CONFERENCE COMMITTEE REPORT

SB 39 **2015 Regular Session** **Mills**

June 10, 2015

To the Honorable President and Members of the Senate and to the Honorable Speaker and Members of the House of Representatives.

Ladies and Gentlemen:

We, the conferees appointed to confer over the disagreement between the two houses concerning Senate Bill No. 39 by Senator Mills, recommend the following concerning the Reengrossed bill:

1. That House Committee Amendments proposed by the House Committee on Health and Welfare and adopted by the House of Representatives on June 1, 2015, be adopted.

2. That House Floor Amendments proposed by Representative Barrow and adopted by the House of Representatives on June 4, 2016, be adopted.

3. That House Floor Amendments proposed by Representative LeBas and adopted by the House of Representatives on June 4, 2016, be rejected.

Respectfully submitted,

Senators:	Representatives:
Senator Fred Mills	Representative H. Bernard LeBas
Senator David Heitmeier	Representative Scott M. Simon
Senator Sherri Smith Buffington	Representative Robert Johnson

The legislative instrument and the following digest, which constitutes no part of the legislative instrument, were prepared by Margaret M. Corley.

CONFERENCE COMMITTEE REPORT DIGEST

SB 39 **2015 Regular Session** **Mills**

Keyword and summary of the bill as proposed by the Conference Committee

HEALTH CARE. Provides for the Louisiana Board of Drug and Device Distributors. (gov sig)

Report adopts House amendments to:

1. Adds to the listing of persons included within the definition of "manufacturer" a person who holds an approved new drug application under the U.S. Food and Drug Administration (FDA) or holds a biologics license issued by the FDA for such product; or, if such product is not the subject of an approved application or license, the person who manufactured the product.

2. Adds definitions for "prescription drug" and "product".

3. Deletes instances of the term "legend drug" and insert in lieu thereof "product".

4. Provides that the term "transaction" does not include a transaction that is exempted from the definition by rules of the board or federal law.

5. Revises the definition of "wholesale distribution".

6. Increases the number of board members of the "Louisiana Board of Drug and Device Distributors" from seven to eight and stipulate that one member shall be actively engaged in the medical device industry.

7. Modifies provisions relative to the board requiring all distributors and wholesale distributors to furnish a bond or other equivalent means of security to change the requirement to an authorization for the board to require that distributors furnish such bonds or other means of security.

8. Provides that the authorization for the board to require distributors and wholesale distributors to furnish a bond or other equivalent means of security shall be in accordance with regulations promulgated by the secretary of the U.S. Dept. of Health and Human Services.

9. Stipulates that furnishing by certain distributors of bonds or other equivalent means of security shall not apply to manufacturers or affiliates or co-licensed partners of manufacturers.

10. Clarifies language relative to injunctions sought by the board enjoining persons from participating in distribution of legend drugs or devices.

11. Directs the La. State Law Institute to change instances of "Louisiana Board of Wholesale Drug Distributors" to "Louisiana Board of Drug and Device Distributors".

Report rejects House amendments which would have:

1. Provides for a sunset of January 1, 2018.

Digest of the bill as proposed by the Conference Committee

Proposed law changes the name of the Louisiana Board of Wholesale Drug Distributors to the Louisiana Board of Drug and Device Distributors, referred to hereafter as "the board".

Proposed law changes the name of the Louisiana Wholesale Drug Distributors Act to the Louisiana Drug and Device Distributors Act.

Proposed law increase the number of board members of the "Louisiana Board of Drug and Device Distributors" from seven to eight, stipulate, that one member shall be actively engaged in the medical device industry, and amends the qualifications of a board member.

Proposed law amends the duties and powers of board to not only approve, deny, revoke, or suspend licenses but to also limit or restrict a license. Authorizes the board to impose a fine, assess cost, or otherwise discipline a licensee and to require a licensee to provide transaction history, transaction information, and a transaction statement. Requires the board to make rules and regulations to comply with the requirements of the Federal Drug Supply Chain Security Act pertaining to distribution.

Proposed law authorizes the board to require all distributors and wholesale distributors to furnish a bond or other equivalent means of security, and provides that any such requirement shall be in accordance with regulations promulgated by the U.S. Department of Health and Human Services. Requires that this requirement to furnish bonds or other equivalent means of security does not apply to manufacturers or affiliates or co-licensed partners of manufacturers.

Proposed law amends requirements for licensure to specify that every applicant for licensure shall meet all qualifications and requirements designated by the board.

Proposed law includes limitation or revocation of license as a discipline option by the board against a licensee.

Proposed law provides that the refusing to permit entry to the licensed distribution or sales facility to comply with any inspection during normal business hours is a cause for discipline.

Proposed law requires that any disciplinary actions or the denial, revocation, suspension, limitation, or restriction of a license be conducted in accordance with rules and regulations adopted pursuant to the Administrative Procedure Act.

Proposed law changes the requirement that distributors provide copies of the U.S. Enforcement Accounting Records Controlled Order Substance Reports of the preceding month to the Louisiana Board of Pharmacy by the fifteenth day of each month. Proposed law requires the reporting but removes the preceding month language and the fifteenth day of each month language.

Proposed law repeals present law related to manufacturer distribution of legend drugs and legend devices.

Effective upon signature of the governor or lapse of time for gubernatorial action.

(Amends R.S. 37:3461, 3462, 3463(A), 3464, 3467, 3469, 3470, 3471(A), 3472, 3473, 3474.1(A)(intro para), 3474.1(A)(1), (2), and (5) and (B), 3474.2(A)(1) and (2), 3474.3(A), 3474.4, 3475, 3477(A), (D), and (E), 3478(A) and (B), 3480, 3481, and 3482; repeals R.S. 37:3474)