LOUISIANA BOARD OF DRUG AND DEVICE DISTRIBUTORS Board Meeting MINUTES October 17, 2016

AGENDA ITEM 1 - Call to Order

The meeting was called to order by Robert Broadus, Chairman, at approximately 9:40 am. The meeting was held in Baton Rouge, Louisiana at the Administrative Office of the Board located at 12091 Bricksome Avenue, Suite B.

AGENDA ITEM 2 - Roll Call and Introduction of Guests

It was noted by Mr. Broadus that those members in attendance were Mr. Broadus, Michael Davis, Randall Brooks, Kenneth Dugas, Chad Gielen, Jacob Dickson, and James DeLatte. Trion Horgan was absent. The members in attendance constituted a voting quorum. Also present from the Board's administrative office were George Lovecchio, Executive Director, and Kimberly Barbier, Executive Assistant. There were no guests in attendance.

AGENDA ITEM 3 - General Motion

Motion was made by Mr. Dickson to approve any agenda items to be taken out of order and to be noted as such in the meeting minutes, seconded by Mr. Dugas, and passed by voice vote – FOR: Mr. Davis, Mr. Brooks, Mr. Dugas, Mr. Gielen, Mr. Dickson, and Mr. DeLatte; AGAINST: None; ABSENT: Mr. Horgan; ABSTAINED: None; RECUSED: None. Agenda item order changes include discussion of items: 10 after 9.a.ii; 9.b after 15.a; and 16 after 9.b.

AGENDA ITEM 4 - Call for Additional Agenda Items [for discussion in Agenda Item 13]

- 1. Uniform Policy Robert Broadus
- 2. Anti-Trust Compliance Policy Michael Davis and Robert Broadus.

Motion was made by Mr. Dugas to add items as noted to the agenda for discussion later in the meeting during agenda item 13, seconded by Mr. Davis, and passed by voice vote – FOR: Mr. Davis, Mr. Brooks, Mr. Dugas, Mr. Gielen, Mr. Dickson, and Mr. DeLatte; AGAINST: None; ABSENT: Mr. Horgan; ABSTAINED: None; RECUSED: None.

AGENDA ITEM 5 - Disciplinary/ Enforcement Actions

- a. Disciplinary Action
- i. Consent Agreements
- 1) Docket 2016001

Mr. Gielen presented disciplinary action docket 2016001 against AOSS Medical Supply, Inc., Monroe LA, Louisiana license number 4029. Sufficient evidence was found to predicate a finding of violation of La. R.S. 37:3474.1(6) and 3474(8), and LAC 46:XCI.311.G(1) and 311.G(2) – selling, distributing, or offering to sell or distribute any

adulterated, counterfeited, or misbranded legend drugs or devices by storing legend drugs at their facility; violation of statutes and rules of the Board; purchasing or receiving drugs or devices from other than a drug or device distributor licensed by the Board; and not notifying the Board of any drug or device distributors not licensed by the Board by purchasing and receiving legend drugs or devices from a company not licensed by the Board. Licensee agreed to and paid a fine in the amount of \$16,000 and administrative costs of \$250 plus attorney fees of \$1,687.50. Mr. Gielen presented a signed consent agreement and noted that the fine, administrative fee, and attorney fees had been paid. Motion was made by Mr. Brooks to approve and accept the consent agreement for disciplinary action docket 2016001 between the Board and AOSS Medical Supply, Inc., Monroe LA, Louisiana license number 4029, seconded by Mr. Davis, and passed by voice vote – FOR: Mr. Davis, Mr. Brooks, Mr. Dugas, Mr. Gielen, Mr. Dickson, and Mr. DeLatte; AGAINST: None; ABSENT: Mr. Horgan; ABSTAINED: None; RECUSED: None.

2) Docket 2016002

Mr. Gielen presented disciplinary action docket 2016002 against Regional Health Services LLC dba Regional Medical Rental and Sales, Shreveport LA, Louisiana license number 8438. Sufficient evidence was found to predicate a finding of violation of La. R.S. 37:3474.1.A(8) and LAC 46:XCI.311.A.2 and 311.C - failure to maintain a current and perpetual inventory and records of all transactions for all drugs, devices, and medical gases, and by gaining to have inventories and records available for inspection and photocopying by an office authorized by the Board for a three year period following disposition. Licensee agreed to and paid a fine in the amount of \$1,000 and administrative costs of \$250. Mr. Gielen presented a signed consent agreement and noted that the fine and administrative fee had been paid. Motion was made by Mr. Dickson to approve and accept the consent agreement for disciplinary action docket 2016002 between the Board and Regional Health Services LLC dba Regional Medical Rental and Sales, Shreveport LA, Louisiana license number 8438, seconded by Mr. Dugas, and passed by voice vote - FOR: Mr. Davis, Mr. Brooks, Mr. Dugas, Mr. Gielen, Mr. Dickson, and Mr. DeLatte; AGAINST: None; ABSENT: Mr. Horgan; ABSTAINED: None; RECUSED: None.

3) Docket 2016003

Mr. Gielen presented disciplinary action docket 2016003 against McKesson medical Surgical, Inc., St. Rose LA, Louisiana license number 4667. Sufficient evidence was found to predicate a finding of violation of La. R.S. 37:3474.1.A(8) and LAC 46:XCI.311.E – failure to maintain copies of current licenses for customers that are shipped or sold drugs or devices, or, if customer licenses are maintained offsite, by failing to maintain at the licensed distribution location a list of customer names, addresses, license numbers, and license expiration dates for all customers that are shipped or sold drugs or devices. Licensee agreed to and paid a fine in the amount of \$2,500 and administrative costs of \$250. Mr. Gielen presented a signed consent

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agreement and noted that the fine and administrative fee had been paid. Motion was made by Mr. Davis to approve and accept the consent agreement for disciplinary action docket 2016003 between the Board and McKesson Medical Surgical, Inc., St. Rose LA, Louisiana license number 4667, seconded by Mr. Dugas, and passed by voice vote – FOR: Mr. Davis, Mr. Brooks, Mr. Dugas, Mr. Gielen, Mr. Dickson, and Mr. DeLatte; AGAINST: None; ABSENT: Mr. Horgan; ABSTAINED: None; RECUSED: None.

AGENDA ITEM 6 - Approval of Meeting Minutes

a. The minutes of the June 7, 2016 Board meeting were presented. Motion was made by Mr. Dickson to dispense with full reading of the minutes and to accept and approve the minutes of the June 7, 2016 Board meeting as presented, seconded by Mr. Brooks, and passed by voice vote – FOR: Mr. Davis, Mr. Brooks, Mr. Dugas, Mr. Gielen, Mr. Dickson, and Mr. DeLatte; AGAINST: None; ABSENT: Mr. Horgan; ABSTAINED: None; RECUSED: None.

AGENDA ITEM 7- Financial Matters

- a. Financial Statements
 - Mr. Lovecchio presented the financial statement for the months of
- i. May 2016
- ii. June 2016 (year end fiscal year 2016)
- iii. July 2016
- iv. August 2016
- v. September 2016

General discussion of the presented information was held. No formal action was taken on this agenda item.

b. Annual Financial Attestation – Fiscal Year 2016 - Report

Mr. Lovecchio presented the Fiscal Year 2016 annual financial attestation as performed by the Louisiana Legislative Auditor office, Financial Audit Services Procedural Report as prepared by the Louisiana Legislative Auditor Office for review. General discussion was held. Motion was made by Mr. Davis to accept and approve the annual Financial Audit Services Procedural Report for FY 2016 (year ending 6/30/2016) as prepared by the Louisiana Legislative Auditor Office, seconded by Mr. Gielen, and passed by voice vote - FOR: Mr. Davis, Mr. Brooks, Mr. Dugas, Mr. Gielen, Mr. Dickson, and Mr. DeLatte; AGAINST: None; ABSENT: Mr. Horgan; ABSTAINED: None; RECUSED: None.

AGENDA ITEM 8 - Professional Services

- a. Contracts
- i. Legal Services

Mr. Lovecchio presented a professional service contract (renewal) for Shows, Cali & Walsh, for legal services. General discussion was held. Motion was made by Mr.

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Dugas to approve the professional service contract between the Board and Shows, Cali & Walsh, to provide legal services in regards to statutory and regulatory review and advice for the period of October 1, 2016 through September 30, 2017 at a maximum of \$25,000 for total of all sums payable, seconded by Mr. Gielen, and passed by voice vote - FOR: Mr. Davis, Mr. Brooks, Mr. Dugas, Mr. Gielen, Mr. Dickson, and Mr. DeLatte; AGAINST: None; ABSENT: Mr. Horgan; ABSTAINED: None; RECUSED: None.

Mr. Lovecchio presented a resolution for the retention of legal contract services of Shows, Cali, & Walsh, LLP as regulatory counsel. Motion was made by Mr. Davis to adopt the resolution for the retention of contract legal service of Shows, Cali, & Walsh, LLP for regulatory and statutory review and advice, seconded by Mr. DeLatte, and passed by voice vote - FOR: Mr. Davis, Mr. Brooks, Mr. Dugas, Mr. Gielen, Mr. Dickson, and Mr. DeLatte; AGAINST: None; ABSENT: Mr. Horgan; ABSTAINED: None; RECUSED: None.

AGENDA ITEM 9 - New Business

- a. Secretary of State / Division of Archives
- i. Records Officer Designation

Mr. Lovecchio presented a form required by the Division of Archives for the designation of a records officer to act as liaison between the Division of Archives, REcors Management and History and the Board on all matters related to records management and communication. Motion was made by Mr. DeLatte to designate Mr. Lovecchio as records officer to act as liaison between the Board and the Division of Archives, Records Management and History of the Secretary of State, on all matters related to records management, second by Mr. Dickson, and passed by voice vote - FOR: Mr. Davis, Mr. Brooks, Mr. Dugas, Mr. Gielen, Mr. Dickson, and Mr. DeLatte; AGAINST: None; ABSENT: Mr. Horgan; ABSTAINED: None; RECUSED: None.

ii. Records Retention Schedule

Mr. Lovecchio presented a draft Records Retention Schedule. Ms. Barbier explained that the records retention schedule form is suppose to be completed and submitted to the Division of Archives, Records Management and History section every five years; the last one submitted for the Board was in 2000. General discussion was held. Motion was made by Mr. Brooks to defer this item to the next Board Meeting allowing Mr. Lovecchio to confer with the Board's attorney, contract accountant, the Legislative Auditor Office, and the Division of Archives regarding the proper procedure for completion and submission of the Record Retention Schedule, seconded by Mr. Davis, and passed by voice vote - FOR: Mr. Davis, Mr. Brooks, Mr. Dugas, Mr. Gielen, Mr. Dickson, and Mr. DeLatte; AGAINST: None; ABSENT: Mr. Horgan; ABSTAINED: None; RECUSED: None.

[Agenda item 10 was discussed after agenda item 9.a.ii.] Agenda item 9.b. was discussed after agenda item 15.a.] b. Senate Concurrent Resoltuion 65 of the 2016 Regular Legislative Session – Meaningful Oversight Task Force

Mr. Lovecchio presented a set of questions developed by the Meaningfule Oversight Task Force that is to be completed by each Board represented on the Meaningful Oversight Task Force and submitted to the Meaningful Oversight Task Force at the next task force meeting. General discussion was held.

[Mr. Dugas exited the meeting during discussion of agenda item 9.b. at approximately 1:00 pm.]

The Board appointed a committee consisting of Mr. Broadus, Mr. DeLatte, and Mr. Davis to work with Mr. Lovecchio in reviewing the questions and develop responses to the SCR 65 task force questions. Motion was made by Mr. DeLatte that the committee, upon completing the responses to the Senate Concurrent Resolution 65 Meaningful Oversight Task Force questions, will submit such responses on behalf of the Board to the Meaningful Oversight Task Force, seconded by Mr. Brooks, and passed by voice vote - FOR: Mr. Davis, Mr. Brooks, Mr. Dugas, Mr. Gielen, Mr. Dickson, and Mr. DeLatte; AGAINST: None; ABSENT: Mr. Horgan; ABSTAINED: None; RECUSED: None.

The responses to the task force questions developed by the committee will be presented to the full Board at its next meeting.

AGENDA ITEM 10 - Old Business

a. Device Distributor White Paper - Addendum

Mr. Lovecchio presented an addendum to the Device Distributor White Paper prepared by Jasos Consulting as authorized by the Board at the June 7, 2016 Board meeting. General discussion was held. No formal action was taken on this agenda item.

AGENDA ITEM 11 - Statutes and Regulations

a. Regulations – Promulgation Update/Tracking Report

Ms. Barbier presented a rule promulgation tracking report. General discussion was held. No formal action was taken on this agenda item.

AGENDA ITEM 12 - Licensing Matters

a. New Licenses Issued List

Ms. Barbier presented for review a list of approximately 105 new licenses as issued by the Board office on behalf of the Board since the June 7, 2016 Board meeting. She noted that approximately 74 of the new licenses issued were first-time Louisiana licensures. General discussion was held. No formal action was taken on this agenda item.

AGENDA ITEM 13 – Additional Agenda Items Properly Brought before the Board (approved in agenda item 3)

1. Uniform Policy

Mr. Broadus presented a revision to the current Board policy on uniforms from 2013 for full-time Board employees. The uniform policy will now allow for the Board to provide polo or oxford style shirts monogrammed with an identifying Board logo to full and part-time employees, service contractors, and board members. Motion was made by Mr. Brooks to approve the new uniform policy with changes as discussed, seconded by Mr. Davis, and passed by voice vote – FOR: Mr. Davis, Mr. Brooks, Mr. Dugas, Mr. Gielen, Mr. Dickson, and Mr. DeLatte; AGAINST: None; ABSENT: Mr. Horgan; ABSTAINED: None; RECUSED: None.

2. Anti-Trust Compliance Policy

Mr. Davis and Mr. Broadus presented information regarding anti-trust compliance policies. General discussion was held. Mr. Lovecchio was directed to prepare a draft anti-trust compliance policy for the Board to be presented to the full Board for review and approve at the next board meeting.

AGENDA ITEM 14 - Policies and Procedures

a. Annual Ethics Training

In response to findings by the Legislative Auditor Office during its financial review for fiscal year 2016, Mr. Lovecchio presented a revised policy for annual ethics training. The policy has been amended to required ethic training be taken annual by all Board members and full-time and part-time office staff as required by Louisiana law in Chapter 15, the Code of Government Ethics. Motion was made by Mr. Gielen to approve the policy on annual ethics training with changes as discussed, seconded by Mr. Dickson, and passed by voice vote - FOR: Mr. Davis, Mr. Brooks, Mr. Dugas, Mr. Gielen, Mr. Dickson, and Mr. DeLatte; AGAINST: None; ABSENT: Mr. Horgan; ABSTAINED: None; RECUSED: None.

b. Annual Sexual Harassment Training

Mr. Lovecchio presented a revised policy for annual sexual harassment training. The policy has been amended to require annual sexual harassment training be taken by all Board members and full and part-time employees of the Board as required by Louisiana Legislative resolution. Motion was made by Mr. Davis to approve the policy on annual sexual harassment training with changes as discussed, seconded by Mr. DeLatte, and passed by voice vote - FOR: Mr. Davis, Mr. Brooks, Mr. Dugas, Mr. Gielen, Mr. Dickson, and Mr. DeLatte; AGAINST: None; ABSENT: Mr. Horgan; ABSTAINED: None; RECUSED: None.

c. Emergency License Relocation and Issuance

Mr. Lovecchio presented information regarding emergency licensing issues which arose during the recent state of emergency/national disaster relative to the great flood of 2016.

i. Emergency Relocation – Board office was contacted by a current licensee located in Louisiana whose licensed place of business had flooded; the licensee requested an emergency relocation to a different location that had not flooded.

ii. Emergency License Issuance – Board office was contacted by a current licensee located in Louisiana that requested emergency license issuance for a new (additional) distribution location for storage and distribution of legend drugs/devices to alleviate any unforeseen drug/device shortages.

Mr. Lovecchio presented a procedure for emergency relocation and/or license issuance requests due to state of emergency and/or national disasters. General discussion was held regarding the proposed procedure and request forms. Motion was made by Mr. Dugas to approve the procedures and forms presented for licensing with regards to emergency relocations of current licensees and emergency license issuance to current licensee for a new distribution location due to states of emergencies and/or national disasters, seconded by Mr. DeLatte, and passed by voice vote - FOR: Mr. Davis, Mr. Brooks, Mr. Dugas, Mr. Gielen, Mr. Dickson, and Mr. DeLatte; AGAINST: None; ABSENT: Mr. Horgan; ABSTAINED: None; RECUSED: None.

AGENDA ITEM 15 - Board Issues

a. Confirmation of Next Board Meeting Date The next Board meeting is tentatively set for Tuesday, December 6, 2016.

[Agenda item 9.b was discussed after agenda item 15.a.] [Agenda item 16 was discussed after agenda item 9.b.]

AGENDA ITEM 16 - Adjournment

There being no further business before the Board, motion was made by Mr. Davis to adjourn the meeting, seconded by Mr. Brooks, and passed by voice vote - FOR: Mr. Davis, Mr. Brooks, Mr. Gielen, Mr. Dickson, and Mr. DeLatte; AGAINST: None; ABSENT: Mr. Horgan and Mr. Dugas; ABSTAINED: None; RECUSED: None.

The meeting adjourned at approximately 2:05 pm.

Approved and accepted by the full Board -

Date:

Randall Brooks Board Secretary/Treasurer

George Lovecchio Executive Director