9 to counsel for said plaintiff(s);

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

12 c. Any information relating to products other than Bextra® and/or
13 Celebrex®.

14 12. Pursuant to 21 C.F.R. §§ 314.430(e) & (f) and 20.63(f), the names of any
15 person or persons reporting adverse experiences of patients and the names of any patients that are
16 not redacted pursuant to Paragraph 11 shall be treated as confidential, regardless of whether the
17 document containing such names is designated as Confidential Information. No such person shall
18 be contacted, either directly or indirectly, based on the information so disclosed without the
19 express written permission of the Supplying Party.

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

23 14. Information disclosed at a deposition taken in connection with the MDL
24 proceeding may be designated as Confidential Information by: (a) designating testimony as
25 confidential on the record during the taking of the deposition, and/or (b) designating the portions
26 of the transcript that are confidential in a letter to be served on the court reporter and opposing
27 counsel within thirty (30) calendar days of the Supplying Party's receipt of the transcript of a
28 deposition. The court reporter will indicate the portions designated as confidential and segregate

1 them as appropriate. Designations of transcripts will apply to audio, video, or other recordings of
2 the testimony. The court reporter shall clearly mark any transcript released prior to the expiration
3 of the 30-day period as “Confidential – Subject to Further Confidentiality Review.” Such
4 transcripts will be treated as Confidential Information until the expiration of the 30-day period.

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

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

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

19 a. Counsel for the Receiving Party, including any in-house counsel,
20 and the attorneys, paralegals, stenographic, and clerical staff employed by such counsel to whom
21 it is reasonably necessary to disclose the Information for purposes of the litigation;

22 b. With respect to any Confidential Information produced by any
23 plaintiff or third party with respect to plaintiff, any employee or agent of the Receiving Party to
24 whom it is reasonably necessary to disclose such information;

25 c. Any plaintiff or claimant who has asserted or intends to assert a
26 claim in the MDL proceedings;

27 d. Any outside consultant or expert to whom it is reasonably necessary
28 to disclose Confidential Information, whether formally retained or not;

1 e. Any witness for the purpose of conducting an examination of such
2 witness during a trial or deposition; provided, however, that Confidential Information shall not
3 lose its confidential or restricted status through such use;

4 f. Any attorney for claimants in other pending litigation in the United
5 States alleging personal injury or economic loss arising from the alleged use or purchase of
6 Bextra® and/or Celebrex® (or attorneys for claimants in any other pending litigation as the
7 parties may mutually agree or the Court directs) for use in this or such other action, provided that
8 the proposed recipient is (i) already operating under a stipulated Protective Order or (ii) agrees to
9 be bound by this Order and signs the “Acknowledgment and Agreement to Be Bound”
10 (“Acknowledgment”) described in paragraph 23;

11 g. Stenographic employees and court reporters recording or
12 transcribing testimony in the MDL proceeding; and

13 h. The Court, any Special Master appointed by the Court, any state
14 court conducting related proceedings, and any members of their staffs to whom it is necessary to
15 disclose Confidential Information.

16 17. Before disclosing Confidential Information to any person who is,
17 independent of this litigation, a current employee of, or a consultant to, a pharmaceutical
18 company other than Pfizer Inc. that is marketing or has in development a selective COX-2
19 inhibitor, the party wishing to make such disclosure shall give at least ten (10) days’ advance
20 notice in writing to the counsel for the party who designated such information as confidential,
21 stating the names and addresses of the person(s) to whom the disclosure will be made and the
22 nature of his or her affiliation with a pharmaceutical company. If, within the 10-day period, the
23 Supplying Party files a motion objecting to the proposed disclosure, then the party seeking
24 disclosure may not disclose any Confidential Information to that person until ten days have
25 elapsed after the appeal period from a Court order denying the motion. In making such motion, it
26 shall be the Supplying Person’s burden to demonstrate good cause for preventing such disclosure.
27 Before disclosing Confidential Information to any person who is, independent of this litigation, a
28 current employee of, or a consultant to, a pharmaceutical company other than Pfizer Inc. (whether

1 or not such company is marketing or has in development a selective COX-2 inhibitor), the party
2 wishing to make such disclosure shall give counsel for the party who designated such information
3 as confidential sufficient information concerning the proposed recipient that does not identify the
4 proposed recipient but is sufficient to permit an informed decision to be made with respect to any
5 potential objection, including at a minimum the name of the pharmaceutical company and the
6 nature of the person's relationship thereto. If there is no consent to the disclosure within ten (10)
7 days, the party wishing to make the disclosure may submit the information to the Court for a
8 determination of whether the disclosure may be made. The objecting party will have
9 opportunities to request that the Court direct the party wishing to make disclosure to produce
10 additional information about the proposed recipient and to submit any other papers and argument
11 it feels necessary to allow the Court to make an informed decision. It shall be the burden of the
12 party wishing to prevent such disclosure to demonstrate good cause for prohibiting disclosure.
13 The party seeking disclosure may not disclose any Confidential Information to that person unless
14 and until the Court has permitted such disclosure and ten days have elapsed after the appeal
15 period from any such order. If the Court allows disclosure of the Confidential Information, the
16 Information remains Confidential Information and the person shall be bound by this order.

17 18. Disclosure of Confidential Information beyond the terms of this Protective
18 Order may be made only if the Supplying Party designating the material as confidential consents
19 in writing to such disclosure, or if the Court, after reasonable written notice to all affected parties,
20 orders such disclosure. The terms of this Order shall not apply to any publicly available
21 information or documents.

22 **IV. USE OF CONFIDENTIAL INFORMATION**

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

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

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

10 **V. PROTECTION OF CONFIDENTIAL INFORMATION**

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

21 23. Prior to the disclosure of any Confidential Information to any person
22 identified in paragraph 16(c) - (f), each putative recipient of Confidential Information shall be
23 provided with a copy of this Protective Order, which he or she shall read. Upon reading this
24 Protective Order, such person shall sign an Acknowledgment, in the form annexed hereto as
25 Exhibit A, acknowledging that he or she has read this Protective Order and shall abide by its
26 terms. These Acknowledgments are strictly confidential. Counsel for each party shall maintain
27 the Acknowledgments without giving copies to the other side. The parties expressly agree, and it
28 is hereby ordered that, except in the event of a violation of this Order, they will make no attempt

1 to seek copies of the Acknowledgments or to determine the identities of the persons signing them.
2 If the Court finds that any disclosure is necessary to investigate a violation of this Order, the
3 disclosure will be limited to outside counsel only and outside counsel shall not disclose any
4 information to their clients that could tend to identify any Acknowledgment signatory unless and
5 until there is specific evidence that a particular signatory may have violated the Order, in which
6 case limited disclosure may be made with respect to that signatory. Persons who come into
7 contact with Confidential Information for clerical or administrative purposes, and who do not
8 retain copies or extracts thereof, are not required to execute Acknowledgments but must comply
9 with the terms of this Order.

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

15 25. All counsel shall at all times keep secure all notes, abstractions, or other
16 work product derived from or containing Confidential Information; shall be obligated to maintain
17 the confidentiality of such work product; and shall not disclose or reveal the contents of said
18 notes, abstractions or other work product after the documents, materials, or other things, or
19 portions thereof (and the information contained therein) and information are returned and
20 surrendered. Nothing in this agreement requires the Receiving Party's counsel to disclose work
21 product at the conclusion of the case.

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

28 /////

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

22 **VI. CHANGES IN AND OBJECTIONS TO DESIGNATION OF INFORMATION**

23 28. Inadvertent production of any document or information without a
24 designation of confidentiality will not be deemed to waive a later claim to its confidential nature
25 or preclude the Supplying Party from designating said document or information as confidential at
26 a later date. Any Supplying Party may designate as Confidential Information or withdraw a
27 Confidential Information designation from any material that it has produced; provided, however,
28 that such redesignation shall be effective only as of the date of such redesignation. Such

1 redesignation shall be accomplished by notifying counsel for each party in writing of such
2 redesignation. Upon receipt of any redesignation that designates material as confidential, the
3 Receiving Party shall (i) treat such material in accordance with this Order; (ii) take reasonable
4 steps to notify any persons known to have possession of any such material of such redesignation
5 under this Protective Order; and (iii) promptly endeavor to procure all copies of such material
6 from any persons known to have possession of such material who are not entitled to receipt under
7 paragraph 16.

8 29. Unless a prompt challenge to a Supplying Party's confidentiality
9 designation is necessary to avoid foreseeable substantial unfairness, unnecessary economic
10 burdens, or a later significant disruption or delay of the litigation, a Receiving Party does not
11 waive its right to challenge a confidentiality designation by electing not to mount a challenge
12 promptly after the original designation is disclosed. A Receiving Party that elects to initiate a
13 challenge to a Supplying Party's confidentiality designation must do so in good faith and must
14 begin the process by conferring directly (in voice to voice dialogue; other forms of
15 communication are not sufficient) with counsel for the Supplying Party. In conferring, the
16 challenging party must explain the basis for its belief that the confidentiality designation was not
17 proper and must give the Supplying Party an opportunity to review the designated material, to
18 reconsider the circumstances, and, if no change in designation is offered, to explain the basis for
19 the chosen designation. A Receiving Party may proceed to the next stage of the challenge process
20 only if it has engaged in this meet and confer first. A Receiving Party that elects to press a
21 challenge to a confidentiality designation after considering the justification offered by the
22 Supplying Party may file and serve a motion under Civil Local Rule 7 (and in compliance with
23 Civil Local Rule 79-5, if applicable) that identifies the challenged material and sets forth in detail
24 the basis for the challenge. Each such motion must be accompanied by a competent declaration
25 that affirms that the movant has complied with the meet and confer requirements imposed in this
26 paragraph and that sets forth with specificity the justification for the confidentiality designation
27 that was given by the Supplying Party in the meet and confer dialogue. The burden of persuasion
28 in any such challenge proceeding shall be on the Supplying Party. Until the Court rules on the

1 challenge, all parties shall continue to afford the material in question the level of protection to
2 which it is entitled under the Supplying Party's designation.

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

4 30. Without written permission from counsel of record for the Supplying Party
5 or a Court order secured after appropriate notice to all interested persons, a party may not file in
6 the public record in the MDL proceedings any Confidential Information. A party that seeks to
7 file under seal any Confidential Information must comply with Civil Local Rule 79-5. Where a
8 party seeks to file any Confidential Information it has obtained as a result of such information
9 being produced or disclosed in the MDL proceeding pursuant to this Protective Order in any court
10 other than in the MDL proceeding, such filing shall be done under seal in accordance with and
11 subject to the law and rules of that court. When submitting deposition testimony pursuant to this
12 paragraph that has been designated confidential, the submitting party shall submit, to the extent
13 reasonably possible, only those pages of the deposition transcript that are cited, referred to, or
14 relied on by the submitting party.

15 **VIII. MISCELLANEOUS PROVISIONS**

16 31. Plaintiffs' Liaison Counsel and Defendants' Liaison Counsel shall meet
17 and confer to determine a method for the Pfizer Defendants to identify which documents they
18 have produced are confidential.

19 32. Within thirty (30) days of the entry of this Order (or within thirty (30) days
20 of entry or execution of any applicable order or stipulation), Defendants' Liaison Counsel shall
21 produce to Plaintiffs' Liaison Counsel copies of any order or stipulation from any related State
22 Court litigation allowing disclosure beyond the protective order in such action that concerns, in
23 whole or in part, the treatment of Confidential Information concerning Bextra® and/or
24 Celebrex®. The parties shall meet and confer to discuss any issues raised by such orders or
25 stipulations.

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

1 EXHIBIT A

2 ACKNOWLEDGMENT AND AGREEMENT TO BE BOUND

3 The undersigned agrees:

4 I declare under penalty of perjury that I have read in its entirety and understand the
5 Stipulated Protective Order that was issued by the United States District Court for the Northern
6 District of California on _____ [date], 2006 in *In Re: Bextra and Celebrex*
7 *Marketing, Sales Practices and Product Liability Litigation, MDL No. 1699*. I agree to comply
8 with and to be bound by all the terms of this Stipulated Protective Order and I understand and
9 acknowledge that failure to so comply could expose me to sanctions and punishment in the nature
10 of contempt. I solemnly promise that I will not disclose in any manner any information or item
11 that is subject to this Stipulated Protective Order to any person or entity except in strict
12 compliance with the provisions of this Order.

13 I further agree to submit to the jurisdiction of the United States District Court for the
14 Northern District of California for the purpose of enforcing the terms of this Stipulated Protective
15 Order, even if such enforcement proceedings occur after termination of these proceedings.

16 I hereby appoint _____ [print or
17 type full name] of _____
18 _____
19 [print or type full address and telephone number] as my California agent for service of process in
20 connection with this action or any proceedings related to enforcement of this Stipulated Protective
21 Order.

22
23 Date: _____

24 City and State where sworn and signed: _____

25 Printed name: _____
26 [printed name]

27 Signature: _____
28 [signature]