

Louisiana State Board of Medical Examiners

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IN THE MATTER OF:

No. 11-I-126

GABRIEL PEREZ LASALA, M.D.
(Certificate No. 10402R),
Respondent

CONSENT ORDER

The Director of Investigation ("DOI") of the Louisiana State Board of Medical Examiners (the "Board") initiated an investigation of Gabriel P. Lasala, M.D. ("Dr. Lasala"), a physician licensed in the state of Louisiana pursuant to Certificate Number 10402R, in 2011. The investigation revealed that Dr. Lasala received FDA approval to conduct clinical trials of experimental stem cell therapies pursuant to FDA-approved protocols, but that Dr. Lasala administered those experimental therapies to patients outside of the trials and/or who did not meet the trial parameters. Upon discovering Dr. Lasala's actions, the FDA conducted its own investigation and issued a warning letter outlining several violations, including that Dr. Lasala (1) failed to conduct clinical investigations in accordance with approved protocols and monitor the progress of the ongoing investigations; (2) initiated clinical investigations without a protocol in effect; (3) initiated clinical investigations without submitting a protocol amendment or a new application to the FDA; (4) administered investigational products in violation of a clinical hold; (5) failed to test specimens from donors for communicable disease; (6) treated patients (one as young as 24 months of age) under the age of eighteen and, therefore, outside of the trial protocols; and (7) used allogenic (non-autologous) stem cells when no such use was authorized. The DOI's investigation confirmed to her satisfaction that there was evidence to support these allegations and also uncovered other violations of the Louisiana Medical Practice Act, including, but not limited to, Dr. Lasala's promotion, through promotional materials available on his website, of stem cell therapies in the absence of scientific proof of the efficacy of those procedures.

As evidenced by his subscription hereto, Dr. Lasala, without admitting any liability or violation of federal or state law or regulation, and for purposes of this Consent Order only, acknowledges that such information provides the DOI with a reasonable basis to initiate formal administrative proceedings against his license pursuant to the Louisiana Medical Practice Act, La. Rev. Stat. §37:1285A(7),¹ (11),² (13),³ and (30),⁴ constituting cause for action against the

¹ Pursuant to La. R.S. §37:1285A(7), the Board may suspend, revoke, or impose probation or other restrictions on the license of an individual licensed to practice medicine in the State of Louisiana as a result of

physician's license to practice medicine in the State of Louisiana as the Board deems appropriate.

Recognizing his right to have an administrative adjudication of such charges, at which time Dr. Lasala would be entitled to be represented by legal counsel, to call witnesses, and to present evidence on his own behalf in defense or in mitigation of the charges made, and to a decision thereon by the Board based upon written findings of fact and conclusions of law, pursuant to La. Rev. Stat. §§49:955-965, Dr. Lasala, nonetheless, hereby waives his right to formal adjudication and, pursuant to La. Rev. Stat. §49:955(D), consents to entry of the Order set forth hereinafter. Dr. Lasala also acknowledges that he hereby waives any right to which he may be entitled pursuant to the Louisiana Administrative Procedure Act, La. Rev. Stat. §49:951, *et seq.*, or to which he otherwise may be afforded by any law to contest his agreement to or the authority of the Board's investigation or this document in any court or other forum. By his subscription hereto, Dr. Lasala also hereby authorizes the DOI to present this Consent Order to the Board for its consideration and to fully disclose to and discuss with the Board the nature and results of the investigation, and he waives any objection to such disclosures under La. Rev. Stat. §49:960. Dr. Lasala expressly acknowledges that the disclosure of such information to the Board by the DOI shall be without prejudice to the DOI's authority to proceed with the adjudication of an Administrative Complaint against him or to the Board's capacity to adjudicate such a Complaint, should the Board decline to approve this Consent Order.

Accordingly, in consideration of the foregoing, and pursuant to the authority vested in the Board by La. Rev. Stat. §37:1285 and La. Rev. Stat. §49:955(D);

IT IS ORDERED that the license of Gabriel P. Lasala, M.D., to engage in the practice of medicine in the State of Louisiana, as evidenced by Certificate No. 10402R, is placed **ON PROBATION** for a period of **five (5) years** from the effective date of this Order (the "probationary period"); *provided, however*, that Dr. Lasala's license to practice medicine and his

"[s]olicitation of patients or self-promotion through advertising or communication, public or private, which is fraudulent, false, deceptive, or misleading."

² Pursuant to La. R.S. §37:1285A(11), the Board may suspend, revoke, or impose probation or other restrictions on the license of an individual licensed to practice medicine in the State of Louisiana as a result of "[m]aking or submitting false, deceptive, or unfounded claims, reports, or opinions to any patient, insurance company or indemnity association, company, individual, or governmental authority for the purpose of obtaining anything of economic value."

³ Pursuant to La. R.S. §37:1285A(13), the Board may suspend, revoke, or impose probation or other restrictions on the license of an individual licensed to practice medicine in the State of Louisiana as a result of "[u]nprofessional conduct."

⁴ Pursuant to La. R.S. §37:1285A(30), the Board may suspend, revoke, or impose probation or other restrictions on the license of an individual licensed to practice medicine in the State of Louisiana as a result of a "[v]iolation of any rules and regulations of the board, or any provisions of this Part." Dr. Lasala's referral of patients to labs in which he held a financial interest may have violated section 4211 of Title 46, part 45 of the Louisiana Administrative Code. *See* La. Admin. Code tit. 46, pt. XLV, § 4211.

continuing exercise of the rights and privileges granted to him thereby shall be restricted as set forth herein and subject to his acceptance of and strict compliance with the following terms, conditions and restrictions:

(1) Divestment of Interests in Stem Cell Laboratories and Other Facilities.

Dr. Lasala shall relinquish any professional affiliation he may have with any stem cell lab, and he shall have no professional affiliation with any stem cell lab in the future, provided however, that Dr. Lasala may continue to retain his ownership interest in TCA Cellular Therapy, LLC until he is reasonably able to divest himself of his ownership interest, which divestment in any event must occur within two years of the effective date of this Consent Order, and further provided that, prior to said divestments, (1) TCA Cellular Therapy, LLC will not engage in the evaluation or treatment of any patient or (2) otherwise actively engage in the purchase, sale or distribution of stem cells to third parties.

(2) Promotion of and Profit from Stem Cell Therapies.

Dr. Lasala shall not offer or promote any non FDA-approved stem cell therapy, and he shall not profit from any referral for any such therapy. For the duration of his medical career, Dr. Lasala shall not (1) hold himself out as a researcher or expert in the field of stem cell treatments or (2) lecture regarding stem cell treatments or present any such data in the scientific arena.

(3) Payment of Fine. Dr. Lasala shall pay a fine of \$5,000 to the Board, which payment shall be made within one (1) year of the acceptance of this Order by the Board.

(4) Attendance at Approved Seminar/Professionalism and Medical Ethics.

Within the first year of the probationary period, Dr. Lasala shall provide written confirmation that he has attended and successfully completed a course of study, acceptable to and pre-approved in writing by the Board, in the area of professionalism and medical ethics.

(5) Continuing Medical Education.

Dr. Lasala shall obtain not less than fifty (50) credit hours per year for each of the five (5) years of his probationary period through attendance at and participation in continuing medical education ("CME") programs accredited by the American Medical Association. On or before the anniversary date of the effective date of this Consent Order, for each of the next five (5) years, Dr. Lasala shall cause to be submitted to the Board written certification of the CME programs and credits completed by him during the preceding twelve (12) months.

(6) Absence from State/Practice/Effect on Probation.

Should Dr. Lasala at any time during the period of probation ordered herein be absent from the State of Louisiana, relocate to and/or take up residency in another state or country, or discontinue practicing medicine for a period of thirty (30) days or more, or should he fail to renew his license to practice medicine in this state, he shall advise the Board in

writing. In such instance, the probationary period ordered herein and all terms, conditions and restrictions thereof, shall be deemed interrupted and extended and shall not commence to run until Dr. Lasala notifies the Board in writing that he has returned to, relocated or taken up residency in, resumed the practice of medicine in the State of Louisiana, or renewed his Louisiana license. In such instance, Dr. Lasala shall not receive credit toward completion of the probationary period for the time during which he was absent from the State of Louisiana or while he was not engaged in or licensed to practice medicine in this state.

(7) Cooperation with the Board's Probation and Compliance Officer. Dr. Lasala shall immediately notify the Board's Probation and Compliance Officer of any change in his current home and professional addresses and telephone numbers, and he shall direct all matters required pursuant to this Order to the attention of the Probation and Compliance Officer, with whom he shall cooperate on all matters and inquiries pertaining to his compliance with the terms and conditions of this Order.

(8) Notification. Dr. Lasala shall provide a complete copy of this Order to each hospital, clinic, facility or other employer or prospective employer at which or for whom he provides services as a physician in this state.

(9) Probation Monitoring Fee. For each year of the probationary period, Dr. Lasala shall pay the Board a probation monitoring fee of Three Hundred (\$300.00) Dollars. Payment of the initial fee shall be due not later than sixty (60) days from the effective date of this Order. All subsequent annual payments shall be due on or before the anniversary date of the initial fee payment.

(10) Effect of Violation/Sanction. By his subscription hereto, Dr. Lasala acknowledges that his receipt of written notification that the Board has received apparently reliable information which indicates his failure to comply with the requirements set forth by this Order in any respect shall, without the need for formal hearing or for providing him with any right to which he may otherwise be entitled pursuant to the Louisiana Administrative Procedure Act, La. Rev. Stat. §§49:951 et seq., or which otherwise may be afforded to him by law, constitute his irrevocable consent to the immediate suspension of his license to practice medicine as a physician in this state pending a hearing before the Board and the conclusion of the administrative proceedings by issuance of a final decision following administrative adjudication of such charges.

(11) Effective Date. This Consent Order shall be effective the date it is approved and accepted by the Board as shown by the signature of its representative below.

IT IS FURTHER ORDERED that any violation or failure of strict compliance with any of the terms, conditions or restrictions set forth by this Order by Dr. Lasala shall be deemed adequate and sufficient cause, upon proof of such violation or failure at a hearing, for the revocation and cancellation of Dr. Lasala's license to practice medicine in the State of Louisiana, or for such other disciplinary action as the Board deems appropriate, as if such violations were enumerated among the causes provided in La. Rev. Stat. §37:1285. Dr. Lasala's right to judicial review of any such Board disciplinary action is reserved.

IT IS FURTHER ORDERED that this Consent Order shall be, and shall be deemed to be, a public record.

New Orleans, Louisiana, this 21 day of May, 2012.

**LOUISIANA STATE BOARD
OF MEDICAL EXAMINERS**

By:


MELVIN G. BOURGEOIS, M.D.
President

*Acknowledgement and Consent
on Following Page*

LOUISIANA STATE BOARD OF MEDICAL EXAMINERS

STATE OF Louisiana
PARISH/COUNTY OF St. Tammany

ACKNOWLEDGMENT
AND CONSENT

I, GABRIEL P. LASALA, M.D., hereby acknowledge, approve, accept and consent to entry of the above and foregoing Order, this 2 day of May, 2012.

G. Lasala
GABRIEL P. LASALA, M.D

WITNESSES:

Amy Milne
Signature

Jean A LeBlanc
Signature

Amy Milne
Printed Name

JEAN A LEBLANC
Printed Name

3 Sanctuary Blvd
Address

3 SANCTUARY BLVD.
Address

Mandeville, LA 70471
City/State/Zip Code

MANDEVILLE, LA 70471
City/State/Zip Code

Sworn to and subscribed before me this 2nd day of May, 2012, in the presence of the two stated witnesses.

Matthew R. Emmons
Notary Public (Signature)

Print name Matthew R. Emmons

Bar/Notary No.: 32442

MATTHEW R. EMMONS
NOTARY PUBLIC
PARISH OF TANGIPAHOA, STATE OF LA.
MY COMMISSION IS ISSUED FOR LIFE.
BAR ROLL NO. 32442