

LOUISIANA BOARD OF DRUG AND DEVICE DISTRIBUTORS

Board Meeting

MINUTES

June 7, 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, Randall Brooks, Kenneth Dugas, Chad Gielen, and Trion Horgan. Jacob Dickson and Jim Delatte were absent. Michael Davis arrived at 10:05 am during discussion of agenda item 10.4. 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 guests in attendance: Wayne Gremillion, former Board Member.

AGENDA ITEM 2.a - General Motion

Motion was made by Mr. Gielen 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. Brooks, Mr. Dugas, Mr. Gielen, and Mr. Horgan; AGAINST: None; ABSENT: Mr. Davis, Mr. Dickson, and Mr. Delatte; ABSTAINED: None; RECUSED: None. Agenda item order changes include discussion of items: 12.a after 2.a; 3 after 12.a; 6 after 3; 4 after 10.4; 7 after 5; 10.4 after 6; executive session after 10.3; 11 after executive session; and 12.b after 11.

[Agenda item 12.a was discussed after agenda item 2.a.]

[Agenda item 3 was discussed after agenda item 12.a.]

AGENDA ITEM 3 - Call for Additional Agenda Items *[for discussion in Agenda Item 10]*

1. North Carolina Case Review and Louisiana Senate Concurrent Resolution 65 of the 2016 Regular Legislative Session- Meaningful Oversight Task Force - George Lovecchio
2. NABP Conference Update - Randall Brooks
3. Hospital to Hospital Transfer Update - George Lovecchio
4. Acknowledgment of Service - Wayne Gremillion - Bob Broadus.

Motion was made by Mr. Dugas to add items as noted to the agenda for discussion later in the meeting during agenda item 10, seconded by Mr. Gielen, and passed by voice vote - FOR: Mr. Brooks, Mr. Dugas, Mr. Gielen, and Mr. Horgan; AGAINST: None; ABSENT: Mr. Davis, Mr. Dickson, and Mr. Delatte; ABSTAINED: None; RECUSED: None.

[Agenda item 6 was discussed after agenda item 3.]
[Agenda item 4 was discussed after agenda item 10.4.]

AGENDA ITEM 4 – Disciplinary/ Enforcement Actions

- a. Enforcement Action
- i. Consent Agreement – Docket 2016EA1001

Mr. Gielen presented enforcement action docket 2016EA1001 against NxStage Medical dba MediSystems of Lawrence MA found to be engaging in distribution of legend devices into Louisiana without being licensed to do so. Mr. Gielen noted that the respondent had applied for and received a Louisiana distributor license. Mr. Gielen presented a signed consent agreement and noted that the fine and administrative fees had been paid. **Motion was made by Mr. Brooks to approve and accept the consent agreement for enforcement action docket 2016EA1001 between the Board and NxStage Medical dba MediSystem, Lawrence MA and adoption of a resolution for such, seconded by Mr. Dugas, and passed by voice vote – FOR: Mr. Davis, Mr. Brooks, Mr. Dugas, and Mr. Horgan; AGAINST: None; ABSENT: Mr. Dickson and Mr. Delatte; ABSTAINED: None; RECUSED: Mr. Gielen.**

AGENDA ITEM 5 - Approval of Meeting Minutes

- a. The minutes of the April 12, 2016 Board meeting were presented. **Motion was made by Mr. Davis to dispense with full reading of the minutes and to accept and approve the minutes of the April 12, 2016 Board meeting as presented, seconded by Mr. Geilen, and passed by voice vote – FOR: Mr. Davis, Mr. Brooks, Mr. Dugas, Mr. Gielen, and Mr. Horgan; AGAINST: None; ABSENT: Mr. Dickson and Mr. Delatte; ABSTAINED: None; RECUSED: None.**

[Agenda item 7 was discussed after agenda item 5.]
[Agenda item 6 was discussed after agenda item 3.]

AGENDA ITEM 6- Financial Matters

- a. Financial Statements

Mr. Lovecchio presented the financial statement for the month of April 2016. General discussion of the presented information was held. No formal action was taken on this agenda item.

- b. Mr. Lovecchio presented the annual financial Attestation questionnaire for review. **Motion was made by Mr. Davis to accept and approve the Attestation Questionnaire for FY 2016 annual financial attestation (year ending 6/30/2016) as presented for signature by authorized Board representatives and submission to the Louisiana Legislative Auditor’s Office and adoption of the resolution for such, seconded by Mr. Horgan, and passed by voice vote - FOR: Mr. Davis, Mr. Brooks, Mr. Dugas, Mr. Gielen, and Mr. Horgan; AGAINST: None; ABSENT: Mr. Dickson and Mr. Delatte; ABSTAINED: None; RECUSED: None.**

[Agenda item 10.4 was discussed after agenda item 6.]
[Agenda item 7 was discussed after agenda item 5.]

AGENDA ITEM 7 – Professional Services

a. Contracts

i. Accounting Services

Mr. Lovecchio presented a professional service contract (renewal) for Nugent Accounting Services- Ouida Nugent, for accounting services. General discussion was held. **Motion was made by Mr. Dugas to approve the professional service contract between the Board and Nugent Accounting Services, Ouida Nugent, Proprietor, to provide accounting services for the period of July 1, 2016 through June 30, 2018 at a maximum fee of \$3,500 and adoption of a resolution for such, seconded by Mr. Brooks, and passed by voice vote - FOR: Mr. Davis, Mr. Brooks, Mr. Dugas, Mr. Gielen, and Mr. Horgan; AGAINST: None; ABSENT: Mr. Dickson and Mr. Delatte; ABSTAINED: None; RECUSED: None.**

ii. Inspection Services

Mr. Lovecchio presented a professional service contract (renewal) for Danny Andrus for in-state facility inspection services. General discussion was held. **Motion was made by Mr. Gielen to approve the professional service contract between the Board and Danny Andrus to provide in-state facility inspection services for the period of July 1, 2016 through June 30, 2017 at a maximum fee of \$24,000 and adoption of a resolution for such, seconded by Mr. Davis, and passed by voice vote - FOR: Mr. Davis, Mr. Brooks, Mr. Dugas, Mr. Gielen, and Mr. Horgan; AGAINST: None; ABSENT: Mr. Dickson and Mr. Delatte; ABSTAINED: None; RECUSED: None.**

AGENDA ITEM 8 – Statutes and Regulations

a. Regulations – Promulgation Update

Ms. Barbier noted that the Fiscal and Economic Impact Statement for the rule amendments approved by the Board at the April 12, 2016 meeting had been submitted to the Louisiana Legislative Fiscal Office for review on May 12, 2016; at this date there has not been any further contact from the agency.

Mr. Broadus gave a general review of the rule amendment process up to this point. Mr. Broadus suggested the Board consider getting an update to the research paper on federal and state regulatory authority related to supply chain integrity of medical device distributors that had previously been done for the Board. The Board directed Mr. Lovecchio to contact Jasos Group, who had initially performed the research and prepared the paper, about updating the research paper for a cost not to exceed the amount of the purchase order for the previous work.

Mr. Lovecchio informed the Board that per 2013 legislation on transparency the Board's website has a new page that will track future rule promulgation progress for the public's use.

AGENDA ITEM 9 - Licensing Matters

a. New Licenses Issued List

Ms. Barbier presented for review a list of approximately 37 new licenses as issued by the Board office on behalf of the Board since the April 12, 2016 Board meeting. She noted that approximately 23 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 10 - Additional Agenda Items Properly Brought before the Board (approved in agenda item 3)

1. North Carolina Case Review and Louisiana Senate Concurrent Resolution 65 of the 2016 Regular Legislative Session- Meaningful Oversight Task Force

Mr. Lovecchio gave a general review of a recent antitrust court case between the North Carolina Board of Pharmacy and the Federal Trade Commission with regards to non-dentist individuals providing teeth whitening services to the public. During the U.S. Supreme Court review of the case, the Court noted that there is no state (NC) oversight of the Pharmacy Board. Mr. Lovecchio presented Senate Concurrent Resolution 65 of the 2016 Louisiana legislative regular session for a Task Force on Meaningful Oversight. The Resolution creates a task force to review current laws on professional healthcare licensing boards which operate autonomously with virtually no detectable oversight from the parent state department. The task force is to review existing laws to ensure compliance with the Supreme Court's decisions in the North Carolina case to minimize exposure of licensing board to antitrust claims, review board composition to diversify members, and to develop a structure for meaningful oversight of boards by the parent state department. The task force's twenty-seven individual membership includes a designee to represent the Louisiana Board of Drug and Device Distributors. **Motion was made by Mr. Dugas to designate George Lovecchio, Executive Director, to represent the Board on the Task Force on Meaningful Oversight as required in Senate Concurrent Resolution 65 of the 2016 Regular Legislative Session, seconded by Mr. Gielen, and passed by voice vote - FOR: Mr. Davis, Mr. Brooks, Mr. Dugas, Mr. Gielen, and Mr. Horgan; AGAINST: None; ABSENT: Mr. Dickson and Mr. Delatte; ABSTAINED: None; RECUSED: None.**

2. NABP Conference Update

Mr. Brooks gave an update on the NABP conference he and Mr. Lovecchio attended on May 13 through 17, 2016 in San Diego CA. They made several good contacts that should be very successful. He noted they presented a very positive image of Louisiana. He noted that the FDA had a presence at the conference but nothing new was presented. General discussion of some other upcoming conferences was held. No formal action was taken on this agenda item.

3. Hospital to Hospital Transfer Update

Mr. Lovecchio presented general background on this issue as previously discussed at the April 12, 2016 Board meeting. He is still working on gathering further information on this issue. No formal action was taken on this agenda item.

[The Board took a short break at 11:43 am; the Board returned to regular session at 11:50 am.]

[Executive session was called after agenda item 10.3.]

[Agenda item 10.4 was discussed after agenda item 6.]

4. Acknowledgment of Service - Wayne Gremillion

Mr. Broadus acknowledged Mr. Gremillion and his twenty-two years of service as a member of the Louisiana Board of (Wholesale) Drug and Device Distributors. Mr. Gremillion's term expired on August 23, 2015 and he continued to serve the Board until April 22, 2016. Several comments were given by some board members on Mr. Gremillion's past Board accomplishments. Mr. Broadus presented Mr. Gremillion with a commemorative plaque and his name plate. Mr. Gremillion thanked the members for their past support of his duties on the Board. Mr. Gremillion exited the meeting.

[Agenda item 4 was discussed after agenda item 10.4.]

[Executive session was called after agenda item 10.3.]

Motion was made by Mr. Horgan to enter into executive session, seconded by Mr. Gielen, and passed by voice vote - FOR: Mr. Davis, Mr. Brooks, Mr. Dugas, Mr. Gielen, and Mr. Horgan; AGAINST: None; ABSENT: Mr. Dickson and Mr. Delatte; ABSTAINED: None; RECUSED: None.

Motion was made by Mr. Dugas to close executive session and return to open session, seconded by Mr. Horgan, and passed by voice vote - FOR: Mr. Davis, Mr. Brooks, Mr. Dugas, Mr. Gielen, and Mr. Horgan; AGAINST: None; ABSENT: Mr. Dickson and Mr. Delatte; ABSTAINED: None; RECUSED: None.

1. Discussion of Performance Evaluation for George Lovecchio, Executive Director was discussed in executive session. **Motion was made to accept the favorable performance evaluation for George Lovecchio, Executive Director, and to grant Mr. Lovecchio a 6% merit raise increase evaluated for years 2014 through 2016, seconded by Mr. Davis, and passed by voice vote - FOR: Mr. Davis, Mr. Brooks, Mr. Dugas, Mr. Gielen, and Mr. Horgan; AGAINST: None; ABSENT: Mr. Dickson and Mr. Delatte; ABSTAINED: None; RECUSED: None.**

[Agenda item 11 was discussed in executive session.]

AGENDA ITEM 11 - Personnel Issues

a. Performance Evaluation - Executive Director

Mr. Lovecchio's performance evaluation was discussed in executive session.

[Agenda item 12.b was discussed after agenda item 11.]
[Agenda item 12.a was discussed after agenda item 2.a.]

AGENDA ITEM 12 - Board Issues

a. Introduction of New Board Members - Oath of Service

Mr. Broadus announced the recent appointments by the Governor of Mr. James Delatte on April 22, 2016, and Mr. Trion Horgan on April 29, 2016. Mr. Delatte will be filling the seat of Wayne Gremillion; and Mr. Trion Horgan will filling the new Board seat created in Act 443 of the 2015 regular legislative session. Mr. Broadus noted that Mr. Delatte was unable to attend the Board meeting due to prior engagement set before his appointment to the Board. Mr. Broadus introduced Mr. Horgan and administered the Oath of Service to Mr. Horgan.

[Agenda item 3 was discussed after agenda item 12.a.]
[Agenda item 12.b was discussed after agenda item 11.]

b. Election of Officers

Nominations were received as follows - Chairman: Mr. Bob Broadus; Vice-Chairman: Mr. Michael Davis; Secretary-Treasurer: Mr. Randall Brooks; and Compliance Officer: Mr. Chad Gielen. **Motion was made by Mr. Dugas to accept the nominations and to elect Bob Broadus as Chairman, Michael Davis as Vice-Chairman, Randall Brooks as Secretary/Treasurer, and Chad Gielen as Compliance Officer, seconded by Mr. Horgan, and passed by voice vote - FOR: Mr. Davis, Mr. Brooks, Mr. Dugas, Mr. Gielen, and Mr. Horgan; AGAINST: None; ABSENT: Mr. Dickson and Mr. Delatte; ABSTAINED: None; RECUSED: None.**

c. Confirmation of Next Board Meeting

The Board confirmed it will tentatively schedule the next meeting for Tuesday, September 13, 2016. The members should also mark their calendars for the December meeting currently tentatively scheduled for Tuesday, December 6, 2016. Any members should contact the Board office if there are any problems with these dates.

AGENDA ITEM 13 - 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. Dugas, Mr. Gielen, and Mr. Horgan; AGAINST: None; ABSENT: Mr. Dickson and Mr. Delatte; ABSTAINED: None; RECUSED: None.**

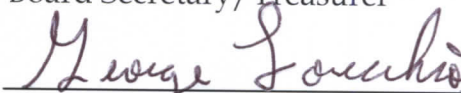
The meeting adjourned at approximately 12:15 pm.

Approved and accepted by the full Board -

Date: 10-17-16



Randall Brooks
Board Secretary/Treasurer



George Lovecchio
Executive Director