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BEFORE THE ARIZONA MEDICAL BOARD

In the Matter of: **LEO BORES, M.D.** Holder of License No. 10380 For the Practice of Allopathic Medicine In the State of Arizona, Respondent.	Board Case No. MD-97-0948 **CONSENT AGREEMENT AND ORDER FOR LETTER OF REPRIMAND AND PROBATION**

RECITALS

In the interest of a prompt and judicious settlement of this case, consistent with the public interest, statutory requirements and responsibilities of the Arizona Medical Board ("Board"), and pursuant to A.R.S. §§ 32-1401 *et seq.* and 41-1092.07(F)(5), the undersigned party, Leo Bores, M.D., holder of License No. 10380 to practice allopathic medicine in the State of Arizona ("Respondent"), and the Board enter into the following Recitals, Findings of Fact, Conclusions of Law and Order ("Consent Agreement") as the final disposition of this matter.

All admissions made by Respondent in this Consent Agreement are made solely for the final disposition of this matter, and any related administrative proceedings or civil litigation involving the Board and Respondent. Therefore, any admissions made by Respondent in this Consent Order are not intended or made for any other use, such as in the

context of another regulatory agency proceeding, or civil or court proceeding, whether in the State of Arizona or in any other state or federal court.

1. Respondent has read and understands this Consent Agreement as set forth herein, and has had the opportunity to discuss this Consent Agreement with an attorney or has waived the opportunity to discuss this Consent Agreement with an attorney. Respondent voluntarily enters into this Consent Agreement for the purpose of avoiding the expense and uncertainty of an administrative hearing.

2. Respondent understands that he has a right to a public administrative hearing concerning each and every allegation set forth in the above-captioned matter, at which administrative hearing he could present evidence and cross-examine witnesses. By entering into this Consent Agreement, Respondent freely and voluntarily relinquishes all rights to such an administrative hearing, as well as all rights of rehearing, review, reconsideration, appeal, judicial review or any other administrative and/or judicial action, concerning the matters set forth herein. Respondent affirmatively agrees that this Consent Agreement shall be irrevocable.

3. Respondent agrees that the Board may adopt this Consent Agreement, or any part thereof, pursuant to A.R.S. §§ 32-1401 *et seq.* and 41-1092.07(F)(5). Respondent understands that this Consent Agreement, or any part thereof, may be considered in any future disciplinary action against him.

4. Respondent understands that this Consent Agreement does not constitute a dismissal or resolution of other matters currently pending before the Board, if any, and does not constitute any waiver, express or implied, of the Board's statutory authority or jurisdiction regarding any other pending or future investigation, action or proceeding. Respondent also understands that acceptance of this Consent Agreement does not preclude any other agency, subdivision or officer of this state from instituting other civil or criminal proceedings with respect to the conduct that is the subject of this Consent Agreement.

5. Respondent acknowledges and agrees that, upon signing this Consent Agreement and returning it to the Board's Executive Director, Respondent may not revoke his acceptance of this Consent Agreement or make any modifications to it, regardless of whether this Consent Agreement has been issued by the Executive Director. Any modification to this original document is ineffective and void unless mutually approved by the parties in writing.

6. Respondent understands that the foregoing Consent Agreement shall not become effective unless and until adopted by the Board and signed by its Executive Director.

7. Respondent understands and agrees that if the Board does not adopt this Consent Agreement, he will not assert as a defense that the Board's consideration of this Consent Agreement constitutes bias, prejudice, prejudgment or other similar defense.

8. Respondent understands that this Consent Agreement is a public record that may be publicly disseminated as a formal action of the Board, and shall be reported as required by law to the National Practitioner Data Bank and the Healthcare Integrity and Protection Data Bank.

9. Respondent understands that any violation of this Consent Agreement constitutes unprofessional conduct pursuant to A.R.S. § 32-1401(24)(r)(violating a formal order, probation, consent agreement or stipulation issued or entered into by the board or its executive director under the provisions of this chapter) and may result in disciplinary action pursuant to A.R.S. § 32-1451.

DATED: 3-4-03

Leo Bores, M.D.

Reviewed and Approved as to Form:

By: _____
Duane Olson, Esq.

FINDINGS OF FACT

10. The parties stipulate that this Consent Order represents a compromise of a disputed matter between the Board and Respondent, and agree to the entry of this Consent Order for the purpose of terminating that disputed matter.

11. The Board is the duly constituted authority for licensing and regulating the practice of allopathic medicine in the State of Arizona.

12. Leo Bores, M.D., is the holder of License No. 10380 for the practice of allopathic medicine in the State of Arizona.

A. IMPROPERLY USING PNT PROCEDURE AS EXPERIMENTAL TREATMENT WITHOUT CONFORMING TO FDA-APPROVED EXPERIMENTAL CRITERIA.

13. Between July 1997 and March 1999, Dr. Bores performed Pneumatic Trabeculoplasty ("PNT") procedures on numerous subjects at the Arizona Glaucoma Institute in Fountain Hills, Arizona.

14. Pneumatic Trabeculoplasty (PNT) is an experimental, non-invasive treatment for chronic open-angle glaucoma which works similarly to Laser Trabeculoplasty except that it produces its effect of lowering intra-ocular pressure mechanically rather than surgically. The effect is produced by placing a suction ring externally over the corneal limbal area above the collector channel/trabecular meshwork complex. Suction is applied to the eye for 1-2 minutes during which time certain changes take place within the trabecular meshwork complex, improving aqueous outflow.

15. A sterile, disposable suction ring is used for each patient. The ring is attached to a special vacuum pump via sterile tubing. The pump is controlled by a computer to maintain a constant vacuum during the treatment.

16. The suction ring used in the PNT procedure is a modified version of a suction ring and microkeratome used in LASIK refractive surgery.

17. The suction ring is manufactured by Ophthalmic International, Inc., a subsidiary of Coronado Industries, Inc. From July 1997 until March 1999, Dr. Bores was the Chief Medical Director of the Arizona Glaucoma Institute, another subsidiary of Coronado Industries. In March 1999, Dr. Bores became the Medical Director for Coronado Industries.

18. Any manufacturer who wants to market a new medical device like the suction ring used in the PNT procedure must submit an application for pre-market approval or a pre-market notification to the U.S. Food and Drug Administration ("FDA"). The FDA reviews the application or notification to determine whether the new device is "substantially equivalent" to a device that was marketed before 1976. If a new device is deemed by the FDA to be substantially equivalent to a device that was marketed before 1976, it may be marketed immediately and is regulated in the same manner as the device to which it is substantially equivalent. If a new device is deemed by the FDA not to be substantially equivalent to a device that was marketed before 1976, it must undergo extensive clinical testing and receive the approval of the FDA before it may be marketed. (*See* FDA Information Sheet, Guidance for Institutional Review Boards and Clinical Investigators, 1998 Update.)

19. However, even before a new medical device receives FDA approval for marketing, it may be used as an "investigational device" in a clinical study designed to evaluate its safety and effectiveness. Such clinical studies must be conducted according to the regulations for an Investigational Device Exemption ("IDE"). 21 C.F.R. part 812. The regulations governing such clinical studies vary according to whether the investigational device is classified as a "significant risk" device or a "non-significant risk" device. 21 C.F.R. § 812.2.

20. A clinical study of a significant risk device ("SR study") requires the submission of an IDE application to the FDA. 21 C.F.R. § 812.20(a). The submission of

an IDE application enables the FDA to review information about the technical features of the device, the results of any prior studies involving the device, and the proposed study protocol and subject consent forms. Based upon its review of this information, the FDA may impose restrictions on the SR study to ensure that the risks to the subjects are minimized, and do not outweigh the anticipated benefits to the subjects and the importance of the knowledge to be gained. A sponsor must conduct an SR study in accordance with the full regulatory requirements for an IDE. That study may not begin until the FDA has approved the IDE application, and an Institutional Review Board ("IRB") has approved the study. 21 C.F.R. §§ 812.20(a)(2) and 812.42.

21. On the other hand, a clinical study of a non-significant risk device ("NSR study") does not require the submission of an IDE application to the FDA. 21 C.F.R. §§ 812.2(b). Instead, the sponsor is required to conduct a NSR study according to certain abbreviated regulatory requirements. If the sponsor follows the abbreviated requirements, an NSR study is deemed to have an approved IDE, unless the sponsor is notified otherwise by the FDA. 21 C.F.R. §§ 812.2(b) and 812.20(a), respectively.

22. The determination of whether an investigational device presents a significant risk is initially made by the sponsor of the device. 21 C.F.R. §§ 812.2(b)(1)(ii). The IRB may agree or disagree with the sponsor's initial determination that an investigational device does not present a significant risk. 21 C.F.R. §§ 812.66. If the IRB agrees with the sponsor's initial determination and approves the study, the study may begin without submission of an IDE application to the FDA. If the IRB disagrees with the sponsor's initial determination, then the sponsor must notify the FDA that the device has been determined to present a significant risk, and submit an IDE application for FDA approval before any study may be conducted. 21 C.F.R. §§ 812.66. Notwithstanding any determination by the sponsor or IRB, the FDA makes the ultimate decision as to whether an investigational device presents a significant risk. If the FDA does not agree with the sponsor's or IRB's decision

that a device does not present a significant risk, an IDE application must be submitted to the FDA. 21 C.F.R. § 812.20(a). (*See also* FDA Information Sheet, Guidance for Institutional Review Boards and Clinical Investigators, 1998 Update.)

23. While conducting a clinical study of an IDE device, a sponsor or investigator, or any person acting for or on behalf of a sponsor or investigator, may not: (a) promote or test market the device until after the FDA has approved the device for commercial distribution; (b) commercialize the device by charging the subjects a price greater than that necessary to recover the costs of manufacture, research, development and handling; and (c) represent that the device is safe or effective for the purpose for which it is being investigated. 21 C.F.R. § 812.7.

24. In response to complaints by local ophthalmologists, the FDA conducted an inspection of the Arizona Glaucoma Institute in November and December 1997.

25. In a letter to the Board dated January 23, 1998, Dr. Bores stated that "[s]ince September of 1997, in excess of 100 patients have been treated with [the PNT] procedure at the Arizona Glaucoma Institute . . . ."

26. In a warning letter dated February 12, 1998, the FDA notified Dr. Bores, the Arizona Glaucoma Institute and Ophthalmic International that they were "required to submit an investigational device exemption (IDE) application to FDA and obtain FDA approval of the application before beginning an investigation of the [suction ring] device for the treatment of glaucoma." The FDA also notified them that they could not "promote or test market [the suction ring] device, or represent that it is safe or effective for the purpose for which it is being investigated."

27. In a letter dated March 30, 1998, Ophthalmic International responded to the warning letter by informing the FDA that it believed the suction ring was a non-significant risk device, and that an IRB at the New York Eye Surgery Center had approved the suction ring for use in an NSR study in October 1994, in accordance with the FDA's abbreviated

regulatory requirements.

28. In a letter dated April 23, 1998, the Scranton-Temple Residency Program's IRB informed Coronado Industries that a revised version of its December 16, 1997 protocol for an NSR study of the suction ring had been approved. In an agreement executed on April 23, 1998, Dr. Bores agreed to become a designated clinical investigator for the NSR study of the suction ring.

29. However, in a letter dated May 4, 1998, the FDA rejected Ophthalmic International's assertion that the suction ring was a non-significant risk device which could be used in an NSR study under abbreviated regulatory requirements, and classified the suction ring as a significant risk device, pending the submission of a PMA application.

30. Ophthalmic International submitted a pre-market notification in an effort to have the FDA classify the suction ring as substantially equivalent to other "fixation" devices that were marketed before 1976, and thereby allow the suction ring to be marketed immediately. However, in a letter dated October 30, 1998, the FDA notified Ophthalmic International that the intended use of the suction ring to decrease the intraocular pressure of patients with glaucoma was "vastly different" from those non-invasive fixation devices that were marketed before 1976. The FDA refused to re-classify the suction ring as a non-significant risk device, and again advised that "[c]linical investigations of this device must be conducted in accordance with the investigational device exemptions (IDE) regulations."

31. On February 4, 1999, Dr. Bores and Ophthalmic International met with FDA officials to discuss the agency's refusal to re-classify the suction ring as a non-significant risk device. As a result of that meeting, Dr. Bores and Ophthalmic International were again advised to submit an IDE application.

32. On December 30, 1999, the FDA conditionally approved Ophthalmic International's IDE application as a "feasibility study," limited to ten subjects at five institutions. The FDA noted that "issues remain which must be resolved prior to the

initiation of [a larger] substantive study for marketing approval. The feasibility study will allow an initial validation of the device design, training of the investigators in the use of the device, and preliminary clinical date to be used to design [a larger] substantive study."

33. Despite repeated warnings from the FDA, Dr. Bores did not stop using the suction ring to perform the PNT procedure on subjects at the Arizona Glaucoma Institute until the FDA approved either a PMA application for marketing the suction ring, or an IDE application for a SR study of the suction ring. A clinical investigator may not allow any subject to participate in a clinical study of a new medical device before obtaining IRB or FDA approval. 21 C.F.R. § 812.110(a).

34. Between July 1997 and April 23, 1998, Dr. Bores used an investigational device in the treatment of more than 100 patients even though the Scranton-Temple Residency Program's IRB had not approved a current NSR study of the suction ring, and he was not a designated clinical investigator for a prior NSR study of the suction ring.

35. Between May 4, 1998 and March 1999, Dr. Bores used an investigational device in the treatment of numerous other patients, even though he had been notified that an IDE application for a SR study had to be submitted to the FDA, and before that SR study had been approved by the FDA.

B. <u>IMPROPERLY ADVERTISING PNT PROCEDURE AS SAFE AND EFFECTIVE TREATMENT WITHOUT DISCLOSING THAT PROCEDURE WAS PART OF CLINICAL STUDY</u>.

36. Advertisements for recruitment into a clinical study of an investigational device may not use terms such as "new treatment," without explaining that the device is investigational. Furthermore, advertisements may not claim, either explicitly or implicitly, that a device is safe or effective for the purposes under investigation. 21 C.F.R. § 812.7(d).

37. The Arizona Glaucoma Institute, under Dr. Bores' medical direction, prepared and distributed a brochure "Announcing a New Treatment for Glaucoma" that stated: "There is a new treatment at the Arizona Glaucoma Institute. Pneumatic Trabeculoplasty (PNT),

a non-invasive 2 minute treatment that lowers Intra-Ocular pressure in most cases." In addition to claiming that the suction ring used in the PNT procedure was safe and effective for the purpose under investigation, the brochure did not disclose that the "new treatment" was part a clinical study to determine whether the suction ring used in the PNT procedure was indeed a safe and effective device for lowering intra-ocular pressure in glaucoma patients.

C. IMPROPERLY BILLING MEDICARE FOR PNT PROCEDURE WHICH USED DEVICE THAT HAD NOT BEEN APPROVED FOR MARKETING BY FDA.

38. IDE regulations allow sponsors to charge for an investigational device, however, the charge should not exceed an amount necessary to recover the costs of manufacture, research, development, and handling of the investigational device. 21 C.F.R. § 812.7(b). A sponsor justifies the proposed charges for the device in the IDE application, states the amount to be charged, and explains why the charge does not constitute commercialization. 21 C.F.R. § 812.20(b)(8). The FDA generally allows sponsors to charge investigators for investigational devices, and this cost is usually passed on to subjects.

39. The Medicare Carrier's Manual ("MCM"), section 2303.1 states: "Medical devices which have not been approved for marketing by the FDA are considered investigational by Medicare and are not reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member. Program payment, therefore, may not be made for medical procedures or services performed using devices which have not been approved for marketing by FDA."

40. On July 28, 1999, Medicare notified Dr. Bores that claims that had been inappropriately submitted to and paid by Medicare for PNT procedures performed on two patients in May and October 1998, and requested reimbursement in the amount of $368.21.

41. On August 23, 1999, Medicare again notified Dr. Bores that claims that had been inappropriately submitted to and paid by Medicare for PNT procedures performed on

another forty-eight patients between December 1997 and February 1999, and requested reimbursement in the amount of $15,171.60.

42. As of January 14, 2003, Medicare had not been reimbursed for those claims.

43. When the PNT procedures were performed on those patients described above, the suction ring used in the PNT procedure had not been approved for marketing by the FDA for use in the PNT procedure.

CONCLUSIONS OF LAW

44. The Board possesses jurisdiction over the subject matter and over Respondent pursuant to A.R.S. § 32-1401 *et seq.*

45. The conduct and circumstances described above constitute unprofessional conduct pursuant to A.R.S. § 32-1401(24)(a)(violating any federal or state laws or rules and regulations applicable to the practice of medicine).

46. The conduct and circumstances described above constitute unprofessional conduct pursuant to A.R.S. § 32-1401(24)(c)(false, fraudulent or misleading advertising by a doctor of medicine or the doctor's staff, employer or representative).

47. The conduct and circumstances described above constitute unprofessional conduct pursuant to A.R.S. § 32-1401(24)(q)(any conduct or practice which is or might be harmful or dangerous to the health of the patient or the public).

48. The conduct and circumstances described above constitute unprofessional conduct pursuant to A.R.S. § 32-1401(24)(y)(the use of experimental forms of diagnosis and treatment without adequate informed patient consent, and without conforming to generally accepted experimental criteria, including protocols, detailed records, periodic analysis of results and periodic review by a medical peer review committee as approved by the federal food and drug administration or its successor agency).

ORDER

49. Based upon the foregoing Findings of Fact and Conclusions of Law, and

pursuant to the authority granted to the Board by A.R.S. §§ 32-1401 *et seq.* and 41-1092.07(F)(5), IT IS HEREBY ORDERED that Respondent Leo Bores, M.D., holder of License No. 10380 for the practice of allopathic medicine in the State of Arizona, shall be issued a Letter of Reprimand for the unprofessional conduct described above.

50. IT IS ALSO ORDERED that Respondent's license to practice allopathic medicine in the State of Arizona shall be placed on probation for a period of two (2) years with the following terms and conditions.

A. Within six (6) months of the date of this Order, Respondent shall provide to Board staff written confirmation from Medicare that it has been fully reimbursed for the claims that had been inappropriately submitted to and paid by Medicare for PNT procedures performed on fifty patients between December 1997 and February 1999.

B. During the entire probationary period, Respondent shall not supervise or conduct any clinical studies of the suction ring in PNT procedures in the State of Arizona or under the jurisdiction of his license to practice medicine in the State of Arizona unless those studies are conducted in accordance with FDA-approved experimental criteria.

C. During the entire probationary period, Respondent shall submit quarterly declarations under penalty of perjury stating: (a) whether he is supervising or conducting any clinical studies of the suction ring in PNT procedures; (b) whether any such clinical studies are being conducted in the State of Arizona or under the jurisdiction of his license to practice medicine in the State of Arizona; and (c) whether any such studies are being conducted in accordance with FDA-approved experimental criteria. The declarations must be submitted on or before the fifteenth (15th) day of March, June, September and December of each year.

D. During the entire probationary period, Respondent shall promptly comply with requests by Board staff for additional information or documents concerning his compliance with the terms and conditions of this probation.

DATED and effective this 4th day of April, 2003.

ARIZONA MEDICAL BOARD

[SEAL]

By: Barry Cassidy
BARRY CASSIDY, Ph.D., PA-C
Executive Director

ORIGINAL OF THE FOREGOING FILED
this 7th day of April, 2003, with:

ARIZONA MEDICAL BOARD
9545 E. Doubletree Ranch Road
Scottsdale, AZ 85258

EXECUTED COPY OF THE FOREGOING MAILED
this 7th day of April, 2003, to:

Leo Bores, M.D.
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Board Operations