

# LOUISIANA BOARD OF DRUG AND DEVICE DISTRIBUTORS

## Board Meeting

### MINUTES

September 8, 2015

#### 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, Chad Gielen, and Jacob Dickson. Wayne Gremillion and Ken Dugas were absent. Mr. Broadus facilitated the meeting and the voting members in attendance constituted a 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 - Call for Additional Agenda Items *[for discussion in Agenda Item 10]*

There were no additional items to add to the agenda.

#### AGENDA ITEM 4 - Approval of Meeting Minutes

a. The minutes of the June 9, 2015 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 9, 2015 Board meeting with minor corrections, seconded by Mr. Davis, and passed by voice vote - FOR: Mr. Davis, Mr. Brooks, Mr. Gielen, and Mr. Dickson; AGAINST: None; ABSTAINED: None; ABSENT: Mr. Gremillion and Mr. Dugas; RECUSED: None.**

#### AGENDA ITEM 5 - Disciplinary and Enforcement Actions

a. Disciplinary Actions

i. Case No. 2015002

Mr. Gielen, Compliance Officer, presented information regarding disciplinary case number 2015002 against Priority Pharmaceuticals, Inc., Louisiana license 5113, relating to action taken against respondent's California license by the California Board of Pharmacy which resulted in respondent's voluntary cancellation of the California license. Compliance officer made an amicable offer for the Respondent to voluntarily surrender their Louisiana license. Respondent agreed to and submitted a request to voluntarily surrender their Louisiana license. **Motion was made by Mr. Brooks to approve the final disposition of disciplinary case 2015002 with voluntary cancellation of Louisiana license 5113 by Priority Pharmaceuticals, Inc., seconded by Mr. Davis, and passed by voice vote - FOR: Mr. Davis, Mr. Brooks, Mr. Gielen, and Mr. Dickson; AGAINST: None; ABSTAINED: None; ABSENT: Mr. Gremillion and Mr. Dugas; RECUSED: None.**

- b. Enforcement Actions
- i. Case No. 2015EA1001

Mr. Gielen, Compliance Officer, presented information regarding enforcement case number 2015EA1001 against Ellman, a trade name of Cynosure, Inc., relating to engaging in distribution of legend devices into Louisiana without a valid Louisiana license and selling and distribution legend devices to persons who are not authorized by law or regulation to procure and possess legend devices. The Respondent agreed there was sufficient evidence upon which to predicate the findings of violations thereby executed a consent agreement and paid a fine. **Motion was made by Mr. Brooks to approve the executed consent agreement for enforcement case 2015EA1001, seconded by Mr. Davis, and passed by voice vote - FOR: Mr. Davis, Mr. Brooks, Mr. Gielen, and Mr. Dickson; AGAINST: None; ABSTAINED: None; ABSENT: Mr. Gremillion and Mr. Dugas; RECUSED: None.**

AGENDA ITEM 6- Professional Services

- a. Contracts
- i. Legal Services - Shows, Cali & Walsh LLP (Renewal)

Mr. Lovecchio presented the (renewal) contract for legal services currently provided by Shows, Cali & Walsh, LLP. General discussion was held. **Motion was made by Mr. Gielen to approve the contract for legal services with Shows, Cali & Walsh LLP covering the period from October 1, 2015 through September 30, 2016 as presented, seconded by Mr. Brooks, and passed by voice vote - FOR: Mr. Davis, Mr. Brooks, Mr. Gielen, and Mr. Dickson; AGAINST: None; ABSTAINED: None; ABSENT: Mr. Gremillion and Mr. Dugas; RECUSED: None.**

- 1) Resolution for Legal Service Contract

Mr. Lovecchio presented a resolution for retention of contracted legal service for regulatory issues. **Motion was made by Mr. Gielen to adopt the resolution for the retention of contracted legal service of Shows, Cali & Walsh, LLP for regulatory issues, seconded by Mr. Brooks, and passed by voice vote - FOR: Mr. Davis, Mr. Brooks, Mr. Gielen, and Mr. Dickson; AGAINST: None; ABSTAINED: None; ABSENT: Mr. Gremillion and Mr. Dugas; RECUSED: None.**

- b. Purchase Orders
- i. Meeting Facilitator Services - SSA Consultants

Mr. Lovecchio presented a purchase order for meeting facilitator services to be utilized for the task force created and provided for by Senate Resolution 177 of the 2015 Regular Session of the Louisiana Legislature. Review and general discussion was held. **Motion was made by Mr. Davis in support and approval of the purchase for meeting facilitator services provided by SSA Consultants, seconded by Mr. Gielen, and passed by voice vote - FOR: Mr. Davis, Mr. Brooks, Mr. Gielen, and Mr. Dickson; AGAINST: None; ABSTAINED: None; ABSENT: Mr. Gremillion and Mr. Dugas; RECUSED: None.**

- ii. Research & White Paper - Medical Device Distribution - JASOS Consulting, LLC

Mr. Lovecchio presented a purchase order for research and a white paper on medical device distribution. Review and general discussion was held. **Motion was made by Mr. Davis in support and approval of the purchase for research and a white paper on medical device distribution provided by JASOS Consulting, LLC, seconded by Mr. Gielen, and passed by voice vote - FOR: Mr. Davis, Mr. Brooks, Mr. Gielen, and Mr. Dickson; AGAINST: None; ABSTAINED: None; ABSENT: Mr. Gremillion and Mr. Dugas; RECUSED: None.**

AGENDA ITEM 7 - Financial Matters

a. Financial Statements

Mr. Lovecchio presented the financial statements for months May, June, and July 2015. Mr. Lovecchio noted June 2015 was the end of the previous fiscal year (2015) and July 2015 was the first month of the new fiscal year (2016). Review and general discussion of the financial statements was held. No formal action was taken on this agenda item.

b. Annual Financial Attestation - Fiscal Year 2015

Mr. Lovecchio informed the Board that the annual attestation of the Board's finances had recently been performed. The Louisiana Legislative Auditor's Office had decided to perform the attestation by CPA from the Legislative Auditor's Office instead of soliciting for independent CPA contracts. The final attestation report had not yet been received for review at this meeting. This agenda item was deferred to the next Board meeting for review of the completed attestation report.

c. Fiscal Year 2015 - Annual Financial Report (AFR)

Mr. Lovecchio informed the Board that the Legislative Auditor's Office is not allowed to complete annual financial reports (AFRs); and since the Legislative Auditor's Office had performed the annual attestation of the Board's finances for fiscal year 2015 instead of a contracted independent CPA, the annual financial report was completed by the Board's contracted accountant, Ms. Ouida Nugent. Mr. Lovecchio presented the AFR as completed by Ms. Nugent. Review and general discussion was held regarding the AFR. No formal action was taken on this agenda item.

AGENDA ITEM 8 - Statutes and Regulations

a. Statutes - 2015 Regular Legislative Session - Act 443

Mr. Lovecchio presented the final text of the Board's statutory amendments presented at the 2015 Regular Session of the Louisiana Legislative as passed and signed by the Governor as Act 443; effective July 1, 2015. General discussion was held. No formal action was taken on this agenda item.

b. Regulations/Administrative Codes - Proposed Amendments

Mr. Lovecchio presented a markup of proposed amendments to the Board's regulations/administrative codes in relation to the recent statutory amendments resulting in Act 443. Mr. Broadus asked that the committee previously assigned to

work on the statutory amendments - the DSCSA Review Committee consisting of Mr. Brooks, Mr. Dickson, and Mr. Gielen - be assigned to review the regulations and present proposed amendments to the regulations to the Board at a later board meeting. This agenda item was deferred to the next Board meeting for committee report. Mr. Lovecchio gave a general presentation regarding the direction the regulatory amendments might take.

AGENDA ITEM 9 - New Business

a. Goals and Objectives from the Executive Director

Mr. Lovecchio presented his goals and objectives for the Board office. Review and general discussion was held regarding the presented objectives of the executive director position, administrative office and licensing, services for licensees, and inspections. No formal action was taken on this agenda item.

*[The Board took a break at approximately 11:00 am after agenda item 9.a. The Board returned to open session at approximately 11:15 am and continued with agenda item 9.a.i.]*

i. Personnel Plan

Mr. Lovecchio and Ms. Barbier presented information regarding their plan and goals for future personnel including two new positions for administrative staffing and filling of the (facility) inspector position within a five year window. Ms. Barbier presented general information regarding classified positions. No formal action was taken on this agenda item.

b. 2015 Medical Device Distributor Task Force - Senate Resolution 177

Mr. Dickson and Mr. Lovecchio presented a general overview of the first task force meeting held on August 31, 2015. No formal action was taken on this agenda item.

c. Policies and Procedures

i. Worker's Compensation Post-Accident Drug Testing Policy

Mr. Lovecchio presented a proposed policy and procedure for Worker's Compensation Post-Accident Drug Testing as required by the Louisiana Office of Risk Management. General discussion was held. This agenda item was deferred to the next Board meeting for further review of requirements.

ii. Appointments and Hires to Classified Positions

Mr. Lovecchio presented a proposed policy and procedure for appointments and hires to classified positions concurrent to the previous agenda item discussion regarding personnel plans. Review and general discussion was held. **Motion was made by Mr. Dickson to approve the policy and procedure for appointments and hires to classified positions as presented, seconded by Mr. Davis, and passed by voice vote - FOR: Mr. Davis, Mr. Brooks, Mr. Gielen, and Mr. Dickson; AGAINST:**

**None; ABSTAINED: None; ABSENT: Mr. Gremillion and Mr. Dugas; RECUSED: None.**

AGENDA ITEM 10- Licensing Matters

a. Application Reviews

Mr. Lovecchio presented two applications for licensure with issues regarding the required qualifications of the designated responsible party (DRP) appointees for review by the Board. Review and discussion of the DRP appointees' work histories/ qualifications were held:

**US Dry Needling & Physio Products LLC, Appleton WI - Motion was made by Mr. Dickson to accept the qualification information presented for the DRP appointee for US Dry Needling & Physio Products LLC, seconded by Mr. Davis, and did not pass by voice vote - FOR: Mr. Gielen; AGAINST: Mr. Davis, Mr. Brooks, and Mr. Dickson; ABSTAINED: None; ABSENT: Mr. Gremillion and Mr. Dugas; RECUSED: None.**

**Medical Purchasing Solutions, Hilliard OH - Motion was made by Mr. Dickson to accept the qualification information presented for the DRP appointee for Medical Purchasing Solutions, seconded by Mr. Davis, and did not pass by voice vote - FOR: None; AGAINST: Mr. Davis, Mr. Brooks, Mr. Gielen, and Mr. Dickson; ABSTAINED: None; ABSENT: Mr. Gremillion and Mr. Dugas; RECUSED: None.**

b. Designated Responsible Party Requirements

Mr. Lovecchio presented the current requirements for the designated responsible party (DRP) for review by the Board. Mr. Brooks had asked to revisit the requirements with regards to dispensing qualifications. General discussion was held. No formal action was taken on this agenda item.

c. New Licenses Issued List

Mr. Lovecchio presented a list of approximately 62 new licenses as issued by the Board office on behalf of the Board since the June 9, 2015 Board meeting for review. General discussion was held. No formal action was taken on this agenda item.

AGENDA ITEM 11 - Additional Agenda Items Properly Brought before the Board (approved in agenda item 3)

There were no additional agenda items brought before the Board.

AGENDA ITEM 12 - Board Issues

a. Report on Nominations for Expired and New Board Seats

Regarding the expired seat of Mr. Davis and his nomination by the state distributor association for reappointment, Mr. Dickson noted that his last conversation with Governor's office indicated should hear something soon. Regarding the expired seat of Mr. Gremillion and nomination of a replacement for his seat by manufacturers

association, Mr. Broadus will contact PhARMA to see where they are with this. Discussion was held regarding the new (eighth) seat created in Act 443 of the 2015 Regular Session of the Louisiana Legislature to be filled by a person actively engaged in the medical device industry. No provisions were made in the statute from where the nomination for the new seat on the Board was to come from. The Board will request nominations for the new seat be sent to the governor from the state distributor association.

b. Confirmation of Next Board Meeting

The Board confirmed it will tentatively schedule the next meeting for Tuesday, December 8, 2015.

Mr. Lovecchio displayed a 5" x 7" white linen card printed with the Board name and state seal on front with envelope he had made to be used for general/casual thank you-s and notes to associates.

AGENDA ITEM 13 - Adjournment

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

The meeting adjourned at approximately 1:40 pm.

Approved and accepted by the full Board -

Date: 12/8/15



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Michael Davis  
Board Vice-Chairman



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George Lovecchio  
Executive Director