

COMMONWEALTH OF KENTUCKY
FRANKLIN CIRCUIT COURT
DIVISION TWO

CIVIL ACTION NO. 03-CI-01135

COMMONWEALTH OF KENTUCKY
Ex rel. GREGORY D. STUMBO,
ATTORNEY GENERAL

PLAINTIFF

V. **FIRST REQUEST FOR PRODUCTION OF DOCUMENTS
TO PLAINTIFF FROM DEFENDANT,
WARRICK PHARMACEUTICALS CORPORATION**

WARRICK PHARMACEUTICALS CORP., et al.

DEFENDANTS

** * * * *

Defendants Warrick Pharmaceuticals Corporation (“Warrick” or “Defendant”) hereby requests, pursuant to Rule 34 of the Kentucky Rules of Civil Procedure, that Plaintiff Commonwealth of Kentucky (“Plaintiff”) respond to the following requests for production of documents and produce for inspection and copying by Defendants the documents described below. Defendants request that the production of documents requested herein be made in accordance with the Definitions and Instructions set forth below, and that the production take place at the offices of Stoll, Keenan & Park, LLP, 300 West Vine Street, Suite 2100, Lexington, Kentucky 40507, or at such other place as may be agreed upon by counsel. Pursuant to Ky. R. Civ. P. (CR) 34.02(2), Plaintiff is required to serve a written response to this request, indicating whether Plaintiff will comply with each request listed below, no later than September 15, 2004.

DEFINITIONS

1. Each of these definitions is incorporated into each of the documents requests to which it pertains.

2. The term "document" is used in its broadest sense and means and includes graphic matter of any kind or nature, whether written, printed, typed, recorded, filmed, punched, transcribed, taped or produced or reproduced by any other means. The term "document" means and includes, without limitation, all appraisals, records, personal notes, e-mails, cablegrams, telexes, facsimiles, studies, calendars, day-timers, diaries, desk calendars, appointment books, agendas, minutes, pamphlets, envelopes, telephone messages, graphs, records of meetings, summaries, records or recordings of telephone conversations, summaries or records of personal conversations of interviews, summaries or records of meetings or conferences, tabulations, analyses, evaluations, projections, work papers, statements, summaries, reports, journals, billing records, invoices, correspondence, letters, financial statements, balance sheets, accounting entries, tax returns, loan documents, and/or all written or recorded matter of any kind whatsoever. The term "document" also means and includes every other means by which information is recorded or transmitted including, without limitation, photographs, videotapes, tape recordings, microfilms, punchcards, computer programs, printouts, computer disks, diskettes or CD-ROMs, software, all recordings made through data processing or computer techniques, and the written information necessary to understand and use such materials. The term "document" is further defined to mean the original, any

drafts, and any nonidentical copies (e.g., those bearing notations or marks not found on the original document).

3. The term "person" means a natural person, a group of natural persons acting as individuals, a group of individuals acting in a collegial capacity (e.g., as a committee, board of directors, agency, etc.), a corporation, a partnership, a limited partnership, a limited liability partnership, a joint venture, a limited liability corporation, a government or governmental agency and/or any other incorporated or incorporated business, government or entity.

4. "Concern" and "Concerning" mean referring to, relating to, regarding, constituting, comprising, containing, setting forth, summarizing, reflecting, stating, describing, recording, noting, embodying, mentioning, studying, analyzing, evidencing, discussing or evaluating, directly or indirectly.

5. "Communication" means the transmittal of information (in the form of facts, ideas, inquiries or otherwise) by any means, including, but not limited to, letter, facsimile, e-mail, voicemail, memorandum, telephone and/or any other type of document.

6. The phrases "documents that relate to" and "documents relating to" mean documents or entries containing, constituting, showing or relating to or referring to in any way, directly or indirectly, and is meant to include, among other documents, documents underlying, supporting, now or previously attached or appended to, or used in the preparation of, any document called for by these Requests.

7. "You," "Your" or "the Commonwealth" refer collectively to Plaintiff, Commonwealth of Kentucky, including but not limited to the Kentucky Cabinet for Health Services, the Office of the Attorney General, the Office of the Inspector General, the Department for Medicaid Services, the Office of the Ombudsman, Drug Management Review Advisory Board, Drugs Technical Advisory Committee, Pharmacy and Therapeutics Advisory Committee, the Kentucky Board of Pharmacy, Kentucky's elected or appointed officials, agents, employees, commissions, committees, divisions, departments, agencies, instrumentalities, administrators and other persons or entities acting on its behalf.

8. "Kentucky Medicaid" means the Commonwealth of Kentucky's Medicaid program.

9. "Medicare" means the Federal Medicare program.

10. "Complaint" means the Amended Complaint filed in this action on or about October 14, 2003.

11. "Warrick" means Warrick Pharmaceuticals Corp. along with any predecessor or successor corporation, its directors, officers, employees, agents, representatives and/or other persons acting on its behalf, including attorneys.

12. "Schering" means Schering-Plough Corp. and Schering Corp., or any one of them, along with any predecessor or successor corporations, its directors, officers, employees, agents, representatives and/or other persons acting on its behalf, including attorneys.

13. "Third Party Administrator" means any entity that provides administrative services to you relating to any medical benefit provided to any Participant or Beneficiary.

14. "Benefit Consultant" means any person or entity that provides information, counsel and/or advice to you regarding any medical benefit and/or service provided by you to any Participant or Beneficiary.

15. "Manufacturer" means a company that manufactures pharmaceutical products, including, without limitation, Subject Drugs.

16. "Provider" means any entity or physician that provides health care to any Participant or Beneficiary.

17. "340B Provider" means a provider described in Section 340B of the federal Public Health Act, 42 U.S.C. § 256b.

18. "Subject Drugs" means the products listed in Exhibit 1 of the Amended Complaint and any other drugs that are in any manner the subject of the allegations in the Complaint, whether or not manufactured by one of the Defendants.

19. "Publisher" or "Publishers" means any pharmaceutical price reporting/publishing service, including but not limited to, First Data Bank or Blue Book, Medical Economics Co., Inc. or Red Book, and Medispan.

20. "AMP" or "Average Manufacturer Price" has the meaning set forth in 42 U.S.C. § 1396r-8(k)(1).

21. "MAC" or "Maximum Allowable Cost" has the meaning ascribed to that term pursuant to 42 C.F.R. § 442.332 or any analogous state statute or regulation, including any State MAC.

22. "EAC" or "Estimated Acquisition Cost" has the meaning ascribed to that term pursuant to 42 C.F.R. § 447.301.

23. "Best Price" has the meaning ascribed to that term pursuant to 42 U.S.C. § 1396r-8(c)(1)(C).

24. "FUL" has the meaning ascribed to that term pursuant to 42 C.F.R. § 447.332.

25. "AWP" means average wholesale price as reported to any "Publisher".

GENERAL INSTRUCTIONS

A. Each of these instructions is incorporated into each of the document requests to which it pertains.

B. You are requested to produce all documents designated below which are in your possession, custody or control, or in the possession, custody or control of your employees, agents, consultants, attorneys, accountants, or other representatives.

C. These requests are continuing in nature so as to require you to serve a supplemental response and/or production, pursuant to Ky. R. Civ. P. (CR) 26.05, in the event you obtain or discover any additional, further, or different information or documents after the production of the documents or things requested herein.

D. You are requested to produce the original and all non-identical copies, including all drafts, of each document requested. If you are not able to produce the original of any document, please produce the best available copy and all nonidentical copies, including drafts.

E. Each request for documents and subparagraphs or subdivision thereof shall be construed independently, and no other request or subparagraph or subdivision thereof shall be referred to or relied on for the purpose of limiting its scope except insofar as the request or subparagraph or subdivision construed expressly refers to another request or subparagraph or subdivision thereof.

F. If any document requested herein was at one time in existence, but has been lost, discarded, deleted, or destroyed, identify each such document including its date, author and subject matter.

G. Each page or sheet produced is to be marked with identification and consecutive document control numbers, with the exception of bound pamphlets or books, which may be marked with a single control number. Within the response to a given request, documents shall be organized and identified according to the file(s) in which they are kept, maintained or found.

H. If objections are made to producing any documents, or any portion thereof, or disclosing any information contained therein, in response to any document request on the basis of a claim of privilege, then you are requested to provide the following information for each document withheld on the grounds of privilege:

1. its date;

2. its title;
3. its author;
4. its addressee;
5. the specific privilege under which it is withheld;
6. its general subject matter; and
7. a description of it that you contend is adequate to support your contention that it is privileged.

I. To the extent that you consider any of the following requests for production of documents objectionable, please respond to the remainder of the production request, and separately state the part of each request to which you object and each ground for each objection.

J. The present tense includes the past and future tenses.

K. The use of the singular form of any word includes the plural and vice-versa.

L. The connectors "and" and "or" shall be construed either disjunctively or conjunctively as necessary to bring within the scope of the discovery request all responses that might otherwise be construed to be outside of its scope.

M. Unless otherwise specified, these requests seek documents prepared on or after January 1, 1993 to the present time.

REQUEST FOR DOCUMENTS TO BE PRODUCED

1. All documents, concerning Kentucky Medicaid's purchase of or reimbursement for any of the Subject Drugs.

2. All documents (including databases, systems or programs) concerning the calculation, monitoring, trading, processing or payment of claims for the Subject Drugs, by Kentucky Medicaid.

3. All contracts, memoranda of understanding or agreements concerning the calculation, monitoring, tracking, processing or payment of claims for the Subject Drugs by Kentucky Medicaid, including Provider contracts.

4. All communications concerning the calculation, monitoring, tracking, processing or payment of claims for the Subject Drugs by Kentucky Medicaid, including but not limited to e-mails, notes, agendas, meeting minutes, memoranda, and the like.

5. All documents concerning Kentucky Medicaid's calculation of reimbursement amounts for the Subject Drugs, including but not limited to guidelines, instructions, manuals and the like.

6. All data, reports, testimony, analyses, information or audits that You considered or that formed the basis of any decision to use published AWP data in any part of Your reimbursement formula.

7. All data, reports, testimony, analyses, information or audits that You considered or that formed the basis of any decisions to discount AWP in any part of Your reimbursement formula.

8. All documents concerning any internal or external assessments, studies, analyses, review or audits conducted by or on behalf of You regarding drug pricing or reimbursement amounts or rates, including but not limited to audits of You, vendors, pharmacies, Providers, or third-party administrators.

9. All documents concerning any internal or external assessments, studies, analyses, review or audits conducted by or on behalf of You regarding fraud relating to the reimbursement of prescription drugs, including but not limited to audits of You, vendors, pharmacies, Providers or third-party administrators.

10. All documents concerning any internal or external assessments, studies, analyses, review or audits conducted by or on behalf of You regarding pharmacy dispensing costs.

11. All documents concerning any internal or external assessments, studies, analyses, reviews or audits (including without limitation any comprehensive audits or statistical sampling) conducted by You or on behalf of You concerning the Kentucky Medicaid program, including audits of their vendors, Providers, and third-party administrators.

12. Documents sufficient to identify all persons participating in the creation in or having access to the various reports and analyses responsive to Requests 5-11.

13. All documents concerning any contract or agreement with any Publisher.

14. All communication by and between You and any Publisher.

15. All documents concerning pricing information provided to you by any Publisher.

16. All price lists, fee schedules or other pricing information concerning the Subject Drugs.

17. All documents concerning the usual and customary charges of the Subject Drugs.

18. All documents concerning any consideration of establishing or actual establishment of a MAC (or State MAC) for any of the Subject Drugs.

19. All documents concerning how any MAC (or State MAC) for any of the Subject Drugs was set.

20. All MAC (or State MAC) lists for any Subject Drug.

21. All documents concerning the FUL for any Subject Drug.

22. All documents concerning or referring to pricing information for the Subject Drugs received from any source.

23. All documents concerning any request made by You or on Your behalf concerning the pricing of prescription drugs.

24. All representations made to You by Schering and/or Warrick regarding the AWP or pricing of the Subject Drugs.

25. All documents concerning any complaint or inquiry You considered or actually made to any Manufacturer concerning pricing of Drugs.

26. All documents that reflect or concern Defendants' awareness of Kentucky Medicaid's drug reimbursement formulas as alleged in paragraph 15 of the Complaint.

27. All documents concerning Warrick's or Schering's alleged promotion, marketing, or manipulation of the alleged "spread" between the reported AWP and the actual cost of the Subject Drugs as alleged in paragraphs 31 through 36 of the Complaint.

28. All documents concerning or relating to Warrick's or Schering's "use of free goods, educational grants or any other incentives to induce providers to purchase their drugs," as alleged in paragraph 34 of the Amended Complaint.

29. All documents concerning or relating to the alleged losses, damages, or overpayments referenced in paragraphs 1, 37, 38, 39, 43, 50, 56, 60, 65, 70, and 80, or any other portion of the Amended Complaint.

30. All documents sufficient to establish that Providers who actually received any alleged "overpayments" from You were eligible to receive those payments.

31. All documents concerning any action, administrative or otherwise, considered or taken to recover the alleged "overpayments" from the providers who actually received the alleged "overpaid" amounts for drug reimbursement.

32. Documents sufficient to identify the name and address of each Provider eligible to submit claims to Kentucky Medicaid concerning the Subject Drugs during the relevant time period.

33. All documents concerning any payment by any Medicare beneficiary for which you seek damages.

34. All documents concerning any purchase of or payment or reimbursement for any of the Subject Drugs by any 340B Providers.

35. All documents concerning any purchase of or payment or reimbursement for any of the Subject Drugs by any Kentucky entity, agency, office, fund, prison or any other organization.

36. All documents concerning the market share of each of the Subject Drugs.

37. All documents concerning any budget that is impacted by, or otherwise relates to, prescription drug pricing or reimbursement, including but not limited to all final budgets, budget proposals and all responses and amendments thereto.

38. All documents from any legislative committees, standing committees, statutory committees or advisory committees, including agendas, minutes, notes and presentations, concerning utilization, reimbursement or cost of prescription drugs, or dispensing fees.

39. All documents concerning any litigation or lobbying efforts by pharmacies or other Providers relating to dispensing fees or the methods used by the Kentucky Medicaid program to calculate or determine pharmaceutical reimbursement rates for prescription drugs.

40. All documents received from or sent to any pharmacy or other Provider concerning dispensing fees or reimbursement of prescription drugs.

41. All communications, including but not limited to e-mails, between Your employees themselves and/or all other parties, including but not limited to Providers, Medicaid fiscal agents and contractors, consultants, and pharmaceutical companies regarding drug pricing, drug reimbursement or dispensing fees.

42. All documents concerning the consideration or setting of dispensing fees as required by 42 C.F.R. § 447.331-333, including but not limited to all

correspondence, memoranda, analysis, agenda, meeting minutes, e-mails, testimony, and the like.

43. All documents provided to or received from Myers and Stauffer LC concerning or relating to drugs, including but not limited to utilization, reimbursement or costs of prescription drugs, or dispensing fees.

44. All documents provided to or received from the University of Kentucky College of Pharmacy Special Unit concerning or relating to drugs, including but not limited to utilization, reimbursement, or costs of prescription drugs, or dispensing fees.

45. All documents concerning or relating to annual reports produced pursuant to K.R.S. 205.561, including but not limited to drafts, summaries, correspondence, memoranda, e-mails or analysis of the reports, and documents consulted in the preparation of or referenced in the reports.

46. Documents sufficient to identify all persons who participated in or communicated with any Kentucky "medical care advisory committee" (42 C.F.R. § 431.12(b))

47. All documents concerning any "medical care advisory committee" (42 C.F.R. § 431.12(b)) relating to utilization, reimbursement, or costs of prescription drugs, or dispensing fees.

48. All documents concerning any effort or plan considered or undertaken to reduce or otherwise limit Kentucky Medicaid's expenditures for drugs, including but not limited to prior authorization requirements, development of formularies, use of generics, group purchasing efforts, and the like.

49. All documents concerning any direct purchasing agreements, collective purchasing arrangements, or other purchasing programs concerning any prescription drugs.

50. All documents concerning any cooperative efforts with any other State considered or implemented to reduce the cost of prescription drugs.

51. All documents concerning Ven-A-Care of the Florida Keys, Inc. ("Ven-A-Care"), including but not limited to communications with or about Ven-A-Care, notes, memoranda or summaries of any presentations, including any presentations to the National Association of Medicaid Fraud Control Units, and the like.

52. All documents concerning all communications by and between any of the following: You, Ven-A-Care, the National Association of Medicaid Fraud Control Units, or any other persons or organizations that review or evaluate Medicaid programs concerning the pricing of prescription drugs or the calculation of reimbursement amounts or rates for such drugs.

53. All documents concerning any application You made for federal funds in connection with the Kentucky Medicaid program.

54. All reports made by You or on Your behalf to any federal or state institution, agency, department, or office, regarding prescription drug reimbursement under the Kentucky Medicaid program.

55. All reports received by You or on Your behalf from any federal or state institution, agency, department, or office, regarding prescription drug reimbursement or pricing.

56. All documents concerning any operating plan or related documents concerning the Kentucky Medicaid program.

57. Communications between You and any state or federal institution, agency, department, or office regarding reimbursement amounts or rates, including but not limited to communications discussing use of AWP, WAC, EAC, AMP or any other drug pricing designations.

58. Organizational charts or similar document(s) that reflect the identity of Your employees involved or in any way responsible for the administration or oversight of the Kentucky Medicaid program.

59. All documents received by You, from any source, previously produced by any of the Defendants in connection with any subpoena, civil action, government investigation, or other, similar proceeding.

60. All documents concerning any Medicaid rebates paid by Warrick or Schering for any of the Subject Drugs.

61. All documents concerning the number of units of the Subject Drugs for which Warrick or Schering paid Medicaid rebates.

62. All documents concerning any efforts by You or on Your behalf to calculate or estimate the AMP for the Subject Drugs.

63. All communications between You and Schering and/or Warrick regarding the Subject Drugs or the pricing of prescription drugs, including but not limited to all documents concerning "AWP and other pricing information [provided] directly to Kentucky Medicaid" by Schering and/or Warrick as alleged in paragraph 24 of the Complaint.

64. All communications between You and any party regarding any price of the Subject Drugs.

65. Documents sufficient to identify all persons who participated in the consideration, determination, calculation or setting of Kentucky Medicaid's reimbursement amounts or rates for prescription drugs during the relevant period.

66. Documents sufficient to identify the drugs eligible for reimbursement by the Kentucky Department of Medicaid Services.

67. All documents concerning communications by and between You and any Benefit Consultant concerning the utilization, reimbursement or acquisition costs of prescription drugs or dispensing fees.

68. All documents concerning the revised AWP prices provided by DOJ and NAMFCU to First Data Bank in 2000, including but not limited to Your consideration of using those revised AWPs.

69. All documents concerning any actions taken or considered by you in response to or following any federal or state assessment, study, analysis, review or audit regarding reimbursement of prescription drugs, definitions or methods of determining EAC, use of AWP, or dispensing fees.

70. All documents relating to the meaning of "AWP" or "Average Wholesale Price," including but not limited to the history or origin of the terms "AWP" or "Average Wholesale Price."

71. All documents relating to any proceedings, including but not limited to lawsuits, administrative or legislative proceedings, and/or criminal or civil

investigations, in which Plaintiff's employees or agents have testified, provided statements, or been interviewed concerning the pricing or reimbursement of pharmaceutical products.

72. All documents relating to any requests to You or responses by You to any requests from Congress, any State, or any federal or state entity for information relating to utilization, cost or reimbursement of the Subject Drugs or dispensing fees.

73. All documents concerning the alleged "spread" (as that term is used in the Complaint) for the Subject Drugs.

74. All documents relating to the difference between AWP and acquisition cost for any drug, including but not limited to reports issued by any government entity or agency publications by Plaintiff or any other State, correspondence sent or addressed to Plaintiff's employees or agents, legislative materials, newspaper and magazine articles, television and radio broadcasts, and transcripts of Congressional testimony.

75. All documents concerning communications by and between You and any PBM.

76. All documents concerning Your consideration of or decision to use a PBM.

77. All documents that compare or relate to utilization, cost, or reimbursement of drugs by Kentucky Medicaid to utilization, cost or reimbursement of drugs by any other entity, including but not limited to any other state Medicaid program.

78. All documents concerning personal service contracts relating to utilization, reimbursement or cost of prescription drugs or dispensing fees.

79. All documents concerning AWP, WAC, AMP, MAC, EAC, FUL, Best Price, or any other drug pricing information for the Subject Drugs.

80. All documents identified or referred to in your response to Warrick's First Set of Interrogatories.

Dated: May 25, 2004

Respectfully submitted,

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By: 
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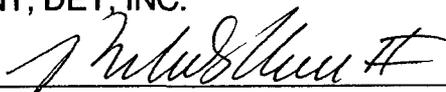
CERTIFICATE OF SERVICE

This will certify that a true and correct copy of the foregoing was served by first class mail, postage prepaid, to the following on this 25th day of May 2004:

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