Court File No.: 98-CV-158832

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN:

SHELIA WILSON

Plaintiff

- and -

SERVIER CANADA INC., LES LABORATOIRES SERVIER, SERVIER AMERIQUE, INSTITUT DE RECHERCHES INTERNATIONALES SERVIER ("I.R.I.S"), SCIENCE UNION ET CIE, ORIL S.A., SERVIER S.A.S., ARTS ET TECHNIQUES DU PROGRES, BIOLOGIE SERVIER, INSTITUT DE DEVELOPEMENT ET DE RECHERCHE SERVIER, ORIL INDUSTRIE, BIO RECHERCHE SERVIER, INSTITUTO DI RICERCA, IDUX, BIOPHARMA ARTEM, SCIENCE UNION S.A.R.L., LABORATOIRES SERVIER INDUSTRIE, I.R.I.S. ET CIE DEVELOPEMENT, INFORMATION SERVIER, SERVIER MONDE, SERVIER INTERNATIONAL, I.R.I.S. SERVICES S.A.R.L., ADIR, SERVIER R&D BENELUX, DR. JACQUES SERVIER and BIOFARMA S.A.

Defendants

Proceeding under the *Class Proceedings Act, 1992*

AFFIDAVIT OF DR. STEPHEN RASKIN

I, STEPHEN RASKIN, of the City of Alameda, in the State of California, United States, **MAKE OATH AND SAY:**

1. I am a medical doctor licensed to practice medicine in the State of California, United States of America. I am a Board Certified cardiologist and echocardiographer. I have been the Director of the Coronary Care Unit at Alameda Hospital, Alameda California, since 1977 and an Associate Clinical

Professor of Medicine at the University of California at San Francisco. I am a Fellow of the American College of Cardiology, a member of the American Heart Association and its Council on Clinical Cardiology and a member of the American Society of Echocardiography.

2. Echocardiography is the generally accepted method of evaluating valvular heart disease ("VHD") and related heart diseases. A substantial portion of my practice consists of reading and interpreting echocardiograms, supervising laboratory and echocardiographic technicians and performing trans-esophageal echocardiograms. I have performed or interpreted many thousands of echocardiograms over the course of my career. The remainder of my practice consists of evaluations, testing and treating patients' cardiovascular conditions, including VHD and related illnesses.

3. As part of my duties as an Associate Clinical Professor of Medicine at the University of California, I teach cardiac auscultation skills and echocardiographic techniques to medical students and cardiac fellows, including the use and correlation of clinical echocardiographic methods. I regularly attend professional conferences, including those of the American College of Cardiology, American Heart Association and American Society of Echocardiography. I have also maintained current knowledge of ongoing research relating to VHD and diet drug exposure. Attached hereto as Exhibit "A" is a true copy of my curriculum vitae which more fully articulates my experience and qualifications.

4. I was retained by counsel for the Plaintiff National Class to serve as an expert witness during this litigation, as well as and throughout the settlement negotiations. As such, I have participated in the drafting of the Medical Conditions List ("MCL") and other portions of the Settlement Agreement relating to the diagnosis of VHD and the appropriate criteria for qualifying for benefits under the Settlement Agreement. As a result, I have knowledge of the facts hereinafter deposed to except where I have been informed of such facts, in which case I have stated the source of such facts and I hereby state that I believe such facts to be true.

5. I swear this affidavit in support of a motion to approve the Settlement Agreement in this action and to comment on matters relating to VHD and the relevant eligibility criteria for benefits under the Settlement Agreement.

Background

6. VHD involves the failure of one or more of the valves of the heart to open or close properly. There are four valves in the human heart – tricuspid, pulmonary, mitral and aortic. The valves function to move blood through the heart (to and from the lungs) in a forward direction.

7. Poor valve closure results in regurgitation, or the backwards flow of blood. Regurgitation increases the workload of the heart and can lead to numerous severe and potentially fatal complications, including congestive heart failure, shortness

of breath, arrhythmias and bacterial endocarditis. VHD can also necessitate surgery to repair or replace the defective valves.

8. The medical literature suggests that both aortic regurgitation ("AR") and mitral regurgitation ("MR") can be progressive at all degrees of severity. Attached hereto at Exhibits "B", "C", "D" and "E" is a selection of relevant scientific literature on the topic of progression in VHD.

Association Between VHD and the Products

9. Fenfluramine, an anorexigen, was introduced in Europe and other markets worldwide in the early 1960s and in Canada in the 1970s.

10. Dexfenfluramine, another anorexigen, was introduced in Europe in the late 1980s and approved for use in Canada by Federal authorities in January 1997.

11. Both fenfluramine and dexfenfluramine were voluntarily withdrawn from the Canadian market in September 1997.

12. For ease of reference, the terms fenfluramine and dexfenfluramine will be collective referred to as "the Products" in the balance of this affidavit.

13. In August 1997, Dr. Heidi Connolly of the Mayo Clinic in Rochester, Minnesota published a case series in the *New England Journal of Medicine* which raised the question of whether there was an association between the Products and the development of VHD. Attached hereto at Exhibit "F" is a copy of the Connolly case series.

14. In the case series, Dr. Connolly and her colleagues reported on 24 patients who suffered from a similar form of heart abnormality, including five patients who had required surgery to replace or repair damaged valves. Of the twenty-four patients, nineteen were reported to have greater than or equal to mild AR and fourteen were reported to have greater than or equal to moderate MR.

15. Further features of the affected heart valves were noted and indicated that the valve morphology was atypical for rheumatic, congenital or degenerative lesions – conditions which can also lead to VHD. On echocardiography, the mitral and aortic valves exhibited features consistent with chronic rheumatic involvement, however there was no evidence of valve obstruction, as one would expect to see in rheumatic cases.

16. In my professional opinion there is enough scientific evidence to lead me to believe that there is a causal link between use of the Products and the development of VHD.

17. I am informed by National Class Counsel that the Defendants contend there is no scientific or medical study that has established a causal link between the use of the Products and VHD and that the existence of such a causal link as well as other legal and factual issues were vigorously contested by the Defendants.

Settlement Negotiations

18. Prior to and during the negotiations over the settlement terms, my opinion was sought by National Class Counsel in relation to several issues including the

drafting of relevant sections of the MCL and other documents as they pertained to VHD issues. The following is a summary of these issues.

(a) Compensable Injuries

19. The Settlement Agreement contemplates benefits for various injuries. The following sections discuss the medical criteria which are to be applied to two broad categories of benefits: FDA Positive Benefits and Matrix VHD Benefits.

(i) Criteria for FDA Positive Benefits

20. Section 4.3.1 of the MCL defines FDA Positive Regurgitation in a manner which is medically appropriate. In my view, these criteria are appropriate.

21. Section 4.3.2 precludes claims for FDA Positive benefits, where the supporting medical documentation demonstrates that the Product Recipient had FDA Positive or greater regurgitation in the valve upon which the claim is based prior to their use of the Products. In my professional opinion, this restriction is reasonable and accords with applicable medical standards.

(ii) Criteria for Matrix level VHD Claims

22. Sections 4.4.3 to 4.4.7 of the MCL define the specific levels of disease severity which form the basis of claims for Matrix level VHD benefits. The specific conditions and associated medical complications are organized according to increasing levels of disease severity.

23. The specific conditions which have been included as bases for Matrix level VHD benefits reflect an appropriate gradation of the levels of disease severity which can be associated with VHD. In addition, the diagnostic standards included in these sections reflect appropriate compromise positions based on the legal and medical issues in this action and in my professional opinion are fair and reasonable.

(b) Additional Medical Factors and Exclusionary Conditions

24. Section 6.1 of the MCL sets out a list of medical conditions which are recognized in the medical literature as being associated with the development of VHD.

25. Except in certain circumstances, if the Claims Adjudicator determines that one or more of the conditions defined in section 6.1 of the MCL is present and is more likely than not the "principal cause" (as "cause" is interpreted for the purposes of this Settlement), the Claimant will not be entitled to benefits. Where, however, there is evidence on pathology of the lesion associated by some investigators with the Products (as that lesion is defined for purposes of the Settlement only), the claim will be approved.

26. Section 6.2 of the MCL sets out a further list of medical conditions which are also recognized in the medical literature as being associated with the development of VHD. In my professional opinion, this section reflects an appropriate compromise position based on the legal and medical issues in this action and is fair and reasonable.

27. If a Product Recipient has one of the listed conditions in section 6.2 of the MCL, the claim for benefits will be rejected unless the supporting medical documentation contains evidence on pathology of the lesion believed to be associated with the Products (as that lesion is defined for purposes of the Settlement only). Where such evidence exists, and the Product Recipient does not have evidence of carcinoid lesions (which cannot be distinguished from lesions associated with the Products) the claim will be approved.

28. Based on my review of the applicable medical and scientific literature, as well as my own clinical experience, it is my professional opinion that the listed additional factors, as well as the ability to overcome the exclusion with evidence on pathology, reflect an appropriate compromise position based on the legal and medical issues in this action and are fair and reasonable.

(c) Progressed Claims

29. To account for the hypothesis possibility that VHD may progress over time, the Settlement Agreement allows Product Recipients to advance Progressed Claims during the five year Administration Period, provided that a qualified claim for an FDA Positive or Matrix VHD benefit was filed within the Claim Period. This approach ensures, within reasonable limits, that Product Recipients whose level of regurgitation worsens during the Administration Period have the ability to increase their benefit level accordingly.

30. In my professional opinion, this provision reflects an appropriate compromise position based on the legal and medical issues in this action and is fair and reasonable.

(d) New Pathology Evidence Claims

31. The Settlement Agreement also makes provision for cases in which the Product Recipient's claim for a VHD benefit was originally rejected, based on the evidence available at the time but who thereafter is able to provide additional pathology evidence supporting his or her claim. Where such Product Recipients have evidence of valve pathology consistent with the type of lesion associated with the Products (as that lesion is defined for purposes of the Settlement only), they will be entitled to benefits at the appropriate level.

32. It is my professional opinion that this provision is reasonable and medically sound and will appropriately compensate Product Recipients who have had their condition confirmed through reliable pathological evidence, even if it is obtained outside of the Claim Period.

(e) Regression

33. Section 4.4.1 of the MCL provides that benefits will be based on the Product Recipient's highest level of disease severity, in the absence of regression without active medical intervention documented within 18 months of the echocardiogram which recorded the highest level of severity.

34. Based on the applicable medical and scientific literature on the subject, as well as my experience in treating patients with VHD, in my professional opinion this approach is reasonable and medically appropriate.

(f) Diagnostic Echocardiographic Criteria

35. Among the issues discussed in the settlement negotiations related to VHD were questions about the appropriate standards relating to echocardiograms which form the basis of claims for benefits.

36. Section 3.3 of the MCL establishes the standards for the performance of the echocardiograms which form the basis of the claims submitted and for the review of those echocardiograms. In my professional opinion, the criteria are appropriate, reasonable, and reflect standard practice.

(g) Supporting Medical Documentation

37. In order to qualify for VHD benefits, Claimants are required to submit various forms and documentation, including supporting medical documentation.

(i) FDA Positive Benefits

38. In order to qualify for an FDA Positive Benefit, the Claims Administration Procedures require that a qualified physician sign the appropriate section of the Medical Diagnosis Form which includes a declaration that the Product Recipient was diagnosed with the FDA Positive condition and that, to the best of his or her knowledge, the specific condition for which the claim was made was not present

prior to the Product Recipient's first use of the Products. In my professional opinion, these requirements are also reasonable and should not preclude legitimate claims.

(ii) Matrix level VHD Claims

39. In submitting a claim for a Matrix level VHD Benefit, medical records dating from five years prior to the Product Recipient's first use of the Products must be submitted and must include, *inter alia,* all available echocardiographic recordings.

40. In order for the Claims Adjudicator to conduct the assessments required under sections 6.1 and 6.2 of the MCL, he or she will need to review the Product Recipient's medical history and in my professional opinion this requirement for supporting medical records is therefore appropriate.

41. In addition to the medical records, the Claims Administration Procedures require that a qualified physician sign the appropriate section of the Medical Diagnosis Form which includes a declaration that the Product Recipient was diagnosed with the Matrix level VHD condition, that, to the best of his or her knowledge, the conditions listed in section 6.1 and 6.2 of the MCL either are or are not present and that the specific condition which forms the basis of the claim was not present prior to the Product Recipient's first use of the Products. In my professional opinion, these requirements are also reasonable and should not preclude legitimate claims.

(iii) Best Efforts

42. Notwithstanding the requirement for supporting documentation referred to above, the Claims Administration Procedures make provision for situations in which, for various reasons beyond the Claimant's control, such documentation is not available. In such cases, a Claimant will not be precluded from qualifying for benefits, so long as there is sufficient evidence to allow the adjudication of the claim. Since there are situations in which records may have been destroyed, in my professional opinion this provision is sound and reasonable.

(h) Duration of Use

43. There is no duration of use requirement in this settlement.

44. It is my professional opinion that where Claimants satisfy the criteria set forth in this settlement, all Product Recipients should be treated the same, regardless of duration of use of the Products. The approach taken under this settlement to the duration of use issue is therefore appropriate and medically sound.

Conclusion

45. Based upon my review of the relevant medical and scientific literature, as well as my personal experience with VHD, it is my professional opinion that the diagnostic and other criteria for qualification for benefits under the Settlement Agreement relating to regurgitation reflect an appropriate compromise position based on the legal and medical issues in this action and in my professional opinion are fair and reasonable.

46. I swear this affidavit in support of a motion for approval of the Settlement Agreement reached between the parties hereto and for no other purpose.

SWORN BEFORE ME at the City of)
BERKELEY , in the State of California,)
U.S., this 22 day of September, 2004.)

9-22-04
Stephen Raskin

9/22/2004
A Commissioner for Taking Affidavits

KULDIP SINGH BHATIA
Comm. # 1384659
NOTARY PUBLIC - CALIFORNIA
Alameda County
My Comm. Expires Nov. 16, 2006