Task Force on Medical Device Distribution in Louisiana

Senate Resolution No. 177
2015 Regular Session

Report of Findings and Recommendations to the Louisiana Legislature

12/1/2015

"…shall review existing regulations and propose revisions of regulations and the elimination of duplicate regulations related to the distribution of medical devices while remaining focused on the protection of the health and safety of Louisiana citizens."
Senate Resolution No. 177, 2015 Regular Session

Introduction

Senate Resolution 177 (SR 177) by Senator Mills, enacted during the 2015 regular session of the Louisiana Legislature, directed the Louisiana Board of Drug and Device Distributors to create the Task Force on Medical Device Distribution for the purpose of investigating "existing regulations and propose revisions of regulations and the elimination of duplicate regulations related to the distribution of medical devices while remaining focused on the protection of the health and safety of Louisiana citizens."[1]

SR 177 specified five members of the committee, and these members were authorized to select designees to serve on the task force. SR 177 further specified that the Executive Director of the Louisiana Board of Drug and Device Distributors (or his designee) would serve as the task force chairperson, and that the task force members would serve without compensation.

Any official action by the task force would require a quorum (a simple majority of the total membership) of the task force present and an affirmative vote of a majority of the quorum present and voting.

The task force was charged to conduct its first meeting on or before September 1, 2015 and to complete its work by submitting a report of its findings and recommendations to the Louisiana Legislature no later than December 15, 2015. The authority of the task force terminates upon submission of the report to the Louisiana Legislature. A copy of SR 177 is provided in *Appendix A* of this document.

This document is the final report of the Task Force on Medical Device Distribution. It includes a listing of the task force members, a summary description of the task force's activities, copies of the task force meeting materials, and the task force's findings and recommendations – all submitted respectfully for review and consideration by the Louisiana Legislature.

The task force members extend a special thank you to Senator Mills for authoring SR 177, and the members of the task force also express their gratitude to the Louisiana Legislature for the opportunity to serve as part of this important study effort.

[1] SR 177 of the 2015 Louisiana Legislative Session

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Executive Summary

Senate Resolution 177 (SR 177) by Senator Mills, enacted during the 2015 regular session of the Louisiana Legislature, created the Task Force on Medical Device Distribution for the purpose of investigating "existing regulations and propose revisions of regulations and the elimination of duplicate regulations related to the distribution of medical devices while remaining focused on the protection of the health and safety of Louisiana Citizens."[2]

SR 177 specified five stakeholder members of the committee. The task force conducted a total of four meetings in the late summer and fall of 2015, the last of which was held on December 1, 2015. All meetings were scheduled to last approximately four hours, and each member of the task force was offered an open opportunity to present information, evidence and arguments relevant to the issue before the task force.

The information, evidence and arguments presented by individual committee members were discussed and debated by the task force but member votes were not taken to either accept or reject any of the arguments presented.

Task Force Recommendations

After completion of all presentations and discussions by the task force, the following eleven recommendations to the Louisiana Legislature were offered (by motion) and approved by the task force.

1. The task force recommends that the Louisiana Department of Health and Hospitals (DHH) collaborate with the federal Food and Drug Administration (FDA) to provide or assist in providing inspection processes required for Louisiana device manufacturers. DHH would need to obtain necessary information and training required to competently fulfill this role. This new inspection role for DHH would be limited to the manufacturing portion of the FDA's inspection processes.

2. The task force recommends that should DHH decline the new inspection responsibility described in recommendation number one above, the Louisiana Board of Drug and Device Distributors (LBDDD) should provide or assist in providing inspection processes required for Louisiana device manufacturers. LBDDD would need to obtain necessary information and training required to competently fulfill this role. This new inspection role for LBDDD would be limited to the manufacturing portion of the FDA's inspection processes.

[2] SR 177 of the 2015 Louisiana Legislative Session

3. The task force affirms the LBDDD's current rule for licensing as required in Section 301.K and the current rule in Section 309 for storage and handling requirements for legend drugs and devices.

4. The task force recommends amending the LBDDD's current rule on the exemption of drug samples, as stated within Section 105.A.6, to read as "drugs and devices."

5. The task force affirms the LBDDD's current law on legend drug and legend device distributors as stated within Louisiana Revised Statute Chapter 54 of Title 37.

6. The task force affirms that legend device and legend drug manufacturers must follow state distribution laws and rules if the manufacturer acts in a distribution role.

7. The task force encourages the National Association of Boards of Pharmacy (NABP) to develop and conduct a workshop with all state members focused on the development of more compatible legend device distribution laws.

8. The task force affirms that the legend device licensing requirement shall be for saleable items only and does not include instruments or samples not withstanding any other safety guidelines or requirements.

9. The task force recommends the exemption for legend device licensing in transit with a courier, agent or employee of the manufacturer of the legend device. Also, in the event of an emergency, natural disaster or state of emergency, legend devices could be stored in an unlicensed facility subject to the review of the LBDDD.

10. The task force recommends the LBDDD monitor the pending federal Drug Supply Chain Security Act (DSCSA) and implement Louisiana rules consistent with the guidelines published by DSCSA.

11. The task force recommends an LBDDD licensing exemption for standalone software or medical software applications currently regulated by the FDA.

Task Force Membership

SR 177 states the task force shall include the following members:

1. The Secretary of the Department of Health and Hospitals, or her designee.
2. The President of the Louisiana Senate, or his designee.
3. The Speaker of the Louisiana House of Representatives, or his designee.
4. The Executive Director of the Louisiana Board of Drug and Device Distributors, or his designee.
5. A representative of the Advanced Medical Technological Association.

Figure 1 includes a roster of the individuals that served on the task force as specified members or designees.

Figure 1. Task Force Members/Designees

Organizations Listed in Legislation:	Designee Name:
Louisiana Department of Health and Hospitals	Evonna Sue Fontenot, R.Ph.
Louisiana Senate	Claire Defelice
Louisiana House of Representatives	Jacob Dickson
Louisiana Board of Drug and Device Distributors	George Lovecchio
Advanced Medical Technological Association (AdvaMed)	John Crenshaw

Sue Fontenot serves as the designee for the Secretary of the Louisiana Department of Health and Hospitals on the Task Force. Fontenot has been with the Department for two years as a Pharmacist 3, and prior to her work with the Department, she was a practicing pharmacist in Louisiana. She received her Bachelor of Pharmacy from Northeast Louisiana University.

Claire Defelice serves as the designee for the Louisiana Senate on the Task Force. She is the President of Medi-Chest, Inc. in New Iberia, Louisiana. Defelice has over 15 years of experience in the distribution of legend drugs and devices.

Jacob Dickson serves on the task force as the designee for the Louisiana House of Representatives. He is a Vice-President of Morris & Dickson in Shreveport, Louisiana. Dickson holds a Master's degree in Business Administration from Louisiana State University.

George Lovecchio serves as the Executive Director for the Louisiana Board of Drug and Device Distributors where he has worked for the last nine years. Prior to his time with the Board, Lovecchio was Vice-President and minority owner of a Louisiana drug and device distribution company for approximately 15 years. He attended Loyola University in New Orleans and the University of New Orleans. Lovecchio currently holds a Food and Drug Administration (FDA) commission and is National Association of Drug Diversion Investigator (NADDI) certified.

John Crenshaw is representing the AdvaMed alliance of the 100+ member companies supporting the medical device industry. Crenshaw is the Director of Distribution for Johnson & Johnson based in New Jersey. He has over 20 years of executive supply chain experience in the pharmaceutical, medical device and OTC industry. He graduated from the University of Southern Mississippi with a Bachelor's of Science in Chemistry degree and a Master's degree in Business Administration.

Task Force Activities

SR 177 created the Task Force on Medical Device Distribution and charged the Louisiana Board of Drug and Device Distributors (LBDDD) with the responsibility of administering the work of the task force. LBDDD engaged the services of SSA Consultants (SSA), a Baton Rouge-based management consulting firm to assist the board in the fulfillment of these responsibilities.

SSA managed all task force meeting logistics (scheduling, materials management, communications, etc.), served as the independent facilitator of the task force's meetings and drafted the task force's report of findings and recommendations (this report).

The task force agreed to and completed a total of four meetings, including:

1. Monday, August 31, 2015;
2. Monday, September 28, 2015;
3. Tuesday, September 29, 2015; and

4. Tuesday, December 1, 2015.

Each of these four meetings lasted approximately four hours and was facilitated by SSA. The following is a summary of activity for each meeting.

Task Force Meeting: Monday, August 31, 2015

The agenda of the first meeting was focused on initial introductions of the task force members, opening statements by task force members, establishing the task force's meeting schedule and agenda outlines for each meeting. Additionally, the task force members discussed the items for further review in regards to their legislative charge.

A copy of all materials from this committee meeting (agenda, presentation materials set and meeting minutes) is provided in *Appendix B* of this document.

Task Force Meeting: Monday, September 28, 2015

The agenda of the second meeting was focused on task force member presentations offering information about the specific functions of the LBDDD and addressing the relevant interface between state and federal regulations. A total of five presentations were developed and presented during this task force meeting.

The first presentation (by task force member John Crenshaw) focused on the definition of medical devices and the current initiatives and regulations acted upon by the FDA.

The second presentation (by task force member George Lovecchio) described the current relevant license types available in Louisiana today. Lovecchio also presented statistics on the total numbers of active licenses and their impact on the state of Louisiana.

The third presentation (by invited task force guest Trion Horgan of Stryker Orthopaedics) demonstrated current distribution models being utilized by the manufacturers and distributors of medical devices to supply clients.

The fourth presentation (by task force member Claire Defelice) detailed how in-state inspections are currently handled by the LBDDD through a comprehensive look at the individual areas of inspection.

The fifth presentation (by task force member George Lovecchio) reviewed the current enabling legislation (H.R. 3204-13) of the LBDDD's authority to carry out inspections and their overall duty to protect the people of Louisiana.

All presentations were followed by facilitated discussion.

A copy of all materials from this committee meeting (agenda, presentation material sets and meeting minutes) is provided in *Appendix C* of this document.

Task Force Meeting: Tuesday, September 29, 2015

The agenda of the third meeting was focused on facilitated deliberations by the task force that included discussion and consideration of specific recommendations offered by individual task force members. Each recommendation offered (by motion) was discussed, debated and voted upon. A total of 12 recommendations were offered for consideration by the task force members and 11 recommendations were approved by a majority vote of the task force. One recommendation – requesting an exemption for legend device trunk stock – was offered for consideration by the task force members but the motion did not carry.

A copy of all materials from this task force meeting (agenda, presentation materials set and meeting minutes) is provided in *Appendix C* of this document.

Task Force Meeting: Tuesday, December 1, 2015

The agenda of the fifth meeting included a review of the task force's draft report of findings and recommendations. The agenda also included review of written letter from the AdvaMed commenting on the work of the task force. A copy of the AdvaMed letter is provided in *Appendix D* of this document.

Suggested changes to the draft report were presented and discussed. Changes to the draft report were voted upon and approved changes were included in a final document that was approved by a vote of the task force.

A copy of all materials from this task force meeting (agenda, presentation materials set and meeting minutes) is provided in *Appendix E* of this document.

Task Force Recommendations

After completion of all task force presentations and discussions, the following eleven recommendations to the Louisiana Legislature were offered (by motion) and approved by the task force.

1. The task force recommends that the Louisiana Department of Health and Hospitals (DHH) collaborate with the federal Food and Drug Administration (FDA) to provide or assist in providing inspection processes required for Louisiana device manufacturers. DHH would need to obtain necessary information and training required to competently fulfill this role. This new inspection role for DHH would be limited to the manufacturing portion of the FDA's inspection processes.

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4. The task force recommends amending the LBDDD's current rule on the exemption of drug samples, as stated within Section 105.A.6, to read as "drugs and devices."

5. The task force affirms the LBDDD's current law on legend drug and legend device distributors as stated within Louisiana Revised Statute Chapter 54 of Title 37.

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Appendices

Appendix A – Senate Resolution 177 of the 2015 Louisiana Legislative Session

Appendix B – Task Force Meeting: Monday, August 31, 2015 Materials

Appendix C – Task Force Meetings: Monday, September 28, 2015 and Tuesday, September 29, 2015 Materials

Appendix D – AdvaMed Letter to Task Force dated November 17, 2015

Appendix E – Task Force Meeting: Tuesday, December 1, 2015 Materials

Appendices

Appendix A – Senate Resolution 177 of the 2015 Louisiana Legislative Session

2015 Regular Session **ENROLLED**

SENATE RESOLUTION NO. 177

BY SENATOR MILLS

A RESOLUTION

To create and provide for the Task Force on Medical Device Distribution in Louisiana which shall review existing regulations and propose revisions of regulations and the elimination of duplicate regulations related to the distribution of medical devices while remaining focused on the protection of the health and safety of Louisiana citizens.

WHEREAS, the manufacture, marketing, and distribution of medical devices is strictly regulated by the federal Food and Drug Administration (FDA); and

WHEREAS, medical devices are atypical in the manner in which they are developed, manufactured, and provided to patients by a licensed healthcare provider and require a unique blueprint for regulation; and

WHEREAS, presently, the FDA is implementing a Unique Device Identification system and other measures to enhance the safety and performance of medical devices; and

WHEREAS, several states, including California, Florida, and Maryland, have recently eliminated state medical device regulations that are duplicative of federal regulations; and

WHEREAS, the current budget issues in Louisiana present an opportunity to identify state operations and regulations that would reduce state expenditures, if eliminated; and

WHEREAS, a task force is needed to review existing regulations and report its findings and make recommendations regarding the balancing of the regulation of medical device distribution with the goal of protecting the health and safety of Louisiana citizens.

THEREFORE, BE IT RESOLVED that the Senate of the Legislature of Louisiana does hereby establish the Task Force on Medical Device Distribution in Louisiana to review existing regulations and propose revisions of regulations and the elimination of duplicate regulations while remaining focused on the protection of the health and safety of Louisiana citizens.

BE IT FURTHER RESOLVED that the membership of the task force shall consist of the following:

(1) The secretary of the Department of Health and Hospitals, or her designee.

(2) The president of the Louisiana Senate, or his designee.

(3) The speaker of the Louisiana House of Representatives, or his designee.

(4) The executive director of the Louisiana Board of Drug and Device Distributors, or his designee.

(5) A representative of the Advanced Medical Technological Association.

BE IT FURTHER RESOLVED that the executive director of the Louisiana Board of Drug and Device Distributors, or his designee, shall serve as the task force chairperson.

BE IT FURTHER RESOLVED that the names of the task force members shall be communicated to the chairperson no later than August 15, 2015.

BE IT FURTHER RESOLVED that the task force chairperson shall call the first meeting of the task force no later than September 1, 2015.

BE IT FURTHER RESOLVED that the Louisiana Board of Drug and Device Distributors shall keep minutes of the task force meetings and shall provide any organizational and secretarial support necessary to accomplish the work of the task force.

BE IT FURTHER RESOLVED that the members of the task force shall serve without pay or per diem.

BE IT FURTHER RESOLVED that the task force shall submit a written report of its findings and any recommendations for legislation to the Senate and the House of Representatives no later than December 15, 2015, at which time the task force shall terminate.

BE IT FURTHER RESOLVED that a copy of this Resolution shall be transmitted to the secretary of the Department of Health and Hospitals, the executive director of the Louisiana Board of Drug and Device Distributors, and the Advanced Medical Technological Association.

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PRESIDENT OF THE SENATE

Appendices

Appendix B – Task Force Meeting: Monday, August 31, 2015 Materials

TASK FORCE ON MEDICAL DEVICE DISTRIBUTION

AUGUST 31, 2015 · MEETING MATERIALS

Meeting Location:
Louisiana Board of Drug and Device Distribution
12091 Bricksome Avenue, Suite B
Baton Rouge, LA 70816

Meeting Time:
9:30 AM to 11:30 AM

Material Packet Contents

- August 31, 2015 Meeting Agenda
- Task Force Member Contact Information
- Senate Resolution 177 of the 2015 Louisiana Legislative Session
- Louisiana Board of Drug and Device Distribution Statutes

ABOUT THE TASK FORCE ON MEDICAL DEVICE DISTRIBUTION
Senate Resolution (SR) 177 of the 2015 Louisiana Legislative Session created the Task Force on Medical Device Distribution "to review existing regulation and propose revisions of regulations and the elimination of duplicate regulations while remaining focused on the protection of the health and safety of Louisiana citizens."

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9:30 AM to 11:30 AM

AGENDA ITEMS

I.	Welcome	George Lovecchio Executive Director, LBDDD Chairman, Task Force
II.	Review of SR 177	George Lovecchio Executive Director, LBDDD Chairman, Task Force
III.	Facilitator Introduction	Rudy Gomez Partner, SSA Consultants Task Force Facilitator
IV.	Task Member Introductions & Opening Statements	Rudy Gomez Partner, SSA Consultants Task Force Facilitator
V.	Review of Material Set	Rudy Gomez Partner, SSA Consultants Task Force Facilitator
VI.	Discussion of Task Force Work Plan	Rudy Gomez Partner, SSA Consultants Task Force Facilitator
VII.	Next Steps	Rudy Gomez Partner, SSA Consultants Task Force Facilitator
VIII.	Adjournment	George Lovecchio Executive Director, LBDDD Chairman, Task Force

ABOUT THE TASK FORCE ON MEDICAL DEVICE DISTRIBUTION

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TASK FORCE ON MEDICAL DEVICE DISTRIBUTION

CONTACT INFORMATION

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TASK FORCE ON MEDICAL DEVICE DISTRIBUTION MEMBERS		
Designee for the Secretary of the Department of Health and Hospitals		
Evonna Sue Fontenot, R.Ph. LA DHH Pharmacy	sue.fontenot@la.gov	(225) 342-1367
Designee for the President of the Louisiana Senate		
Claire Defelice Medi-Chest, Inc.	claire@medichest.net	(337) 367-8545
Designee for the Speaker of the Louisiana House of Representatives		
Jacob Dickson Morris Dickson	jdickson@morrisdickson.com	(800) 388-3833
Executive Director of the Louisiana Board of Drug and Device Distributors		
George Lovecchio LBDDD	g.lovecchio@lsbwdd.org	(225) 295-8567
Representative of the Advanced Medical Technological Association		
John Crenshaw Johnson & Johnson Health Care Systems, Inc.	jcrensha@its.jnj.com	(908) 874-1000

Additional Task Force Resources:

- Rudy Gomez – SSA Consultants; Task Force Facilitator
  - rgomez@consultssa.com
  - (225) 769-2676
- Anita Byrne – SSA Consultants
  - abyrne@consultssa.com
  - (225) 769-2676

2015 Regular Session **ENROLLED**

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BY SENATOR MILLS

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PRESIDENT OF THE SENATE

LOUISIANA LICENSING LAW FOR DRUG AND DEVICE DISTRIBUTORS

Louisiana Revised Statutes

TITLE 37

CHAPTER 54. DRUG AND DEVICE DISTRIBUTORS

§3461. General provisions and short title

A. This Chapter shall be known and may be cited as the "Louisiana Drug and Device Distributors Act".

B. In order to safeguard life and health and to promote the public welfare, any person engaged in the distribution of legend drugs or legend devices as defined in this Chapter shall be required to submit evidence of qualification to be engaged in the legend drug or legend device distribution business and shall be licensed as hereinafter provided.

Acts 1988, No. 852, §1; Acts 1995, No. 1152, §1, eff. June 29, 1995; Acts 2008, No. 597, §1; Acts 2015, No. 443, §1.

§3462. Definitions

As used in this Chapter:

(1) "Applicant" means a person who applies for licensure as a legend drug or legend device distributor.

(2) "Board" means the Louisiana Board of Drug and Device Distributors.

(3) "Bureau" means the Louisiana Bureau of Criminal Identification and Information of the office of state police within the Department of Public Safety and Corrections.

(4) "Criminal history record information" means information collected by state and federal criminal justice agencies on persons consisting of identifiable descriptions and notations of arrests, detentions, indictments, bills of information, or any formal criminal charges, and any disposition arising therefrom, including sentencing, criminal correctional supervision, and release, but does not include intelligence for investigatory purposes, nor does it include any identification information which does not indicate involvement of the person in the criminal justice system.

(5) “Designated responsible party” means a natural person designed by the applicant or licensee as responsible for facility operations of the applicant or licensee facility.

(6) “Distribution” means the sale or facilitation of deliver of legend drugs or legend devices to a person other than the consumer or patient, including but not limited to distribution by manufacturers, repackagers, own-label distributors, jobbers, third-party logistics providers, retail pharmacy warehouses, pharmacies, brokers, agents, and wholesale distributors

(7) Distributors” means any person engaged in distribution, including but not limited to manufacturers, repackagers, own-label distributors, jobbers, third-party logistics providers, retail pharmacy warehouses, pharmacies, brokers, agents, and wholesale distributors.

(8) "FBI" means the Federal Bureau of Investigation of the United States Department of Justice.

(9) "Legend device" means any device intended for use by humans that carries on its label "Rx", "Rx only", a designation for physician use only, or a statement that federal law restricts the device to sale by or on the order of a licensed health care practitioner.

(10) "Legend drug" means any drug intended for use by humans that carries on its label any of the following: "Caution: Federal law prohibits dispensing without a prescription", "Rx", or "Rx Only".

(11) "Licensure" means any license, permit, or registration that the board is authorized by law to issue.

(12) "Manufacturer" means any of the following:

(a) A person who manufactures legend drugs or legend devices and includes a labeler or distributor.

(b) A person who prepares legend drugs in dosage form by mixing, compounding, encapsulating, entableting, or by other processes.

(c) A person who manufactures, assembles, processes, or modifies legend devices.

(d) An affiliate of a person described in Subparagraph (a), (b), (c), or (f) of this Paragraph that received the legend drugs or legend devices direcdtly from a person described in this Subparagraph or Subparagraph (a), (b), (c), or (f) of this Paragraph.

(e) A co-licensed parther of the person described in Subparagraph (a), (b), (c), or (f) of this Paragraph that obtains the legend drugs or legend devices directly from a person described in this Subparagraph or Subparagraph (a), (b), (c), or (f) of this Paragraph.

(f) A person who holds an approved new drug applciaiton under the United States Food and Drug Administration or holds a biologics license issued by the United States Food and Drug Administration for such product; or, if such product is not the subject of an approved application or license, the person who manufactured the product.

(13) "Owner" means a natural person who owns greater than a ten percent interest in the distributor.

(14) "Person" means a natural or juridical person, including a proprietorship, partnership, corporation, limited liability company, trust, business firm, association, franchise arrangement, combination of any of these entities, or any other legal entity.

(15) “Prescription drug” means a drug for human use which, because of its toxicity or other potentiality for harmful effects, the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or a drug which is limited by a Untied States Food and Drug Administration new drug application to use under the professional supervision of a practitioner licensed by law to administer such drug.

(16) “Product” means a prescription drug in a finished dose form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitiution); however, “product”, as used in this Chapter, does not include any of the following:

(a) Blood or blood components intended for transfusion.

(b) A radioactive drug or radioactive biological product regulated by the Nuclear Regulatory Commission or by a state pursuant to an agreement with the Nuclear Regulatory Commission.

(c) An imaging drug.

(d) An intravenous product that, by its formulation, is intended for replenishment of fluids and electrolytes or calories, for use to maintain the equilibrium of water and minerals in the body, or for irrigationor sterile water whether for such purpose or injection.

(e) Any medical gas.

(f) A homeopathic drug marketed in accordance with applicable guidance under the federal Drug Supply Chain Security Act.

(g) A drug compounded incompliance with the federal Food, Drug, and Cosmetic Act.

(17) “Repackager” means a person who owns or operates an establishment that repacks and relabels a legend drug, legend device, or package thereof for one of the following purposes:

(a) Further sale.

(b) Distribution without a further transaction.

(18) "Third-party logistics provider" means a person that provides or coordinates warehousing, facilitation of delivery, or other logistic services for a legend drug or legend device in interstate and intrastate commerce on behalf of a manufacturer, distributor, or dispenser of a legend drug or legend device but does not take ownership of the legend drug or legend device nor have responsibility to direct the sale or disposition of the legend drug or legend device.

(19) “Transaction” means the transfer of a product between persons in which a change of ownership occurs, but does not include a transaction that is exempted from the definition by rules of the Board or federal law.

(20) “Transaction history” means a statement, in paper or electronic form, that includes the transaction information for each prior transaction going back to the manufacturer of the product.

(21) “Transaction information” means:

(a) The proprietary or established name or names of the product.

(b) The strength and dosage form of the product.

(c) The National Drug Code number of the product.

(d) The container size.

(e) The number of containers.

(f) The lot number of the product.

(g) The date of the transaction.

(h) The date of the shipment, if more than twenty-four hours after the date of the transaction.

(i) The business name and address of the person from whom ownership is being transferred.

(j) The business name and address of the person to whom ownership is being transferred.

(22) “Transaction statement” means a statement, in paper or electronic form, that the entity transferring ownership in a transaction meets all of the following conditions:

(a) Is authorized as required under the federal Drug Supply Chain Security Act.

(b) Received the product from a person that is authorized as required under the federal Drug Supply Chain Security Act.

(c) Received transaction information and a transaction statement from the prior owner of the product.

(d) Did not knowingly ship a suspect or illegitimate product.

(e) Had systems and processes in place to comply with verification requirements under the federal Drug Supply Chain Security Act.

(f) Did not knowingly provide false transaction information.

(g) Did not knowingly provide false transaction history.

(23) "Wholesale distribution" means the distribution of legend drugs or legend devices to a person other than the consumer or patient except as exempted in the standards of the federal Drug Supply Chain Security Act as the act pertains to wholesale distribution.

(24) "Wholesale distributor" means any person engaged in wholesale distribution.

Acts 1988, No. 852, §1; Acts 2008, No. 597, §1; Acts 2015, No. 443, §1.

§3463. Board; appointments; terms; removal; compensation; officers

A. The Louisiana Board of Drug and Device Distributors is hereby created within the Department of Health and Hospitals and is subject to the provisions of R.S. 36:803. The board shall administer the provisions of this Chapter. It shall be composed of eight members, five of whom shall be licensed distributors, two of whom shall be actively engaged in the pharmaceutical manufacturing industry, and one of whom shall be actively engaged in the medical device industry.

B. The governor shall appoint, subject to Senate confirmation, members to the board from a list containing the names of five persons, submitted by the Louisiana Association of Wholesale Drug Distributors and from a list containing the names of two persons, submitted by the Pharmaceutical Research and Manufacturers of America. In the event of the death or resignation of any member of the board, the governor shall appoint his successor in the manner of the original appointment for the remainder of the unexpired term.

C. Each member appointed to the board shall serve a term of five years.

D. Each member shall serve until his successor has been appointed and qualified.

E. The presidents of the Pharmaceutical Research and Manufacturers of America and the Louisiana Association of Wholesale Drug Distributors shall submit the nominations within sixty days after receipt of notice of death, resignation, or removal of a member of the board and at least thirty days prior to the expiration of the term of a member of the board.

F.(1) Any member of the board may be removed by the governor, or a majority vote of the board, after notice and a hearing by the board wherein grounds for removal have been established. Grounds for removal shall include but not be limited to incompetence, neglect of duty, unprofessional or dishonorable conduct, or a violation of this Chapter.

(2) A board member's seat shall be considered vacant after two consecutive absences by that member from official board meetings without a reason acceptable by the board.

G. Each member of the board shall receive seventy-five dollars a day and reimbursement for actual expenses and mileage at the same rate set by the division of administration for state employees under the provisions of R.S. 39:231 for each day while engaged in the discharge of their duties.

H. The board shall elect a chairman, vice chairman, secretary-treasurer, and such other officers as it considers necessary to carry out the duties or functions of the board.

Acts 1988, No. 852, §1; Acts 1995, No. 1152, §1, eff. June 29, 1995; Acts 2008, No. 597, §1; Acts 2015, No. 443, §1.

§3464. Qualifications of board members

Each member of the board shall be at least twenty-one years of age, of good moral character and temperate habits, and a resident of this state and shall have engaged in distribution as defined by this Chapter.

Acts 1988, No. 852, §1; Acts 1995, No. 1152, §1, eff. June 29, 1995; Acts 2015, No. 443, §1.

§3465. Organization meetings

The board shall hold at least two regular meetings each year. Special meetings may be held at such time and place as specified by a call of the chairman or secretary. Reasonable notice of all meetings shall be given in writing to each member of the board. A quorum of the board shall be a majority of its members.

Acts 1988, No. 852, §1; Acts 1995, No. 1152, §1, eff. June 29, 1995.

§3466. Domicile of the board

The domicile of the board shall be East Baton Rouge Parish, Louisiana.

Acts 1988, No. 852, §1.

§3467. Duties and powers of the board

A. The board may perform all of the following functions:

(1) Approve, deny, revoke, suspend, limit, or restrict licenses of qualified applicants for licensure as distributors and renew licenses.

(2) Impose fines, assess costs, or otherwise discipline a licensee.

(3) Regulate the distribution of legend drugs or legend devices.

(4) Monitor compliance with all federal and state laws and regulations regarding the distribution of legend drugs or legend devices by distributors and promulgate rules and regulations relative thereto.

(5) Conduct inspections of wholesale distribution facilities.

(6) Conduct hearings on charges relative to the violation of any provision of this Chapter.

(7) Issue subpoenas and administer oaths to persons giving testimony at hearings.

(8) Employ and fix compensation of persons necessary to carry on the work of the board.

(9) Appoint an attorney to represent the board in all matters pertaining to the administration of this Chapter, define his duties, and fix his compensation.

(10) Adopt all rules and regulations necessary to implement the provisions of this Chapter.

(11) Require licensees to provide transaction history, transaction information, and a transaction statement.

(12) Designate and assign license types and sub-types for distributors, which include wholesale distributors, manufacturers, repackagers, and third-party logistic providers, which it will approve, deny , revoke, suspend, limit, or restrict, and renew pursuant to Paragraph (A)(1) of this Section.

(13) Exercise all other powers necessary and proper to perform its duties within the scope of this Chapter.

B. The board shall make rules and regulations, not inconsistent with law, and shall take such other action as may be necessary to comply with the requirements set forth in the federal Food, Drug, and Cosmetic Act and the federal Drug Supply Chain Security Act, as those acts pertain to distribution as defined by this Chapter; and with the rules and regulations promulgated pursuant to those acts, and other pertinent federal authority.

C. (1) The board may require all distributors and wholesale distributors to furnish a bond or other equivalent means of security in accordance with regulations promulgated by the secretary of the United States Department of Health and Human Services.

(2) This Subsection shall not apply to manufacturers or affiliates or co-licensed partners of manufacturers.

Acts 1988, No. 852, §1; Acts 1991, No. 528, §1; Acts 1995, No. 1152, §1, eff. June 29, 1995; Acts 2008, No. 597, §1; Acts 2015, No. 443, §1.

§3468. Records, prima facie evidence

The books, registers, and records of the board shall be prima facie evidence of the matter therein recorded in any court of law. The board shall keep a full record of all acts and proceedings of the board.

Acts 1988, No. 852, §1.

§3469. Qualifications and requirements for licensure

A. Every applicant for licensure as a distributor shall meet all qualifications and requirements designed by the board in accordance with this Chapter and all applicable requirements of federal law and regulations.

B. The application for licensure shall be made on a form provided by the board. Each application shall be accompanied with the reasonable licensure fee prescribed by the board. Each application form shall contain language that authorizes the board to obtain a criminal history record on the applicant, designated responsible party, and any owners to determine if the applicant, designated responsible party, or owners have ever been convicted of a felony violation of federal or state law.

Acts 1988, No. 852, §1; Acts 1992, No. 802, §1; Acts 1995, No. 1152, §1, eff. June 29, 1995; Acts 2008, No. 597, §1; Acts 2015, No. 443, §1.

§3470. Inspections

The board, or a representative of the board, may conduct inspections of distribution and sales facilities during normal business hours upon receipt of an application for licensure. The board may conduct inspections during normal business hours of facilities that appear to be used by a distributor. The board may also conduct unannounced inspections of current licensees at sufficient intervals to determine compliance with state and federal requirements or when it considers it necessary. Upon inspection, a written report shall be submitted to the board by the inspector. Applicants for licensure and licensees shall be notified in writing by certified mail if any discrepancies are found, and a deadline shall be set by which such discrepancies must be corrected.

Acts 1988, No. 852, §1; Acts 1995, No. 1152, §1, eff. June 29, 1995; Acts 2008, No. 597, §1; Acts 2015, No. 443, §1.

§3471. License; registering; evidence

A. Each applicant who meets the provisions of R.S. 37:3469 and successfully passes the inspection provided in R.S. 37:3470 shall receive a license from the board authorizing him to act as a distributor in this state. The license or a renewal thereof shall be the only evidence of the right of a person to act as a distributor.

B. The license shall be registered in a record book to be kept by the board for that purpose. A copy of the license certified by the secretary of the board shall be received as evidence in all courts of this state.

Acts 1988, No. 852, §1; Acts 1995, No. 1152, §1, eff. June 29, 1995; Acts 2015, No. 443, §1.

§3472. Reinspection

Reinspections of distribution and sales facilities may be conducted as follow-ups to the regular inspections or to guarantee that the applicant or licensee has corrected any discrepancy found by the board. Failure to comply with state and federal laws or the board's regulations shall be prima facie evidence of a violation of this Chapter and shall subject the applicant or licensee either to disciplinary action by the board or forfeiture of the license.

Acts 1988, No. 852, §1; Acts 1995, No. 1152, §1, eff. June 29, 1995; Acts 2008, No. 597, §1; Acts 2015, No. 443, §1.

§3473. Applicants from other states; waiver of inspection

The board may waive the inspection provided in R.S. 37:3470, if the applicant presents to the board a satisfactory certificate of registration or license from an entity which licenses distributors of the same type in another state, and if the standards adopted and enforced by such entity are comparable to those provided in this Chapter.

Acts 1988, No. 852, §1; Acts 1995, No. 1152, §1, eff. June 29, 1995; Acts 2008, No. 597, §1; Acts 2015, No. 443, §1.

§3474. Manufacturer distribution of legend drugs and legend devices

Repealed.

Acts 2008, No. 597, §1; Acts 2015, No. 443, §1.

§3474.1. Discipline for licensees

A. Any person licensed as a distributor under this Chapter may have his license revoked, suspended, limited, or restricted for a fixed period to be determined by the board for any of the following causes:

(1) Conviction of a felony of the licensee, responsible party, or owner. The record of such conviction, or certified copy thereof from the clerk of court where such conviction occurred or by the judge of such court, shall be sufficient evidence to warrant revocation, suspension, limitation, or restriction.

(2) Suspension, revocation, or other disciplinary action taken by any state or federal agency of a license to distribute legend drugs or legend devices. A certified copy of the record of suspension or revocation by the state where such suspension or revocation occurred shall be conclusive evidence thereof.

(3) Making any fraudulent or untrue statement to the board.

(4) Refusing to respond or otherwise comply with any request from the board.

(5) Refusing to permit entry to the licensed distribution or sales facility to comply with any inspection during normal business hours.

(6) Selling, distributing, or offering to sell or distribute any adulterated, counterfeited, or misbranded legend drug or legend device.

(7) Altering, mutilating, destroying, obliterating, or removing any part of the label of a legend drug or legend device.

(8) Violating any of the provisions of this Chapter or rules and regulations adopted by the board.

B. Proceedings for any disciplinary actions or for the denial, revocation, suspension, limitation, or restriction of a license shall be conducted in accordance with rules and regulations adopted by the board pursuant to the Administrative Procedure Act.

C. The board may require a person who is subject to the authority of the board and against whom disciplinary action has been taken to pay a fine of not more than one thousand dollars per violation.

D. Each day on which a violation occurs shall constitute a separate violation.

E. In addition to the fine, the board may assess all costs incurred in connection with the proceedings to a person who is subject to the authority of the board, including but not limited to investigator, stenographer, and attorney fees.

F. No license shall be issued, reinstated, or renewed until the monetary penalties pursuant to this Section have been paid in full.

Acts 1991, No. 528, §1; Acts 1995, No. 1152, §1, eff. June 29, 1995; Acts 2008, No. 597, §1; Acts 2015, No. 443, §1.

§3474.2. Enforcement action against other persons; penalties

A. The board shall have the authority to take enforcement action against any non-licensee found by the board to be guilty of any of the following acts or offenses:

(1) Participating or engaging in distribution as defined by this Chapter.

(2) Using the term “distributor” or "wholesale distributor" as defined by this Chapter, or otherwise assuming or using such term or advertising in any manner intended to convey the impression that he is a licensed distributor or wholesale distributor.

(3) Violating any of the provisions of this Chapter or any rules or regulations adopted by the board.

B. For the purposes of this Section, the term "enforcement action" shall include but not be limited to the assessment of a fine in an amount not to exceed one thousand dollars per violation. Each day on which a violation occurs shall constitute a separate violation.

C. In addition to any other action, the board may assess to a person all reasonable costs incurred in connection with an enforcement action, including investigator, stenographer, and attorney fees.

D. Proceedings for an enforcement action shall be conducted through the promulgation of rules and regulations in accordance with the Administrative Procedure Act.

Acts 2008, No. 597, §1; Acts 2015, No. 443, §1.

§3474.3. Injunction proceedings; penalties

A. The board may seek in any court of competent jurisdiction a writ of injunction enjoining any person from participating in distribution as defined by this Chapter until such person obtains the necessary license under the provisions of this Chapter. Posting of a bond shall not be a cause for dissolution of the injuction.

B. In the suit for an injunction, the board may demand of the defendant a penalty of not more than five thousand dollars, reasonable attorney fees, and court costs. This judgment

for penalty, attorney fees, and court costs may be rendered in the same judgment in which the injunction is made absolute.

C. The trial of the proceeding by injunction shall be summary and by the judge, without a jury.

D. This Section shall not be construed as barring criminal prosecution for violations of this Chapter.

Acts 2008, No. 597, §1; Acts 2015, No. 443, §1.

§3474.4. Order to quarantine a legend drug or legend device

A. If the board finds a reasonable probability that a distributor possesses an adulterated, misbranded, counterfeited, or recalled legend drug or legend device, the board may issue an order to quarantine the legend drug or legend device.

B. Any order issued pursuant to this Section shall subject the distributor to the order with an opportunity for hearing to be held no later than thirty days after issuance of the order on the actions required by the order. If, after the hearing, the board determines that inadequate grounds exist to support the order, the board shall vacate the order.

Acts 2008, No. 597, §1; Acts 2015, No. 443, §1.

§3475. Annual renewal of license

All licensed distributors shall pay to the board a renewal fee as shall be determined by the board.

Acts 1988, No. 852, §1; Acts 1995, No. 1152, §1, eff. June 29, 1995; Acts 2015, No. 443, §1.

§3476. Failure to renew license; penalties

The failure to pay the renewal fee required by R.S. 37:3475 shall result in an automatic revocation of the license. In such cases, the person shall be reinstated if he files an application for reinstatement with the board within one year after the revocation and pays a reinstatement fee and all delinquent charges as provided by the board.

Acts 1988, No. 852, §1; Acts 1995, No. 1152, §1, eff. June 29, 1995.

§3477. Authorization to obtain criminal history record information

A. The board may require that the applicant, designated responsible party, and any owners provide written consent to the board to request and obtain state and national criminal history record information as a condition for consideration of the licensure application.

B. The board may charge and collect from the applicant, in addition to all other applicable fees and costs, such amount as may be incurred by the board in requesting and obtaining state and national criminal history record information.

C. The board shall provide each applicant with a copy of the written standards specifying the requirements that shall be met by an applicant and the grounds on which a license may be denied or revoked.

D. Pursuant to this Section, or any other law or board rules or regulations promulgated and adopted by the board, the board may request and obtain state and national criminal history record information from the bureau and the FBI relative to any applicant, designated responsible party, or owner whose fingerprints the board has obtained for the purpose of determining an applicant's suitability and eligibility for licensure.

E. Upon request by the board and upon the board's submission of fingerprints and other identifying information as may be required, the bureau shall conduct a search of its criminal history record information relative to the applicant, designated responsible party, or owner and report the results of its search to the board within sixty days from receipt of any such request. The bureau may charge the board a processing fee pursuant to R.S. 15:587 for conducting and reporting on any such search.

F. If the criminal history record information reported by the bureau to the board does not provide grounds for disqualification of the applicant for licensure, the board shall have the authority to forward the fingerprints and other identifying information as may be required to the FBI with a request for a search of national criminal history record information.

G. Any and all state or national criminal history record information obtained by the board from the bureau or FBI which is not already a matter of public record shall be deemed nonpublic and confidential information restricted to the exclusive use of the board, its members, officers, investigators, agents, and attorneys in evaluating the applicant's eligibility or disqualification for licensure. No such information or records related thereto shall, except with the written consent of the individual or by order of a court of competent jurisdiction, be released or otherwise disclosed by the board to any other person or agency.

Acts 2008, No. 597, §1; Acts 2015, No. 443, §1.

§3478. Unlawful participation; penalty

A. No person shall participate or engage in the business of distribution as defined by this Chapter without a license issued therefor and compliance with other requirements as provided for in this Chapter.

B. No person shall use in connection with his name the term “distributor” or "wholesale distributor", or otherwise assume or use such term or advertise in any manner intending to convey the impression that he is a distributor or wholesale distributor as defined by this Chapter, unless such person has been duly licensed under the provisions of this Chapter.

C. Whoever violates the provisions of this Section shall be fined not less than one thousand dollars nor more than fifty thousand dollars or imprisoned for not less than ten days nor more than thirty days, or both.

Acts 1988, No. 852, §1; Acts 1995, No. 1152, §1, eff. June 29, 1995; Acts 2008, No. 597, §1; Acts 2015, No. 443, §1.

§3479. Fees

A. To defray the cost of administering the provisions of this Chapter, the board shall fix fees not to exceed the following:

(1) Initial license fee	$600
(2) License renewal fee	$600
(3) Initial inspection fee	$300
(4) Duplicate license fee	$100
(5) Reinstatement fee for licenses suspended, revoked, or expired	$600
(6) License verification fee	$100

B. Any fees fixed by the board shall be subject to legislative oversight review pursuant to the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

C. All monies collected under this Chapter shall be paid into the treasury of the board and may be expended by the board without appropriation for costs of administration, including salary of employees, travel allowances, and other necessary expenses. Any funds remaining unexpended and unencumbered at the end of each fiscal year shall be retained by the board for expenditure in succeeding years and no part thereof shall revert to the General Fund of the state of Louisiana.

D. This board shall be financially self-sufficient. It shall receive no state funds through appropriation or otherwise and shall not expend any such state funds. No state funds shall be expended or committed to expenditure for the group benefits program or any other health insurance or employee benefit program, for any retirement system, for any salary, per diem payment, travel or expenses, office supplies and materials, rent, purchase of any product or service, or for any other purpose.

Acts 1988, No. 852, §1; Acts 2008, No. 597, §1.

§3480. Unauthorized sales

Distributors shall sell or distribute legend drugs or legend devices only to a person who is authorized, by law or regulation, to procure or possess legend drugs or legend devices.

Acts 1988, No. 852, §1; Acts 2008, No. 597, §1; Acts 2015, No. 443, §1.

§3481. Mandatory reporting

Distributors shall provide copies of their United States Enforcement Accounting Records Controlled Order Substance Reports (ARCOS) to the Louisiana Board of Pharmacy, and copies of their controlled substance sales register for a specific controlled substance registrant in Louisiana and excessive controlled substance purchase reports for all controlled substance registrants in Louisiana required by 21 CFR 1301.74(b) as requested by the Louisiana Board of Pharmacy. Notwithstanding any other law to the contrary, these reports shall be confidential and shall be destroyed when they have served their purpose.

Acts 1988, No. 852, §1; Acts 1995, No. 1152, §1, eff. June 29, 1995; Acts 2015, No. 443, §1.

§3482. Applicability; conflicts

Nothing in this Chapter shall be construed to authorize the Louisiana Board of Drug and Device Distributors to regulate the practice of pharmacy as provided in Chapter 14 of Title 37 of the Louisiana Revised Statutes of 1950. If any provision of this Chapter conflicts with the provisions of Chapter 14 of Title 37 of the Louisiana Revised Statutes of 1950, the provisions of Chapter 14 of Title 37 of the Louisiana Revised Statutes of 1950 shall prevail.

Acts 1988, No. 852, §1; Acts 2015, No. 443, §1.

Appendices

Appendix C – Task Force Meetings: Monday, September 28, 2015 and Tuesday, September 29, 2015 Materials

TASK FORCE ON MEDICAL DEVICE DISTRIBUTION

SEPTEMBER 28 -29, 2015 · MEETINGS MATERIALS

Meetings Location:
Louisiana Board of Drug and Device Distribution
12091 Bricksome Avenue, Suite B
Baton Rouge, LA 70816

Meetings Time:
September 28, 2015
9:30 AM to 4:00 PM

September 29, 2015
9:30 AM to Noon

Material Packet Contents

- August 31, 2015 Task Force Meeting Minutes
- September 28, 2015 Meeting Agenda
- September 28, 2015 Meeting Presentation Materials
    - Presentation: by John Crenshaw (Director, U.S. Distribution, Johnson & Johnson Health Care Systems Inc. and Task Force Member)
    - Presentations: by George Lovecchio (Executive Director, Louisiana Board of Drug and Device Distribution and Task Force Member); Trion Horgan (Branch Operations Manager, Stryker Orthopaedics; Claire Defelice (Medi-Chest, Inc., Task Force Member)
        - LBDDD Sample Inspection Checklist
        - "Comparison and Gap Analysis of Federal and State Regulatory Authority Related to Supply Chain Integrity of Medical Device Distributors", Charles C. Lewis, B.S. Pharm, R.Ph., MBA with Jasos Group, LLC, August 2015.*
- U.S. Drug Quality and Security Act, November 2013
- September 29, 2015 Meeting Agenda
- September 29, 2015 Meeting Presentation

*Note included in this material set

ABOUT THE TASK FORCE ON MEDICAL DEVICE DISTRIBUTION
Senate Resolution (SR) 177 of the 2015 Louisiana Legislative Session created the Task Force on Medical Device Distribution "to review existing regulation and propose revisions of regulations and the elimination of duplicate regulations while remaining focused on the protection of the health and safety of Louisiana citizens."

TASK FORCE ON MEDICAL DEVICE DISTRIBUTION

AUGUST 31, 2015 · MEETING MINUTES

Meeting Location:
Louisiana Board of Drug and Device Distribution
12091 Bricksome Avenue, Suite B
Baton Rouge, LA 70816

Meeting Time:
9:30 AM to 11:30 AM

AGENDA ITEMS

I. Welcome – 9:26 AM

George Lovecchio
Executive Director, LBDDD
Chairman, Task Force

The meeting call was called to order by George Lovecchio, Louisiana Board of Drug and Device Distributors (LBDDD) Executive Director and Task Force on Medical Device Distribution Chairman. Chairman Lovecchio welcomed the Task Force to the LBDDD office. This past 2015 Louisiana Legislative Session the Board name was changed to the current Louisiana Board of Drug and Device Distributors from the Louisiana Board Wholesale Drug Distributors. He also expressed his appreciation to everyone for their service on Task Force.

Lovecchio also offered comments on the Board's interest in medical device distribution and his history with the Board as an investigator for several years before becoming Executive Director.

II. Review of SR 177

George Lovecchio
Executive Director, LBDDD
Chairman, Task Force

Lovecco then referenced Senator Resolution 177 of the 2015 Louisiana Legislative Session which created the Task Force on Medical Device Distribution. A copy of the resolution was provided in the material set provided for Task Force members.

III. Facilitator Introduction – 9:35 AM

Rudy Gomez
Partner, SSA Consultants
Task Force Facilitator

Rudy Gomez, Partner with SSA Consultants, was introduced as the Task Force Facilitator. Gomez then provided a brief overview of SSA Consultants, the role of the facilitator, and the path of the Task Force moving forward.

Gomez also discussed the open meeting law compliance of the Task Force and the work plan for the day. He also addressed the material set provided to the Task Force members. (9:40 AM)

IV. Task Member Introductions & Opening Statements – 9:48 AM

Rudy Gomez
Partner, SSA Consultants
Task Force Facilitator

Each Task Force member was asked to introduce themselves and established a quorum with all Task Force members present at the meeting. Each Task Force member was also allowed to offer a brief opening statements.

Task Force Members Present:

1. Jacob Dickson - Designee for the LA House of Representatives
   Wholesale pharmaceutical company; on Board; passionate about health and citizen safety
2. Sue Fontenot - Designee for the LA Dept. of Health & Hospitals
   DHH pharmacy retail section; is a pharmacists and has worked in a variety of setting
3. Claire Defelice - Designee for LA Senate
   Supply OTC to oil and gas; does not like a lot of the regulations, looking for parity between the environments that ensures safety of citizens
4. George Lovecchio - Designee for LA Board for Drug and Device Distributors
   Promote the health and welfare of state of LA; maintain the supply chain integrity; open to studying recommendations and creating a safe, protective environment
5. John Crenshaw - Designee for AdvaMed
   With Johnson & Johnson; AdvaMed representative; 22 years of medical device and drug distributions; challenge is manage the process to ensure the safety for patient; appreciate the efficiency aspect; drug supply security act - feeling pressure, alignment between states and FDA; applaud LA for efforts to date

Others Present:

- Rudy Gomez - SSA Consultants (facilitator)
- Anita Byrne - SSA Consultants
- Landon Corbin - SSA Consultants

V. Review of Material Set

Rudy Gomez
Partner, SSA Consultants
Task Force Facilitator

NOTE: previously discussed agenda item

VI. Discussion of Task Force Work Plan – 10:00 AM Rudy Gomez
Partner, SSA Consultants
Task Force Facilitator

Task Force members participated in a discussion regarding the Task Force, their legislative charge, and their work plan. Key highlights of discussion include:

- Distribution is not dispensing; dispensing done to a patient or administrated by a professional; Distribution occurs to other than the patient or consumer
    - This is about distribution
- Written as medical devices but should say legend devices (do not regulate non-legend devices, like a wheelchair)
- Clarity sake - limited to the three descriptors (labels) legend: product dealing with legends (This was agreed upon by the Task Force.)
- Clarity sake - focus is on the legend device, not drug (This was agreed upon by the Task Force.)
- Combination products interesting topic to discuss - especially for those who handle both; two licensees vs one
- Two key elements - Inspection process (This is where they enforce the law); Has several examples of when there are not regulations in place - balance of regulation, policy
- Who does the licensing structure applies to? Would like the Task Force to look at the clarity of language, particularly in the orthopedic realm.
    - Includes statutory and regulations
- Why is the manufacturing not covered in Louisiana by LBDDD?
    - In Louisiana, under the FDA regulation and Louisiana covers the dispensing piece
    - Clarity around the various roles to help people understand
- Clarity of roles is important and understanding roles will help the Task Force make recommendations to the Medical Device Distribution; need to ensure the health and safety of Louisiana citizens while allowing for free enterprise
- Request from Task Force member to see LBDDD inspections sheet and receive a copy of referenced federal regulations in the Chapter 37 page 5; Also a question: Who is handling the manufacturing side inspections?
- The LBDDD Executive Director George Lovecchio holds an FDA commission and is authorized on behalf of FDA. He sees the FDA looking more to the states to help fill the gap.
- The movement from manufacturing have to maintain the annual registration; FDA does the intrastate and international regulation
- How does the LA Board of Pharmacy handle the out of state pharmacy piece?
    - Industry anticipates the next release of information in November on the federal level
    - FDA has the only real heavy arm - adverse event for the medical device reported to FDA and LA Board

  - Looking for clarity around terms and connectivity between the FDA and licensee board
- Explanation of a closed circle of distribution
  - Manufacturing at the top of the circle
  - About supply chain integrity/safety
  - Distributor
  - Pharmacy
  - Can be a very complicated with five or six different people touching the product before getting to the patient
  - Have to ensure the manufacturing side and the retail licensed
- Federal law allows states to regulate - uniformity act
- LA Board of Pharmacy regulating internet pharmacy
- Working with LA State Board of Medical Examiners to address those settings where using legend devices in non-medical setting
- How many devices go through closed circle vs. direct to patient?
- UDI and 21st CURES - is where the federal level is moving
  - Would like see more information about these new federal legislative pieces; thinks will strengthen the supply chain as a whole; huge data interchange
- Clarity on language around agent of the company especially in the orthopedic realm, particularly around the time sensitive surgical needs (like a trauma set)
- LBDDD does have an exemption for emergency
- Impact on the Board: Do they have the ability to handle increase in volume? Keep infrastructure flowing, getting licensees out

VII. Next Steps

Rudy Gomez
Partner, SSA Consultants
Task Force Facilitator

Gomez led the Task Force through a discussion of the next steps for the Task Force.

- Presentations in a six-hour day scheduled roughly a month from now in late September/early October
  - With a second date for deliberations to use if necessary to maximize travel time for Task Force members
  - With focus on comparative nature; recommendations to changes in Louisiana
  - Discuss and create preliminary recommendations
- Will have to meet a third time to approve the report
- The Task Force was also introduced to Kim Barbier who is with the LBDDD.

VIII. Adjournment – 11:35 AM

George Lovecchio
Executive Director, LBDDD
Chairman, Task Force

The Task Force was adjourned by George Lovecchio.

ABOUT THE TASK FORCE ON MEDICAL DEVICE DISTRIBUTION

Senate Resolution (SR) 177 of the 2015 Louisiana Legislative Session created the Task Force on Medical Device Distribution "to review existing regulation and propose revisions of regulations and the elimination of duplicate regulations while remaining focused on the protection of the health and safety of Louisiana citizens."

TASK FORCE ON MEDICAL DEVICE DISTRIBUTION

SEPTEMBER 28, 2015 · MEETING AGENDA

Meeting Location:
Louisiana Board of Drug and Device Distribution
12091 Bricksome Avenue, Suite B
Baton Rouge, LA 70816

Meeting Time:
9:30 AM to 4:00 PM

AGENDA ITEMS

I.	Welcome	George Lovecchio Executive Director, LBDDD Chairman, Task Force
II.	Agenda Review	Rudy Gomez Partner, SSA Consultants Task Force Facilitator
III.	Presentation	John Crenshaw Director, U.S. Distribution Johnson & Johnson Health Care Systems Inc. Task Force Member
IV.	Lunch *(provided)*	11:30 AM to 12:30 PM
V.	Presentation	George Lovecchio Executive Director, LBDDD Chairman, Task Force Trion Horgan Branch Operations Manager Stryker Orthopaedics Claire Defelice Medi-Chest, Inc. Task Force Member
VI.	Next Steps	Rudy Gomez Partner, SSA Consultants Task Force Facilitator
VII.	Adjournment	George Lovecchio Executive Director, LBDDD Chairman, Task Force

Task Force on Medical Device Distribution

SEPTEMBER 28, 2015

1

Agenda

I. Welcome
II. Agenda Review
III. Presentation I
IV. Lunch *(provided)*
V. Presentation II
VI. Next Steps
VII. Adjournment

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Task Force Minutes

- Approval of August 31, 2015 Task Force Meeting Minutes

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Presentation I

Presented by:

John Crenshaw
Director, U.S. Distribution
Johnson & Johnson Health Care Systems Inc.
Task Force Member

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Areas to Review

- What is a Device?
- Current FDA processes for Device providers
- Initiatives and Regulation for Medical Devices
  - UDI
  - 21st Century cures
  - DQSA (Drug Quality & Security Act)

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Empowerment the FDA for Medical Devices

- (FCA) Federal Food Drug & Cosmetic Act
- (CDRH) FDA Center for Devices & Radiological Health
- (CFR)Code of Federal Regulations
- Title 21 CFR Parts 800-1299

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What is a Device?

"An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- Intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

This definition provides a clear distinction between a medical device and other FDA regulated products such as drugs. If the primary intended use of the product is achieved through chemical action or by being metabolized by the body, the product is usually a drug.

- Human drugs are regulated by FDA's Center for Drug Evaluation and Research (CDER).
- Biological products which include blood and blood products, and blood banking equipment are regulated by FDA's Center for Biologics Evaluation and Research (CBER).
- FDA's (CVM) regulates products used with animals.

Source: http://www.fda.gov/AboutFDA/Transparency/Basics/ucm211822.htm 7

Device Classification?

- The MDA (Medical Device Amendment) directed FDA to issue regulations that classify all devices that were in commercial distribution at that time into one of three regulatory control categories:
  - Class I, II, or III, depending upon the degree of regulation necessary to provide reasonable assurance of their safety and effectiveness.
  - The class into which a device is placed determines the requirements that a medical device manufacturer must meet prior to distributing a device in interstate commerce.

Source: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284443.pdf 8

Process Approval

- Depending on the classification of an item, various levels of approval are required before products can legally come to market.
- Organizations planning to manufacturer and /or sell medical device products in or to the USA must to register all products with the FDA. Requirements build depending on level of product complexity and associated risk addressed by the device.

Class I Medical Device?

- Class I devices are deemed to be low risk and are therefore subject to the least regulatory controls
- Medical devices classified as type I must follow general FDA policy which includes registering the medical device, proper branding and labeling, proper manufacturing techniques and the FDA must be notified prior to marketing the device.
- Class I Medical Devices include tongue depressors, elastic bandages, hand held dental instruments and examination gloves.

Class II Medical Device?

- Class II devices are higher risk devices than Class I and require greater regulatory controls to provide reasonable assurance of the device's safety and effectiveness.
- Medical devices classified as type II must follow policy and special labeling requirements, mandatory performance specification and post market surveillance.
- Most medical devices fall into the Class II medical devices category such as hearing aids, condoms, X-ray machines, powered wheelchairs, infusion pump and surgical acupuncture needles.

Class III Medical Device?

- Class III devices are generally the highest risk devices and are therefore subject to the highest level of regulatory control.
- Class III Medical Devices must follow other classes guidelines but must also have pre-market approval by the FDA and a full scientific review of the medical device must be made prior to marketing.
- Class III medical devices are critical to support human life
- Class III Medical Devices include implanted pacemakers, heart valves and implanted cerebral simulators.

Source: http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194438.htm; http://www.litron.com/Classification-of-Medical-Devices.asp http://http://www.fda.gov/MedicalDevices/ResourcesforYou/Consumers/ ucm142523.htm; http://http://en.wikipedia.org/wiki/Medical_device

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510K Clearance to Market

The majority of Class II medical devices are cleared to market by submission and FDA review of a 510(k) Pre-Market Notification submission. The 510(k) submission identifies characteristics of the new or modified medical device as compared to a medical device with similar intended use, currently legally marketed in the United States. The currently legally marketed device is referred to as the "predicate" device.

The information required in a 510(k) submission is defined 21 CFR 807.87. A 510(k) submission includes:

- Device trade or proprietary name, common or usual name or classification, Class of the device (Class I, II, III)
- Submitter's name and address, Contact person, telephone number and fax number, Representative/Consultant if applicable
- Name and address of manufacturing/packaging/sterilization facilities, Registration number of each manufacturing facility
- Action taken to comply with the requirements of the Special Controls.
- Proposed labels, labeling, and advertisements to describe the device, its intended use, and the directions for its use.
- 510(k) summary or a 510(k) statement.
- For Class III medical device, a Class III certification and a Class III summary.
- Photographs of the device, Engineering drawings of the device.
- Identification of the marketed device(s) to which equivalence is claimed including labeling and description of the medical device.
- Statement of similarities and/or differences with marketed device(s)
- Data to show consequences and effects of a modified device, performance Data (bench, animal, clinical)
- Sterilization information (as applicable)
- Software development, verification and validation information
- Hardware design and development information
- Information requested in specific guidance documents (as applicable)
- Kit Certification Statement (for a 510(k) submission with kit components only)
- Truthful and Accurate Statement

Source: www.fda.gov/howtomarketyourdevice/premarketsubmissions/premarketnotification510k/default.htm

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Pre-Market Approval Process

Steps in the PMA Application Process

- ODE filing review
- OSB statistical review for filing
- OC review of manufacturing information for compliance with the Quality System regulation (21 CFR 820).
- PMA filing decision
- Day-100 Meeting
- Quality System Inspection(s) by the FDA field personnel. An FDA manufacturing inspection is conducted for all original PMAs and may be conducted for PMA supplements requesting approval of alternate or additional manufacturing and sterilization facilities.
- Bioresearch Monitoring (BIMO) Audit (audit of clinical study data)
- Substantive review coordination and completion in areas such as:
  - Preparation of FDA Summary of Safety and Effectiveness Data (SSED)
  - Nonclinical Studies
    [Microbiological, Toxicological, Immunological, Biocompatibility, Shelf Life, Analytical (for IVDs), Animal, Engineering (Stress, Wear, Fatigue, etc.)]
  - Clinical Studies
  - Panel Meeting Decision and Mailing (if panel meeting is appropriate)
  - Panel Date (if appropriate)
  - Transcripts Received, Reviewed and Placed in Administrative Record
  - QS/GMP Clearance
  - Final Response from OC for GMP/BIMO
  - Final ODE Decision Memo
  - Approval Package
  - Approval Order, SSED, Final Draft Labeling

Source:http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm047991.htm#overview

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FDA Control & Enforcement

- Establishment of registration and approved product listing
- Marketing clearance & approvals
- Reports & Inspections
- Notices of Violations (FDA 483, Warning Letters, etc.)
- Product Recalls
- Penalties (Punitive civil)
- Product & facility Seizure
- Operational Injunctions
- Criminal Prosecution

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FDA Onsite Inspections

- The FDA conducts inspections of medical device manufacturers to check that they are complying with medical device regulatory requirements. When a medical device manufacturer fails to comply with these requirements, the FDA responds with tools that include warning letters and recalls. In most cases, a company (manufacturer, distributor, or other responsible party) will take voluntary action to correct the violations identified by the FDA.
- The CDRH Inspections Database provides information about FDA medical device inspections from 2008 to the present. The database contains information about the firms, types of devices and inspections, and links to warning letters (when available).
- Each year, the FDA conducts inspections of medical device manufacturers to assess compliance with regulatory requirements, including the Quality System regulation. These inspections can result in the issuance of document known as a "Form 483," named for the form on which the investigator records any observations.
- After an inspection, FDA staff reviews the Form 483 and decides whether agency action is needed to assure correction of the cited violations.
- In the interest of supporting better quality medical devices and communication with industry, the FDA is providing data related quality system observations over past 5 years.

Source:http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm199911.htm

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UDI (Unique Device Identifier)

FDA is establishing a unique device identification system to adequately identify medical devices through their distribution and use. When fully implemented, the label of most devices will include a unique device identifier (UDI) in human- and machine-readable form. Device labelers must also submit certain information about each device to FDA's Global Unique Device Identification Database (GUDID).

A unique device identifier (UDI) on a device label appears in both plain text and in machine-readable format. Below is an example of a unique device identifier (UDI) from GS1, one of the FDA-accredited issuing agencies. It uses a 1D barcode for its machine-readable format.

(01)12345678901234(17)140102(11)100102(10)A1234(21)1234

Human Readable Barcode: (01)12345678901234(17)140102(11)100102(10)A1234(21)1234

In GS1's system, the numbers in the parentheses indicate the different parts of the UDI.
Device Identifier (DI) - 12345678901234

Production Identifiers (PI):
- Expiration Date: 140102
- Manufacturing Date: 100102
- Lot Number: A1234
- Serial Number: 1234

Source: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm

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UDI Timeline

Compliance Date	Requirement
1 year after publication of the final rule (September 24, 2014)	The labels and packages of class III medical devices and devices licensed under the Public Health Service Act (PHS Act) must bear a UDI. § 801.20. Dates on the labels of these devices must be formatted as required by § 801.18. Data for these devices must be submitted to the GUDID database. § 830.300. A 1-year extension of this compliance date may be requested under § 801.55; such a request must be submitted no later than June 23, 2014. Class III stand-alone software must provide its UDI as required by § 801.50(b).
2 years after publication of the final rule (September 24, 2015)	The labels and packages of implantable, life-supporting, and life-sustaining devices must bear a UDI. § 801.20. Dates on the labels of these devices must be formatted as required by § 801.18.
	A device that is a life-supporting or life-sustaining device that is required to be labeled with a UDI must a bear UDI as a permanent marking on the device itself if the device is intended to be used more than once and intended to be reprocessed before each use. § 801.45. Stand-alone software that is a life-supporting or life-sustaining device must provide its UDI as required by § 801.50(b).
	Data for implantable, life-supporting, and life-sustaining devices that are required to be labeled with a UDI must be submitted to the GUDID database. § 830.300.
3 years after publication of the final rule (September 24, 2016)	Class III devices required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use. § 801.45.
	The labels and packages of class II medical devices must bear a UDI. § 801.20. Dates on the labels of these devices must be formatted as required by § 801.18. Class II stand-alone software must provide its UDI as required by § 801.50(b).
5 years after publication of the final rule (September 24, 2018)	A class II device that is required to be labeled with a UDI must bear a UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use. § 801.45.
	The labels and packages of class I medical devices and devices that have not been classified into class I, class II, or class III must bear a UDI. § 801.20. Dates on the labels of all devices, including devices that have been excepted from UDI labeling requirements, must be formatted as required by § 801.18.
	Data for class I devices and devices that have not been classified into class I, class II, or class III that are required to be labeled with a UDI must be submitted to the GUDID database. § 830.300. Class I stand-alone software must provide its UDI as required by § 801.50(b).
7 years after publication of the final rule (September 24, 2020)	Class I devices, and devices that have not been classified into class I, class II, or class III that are required to be labeled with a UDI, must a bear UDI as a permanent marking on the device itself if the device is a device intended to be used more than once and intended to be reprocessed before each use. § 801.45.

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The 21st Century Cures Act (HR 6)

Help and Hope for Patients Through Biomedical Innovation (Passed the House by a vote of 344-77 on July 10, 2015) The pace of scientific advancement over the past two decades, including the mapping of the human genome, has been impressive, giving us a myriad of genetic clues about the underpinnings of disease. Translating these discoveries into new treatments for patients, however, has proven to be difficult. HR 6 accelerates the discovery, development and delivery of life saving and life improving therapies, and transforms the quest for faster cures by:

- Removing barriers to increased research collaboration.
- Incorporating the patient perspective into the drug development and regulatory review process.
- Measuring success and identifying diseases earlier through personalized medicine.
- Modernizing clinical trials. Personalized medicine allows researchers to design more targeted clinical trials that can produce results faster and cheaper.
- Removing regulatory uncertainty for the development of new medical apps.
- Providing new incentives for the development of drugs for rare diseases.
- Helping the entire biomedical ecosystem coordinate more efficiently to find faster cures.
- Investing in 21st century science and next generation investigators.
- HR 6 helps keep and create jobs here at home. HR 6 is not only a patients bill; it is a jobs bill
- HR 6 reduces the deficit by over $500 million.

Source: http://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/114/Cures2015FACTSHEET.pdf 16

DQSA (Drug Quality Security Act)

Overview of the Drug Supply Chain Security Act

- The Drug Supply Chain Security Act (DSCSA) is contained within the Drug Quality and Security Act (DQSA).
- The DQSA was the name of the overall act that was enacted as a single entity, but it is really a packaging of two different acts,
- Title I is the ***Compounding Quality Act***
- Title II is the **Drug Supply Chain Security Act**.
- The DSCSA has some similarities to some of the existing state to state pedigree laws that preceded it, but it is also a big departure as it covers the entire United States and because it will be overseen by the FDA. All drug manufacturers, repackagers, wholesale distributors, third-party logistics providers and dispers must conform to the law nationwide. Also federal standards for licensing and reporting will be established.

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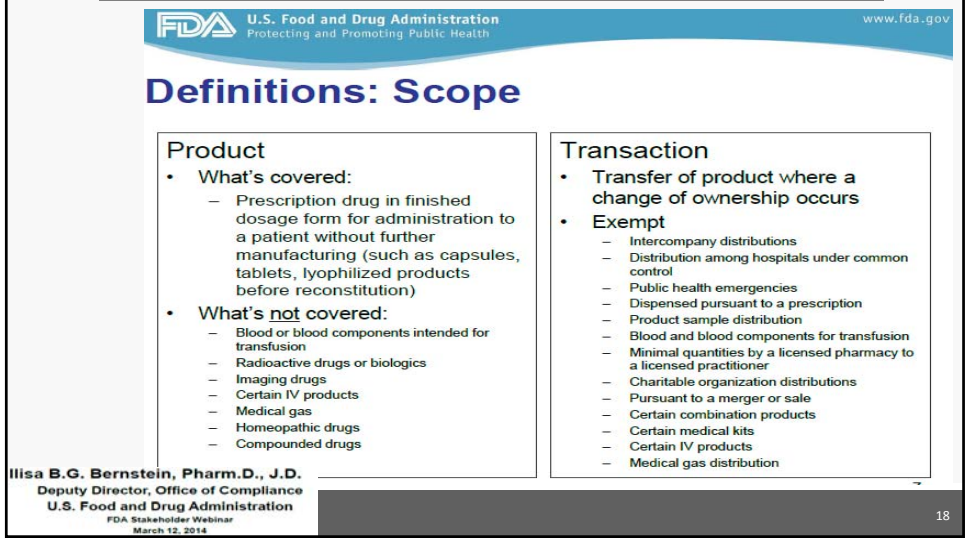
DQSA (Drug Quality Supply Act)



Ilisa B.G. Bernstein, Pharm.D., J.D.
Deputy Director, Office of Compliance
U.S. Food and Drug Administration
FDA Stakeholder Webinar
March 12, 2014

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DSCSA (Drug Supply Chain Security Act)

Lunch

Provided by Louisiana Board of Drug and Device Distributors

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Presentation II

Presented by:

George Lovecchio
Executive Director, LBDDD
Chairman, Task Force

See Material Set

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Orthopedic Distribution Models

TRION HORGAN
OPERATIONS MANAGER
STRYKER ORTHOPAEDICS LOUISIANA

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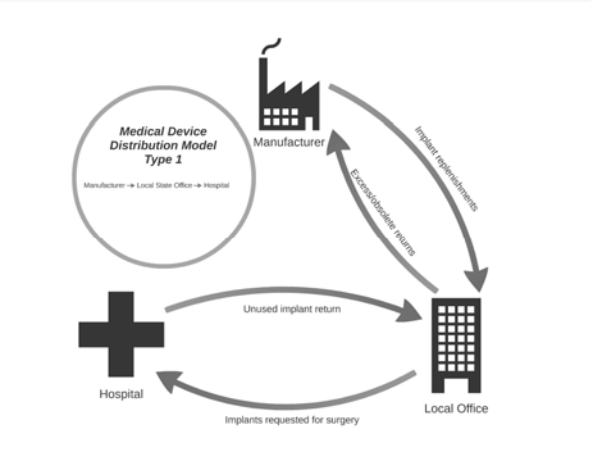
Medical Device Distribution Type 1



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Manufacturer → Local State Office

- Shipments are sent via FedEx with tracking
  - Local office tracks and confirms all inbound shipments arrive; keeps record of all outbound
  - Manufacturing facility is exempt from needing a license since shipments are sent intra-company to local office licensed with state

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Local State Office → Hospital

- Local State Office procedure flow:
  - Local rep books case using handheld app linked to warehouse management system
  - Distribution team receives implant preferences for case; pulls implant kits; assigns to case
  - Implants kits are delivered in company van to local facility and shown as shipped in warehouse management system
  - Sales rep covers the case, reports usage in app; customer service team processes replenishment order to ship with next-day delivery
  - Implant kits are retrieved from hospital, checked in using RFID and refilled in preparation for next case
  - All policies and procedures created by Stryker QMS for field traceability are in compliance with FDA 21CFR - part 820

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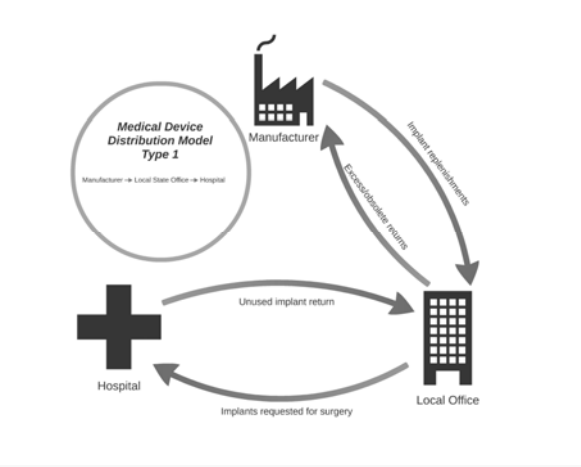
Conclusion/Q&A



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Presentation II

Presented by:

George Lovecchio
Executive Director, LBDDD
Chairman, Task Force

See Material Set

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Inspection Guidelines

CLAIRE DEFELICE

MEDI-CHEST, INC.

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ARE YOU READY FOR INSPECTION?

TEST INSPECTION - CHECKLIST

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Test Inspection – Checklist

- ❑ Current LBWDD license displayed [46:XCI.301.E] *(not for initial (new) applications)*
- ❑ Has off-site storage facility(s) [46:XCI.301.J]
- ❑ Facility is of suitable size and construction [46:XCI.309.A.1.a]
- ❑ Facility is clean and orderly [46:XCI.309.1.d]
- ❑ Facility is free from infestation by insects, rodents, birds, etc. [46:XCI.309.1.e]
- ❑ Storage area provides adequate: [46:XCI.309.1.b]
  - ❑ Lighting
  - ❑ Ventilation
  - ❑ Temperature
  - ❑ Sanitation
  - ❑ Humidity
  - ❑ Space
  - ❑ Equipment
  - ❑ Security

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Test Inspection – Checklist

- ❑ Storage area has a designated and clearly marked quarantine area [46:XCI.309.1.c]
- ❑ Storage facility has working monitored alarm system OR (medical gas only) is a Board-approved facility kept under lock and key [46:XCI.309.2.b/c]
- ❑ Medical gases stored on open dock area has a working monitored alarm system [46:XCI.309.2.d]
- ❑ Facility is equipped with working security system suitable for protection against theft or diversion of product and tampering with computer or electronic records [46:XCI.309.2.e]
- ❑ Drug or Device products are stored at appropriate temperature [46:XCI.309.3]
- ❑ Inventory records readily available for inspection [46:XCI.311.B/C]
- ❑ Perpetual inventories and records of all transactions for all drugs, devices, and/or medical gases are current [46:XCI.311.A]
- ❑ Temperature monitoring logs are maintained and current (excluding medical gases only) [46:XCI.309.A.3.b]
- ❑ Copies of customer licenses verifying authority to purchase drug products on file and current [46:XCI.311.D]
- ❑ Has verified all suppliers are licensed by LBWDD [46:XCI.311.F]

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Test Inspection – Checklist

- ❑ Has established and maintains policies and procedures covering: [46:XCI.313]
  - ❑ Receipt of drug, devices, and/or medical gases
  - ❑ Storage
  - ❑ Inventory and distribution
  - ❑ Correction of inventory errors and inaccuracy
  - ❑ Inspection of all incoming & outgoing shipments [45:XCI.309.A.4]
  - ❑ Product rotation
  - ❑ Recalls and withdrawals
  - ❑ Out-dated product segregation
  - ❑ Product returns or destruction [45:XCI.309.A.5]
  - ❑ Reporting of loss and theft
  - ❑ Security and crisis handling
  - ❑ Validation of customer licenses [46:XCI.311.D]
  - ❑ Notification of theft & diversions; findings of contraband, counterfeit or misbranded drugs
  - ❑ Verification of suppliers [46:XCI.311.F]
  - ❑ Review of excessive or suspicious purchases
  - ❑ Monitoring & recording of storage temperatures [46:XCI.309.A.3]

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Test Inspection – Checklist

- ❑ Has current list of responsible persons – owners, officers, directors, and responsible party [46:XCI.315]
  - ❑ List of employees with access to product
  - ❑ List of employees with access to building after hours
  - ❑ Facilities handling controlled substances = [46:XCI.317.2]
  - ❑ Has current CDS registration *Not Applicable*
  - ❑ Has current DEA registration *Not Applicable*

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Conclusion

- To my knowledge there are no duplicated State and Federal Regulations.
- The FDA focuses more on quality control and the State focuses more on how the product is handled after being packaged by the manufacturer and keeping the supply chain safe.

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Presentation II

Presented by:

George Lovecchio
Executive Director, LBDDD
Chairman, Task Force

See Material Set

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Next Steps

- Task Force Meeting #3 September 29, 2015 (tomorrow)
- LBDDD Office
- 9:30 AM to Noon

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Adjournment

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License Types

- Currently have one license
- Product Types:
    - Legend Drugs, Controlled Dangerous Substances, Legend Devices, Medical Gas
- By the Numbers:
    - 2193 Active
        - 850 Manufacturers LD\DV
            - 499 Legend Drug
            - 464 Legend Device
            - 350 Legend Device w/o Legend Drugs
            - 385 Legend Drug w/o Legend Device
            - 114 Legend Drug and Legend Device
- LOUISIANA
    - 239 Active
        - 12 Manufacturers LD\DV
            - 9 Legend Drug
            - 3 Legend Device
            - 3 Legend Device w/o Legend Drugs
            - 9 Legend Drug w/o Legend Device
            - 0 Legend Drug and Legend Device
- We recently received approval from the Louisiana Legislators on July 1, 2015, for license types.
- Rule promulgation expected 2015-2016.

Budget Issues License Impact

- 2193 Active $657,900.00
    - 850 Manufacturers LD\DV $255,000.00
        - 499 Legend Drug $149,700.00
        - 464 Legend Device $139,200.00
        - 350 Legend Device w/o Legend Drugs $105,000.00
        - 385 Legend Drug w/o Legend Device $115,500.00
        - 114 Legend Drug and Legend Device $ 34,200.00
- LOUISIANA
    - 239 Active $ 71,700.00
        - 12 Manufacturers LD\DV
            - 9 Legend Drug
            - 3 Legend Device
            - 3 Legend Device w/o Legend Drugs
            - 9 Legend Drug w/o Legend Device
            - 0 Legend Drug and Legend Device
- License impact
- Approval time
    - Six to eight week wait for background check (in-state only)
    - Should improve with technology.
    - We have recommended to FDA that background checks should be home state only
    - Responsibility
- We have not expanded any authority
- License type
- Emergency access

Orthopedic Distribution Models

- **Type 1:** Manufacturer → Manufacturer Location → Hospital
  - Manufacture is exempt under Louisiana Law
    - §105. Wholesale Drug Distribution
      Exemptions A. Wholesale drug distribution does not include:
      1. intra-company sales to licensed wholesale drug distributors physically located in Louisiana;
  - Manufacturer location would be licensed
  - Hospital is licensed

ORTHOPEDIC DISTRIBUTION MODELS INFORMATION
Trion Horgan
Operations Manager
Stryker Orthopaedics Louisiana

- **Type 2:** Manufacturer → Agent/Broker → Hospital
  - Manufacturer is licensed
  - Agent/Broker is licensed
  - Hospital is licensed
- **Type 3:** Manufacturer → Hospital
  - Manufacturer is licensed
  - Hospital is licensed

State Inspection Process

- LDDD Sample Inspection Checklist provided in material set

INSPECTION GUIDELINES INFORMATION
Claire Defelice
Medi-Chest, Inc.

NABP Certifications (Third Party Accreditation)

- National Association of Boards of Pharmacy (NABP)
  - Verified-Accredited Wholesale Distributors (VAWD)
  - Three states require VAWD: Indiana, North Dakota, and Wyoming
  - VAWD Fees
    - Application fee: $1,500
    - Survey fee: $3,000
    - Annual participation fee (year 1): $1,000
    - Year 1 subtotal: $5,500
    - Annual participation fee (year 2): $1,000
    - Annual participation fee (year 3): $1,000
    - Estimated total for three-year accreditation: $7,500

State vs Federal Regulation

- See material set for “Comparison and Gap Analysis of Federal and State Regulatory Authority Related to Supply Chain Integrity of Medical Device Distributors”, Charles C. Lewis, B.S. Pharm, R.Ph., MBA with Jasos Group, LLC, August 2015.
    - Comparison and Gap Analysis of Federal and State Regulatory Authority
    - Related to Supply Chain Integrity of Medical Device Distributors

LOUISIANA BOARD OF WHOLESALE DRUG DISTRIBUTORS

12091 Bricksome Avenue, Suite B, Baton Rouge, LA 70816
(225)295-8567 (225)295-8568 Lsbwdd@Lsbwdd.org www.Lsbwdd.org

License #: «License_Number» Inspection Date:

Licensed Facility Name: «Company_Name» «DBA» «CO»

Facility Address: «Physical_Address», «Physical_City», «Physical_State» «Physical_Zip»

Product: «LD» LD «CS» CS «DV» DV «DV1» MG

Facility Contact: «Facility_Contact» Telephone: «Facility_Phone»

Date of Last Inspection: «Last_Ins»(#«Ins»)

Designated Responsible Party «DRP_Contact»

Facility Changes Since Last Inspection? YES NO

Outstanding Violations? YES NO

Previous Thefts or Losses of Product? YES NO

	YES	NO	Comments:
1. Current LBWDD license displayed [46:XCI.301.E]			
2. Has off-site storage facility(s) [46:XCI.301.J]			
3. Facility is of suitable size and Construction [46:XCI.309.A.1.a]			
4. Facility is clean and orderly [46:XCI.309.1.d]			
5. Facility is free from infestation by insects, rodents, birds, etc. [46:XCI.309.1.e]			
6. Storage area provides adequate: [46:XCI.309.1.b]			
a. Lighting			
b. Ventilation			
c. Temperature			
d. Sanitation			
e. Humidity			
f. Space			
g. Equipment			
h. Security			
7. Storage area has a designated and clearly marked quarantine area [46:XCI.309.1.c]			
8. Storage facility has working monitored alarm system OR (medical gas only) is a Board-approved facility kept under lock and key [46:XCI.309.2.b/c]			
9. Medical gases stored on open dock area hasa working monitored alarm system [46:XCI.309.2.d]			
10. Facility is equipped with working security system suitable for protection against theft or diversion of product and tampering with computer or electronic records [46:XCI.309.2.e]			
11. Drug or Device products are stored at Appropriate temperature [46:XCI.309.3]			
12. Inventory records readily available for inspection [46:XCI.311.B/C]			

SAMPLE

LOUISIANA BOARD OF WHOLESALE DRUG DISTRIBUTORS
12091 Bricksome Avenue, Suite B, Baton Rouge, LA 70816
(225)295-8567 (225)295-8568 Lsbwdd@Lsbwdd.org www.Lsbwdd.org

License #: «License_Number» Inspection Date:

Licensed Facility Name: «Company_Name» «DBA» «co»

	YES	NO	Comments:
13. Perpetual inventories and records of all Transactions for all drugs, devices, and/ or medical gases are current [46:XCI.311.A]			
14. Temperature monitoring logs are maintained and current (excluding medical gases only) [46:XCI.309.A.3.b]			
15. Copies of customer licenses verifying authority to purchase drug products on file and current [46:XCI.311.D]			
16. Has verified all suppliers are licensed by LBWDD [46:XCI.311.F]			
17. Has established and maintains policies and procedures covering: [46:XCI.313]			
a. Receipt of drug, devices, and/or medical gases			
b. Storage			
c. Inventory and distribution			
d. Correction of inventory errors and inaccuracy			
e. Inspection of all incoming & outgoing shipments [45:XCI.309.A.4]			
f. Product rotation			
g. Recalls and withdrawals			
h. Out-dated product segregation			
i. Product returns or destruction [45:XCI.309.A.5]			
j. Reporting of loss and theft			
k. Security and crisis handling			
l. Validation of customer licenses [46:XCI.311.D]			
m. Notification of theft & diversions; findings of contraband, counterfeit or misbranded drugs			
n. Verification of suppliers [46:XCI.311.F]			
o. Review of excessive or suspicious purchases			
p. Monitoring & recording of storage temperatures [46:XCI.309.A.3]			
18. Has current list of responsible persons – owners, officers, directors, and responsible party [46:XCI.315]			
a. List of employees with access to product			
b. List of employees with access to building after hours			

SAMPLE

LOUISIANA BOARD OF WHOLESALE DRUG DISTRIBUTORS
12091 Bricksome Avenue, Suite B, Baton Rouge, LA 70816
(225)295-8567 (225)295-8568 Lsbwdd@Lsbwdd.org www.Lsbwdd.org

License #: «License_Number» Inspection Date:

Licensed Facility Name: «Company_Name» «DBA» «co»

	YES	NO	Comments:
19. Facilities handling controlled substances = [46:XCI.317.2]			
a. Has current CDS registration			
b. Has current DEA registration			

Notes:

The signature of licensee representative only validates that an inspection took place.

Licensee Representative: Inspected By:

Sample

H. R. 3204

One Hundred Thirteenth Congress of the United States of America

AT THE FIRST SESSION

Begun and held at the City of Washington on Thursday, the third day of January, two thousand and thirteen

An Act

To amend the Federal Food, Drug, and Cosmetic Act with respect to human drug compounding and drug supply chain security, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Drug Quality and Security Act".

SEC. 2. REFERENCES IN ACT; TABLE OF CONTENTS.

(a) REFERENCES IN ACT.—Except as otherwise specified, amendments made by this Act to a section or other provision of law are amendments to such section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

TITLE I—DRUG COMPOUNDING

SEC. 101. SHORT TITLE.

This Act may be cited as the "Compounding Quality Act".

SEC. 102. VOLUNTARY OUTSOURCING FACILITIES.

(a) IN GENERAL.—Subchapter A of chapter V (21 U.S.C. 351 et seq.) is amended—

(1) by redesignating section 503B as section 503C; and

(2) by inserting after section 503A the following new section:

"SEC. 503B. OUTSOURCING FACILITIES.

"(a) IN GENERAL.—Sections 502(f)(1), 505, and 582 shall not apply to a drug compounded by or under the direct supervision of a licensed pharmacist in a facility that elects to register as an outsourcing facility if each of the following conditions is met:

"(1) REGISTRATION AND REPORTING.—The drug is compounded in an outsourcing facility that is in compliance with the requirements of subsection (b).

"(2) BULK DRUG SUBSTANCES.—The drug is compounded in an outsourcing facility that does not compound using bulk drug substances (as defined in section 207.3(a)(4) of title 21, Code of Federal Regulations (or any successor regulation)), unless—

"(A)(i) the bulk drug substance appears on a list established by the Secretary identifying bulk drug substances for which there is a clinical need, by—

"(I) publishing a notice in the Federal Register proposing bulk drug substances to be included on the list, including the rationale for such proposal;

"(II) providing a period of not less than 60 calendar days for comment on the notice; and

"(III) publishing a notice in the Federal Register designating bulk drug substances for inclusion on the list; or

"(ii) the drug compounded from such bulk drug substance appears on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing;

"(B) if an applicable monograph exists under the United States Pharmacopeia, the National Formulary, or another compendium or pharmacopeia recognized by the Secretary for purposes of this paragraph, the bulk drug substances each comply with the monograph;

"(C) the bulk drug substances are each manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and

"(D) the bulk drug substances are each accompanied by a valid certificate of analysis.

"(3) INGREDIENTS (OTHER THAN BULK DRUG SUBSTANCES).—If any ingredients (other than bulk drug substances) are used in compounding the drug, such ingredients comply with the standards of the applicable United States Pharmacopeia or National Formulary monograph, if such monograph exists, or of another compendium or pharmacopeia recognized by the Secretary for purposes of this paragraph if any.

"(4) DRUGS WITHDRAWN OR REMOVED BECAUSE UNSAFE OR NOT EFFECTIVE.—The drug does not appear on a list published by the Secretary of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective.

"(5) ESSENTIALLY A COPY OF AN APPROVED DRUG.—The drug is not essentially a copy of one or more approved drugs.

"(6) DRUGS PRESENTING DEMONSTRABLE DIFFICULTIES FOR COMPOUNDING.—The drug—

"(A) is not identified (directly or as part of a category of drugs) on a list published by the Secretary, through the process described in subsection (c), of drugs or categories of drugs that present demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug or category of drugs, taking into account the risks and benefits to patients; or

"(B) is compounded in accordance with all applicable conditions identified on the list described in subparagraph (A) as conditions that are necessary to prevent the drug or category of drugs from presenting the demonstrable difficulties described in subparagraph (A).

"(7) ELEMENTS TO ASSURE SAFE USE.—In the case of a drug that is compounded from a drug that is the subject of a risk evaluation and mitigation strategy approved with elements to assure safe use pursuant to section 505–1, or from a bulk drug substance that is a component of such drug, the outsourcing facility demonstrates to the Secretary prior to beginning compounding that such facility will utilize controls comparable to the controls applicable under the relevant risk evaluation and mitigation strategy.

"(8) PROHIBITION ON WHOLESALING.—The drug will not be sold or transferred by an entity other than the outsourcing facility that compounded such drug. This paragraph does not prohibit administration of a drug in a health care setting or dispensing a drug pursuant to a prescription executed in accordance with section 503(b)(1).

"(9) FEES.—The drug is compounded in an outsourcing facility that has paid all fees owed by such facility pursuant to section 744K.

"(10) LABELING OF DRUGS.—

"(A) LABEL.—The label of the drug includes—

"(i) the statement 'This is a compounded drug.' or a reasonable comparable alternative statement (as specified by the Secretary) that prominently identifies the drug as a compounded drug;

"(ii) the name, address, and phone number of the applicable outsourcing facility; and

"(iii) with respect to the drug—

"(I) the lot or batch number;

"(II) the established name of the drug;

"(III) the dosage form and strength;

"(IV) the statement of quantity or volume, as appropriate;

"(V) the date that the drug was compounded;

"(VI) the expiration date;

"(VII) storage and handling instructions;

"(VIII) the National Drug Code number, if available;

"(IX) the statement 'Not for resale', and, if the drug is dispensed or distributed other than pursuant to a prescription for an individual identified patient, the statement 'Office Use Only'; and

"(X) subject to subparagraph (B)(i), a list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

"(B) CONTAINER.—The container from which the individual units of the drug are removed for dispensing or for administration (such as a plastic bag containing individual product syringes) shall include—

"(i) the information described under subparagraph (A)(iii)(X), if there is not space on the label for such information;

"(ii) the following information to facilitate adverse event reporting: www.fda.gov/medwatch and 1–800–FDA–1088 (or any successor Internet Web site or phone number); and

"(iii) directions for use, including, as appropriate, dosage and administration.

"(C) ADDITIONAL INFORMATION.—The label and labeling of the drug shall include any other information as determined necessary and specified in regulations promulgated by the Secretary.

"(11) OUTSOURCING FACILITY REQUIREMENT.—The drug is compounded in an outsourcing facility in which the compounding of drugs occurs only in accordance with this section.

"(b) REGISTRATION OF OUTSOURCING FACILITIES AND REPORTING OF DRUGS.—

"(1) REGISTRATION OF OUTSOURCING FACILITIES.—

"(A) ANNUAL REGISTRATION.—Upon electing and in order to become an outsourcing facility, and during the period beginning on October 1 and ending on December 31 of each year thereafter, a facility—

"(i) shall register with the Secretary its name, place of business, and unique facility identifier (which shall conform to the requirements for the unique facility identifier established under section 510), and a point of contact email address; and

"(ii) shall indicate whether the outsourcing facility intends to compound a drug that appears on the list in effect under section 506E during the subsequent calendar year.

"(B) AVAILABILITY OF REGISTRATION FOR INSPECTION; LIST.—

"(i) REGISTRATIONS.—The Secretary shall make available for inspection, to any person so requesting, any registration filed pursuant to this paragraph.

"(ii) LIST.—The Secretary shall make available on the public Internet Web site of the Food and Drug Administration a list of the name of each facility registered under this subsection as an outsourcing facility, the State in which each such facility is located, whether the facility compounds from bulk drug substances, and whether any such compounding from bulk drug substances is for sterile or nonsterile drugs.

"(2) DRUG REPORTING BY OUTSOURCING FACILITIES.—

"(A) IN GENERAL.—Upon initially registering as an outsourcing facility, once during the month of June of each

year, and once during the month of December of each year, each outsourcing facility that registers with the Secretary under paragraph (1) shall submit to the Secretary a report—

"(i) identifying the drugs compounded by such outsourcing facility during the previous 6-month period; and

"(ii) with respect to each drug identified under clause (i), providing the active ingredient, the source of such active ingredient, the National Drug Code number of the source drug or bulk active ingredient, if available, the strength of the active ingredient per unit, the dosage form and route of administration, the package description, the number of individual units produced, and the National Drug Code number of the final product, if assigned.

"(B) FORM.—Each report under subparagraph (A) shall be prepared in such form and manner as the Secretary may prescribe by regulation or guidance.

"(C) CONFIDENTIALITY.—Reports submitted under this paragraph shall be exempt from inspection under paragraph (1)(B)(i), unless the Secretary finds that such an exemption would be inconsistent with the protection of the public health.

"(3) ELECTRONIC REGISTRATION AND REPORTING.—Registrations and drug reporting under this subsection (including the submission of updated information) shall be submitted to the Secretary by electronic means unless the Secretary grants a request for waiver of such requirement because use of electronic means is not reasonable for the person requesting waiver.

"(4) RISK-BASED INSPECTION FREQUENCY.—

"(A) IN GENERAL.—Outsourcing facilities—

"(i) shall be subject to inspection pursuant to section 704; and

"(ii) shall not be eligible for the exemption under section 704(a)(2)(A).

"(B) RISK-BASED SCHEDULE.—The Secretary, acting through one or more officers or employees duly designated by the Secretary, shall inspect outsourcing facilities in accordance with a risk-based schedule established by the Secretary.

"(C) RISK FACTORS.—In establishing the risk-based schedule, the Secretary shall inspect outsourcing facilities according to the known safety risks of such outsourcing facilities, which shall be based on the following factors:

"(i) The compliance history of the outsourcing facility.

"(ii) The record, history, and nature of recalls linked to the outsourcing facility.

"(iii) The inherent risk of the drugs compounded at the outsourcing facility.

"(iv) The inspection frequency and history of the outsourcing facility, including whether the outsourcing facility has been inspected pursuant to section 704 within the last 4 years.

"(v) Whether the outsourcing facility has registered under this paragraph as an entity that intends to

compound a drug that appears on the list in effect under section 506E.

"(vi) Any other criteria deemed necessary and appropriate by the Secretary for purposes of allocating inspection resources.

"(5) ADVERSE EVENT REPORTING.—Outsourcing facilities shall submit adverse event reports to the Secretary in accordance with the content and format requirements established through guidance or regulation under section 310.305 of title 21, Code of Federal Regulations (or any successor regulations).

"(c) REGULATIONS.—

"(1) IN GENERAL.—The Secretary shall implement the list described in subsection (a)(6) through regulations.

"(2) ADVISORY COMMITTEE ON COMPOUNDING.—Before issuing regulations to implement subsection (a)(6), the Secretary shall convene and consult an advisory committee on compounding. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopeia, pharmacists with current experience and expertise in compounding, physicians with background and knowledge in compounding, and patient and public health advocacy organizations.

"(3) INTERIM LIST.—

"(A) IN GENERAL.—Before the effective date of the regulations finalized to implement subsection (a)(6), the Secretary may designate drugs, categories of drugs, or conditions as described such subsection by—

"(i) publishing a notice of such substances, drugs, categories of drugs, or conditions proposed for designation, including the rationale for such designation, in the Federal Register;

"(ii) providing a period of not less than 60 calendar days for comment on the notice; and

"(iii) publishing a notice in the Federal Register designating such drugs, categories of drugs, or conditions.

"(B) SUNSET OF NOTICE.—Any notice provided under subparagraph (A) shall not be effective after the earlier of—

"(i) the date that is 5 years after the date of enactment of the Compounding Quality Act; or

"(ii) the effective date of the final regulations issued to implement subsection (a)(6).

"(4) UPDATES.—The Secretary shall review, and update as necessary, the regulations containing the lists of drugs, categories of drugs, or conditions described in subsection (a)(6) regularly, but not less than once every 4 years. Nothing in the previous sentence prohibits submissions to the Secretary, before or during any 4-year period described in such sentence, requesting updates to such lists.

"(d) DEFINITIONS.—In this section:

"(1) The term 'compounding' includes the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug.

"(2) The term 'essentially a copy of an approved drug' means—

"(A) a drug that is identical or nearly identical to an approved drug, or a marketed drug not subject to section 503(b) and not subject to approval in an application submitted under section 505, unless, in the case of an approved drug, the drug appears on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing; or

"(B) a drug, a component of which is a bulk drug substance that is a component of an approved drug or a marketed drug that is not subject to section 503(b) and not subject to approval in an application submitted under section 505, unless there is a change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

"(3) The term 'approved drug' means a drug that is approved under section 505 and does not appear on the list described in subsection (a)(4) of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective.

"(4)(A) The term 'outsourcing facility' means a facility at one geographic location or address that—

"(i) is engaged in the compounding of sterile drugs;

"(ii) has elected to register as an outsourcing facility; and

"(iii) complies with all of the requirements of this section.

"(B) An outsourcing facility is not required to be a licensed pharmacy.

"(C) An outsourcing facility may or may not obtain prescriptions for identified individual patients.

"(5) The term 'sterile drug' means a drug that is intended for parenteral administration, an ophthalmic or oral inhalation drug in aqueous format, or a drug that is required to be sterile under Federal or State law.".

"(d) OBLIGATION TO PAY FEES.—Payment of the fee under section 744K, as described in subsection (a)(9), shall not relieve an outsourcing facility that is licensed as a pharmacy in any State that requires pharmacy licensing fees of its obligation to pay such State fees.".

(b) FEES.—Subchapter C of chapter VII (21 U.S.C. 379f et seq.) is amended by adding at the end the following:

"PART 9—FEES RELATING TO OUTSOURCING FACILITIES

"SEC. 744J. DEFINITIONS.

"In this part:

"(1) The term 'affiliate' has the meaning given such term in section 735(11).

"(2) The term 'gross annual sales' means the total worldwide gross annual sales, in United States dollars, for an outsourcing facility, including the sales of all the affiliates of the outsourcing facility.

"(3) The term 'outsourcing facility' has the meaning given to such term in section 503B(d)(4).

"(4) The term 'reinspection' means, with respect to an outsourcing facility, 1 or more inspections conducted under section 704 subsequent to an inspection conducted under such provision which identified noncompliance materially related to an applicable requirement of this Act, specifically to determine whether compliance has been achieved to the Secretary's satisfaction.

"SEC. 744K. AUTHORITY TO ASSESS AND USE OUTSOURCING FACILITY FEES.

"(a) ESTABLISHMENT AND REINSPECTION FEES.—

"(1) IN GENERAL.—For fiscal year 2015 and each subsequent fiscal year, the Secretary shall, in accordance with this subsection, assess and collect—

"(A) an annual establishment fee from each outsourcing facility; and

"(B) a reinspection fee from each outsourcing facility subject to a reinspection in such fiscal year.

"(2) MULTIPLE REINSPECTIONS.—An outsourcing facility subject to multiple reinspections in a fiscal year shall be subject to a reinspection fee for each reinspection.

"(b) ESTABLISHMENT AND REINSPECTION FEE SETTING.—The Secretary shall—

"(1) establish the amount of the establishment fee and reinspection fee to be collected under this section for each fiscal year based on the methodology described in subsection (c); and

"(2) publish such fee amounts in a Federal Register notice not later than 60 calendar days before the start of each such year.

"(c) AMOUNT OF ESTABLISHMENT FEE AND REINSPECTION FEE.—

"(1) IN GENERAL.—For each outsourcing facility in a fiscal year—

"(A) except as provided in paragraph (4), the amount of the annual establishment fee under subsection (b) shall be equal to the sum of—

"(i) $15,000, multiplied by the inflation adjustment factor described in paragraph (2); plus

"(ii) the small business adjustment factor described in paragraph (3); and

"(B) the amount of any reinspection fee (if applicable) under subsection (b) shall be equal to $15,000, multiplied by the inflation adjustment factor described in paragraph (2).

"(2) INFLATION ADJUSTMENT FACTOR.—

"(A) IN GENERAL.—For fiscal year 2015 and subsequent fiscal years, the fee amounts established in paragraph (1) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year by the amount equal to the sum of—

"(i) 1;

"(ii) the average annual percent change in the cost, per full-time equivalent position of the Food and Drug Administration, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and

benefits costs to total costs of an average full-time equivalent position of the Food and Drug Administration for the first 3 years of the preceding 4 fiscal years; plus

"(iii) the average annual percent change that occurred in the Consumer Price Index for urban consumers (U.S. City Average; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of an average full-time equivalent position of the Food and Drug Administration for the first 3 years of the preceding 4 fiscal years.

"(B) COMPOUNDED BASIS.—The adjustment made each fiscal year under subparagraph (A) shall be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2014 under subparagraph (A).

"(3) SMALL BUSINESS ADJUSTMENT FACTOR.—The small business adjustment factor described in this paragraph shall be an amount established by the Secretary for each fiscal year based on the Secretary's estimate of—

"(A) the number of small businesses that will pay a reduced establishment fee for such fiscal year; and

"(B) the adjustment to the establishment fee necessary to achieve total fees equaling the total fees that the Secretary would have collected if no entity qualified for the small business exception in paragraph (4).

"(4) EXCEPTION FOR SMALL BUSINESSES.—

"(A) IN GENERAL.—In the case of an outsourcing facility with gross annual sales of $1,000,000 or less in the 12 months ending April 1 of the fiscal year immediately preceding the fiscal year in which the fees under this section are assessed, the amount of the establishment fee under subsection (b) for a fiscal year shall be equal to \1/3\ of the amount calculated under paragraph (1)(A)(i) for such fiscal year.

"(B) APPLICATION.—To qualify for the exception under this paragraph, a small business shall submit to the Secretary a written request for such exception, in a format specified by the Secretary in guidance, certifying its gross annual sales for the 12 months ending April 1 of the fiscal year immediately preceding the fiscal year in which fees under this subsection are assessed. Any such application shall be submitted to the Secretary not later than April 30 of such immediately preceding fiscal year.

"(5) CREDITING OF FEES.—In establishing the small business adjustment factor under paragraph (3) for a fiscal year, the Secretary shall—

"(A) provide for the crediting of fees from the previous year to the next year if the Secretary overestimated the amount of the small business adjustment factor for such previous fiscal year; and

"(B) consider the need to account for any adjustment of fees and such other factors as the Secretary determines appropriate.

"(d) USE OF FEES.—The Secretary shall make all of the fees collected pursuant to subparagraphs (A) and (B) of subsection (a)(1) available solely to pay for the costs of oversight of outsourcing facilities.

"(e) SUPPLEMENT NOT SUPPLANT.—Funds received by the Secretary pursuant to this section shall be used to supplement and not supplant any other Federal funds available to carry out the activities described in this section.

"(f) CREDITING AND AVAILABILITY OF FEES.—Fees authorized under this section shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the purpose of paying the costs of oversight of outsourcing facilities.

"(g) COLLECTION OF FEES.—

"(1) ESTABLISHMENT FEE.—An outsourcing facility shall remit the establishment fee due under this section in a fiscal year when submitting a registration pursuant to section 503B(b) for such fiscal year.

"(2) REINSPECTION FEE.—The Secretary shall specify in the Federal Register notice described in subsection (b)(2) the manner in which reinspection fees assessed under this section shall be collected and the timeline for payment of such fees. Such a fee shall be collected after the Secretary has conducted a reinspection of the outsourcing facility involved.

"(3) EFFECT OF FAILURE TO PAY FEES.—

"(A) REGISTRATION.—An outsourcing facility shall not be considered registered under section 503B(b) in a fiscal year until the date that the outsourcing facility remits the establishment fee under this subsection for such fiscal year.

"(B) MISBRANDING.—All drugs manufactured, prepared, propagated, compounded, or processed by an outsourcing facility for which any establishment fee or reinspection fee has not been paid, as required by this section, shall be deemed misbranded under section 502 until the fees owed for such outsourcing facility under this section have been paid.

"(4) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under this section within 30 calendar days after it is due, such fee shall be treated as a claim of the United States Government subject to provisions of subchapter II of chapter 37 of title 31, United States Code.

"(h) ANNUAL REPORT TO CONGRESS.—Not later than 120 calendar days after each fiscal year in which fees are assessed and collected under this section, the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, to include a description of fees assessed and collected for such year, a summary description of entities paying the fees, a description of the hiring and placement of new staff, a description of the use of fee resources to support inspecting

outsourcing facilities, and the number of inspections and reinspections of such facilities performed each year.

"(i) AUTHORIZATION OF APPROPRIATIONS.—For fiscal year 2014 and each subsequent fiscal year, there is authorized to be appropriated for fees under this section an amount equivalent to the total amount of fees assessed for such fiscal year under this section.".

SEC. 103. PENALTIES.

(a) PROHIBITED ACTS.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

"(ccc)(1) The resale of a compounded drug that is labeled 'not for resale' in accordance with section 503B.

"(2) With respect to a drug to be compounded pursuant to section 503A or 503B, the intentional falsification of a prescription, as applicable.

"(3) The failure to report drugs or adverse events by an entity that is registered in accordance with subsection (b) of section 503B.".

(b) MISBRANDED DRUGS.—Section 502 (21 U.S.C. 352) is amended by adding at the end the following:

"(bb) If the advertising or promotion of a compounded drug is false or misleading in any particular.".

SEC. 104. REGULATIONS.

In promulgating any regulations to implement this title (and the amendments made by this title), the Secretary of Health and Human Services shall—

(1) issue a notice of proposed rulemaking that includes the proposed regulation;

(2) provide a period of not less than 60 calendar days for comments on the proposed regulation; and

(3) publish the final regulation not more than 18 months following publication of the proposed rule and not less than 30 calendar days before the effective date of such final regulation.

SEC. 105. ENHANCED COMMUNICATION.

(a) SUBMISSIONS FROM STATE BOARDS OF PHARMACY.—In a manner specified by the Secretary of Health and Human Services (referred to in this section as the "Secretary"), the Secretary shall receive submissions from State boards of pharmacy—

(1) describing actions taken against compounding pharmacies, as described in subsection (b); or

(2) expressing concerns that a compounding pharmacy may be acting contrary to section 503A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353a).

(b) CONTENT OF SUBMISSIONS FROM STATE BOARDS OF PHARMACY.—An action referred to in subsection (a)(1) is, with respect to a pharmacy that compounds drugs, any of the following:

(1) The issuance of a warning letter, or the imposition of sanctions or penalties, by a State for violations of a State's pharmacy regulations pertaining to compounding.

(2) The suspension or revocation of a State-issued pharmacy license or registration for violations of a State's pharmacy regulations pertaining to compounding.

(3) The recall of a compounded drug due to concerns relating to the quality or purity of such drug.

(c) CONSULTATION.—The Secretary shall implement subsection (a) in consultation with the National Association of Boards of Pharmacy.

(d) NOTIFYING STATE BOARDS OF PHARMACY.—The Secretary shall immediately notify State boards of pharmacy when—

(1) the Secretary receives a submission under subsection (a)(1); or

(2) the Secretary makes a determination that a pharmacy is acting contrary to section 503A of the Federal Food, Drug, and Cosmetic Act.

SEC. 106. SEVERABILITY.

(a) IN GENERAL.—Section 503A (21 U.S.C. 353a) is amended—

(1) in subsection (a), in the matter preceding paragraph (1), by striking "unsolicited";

(2) by striking subsection (c);

(3) by redesignating subsections (d) through (f) as subsections (c) through (e), respectively; and

(4) in subsection (b)(1)(A)(i)(III), by striking "subsection (d)" and inserting "subsection (c)".

(b) SEVERABILITY.—If any provision of this Act (including the amendments made by this Act) is declared unconstitutional, or the applicability of this Act (including the amendments made by this Act) to any person or circumstance is held invalid, the constitutionality of the remainder of this Act (including the amendments made by this Act) and the applicability thereof to other persons and circumstances shall not be affected.

SEC. 107. GAO STUDY.

(a) STUDY.—Not later than 36 months after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on pharmacy compounding and the adequacy of State and Federal efforts to assure the safety of compounded drugs.

(b) CONTENTS.—The report required under this section shall include—

(1) a review of pharmacy compounding in each State, and the settings in which such compounding occurs;

(2) a review of the State laws and policies governing pharmacy compounding, including enforcement of State laws and policies;

(3) an assessment of the available tools to permit purchasers of compounded drugs to determine the safety and quality of such drugs;

(4) an evaluation of the effectiveness of the communication among States and between States and the Food and Drug Administration regarding compounding; and

(5) an evaluation of the Food and Drug Administration's implementation of sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act.

TITLE II—DRUG SUPPLY CHAIN SECURITY

SEC. 201. SHORT TITLE.

This title may be cited as the "Drug Supply Chain Security Act".

SEC. 202. PHARMACEUTICAL DISTRIBUTION SUPPLY CHAIN.

Chapter V (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"Subchapter H—Pharmaceutical Distribution Supply Chain

"SEC. 581. DEFINITIONS.

"In this subchapter:

"(1) AFFILIATE.—The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—

"(A) one business entity controls, or has the power to control, the other business entity; or

"(B) a third party controls, or has the power to control, both of the business entities.

"(2) AUTHORIZED.—The term 'authorized' means—

"(A) in the case of a manufacturer or repackager, having a valid registration in accordance with section 510;

"(B) in the case of a wholesale distributor, having a valid license under State law or section 583, in accordance with section 582(a)(6), and complying with the licensure reporting requirements under section 503(e), as amended by the Drug Supply Chain Security Act;

"(C) in the case of a third-party logistics provider, having a valid license under State law or section 584(a)(1), in accordance with section 582(a)(7), and complying with the licensure reporting requirements under section 584(b); and

"(D) in the case of a dispenser, having a valid license under State law.

"(3) DISPENSER.—The term 'dispenser'—

"(A) means a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor; and

"(B) does not include a person who dispenses only products to be used in animals in accordance with section 512(a)(5).

"(4) DISPOSITION.—The term 'disposition', with respect to a product within the possession or control of an entity, means the removal of such product from the pharmaceutical distribution supply chain, which may include disposal or return of the product for disposal or other appropriate handling and other actions, such as retaining a sample of the product for further additional physical examination or laboratory analysis

of the product by a manufacturer or regulatory or law enforcement agency.

"(5) DISTRIBUTE OR DISTRIBUTION.—The term 'distribute' or 'distribution' means the sale, purchase, trade, delivery, handling, storage, or receipt of a product, and does not include the dispensing of a product pursuant to a prescription executed in accordance with section 503(b)(1) or the dispensing of a product approved under section 512(b).

"(6) EXCLUSIVE DISTRIBUTOR.—The term 'exclusive distributor' means the wholesale distributor that directly purchased the product from the manufacturer and is the sole distributor of that manufacturer's product to a subsequent repackager, wholesale distributor, or dispenser.

"(7) HOMOGENEOUS CASE.—The term 'homogeneous case' means a sealed case containing only product that has a single National Drug Code number belonging to a single lot.

"(8) ILLEGITIMATE PRODUCT.—The term 'illegitimate product' means a product for which credible evidence shows that the product—

"(A) is counterfeit, diverted, or stolen;

"(B) is intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

"(C) is the subject of a fraudulent transaction; or

"(D) appears otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death to humans.

"(9) LICENSED.—The term 'licensed' means—

"(A) in the case of a wholesale distributor, having a valid license in accordance with section 503(e) or section 582(a)(6), as applicable;

"(B) in the case of a third-party logistics provider, having a valid license in accordance with section 584(a) or section 582(a)(7), as applicable; and

"(C) in the case of a dispenser, having a valid license under State law.

"(10) MANUFACTURER.—The term 'manufacturer' means, with respect to a product—

"(A) a person that holds an application approved under section 505 or a license issued under section 351 of the Public Health Service Act for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product;

"(B) a co-licensed partner of the person described in subparagraph (A) that obtains the product directly from a person described in this subparagraph or subparagraph (A) or (C); or

"(C) an affiliate of a person described in subparagraph (A) or (B) that receives the product directly from a person described in this subparagraph or subparagraph (A) or (B).

"(11) PACKAGE.—

"(A) IN GENERAL.—The term 'package' means the smallest individual saleable unit of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser of such product.

"(B) INDIVIDUAL SALEABLE UNIT.—For purposes of this paragraph, an 'individual saleable unit' is the smallest container of product introduced into commerce by the manufacturer or repackager that is intended by the manufacturer or repackager for individual sale to a dispenser.

"(12) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug for human use subject to section 503(b)(1).

"(13) PRODUCT.—The term 'product' means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution), but for purposes of section 582, does not include blood or blood components intended for transfusion, radioactive drugs or radioactive biological products (as defined in section 600.3(ee) of title 21, Code of Federal Regulations) that are regulated by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021), imaging drugs, an intravenous product described in clause (xiv), (xv), or (xvi) of paragraph (24)(B), any medical gas (as defined in section 575), homeopathic drugs marketed in accordance with applicable guidance under this Act, or a drug compounded in compliance with section 503A or 503B.

"(14) PRODUCT IDENTIFIER.—The term 'product identifier' means a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product.

"(15) QUARANTINE.—The term 'quarantine' means the storage or identification of a product, to prevent distribution or transfer of the product, in a physically separate area clearly identified for such use or through other procedures.

"(16) REPACKAGER.—The term 'repackager' means a person who owns or operates an establishment that repacks and relabels a product or package for—

"(A) further sale; or

"(B) distribution without a further transaction.

"(17) RETURN.—The term 'return' means providing product to the authorized immediate trading partner from which such product was purchased or received, or to a returns processor or reverse logistics provider for handling of such product.

"(18) RETURNS PROCESSOR OR REVERSE LOGISTICS PROVIDER.—The term 'returns processor' or 'reverse logistics provider' means a person who owns or operates an establishment that dispositions or otherwise processes saleable or nonsaleable product received from an authorized trading partner such that the product may be processed for credit to the purchaser, manufacturer, or seller or disposed of for no further distribution.

"(19) SPECIFIC PATIENT NEED.—The term 'specific patient need' refers to the transfer of a product from one pharmacy to another to fill a prescription for an identified patient. Such term does not include the transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need.

"(20) STANDARDIZED NUMERICAL IDENTIFIER.—The term 'standardized numerical identifier' means a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters.

"(21) SUSPECT PRODUCT.—The term 'suspect product' means a product for which there is reason to believe that such product—

"(A) is potentially counterfeit, diverted, or stolen;

"(B) is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

"(C) is potentially the subject of a fraudulent transaction; or

"(D) appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

"(22) THIRD-PARTY LOGISTICS PROVIDER.—The term 'third-party logistics provider' means an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor have responsibility to direct the sale or disposition of the product.

"(23) TRADING PARTNER.—The term 'trading partner' means—

"(A) a manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct ownership of a product; or

"(B) a third-party logistics provider from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct possession of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct possession of a product.

"(24) TRANSACTION.—

"(A) IN GENERAL.—The term 'transaction' means the transfer of product between persons in which a change of ownership occurs.

"(B) EXEMPTIONS.—The term 'transaction' does not include—

"(i) intracompany distribution of any product between members of an affiliate or within a manufacturer;

"(ii) the distribution of a product among hospitals or other health care entities that are under common control;

"(iii) the distribution of a product for emergency medical reasons including a public health emergency declaration pursuant to section 319 of the Public Health Service Act, except that a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

"(iv) the dispensing of a product pursuant to a prescription executed in accordance with section 503(b)(1);

"(v) the distribution of product samples by a manufacturer or a licensed wholesale distributor in accordance with section 503(d);

"(vi) the distribution of blood or blood components intended for transfusion;

"(vii) the distribution of minimal quantities of product by a licensed retail pharmacy to a licensed practitioner for office use;

"(viii) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1986 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

"(ix) the distribution of a product pursuant to the sale or merger of a pharmacy or pharmacies or a wholesale distributor or wholesale distributors, except that any records required to be maintained for the product shall be transferred to the new owner of the pharmacy or pharmacies or wholesale distributor or wholesale distributors;

"(x) the dispensing of a product approved under section 512(c);

"(xi) products transferred to or from any facility that is licensed by the Nuclear Regulatory Commission or by a State pursuant to an agreement with such Commission under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021);

"(xii) a combination product that is not subject to approval under section 505 or licensure under section 351 of the Public Health Service Act, and that is—

"(I) a product comprised of a device and 1 or more other regulated components (such as a drug/device, biologic/device, or drug/device/biologic) that are physically, chemically, or otherwise combined or mixed and produced as a single entity;

"(II) 2 or more separate products packaged together in a single package or as a unit and comprised of a drug and device or device and biological product; or

"(III) 2 or more finished medical devices plus one or more drug or biological products that are packaged together in what is referred to as a 'medical convenience kit' as described in clause (xiii);

"(xiii) the distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in this clause as a 'medical convenience kit') if—

"(I) the medical convenience kit is assembled in an establishment that is registered with the Food and Drug Administration as a device manufacturer in accordance with section 510(b)(2);

"(II) the medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of 1970;

"(III) in the case of a medical convenience kit that includes a product, the person that manufacturers the kit—

"(aa) purchased such product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

"(bb) does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and

"(IV) in the case of a medical convenience kit that includes a product, the product is—

"(aa) an intravenous solution intended for the replenishment of fluids and electrolytes;

"(bb) a product intended to maintain the equilibrium of water and minerals in the body;

"(cc) a product intended for irrigation or reconstitution;

"(dd) an anesthetic;

"(ee) an anticoagulant;

"(ff) a vasopressor; or

"(gg) a sympathomimetic;

"(xiv) the distribution of an intravenous product that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

"(xv) the distribution of an intravenous product used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

"(xvi) the distribution of a product that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

"(xvii) the distribution of a medical gas (as defined in section 575); or

"(xviii) the distribution or sale of any licensed product under section 351 of the Public Health Service Act that meets the definition of a device under section 201(h).

"(25) TRANSACTION HISTORY.—The term 'transaction history' means a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.

"(26) TRANSACTION INFORMATION.—The term 'transaction information' means—

"(A) the proprietary or established name or names of the product;

"(B) the strength and dosage form of the product;

"(C) the National Drug Code number of the product;

"(D) the container size;

"(E) the number of containers;

"(F) the lot number of the product;

"(G) the date of the transaction;

"(H) the date of the shipment, if more than 24 hours after the date of the transaction;

"(I) the business name and address of the person from whom ownership is being transferred; and

"(J) the business name and address of the person to whom ownership is being transferred.

"(27) TRANSACTION STATEMENT.—The 'transaction statement' is a statement, in paper or electronic form, that the entity transferring ownership in a transaction—

"(A) is authorized as required under the Drug Supply Chain Security Act;

"(B) received the product from a person that is authorized as required under the Drug Supply Chain Security Act;

"(C) received transaction information and a transaction statement from the prior owner of the product, as required under section 582;

"(D) did not knowingly ship a suspect or illegitimate product;

"(E) had systems and processes in place to comply with verification requirements under section 582;

"(F) did not knowingly provide false transaction information; and

"(G) did not knowingly alter the transaction history.

"(28) VERIFICATION OR VERIFY.—The term 'verification' or 'verify' means determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the standardized numerical identifier or lot number and expiration date assigned to the product by the manufacturer or the repackager, as applicable in accordance with section 582.

"(29) WHOLESALE DISTRIBUTOR.—The term 'wholesale distributor' means a person (other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager) engaged in wholesale distribution (as defined in section 503(e)(4), as amended by the Drug Supply Chain Security Act).

"SEC. 582. REQUIREMENTS.

"(a) IN GENERAL.—

"(1) OTHER ACTIVITIES.—Each manufacturer, repackager, wholesale distributor, and dispenser shall comply with the requirements set forth in this section with respect to the role of such manufacturer, repackager, wholesale distributor, or dispenser in a transaction involving product. If an entity meets the definition of more than one of the entities listed in the preceding sentence, such entity shall comply with all applicable requirements in this section, but shall not be required to duplicate requirements.

"(2) INITIAL STANDARDS.—

"(A) IN GENERAL.—The Secretary shall, in consultation with other appropriate Federal officials, manufacturers, repackagers, wholesale distributors, dispensers, and other pharmaceutical distribution supply chain stakeholders, issue a draft guidance document that establishes standards for the interoperable exchange of transaction information,

transaction history, and transaction statements, in paper or electronic format, for compliance with this subsection and subsections (b), (c), (d), and (e). In establishing such standards, the Secretary shall consider the feasibility of establishing standardized documentation to be used by members of the pharmaceutical distribution supply chain to convey the transaction information, transaction history, and transaction statement to the subsequent purchaser of a product and to facilitate the exchange of lot level data. The standards established under this paragraph shall take into consideration the standards established under section 505D and shall comply with a form and format developed by a widely recognized international standards development organization.

"(B) PUBLIC INPUT.—Prior to issuing the draft guidance under subparagraph (A), the Secretary shall gather comments and information from stakeholders and maintain such comments and information in a public docket for at least 60 days prior to issuing such guidance.

"(C) PUBLICATION.—The Secretary shall publish the standards established under subparagraph (A) not later than 1 year after the date of enactment of the Drug Supply Chain Security Act.

"(3) WAIVERS, EXCEPTIONS, AND EXEMPTIONS.—

"(A) IN GENERAL.—Not later than 2 years after the date of enactment of the Drug Supply Chain Security Act, the Secretary shall, by guidance—

"(i) establish a process by which an authorized manufacturer, repackager, wholesale distributor, or dispenser may request a waiver from any of the requirements set forth in this section, which the Secretary may grant if the Secretary determines that such requirements would result in an undue economic hardship or for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act;

"(ii) establish a process by which the Secretary determines exceptions, and a process through which a manufacturer or repackager may request such an exception, to the requirements relating to product identifiers if a product is packaged in a container too small or otherwise unable to accommodate a label with sufficient space to bear the information required for compliance with this section; and

"(iii) establish a process by which the Secretary may determine other products or transactions that shall be exempt from the requirements of this section.

"(B) CONTENT.—The guidance issued under subparagraph (A) shall include a process for the biennial review and renewal of such waivers, exceptions, and exemptions, as applicable.

"(C) PROCESS.—In issuing the guidance under this paragraph, the Secretary shall provide an effective date that is not later than 180 days prior to the date on which manufacturers are required to affix or imprint a product identifier to each package and homogenous case of product

intended to be introduced in a transaction into commerce consistent with this section.

"(4) SELF-EXECUTING REQUIREMENTS.—Except where otherwise specified, the requirements of this section may be enforced without further regulations or guidance from the Secretary.

"(5) GRANDFATHERING PRODUCT.—

"(A) PRODUCT IDENTIFIER.—Not later than 2 years after the date of enactment of the Drug Supply Chain Security Act, the Secretary shall finalize guidance specifying whether and under what circumstances product that is not labeled with a product identifier and that is in the pharmaceutical distribution supply chain at the time of the effective date of the requirements of this section shall be exempted from the requirements of this section.

"(B) TRACING.—For a product that entered the pharmaceutical distribution supply chain prior to January 1, 2015—

"(i) authorized trading partners shall be exempt from providing transaction information as required under subsections (b)(1)(A)(i), (c)(1)(A)(ii), (d)(1)(A)(ii), and (e)(1)(A)(ii);

"(ii) transaction history required under this section shall begin with the owner of such product on such date; and

"(iii) the owners of such product on such date shall be exempt from asserting receipt of transaction information and transaction statement from the prior owner as required under this section.

"(6) WHOLESALE DISTRIBUTOR LICENSES.—Notwithstanding section 581(9)(A), until the effective date of the wholesale distributor licensing regulations under section 583, the term 'licensed' or 'authorized', as it relates to a wholesale distributor with respect to prescription drugs, shall mean a wholesale distributor with a valid license under State law.

"(7) THIRD-PARTY LOGISTICS PROVIDER LICENSES.—Until the effective date of the third-party logistics provider licensing regulations under section 584, a third-party logistics provider shall be considered 'licensed' under section 581(9)(B) unless the Secretary has made a finding that the third-party logistics provider does not utilize good handling and distribution practices and publishes notice thereof.

"(8) LABEL CHANGES.—Changes made to package labels solely to incorporate the product identifier may be submitted to the Secretary in the annual report of an establishment, in accordance with section 314.70(d) of chapter 21, Code of Federal Regulations (or any successor regulation).

"(9) PRODUCT IDENTIFIERS.—With respect to any requirement relating to product identifiers under this subchapter—

"(A) unless the Secretary allows, through guidance, the use of other technologies for data instead of or in addition to the technologies described in clauses (i) and (ii), the applicable data—

"(i) shall be included in a 2-dimensional data matrix barcode when affixed to, or imprinted upon, a package; and

"(ii) shall be included in a linear or 2-dimensional data matrix barcode when affixed to, or imprinted upon, a homogeneous case; and

"(B) verification of the product identifier may occur by using human-readable or machine-readable methods.

"(b) MANUFACTURER REQUIREMENTS.—

"(1) PRODUCT TRACING.—

"(A) IN GENERAL.—Beginning not later than January 1, 2015, a manufacturer shall—

"(i) prior to, or at the time of, each transaction in which such manufacturer transfers ownership of a product, provide the subsequent owner with transaction history, transaction information, and a transaction statement, in a single document in an paper or electronic format; and

"(ii) capture the transaction information (including lot level information), transaction history, and transaction statement for each transaction and maintain such information, history, and statement for not less than 6 years after the date of the transaction.

"(B) REQUESTS FOR INFORMATION.—Upon a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product, a manufacturer shall, not later than 1 business day, and not to exceed 48 hours, after receiving the request, or in other such reasonable time as determined by the Secretary, based on the circumstances of the request, provide the applicable transaction information, transaction history, and transaction statement for the product.

"(C) ELECTRONIC FORMAT.—

"(i) IN GENERAL.—Beginning not later than 4 years after the date of enactment of the Drug Supply Chain Security Act, except as provided under clause (ii), a manufacturer shall provide the transaction information, transaction history, and transaction statement required under subparagraph (A)(i) in electronic format.

"(ii) EXCEPTION.—A manufacturer may continue to provide the transaction information, transaction history, and transaction statement required under subparagraph (A)(i) in a paper format to a licensed health care practitioner authorized to prescribe medication under State law or other licensed individual under the supervision or direction of such a practitioner who dispenses product in the usual course of professional practice.

"(2) PRODUCT IDENTIFIER.—

"(A) IN GENERAL.—Beginning not later than 4 years after the date of enactment of the Drug Supply Chain Security Act, a manufacturer shall affix or imprint a product identifier to each package and homogenous case of a product intended to be introduced in a transaction into commerce. Such manufacturer shall maintain the product identifier information for such product for not less than 6 years after the date of the transaction.

"(B) EXCEPTION.—A package that is required to have a standardized numerical identifier is not required to have a unique device identifier.

"(3) AUTHORIZED TRADING PARTNERS.—Beginning not later than January 1, 2015, the trading partners of a manufacturer may be only authorized trading partners.

"(4) VERIFICATION.—Beginning not later than January 1, 2015, a manufacturer shall have systems in place to enable the manufacturer to comply with the following requirements:

"(A) SUSPECT PRODUCT.—

"(i) IN GENERAL.—Upon making a determination that a product in the possession or control of the manufacturer is a suspect product, or upon receiving a request for verification from the Secretary that has made a determination that a product within the possession or control of a manufacturer is a suspect product, a manufacturer shall—

"(I) quarantine such product within the possession or control of the manufacturer from product intended for distribution until such product is cleared or dispositioned; and

"(II) promptly conduct an investigation in coordination with trading partners, as applicable, to determine whether the product is an illegitimate product, which shall include validating any applicable transaction history and transaction information in the possession of the manufacturer and otherwise investigating to determine whether the product is an illegitimate product, and, beginning 4 years after the date of enactment of the Drug Supply Chain Security Act, verifying the product at the package level, including the standardized numerical identifier.

"(ii) CLEARED PRODUCT.—If the manufacturer makes the determination that a suspect product is not an illegitimate product, the manufacturer shall promptly notify the Secretary, if applicable, of such determination and such product may be further distributed.

"(iii) RECORDS.—A manufacturer shall keep records of the investigation of a suspect product for not less than 6 years after the conclusion of the investigation.

"(B) ILLEGITIMATE PRODUCT.—

"(i) IN GENERAL.—Upon determining that a product in the possession or control of a manufacturer is an illegitimate product, the manufacturer shall, in a manner consistent with the systems and processes of such manufacturer—

"(I) quarantine such product within the possession or control of the manufacturer from product intended for distribution until such product is dispositioned;

"(II) disposition the illegitimate product within the possession or control of the manufacturer;

"(III) take reasonable and appropriate steps to assist a trading partner to disposition an illegitimate product not in the possession or control of the manufacturer; and

"(IV) retain a sample of the product for further physical examination or laboratory analysis of the product by the manufacturer or Secretary (or other appropriate Federal or State official) upon request by the Secretary (or other appropriate Federal or State official), as necessary and appropriate.

"(ii) MAKING A NOTIFICATION.—

"(I) ILLEGITIMATE PRODUCT.—Upon determining that a product in the possession or control of the manufacturer is an illegitimate product, the manufacturer shall notify the Secretary and all immediate trading partners that the manufacturer has reason to believe may have received such illegitimate product of such determination not later than 24 hours after making such determination.

"(II) HIGH RISK OF ILLEGITIMACY.—A manufacturer shall notify the Secretary and immediate trading partners that the manufacturer has reason to believe may have in the trading partner's possession a product manufactured by, or purported to be a product manufactured by, the manufacturer not later than 24 hours after determining or being notified by the Secretary or a trading partner that there is a high risk that such product is an illegitimate product. For purposes of this subclause, a 'high risk' may include a specific high risk that could increase the likelihood that illegitimate product will enter the pharmaceutical distribution supply chain and other high risks as determined by the Secretary in guidance pursuant to subsection (h).

"(iii) RESPONDING TO A NOTIFICATION.—Upon the receipt of a notification from the Secretary or a trading partner that a determination has been made that a product is an illegitimate product, a manufacturer shall identify all illegitimate product subject to such notification that is in the possession or control of the manufacturer, including any product that is subsequently received, and shall perform the activities described in subparagraph (A).

"(iv) TERMINATING A NOTIFICATION.—Upon making a determination, in consultation with the Secretary, that a notification is no longer necessary, a manufacturer shall promptly notify immediate trading partners that the manufacturer notified pursuant to clause (ii) that such notification has been terminated.

"(v) RECORDS.—A manufacturer shall keep records of the disposition of an illegitimate product for not less than 6 years after the conclusion of the disposition.

"(C) REQUESTS FOR VERIFICATION.—Beginning 4 years after the date of enactment of the Drug Supply Chain Security Act, upon receiving a request for verification from

an authorized repackager, wholesale distributor, or dispenser that is in possession or control of a product such person believes to be manufactured by such manufacturer, a manufacturer shall, not later than 24 hours after receiving the request for verification or in other such reasonable time as determined by the Secretary, based on the circumstances of the request, notify the person making the request whether the product identifier, including the standardized numerical identifier, that is the subject of the request corresponds to the product identifier affixed or imprinted by the manufacturer. If a manufacturer responding to a request for verification identifies a product identifier that does not correspond to that affixed or imprinted by the manufacturer, the manufacturer shall treat such product as suspect product and conduct an investigation as described in subparagraph (A). If the manufacturer has reason to believe the product is an illegitimate product, the manufacturer shall advise the person making the request of such belief at the time such manufacturer responds to the request for verification.

"(D) ELECTRONIC DATABASE.—A manufacturer may satisfy the requirements of this paragraph by developing a secure electronic database or utilizing a secure electronic database developed or operated by another entity. The owner of such database shall establish the requirements and processes to respond to requests and may provide for data access to other members of the pharmaceutical distribution supply chain, as appropriate. The development and operation of such a database shall not relieve a manufacturer of the requirement under this paragraph to respond to a request for verification submitted by means other than a secure electronic database.

"(E) SALEABLE RETURNED PRODUCT.—Beginning 4 years after the date of enactment of the Drug Supply Chain Security Act (except as provided pursuant to subsection (a)(5)), upon receipt of a returned product that the manufacturer intends to further distribute, before further distributing such product, the manufacturer shall verify the product identifier, including the standardized numerical identifier, for each sealed homogeneous case of such product or, if such product is not in a sealed homogeneous case, verify the product identifier, including the standardized numerical identifier, on each package.

"(F) NONSALEABLE RETURNED PRODUCT.—A manufacturer may return a nonsaleable product to the manufacturer or repackager, to the wholesale distributor from whom such product was purchased, or to a person acting on behalf of such a person, including a returns processor, without providing the information described in paragraph (1)(A)(i).

"(c) WHOLESALE DISTRIBUTOR REQUIREMENTS.—

"(1) PRODUCT TRACING.—

"(A) IN GENERAL.—Beginning not later than January 1, 2015, the following requirements shall apply to wholesale distributors:

"(i) A wholesale distributor shall not accept ownership of a product unless the previous owner prior to,

or at the time of, the transaction provides the transaction history, transaction information, and a transaction statement for the product, as applicable under this subparagraph.

"(ii)(I)(aa) If the wholesale distributor purchased a product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer, then prior to, or at the time of, each transaction in which the wholesale distributor transfers ownership of a product, the wholesale distributor shall provide to the subsequent purchaser—

"(AA) a transaction statement, which shall state that such wholesale distributor, or a member of the affiliate of such wholesale distributor, purchased the product directly from the manufacturer, exclusive distributor of the manufacturer, or repackager that purchased the product directly from the manufacturer; and

"(BB) subject to subclause (II), the transaction history and transaction information.

"(bb) The wholesale distributor shall provide the transaction history, transaction information, and transaction statement under item (aa)—

"(AA) if provided to a dispenser, on a single document in a paper or electronic format; and

"(BB) if provided to a wholesale distributor, through any combination of self-generated paper, electronic data, or manufacturer-provided information on the product package.

"(II) For purposes of transactions described in subclause (I), transaction history and transaction information shall not be required to include the lot number of the product, the initial transaction date, or the initial shipment date from the manufacturer (as defined in subparagraphs (F), (G), and (H) of section 581(26)).

"(iii) If the wholesale distributor did not purchase a product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer, as described in clause (ii), then prior to, or at the time of, each transaction or subsequent transaction, the wholesale distributor shall provide to the subsequent purchaser a transaction statement, transaction history, and transaction information, in a paper or electronic format that complies with the guidance document issued under subsection (a)(2).

"(iv) For the purposes of clause (iii), the transaction history supplied shall begin only with the wholesale distributor described in clause (ii)(I), but the wholesale distributor described in clause (iii) shall inform the subsequent purchaser that such wholesale distributor received a direct purchase statement from a wholesale distributor described in clause (ii)(I).

"(v) A wholesale distributor shall—

"(I) capture the transaction information (including lot level information) consistent with the requirements of this section, transaction history, and transaction statement for each transaction described in clauses (i), (ii), and (iii) and maintain such information, history, and statement for not less than 6 years after the date of the transaction; and

"(II) maintain the confidentiality of the transaction information (including any lot level information consistent with the requirements of this section), transaction history, and transaction statement for a product in a manner that prohibits disclosure to any person other than the Secretary or other appropriate Federal or State official, except to comply with clauses (ii) and (iii), and, as applicable, pursuant to an agreement under subparagraph (D).

"(B) RETURNS.—

"(i) SALEABLE RETURNS.—Notwithstanding subparagraph (A)(i), the following shall apply:

"(I) REQUIREMENTS.—Until the date that is 6 years after the date of enactment of the Drug Supply Chain Security Act (except as provided pursuant to subsection (a)(5)), a wholesale distributor may accept returned product from a dispenser or repackager pursuant to the terms and conditions of any agreement between the parties, and, notwithstanding subparagraph (A)(ii), may distribute such returned product without providing the transaction history. For transactions subsequent to the return, the transaction history of such product shall begin with the wholesale distributor that accepted the returned product, consistent with the requirements of this subsection.

"(II) ENHANCED REQUIREMENTS.—Beginning 6 years after the date of enactment of the Drug Supply Chain Security Act (except as provided pursuant to subsection (a)(5)), a wholesale distributor may accept returned product from a dispenser or repackager only if the wholesale distributor can associate returned product with the transaction information and transaction statement associated with that product. For all transactions after such date, the transaction history, as applicable, of such product shall begin with the wholesale distributor that accepted and verified the returned product. For purposes of this subparagraph, the transaction information and transaction history, as applicable, need not include transaction dates if it is not reasonably practicable to obtain such dates.

"(ii) NONSALEABLE RETURNS.—A wholesale distributor may return a nonsaleable product to the manufacturer or repackager, to the wholesale distributor from whom such product was purchased, or to a person acting on behalf of such a person, including a returns

processor, without providing the information required under subparagraph (A)(i).

"(C) REQUESTS FOR INFORMATION.—Upon a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product, a wholesale distributor shall, not later than 1 business day, and not to exceed 48 hours, after receiving the request or in other such reasonable time as determined by the Secretary, based on the circumstances of the request, provide the applicable transaction information, transaction history, and transaction statement for the product.

"(D) TRADING PARTNER AGREEMENTS.—Beginning 6 years after the date of enactment of the Drug Supply Chain Security Act, a wholesale distributor may disclose the transaction information, including lot level information, transaction history, or transaction statement of a product to the subsequent purchaser of the product, pursuant to a written agreement between such wholesale distributor and such subsequent purchaser. Nothing in this subparagraph shall be construed to limit the applicability of subparagraphs (A) through (C).

"(2) PRODUCT IDENTIFIER.—Beginning 6 years after the date of enactment of the Drug Supply Chain Security Act, a wholesale distributor may engage in transactions involving a product only if such product is encoded with a product identifier (except as provided pursuant to subsection (a)(5)).

"(3) AUTHORIZED TRADING PARTNERS.—Beginning not later than January 1, 2015, the trading partners of a wholesale distributor may be only authorized trading partners.

"(4) VERIFICATION.—Beginning not later than January 1, 2015, a wholesale distributor shall have systems in place to enable the wholesale distributor to comply with the following requirements:

"(A) SUSPECT PRODUCT.—

"(i) IN GENERAL.—Upon making a determination that a product in the possession or control of a wholesale distributor is a suspect product, or upon receiving a request for verification from the Secretary that has made a determination that a product within the possession or control of a wholesale distributor is a suspect product, a wholesale distributor shall—

"(I) quarantine such product within the possession or control of the wholesale distributor from product intended for distribution until such product is cleared or dispositioned; and

"(II) promptly conduct an investigation in coordination with trading partners, as applicable, to determine whether the product is an illegitimate product, which shall include validating any applicable transaction history and transaction information in the possession of the wholesale distributor and otherwise investigating to determine whether the product is an illegitimate product, and, beginning 6 years after the date of enactment of the Drug Supply Chain Security Act (except as provided pursuant to subsection (a)(5)),

verifying the product at the package level, including the standardized numerical identifier.

"(ii) CLEARED PRODUCT.—If the wholesale distributor determines that a suspect product is not an illegitimate product, the wholesale distributor shall promptly notify the Secretary, if applicable, of such determination and such product may be further distributed.

"(iii) RECORDS.—A wholesale distributor shall keep records of the investigation of a suspect product for not less than 6 years after the conclusion of the investigation.

"(B) ILLEGITIMATE PRODUCT.—

"(i) IN GENERAL.—Upon determining, in coordination with the manufacturer, that a product in the possession or control of a wholesale distributor is an illegitimate product, the wholesale distributor shall, in a manner that is consistent with the systems and processes of such wholesale distributor—

"(I) quarantine such product within the possession or control of the wholesale distributor from product intended for distribution until such product is dispositioned;

"(II) disposition the illegitimate product within the possession or control of the wholesale distributor;

"(III) take reasonable and appropriate steps to assist a trading partner to disposition an illegitimate product not in the possession or control of the wholesale distributor; and

"(IV) retain a sample of the product for further physical examination or laboratory analysis of the product by the manufacturer or Secretary (or other appropriate Federal or State official) upon request by the manufacturer or Secretary (or other appropriate Federal or State official), as necessary and appropriate.

"(ii) MAKING A NOTIFICATION.—Upon determining that a product in the possession or control of the wholesale distributor is an illegitimate product, the wholesale distributor shall notify the Secretary and all immediate trading partners that the wholesale distributor has reason to believe may have received such illegitimate product of such determination not later than 24 hours after making such determination.

"(iii) RESPONDING TO A NOTIFICATION.—Upon the receipt of a notification from the Secretary or a trading partner that a determination has been made that a product is an illegitimate product, a wholesale distributor shall identify all illegitimate product subject to such notification that is in the possession or control of the wholesale distributor, including any product that is subsequently received, and shall perform the activities described in subparagraph (A).

"(iv) TERMINATING A NOTIFICATION.—Upon making a determination, in consultation with the Secretary, that a notification is no longer necessary, a wholesale

distributor shall promptly notify immediate trading partners that the wholesale distributor notified pursuant to clause (ii) that such notification has been terminated.

"(v) RECORDS.—A wholesale distributor shall keep records of the disposition of an illegitimate product for not less than 6 years after the conclusion of the disposition.

"(C) ELECTRONIC DATABASE.—A wholesale distributor may satisfy the requirements of this paragraph by developing a secure electronic database or utilizing a secure electronic database developed or operated by another entity. The owner of such database shall establish the requirements and processes to respond to requests and may provide for data access to other members of the pharmaceutical distribution supply chain, as appropriate. The development and operation of such a database shall not relieve a wholesale distributor of the requirement under this paragraph to respond to a verification request submitted by means other than a secure electronic database.

"(D) VERIFICATION OF SALEABLE RETURNED PRODUCT.—Beginning 6 years after the date of enactment of the Drug Supply Chain Security Act, upon receipt of a returned product that the wholesale distributor intends to further distribute, before further distributing such product, the wholesale distributor shall verify the product identifier, including the standardized numerical identifier, for each sealed homogeneous case of such product or, if such product is not in a sealed homogeneous case, verify the product identifier, including the standardized numerical identifier, on each package.

"(d) DISPENSER REQUIREMENTS.—

"(1) PRODUCT TRACING.—

"(A) IN GENERAL.—Beginning July 1, 2015, a dispenser—

"(i) shall not accept ownership of a product, unless the previous owner prior to, or at the time of, the transaction, provides transaction history, transaction information, and a transaction statement;

"(ii) prior to, or at the time of, each transaction in which the dispenser transfers ownership of a product (but not including dispensing to a patient or returns) shall provide the subsequent owner with transaction history, transaction information, and a transaction statement for the product, except that the requirements of this clause shall not apply to sales by a dispenser to another dispenser to fulfill a specific patient need; and

"(iii) shall capture transaction information (including lot level information, if provided), transaction history, and transaction statements, as necessary to investigate a suspect product, and maintain such information, history, and statements for not less than 6 years after the transaction.

"(B) AGREEMENTS WITH THIRD PARTIES.—A dispenser may enter into a written agreement with a third party, including an authorized wholesale distributor, under which

the third party confidentially maintains the transaction information, transaction history, and transaction statements required to be maintained under this subsection on behalf of the dispenser. If a dispenser enters into such an agreement, the dispenser shall maintain a copy of the written agreement and shall not be relieved of the obligations of the dispenser under this subsection.

"(C) RETURNS.—

"(i) SALEABLE RETURNS.—A dispenser may return product to the trading partner from which the dispenser obtained the product without providing the information required under subparagraph (A).

"(ii) NONSALEABLE RETURNS.—A dispenser may return a nonsaleable product to the manufacturer or repackager, to the wholesale distributor from whom such product was purchased, to a returns processor, or to a person acting on behalf of such a person without providing the information required under subparagraph (A).

"(D) REQUESTS FOR INFORMATION.—Upon a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect or an illegitimate product, a dispenser shall, not later than 2 business days after receiving the request or in another such reasonable time as determined by the Secretary, based on the circumstances of the request, provide the applicable transaction information, transaction statement, and transaction history which the dispenser received from the previous owner, which shall not include the lot number of the product, the initial transaction date, or the initial shipment date from the manufacturer unless such information was included in the transaction information, transaction statement, and transaction history provided by the manufacturer or wholesale distributor to the dispenser. The dispenser may respond to the request by providing the applicable information in either paper or electronic format. Until the date that is 4 years after the date of enactment of the Drug Supply Chain Security Act, the Secretary or other appropriate Federal or State official shall grant a dispenser additional time, as necessary, only with respect to a request to provide lot level information described in subparagraph (F) of section 581(26) that was provided to the dispenser in paper format, limit the request time period to the 6 months preceding the request or other relevant date, and, in the event of a recall, the Secretary, or other appropriate Federal or State official may request information only if such recall involves a serious adverse health consequence or death to humans.

"(2) PRODUCT IDENTIFIER.—Beginning not later than 7 years after the date of enactment of the Drug Supply Chain Security Act, a dispenser may engage in transactions involving a product only if such product is encoded with a product identifier (except as provided pursuant to subsection (a)(5)).

"(3) AUTHORIZED TRADING PARTNERS.—Beginning not later than January 1, 2015, the trading partners of a dispenser may be only authorized trading partners.

"(4) VERIFICATION.—Beginning not later than January 1, 2015, a dispenser shall have systems in place to enable the dispenser to comply with the following requirements:

"(A) SUSPECT PRODUCT.—

"(i) IN GENERAL.—Upon making a determination that a product in the possession or control of the dispenser is a suspect product, or upon receiving a request for verification from the Secretary that has made a determination that a product within the possession or control of a dispenser is a suspect product, a dispenser shall—

"(I) quarantine such product within the possession or control of the dispenser from product intended for distribution until such product is cleared or dispositioned; and

"(II) promptly conduct an investigation in coordination with trading partners, as applicable, to determine whether the product is an illegitimate product.

"(ii) INVESTIGATION.—An investigation conducted under clause (i)(II) shall include—

"(I) beginning 7 years after the date of enactment of the Drug Supply Chain Security Act, verifying whether the lot number of a suspect product corresponds with the lot number for such product;

"(II) beginning 7 years after the date of enactment of such Act, verifying that the product identifier, including the standardized numerical identifier, of at least 3 packages or 10 percent of such suspect product, whichever is greater, or all packages, if there are fewer than 3, corresponds with the product identifier for such product;

"(III) validating any applicable transaction history and transaction information in the possession of the dispenser; and

"(IV) otherwise investigating to determine whether the product is an illegitimate product.

"(iii) CLEARED PRODUCT.—If the dispenser makes the determination that a suspect product is not an illegitimate product, the dispenser shall promptly notify the Secretary, if applicable, of such determination and such product may be further distributed or dispensed.

"(iv) RECORDS.—A dispenser shall keep records of the investigation of a suspect product for not less than 6 years after the conclusion of the investigation.

"(B) ILLEGITIMATE PRODUCT.—

"(i) IN GENERAL.—Upon determining, in coordination with the manufacturer, that a product in the possession or control of a dispenser is an illegitimate product, the dispenser shall—

"(I) disposition the illegitimate product within the possession or control of the dispenser;

"(II) take reasonable and appropriate steps to assist a trading partner to disposition an illegitimate product not in the possession or control of the dispenser; and

"(III) retain a sample of the product for further physical examination or laboratory analysis of the product by the manufacturer or Secretary (or other appropriate Federal or State official) upon request by the manufacturer or Secretary (or other appropriate Federal or State official), as necessary and appropriate.

"(ii) MAKING A NOTIFICATION.—Upon determining that a product in the possession or control of the dispenser is an illegitimate product, the dispenser shall notify the Secretary and all immediate trading partners that the dispenser has reason to believe may have received such illegitimate product of such determination not later than 24 hours after making such determination.

"(iii) RESPONDING TO A NOTIFICATION.—Upon the receipt of a notification from the Secretary or a trading partner that a determination has been made that a product is an illegitimate product, a dispenser shall identify all illegitimate product subject to such notification that is in the possession or control of the dispenser, including any product that is subsequently received, and shall perform the activities described in subparagraph (A).

"(iv) TERMINATING A NOTIFICATION.—Upon making a determination, in consultation with the Secretary, that a notification is no longer necessary, a dispenser shall promptly notify immediate trading partners that the dispenser notified pursuant to clause (ii) that such notification has been terminated.

"(v) RECORDS.—A dispenser shall keep records of the disposition of an illegitimate product for not less than 6 years after the conclusion of the disposition.

"(C) ELECTRONIC DATABASE.—A dispenser may satisfy the requirements of this paragraph by developing a secure electronic database or utilizing a secure electronic database developed or operated by another entity.

"(5) EXCEPTION.—Notwithstanding any other provision of law, the requirements under paragraphs (1) and (4) shall not apply to licensed health care practitioners authorized to prescribe or administer medication under State law or other licensed individuals under the supervision or direction of such practitioners who dispense or administer product in the usual course of professional practice.

"(e) REPACKAGER REQUIREMENTS.—

"(1) PRODUCT TRACING.—

"(A) IN GENERAL.—Beginning not later than January 1, 2015, a repackager described in section 581(16)(A) shall—

"(i) not accept ownership of a product unless the previous owner, prior to, or at the time of, the transaction, provides transaction history, transaction

information, and a transaction statement for the product;

"(ii) prior to, or at the time of, each transaction in which the repackager transfers ownership of a product, provide the subsequent owner with transaction history, transaction information, and a transaction statement for the product; and

"(iii) capture the transaction information (including lot level information), transaction history, and transaction statement for each transaction described in clauses (i) and (ii) and maintain such information, history, and statement for not less than 6 years after the transaction.

"(B) RETURNS.—

"(i) NONSALEABLE PRODUCT.—A repackager described in section 581(16)(A) may return a nonsaleable product to the manufacturer or repackager, or to the wholesale distributor from whom such product was purchased, or to a person acting on behalf of such a person, including a returns processor, without providing the information required under subparagraph (A)(ii).

"(ii) SALEABLE OR NONSALEABLE PRODUCT.—A repackager described in section 581(16)(B) may return a saleable or nonsaleable product to the manufacturer, repackager, or to the wholesale distributor from whom such product was received without providing the information required under subparagraph (A)(ii) on behalf of the hospital or other health care entity that took ownership of such product pursuant to the terms and conditions of any agreement between such repackager and the entity that owns the product.

"(C) REQUESTS FOR INFORMATION.—Upon a request by the Secretary or other appropriate Federal or State official, in the event of a recall or for the purpose of investigating a suspect product or an illegitimate product, a repackager described in section 581(16)(A) shall, not later than 1 business day, and not to exceed 48 hours, after receiving the request or in other such reasonable time as determined by the Secretary, provide the applicable transaction information, transaction history, and transaction statement for the product.

"(2) PRODUCT IDENTIFIER.—

"(A) IN GENERAL.—Beginning not later than 5 years after the date of enactment of the Drug Supply Chain Security Act, a repackager described in section 581(16)(A)—

"(i) shall affix or imprint a product identifier to each package and homogenous case of product intended to be introduced in a transaction in commerce;

"(ii) shall maintain the product identifier information for such product for not less than 6 years after the date of the transaction;

"(iii) may engage in transactions involving a product only if such product is encoded with a product identifier (except as provided pursuant to subsection (a)(5)); and

"(iv) shall maintain records for not less than 6 years to allow the repackager to associate the product identifier the repackager affixes or imprints with the product identifier assigned by the original manufacturer of the product.

"(B) EXCEPTION.—A package that is required to have a standardized numerical identifier is not required to have a unique device identifier.

"(3) AUTHORIZED TRADING PARTNERS.—Beginning January 1, 2015, the trading partners of a repackager described in section 581(16) may be only authorized trading partners.

"(4) VERIFICATION.—Beginning not later than January 1, 2015, a repackager described in section 581(16)(A) shall have systems in place to enable the repackager to comply with the following requirements:

"(A) SUSPECT PRODUCT.—

"(i) IN GENERAL.—Upon making a determination that a product in the possession or control of the repackager is a suspect product, or upon receiving a request for verification from the Secretary that has made a determination that a product within the possession or control of a repackager is a suspect product, a repackager shall—

"(I) quarantine such product within the possession or control of the repackager from product intended for distribution until such product is cleared or dispositioned; and

"(II) promptly conduct an investigation in coordination with trading partners, as applicable, to determine whether the product is an illegitimate product, which shall include validating any applicable transaction history and transaction information in the possession of the repackager and otherwise investigating to determine whether the product is an illegitimate product, and, beginning 5 years after the date of enactment of the Drug Supply Chain Security Act (except as provided pursuant to subsection (a)(5)), verifying the product at the package level, including the standardized numerical identifier.

"(ii) CLEARED PRODUCT.—If the repackager makes the determination that a suspect product is not an illegitimate product, the repackager shall promptly notify the Secretary, if applicable, of such determination and such product may be further distributed.

"(iii) RECORDS.—A repackager shall keep records of the investigation of a suspect product for not less than 6 years after the conclusion of the investigation.

"(B) ILLEGITIMATE PRODUCT.—

"(i) IN GENERAL.—Upon determining, in coordination with the manufacturer, that a product in the possession or control of a repackager is an illegitimate product, the repackager shall, in a manner that is consistent with the systems and processes of such repackager—

"(I) quarantine such product within the possession or control of the repackager from product

intended for distribution until such product is dispositioned;

"(II) disposition the illegitimate product within the possession or control of the repackager;

"(III) take reasonable and appropriate steps to assist a trading partner to disposition an illegitimate product not in the possession or control of the repackager; and

"(IV) retain a sample of the product for further physical examination or laboratory analysis of the product by the manufacturer or Secretary (or other appropriate Federal or State official) upon request by the manufacturer or Secretary (or other appropriate Federal or State official), as necessary and appropriate.

"(ii) MAKING A NOTIFICATION.—Upon determining that a product in the possession or control of the repackager is an illegitimate product, the repackager shall notify the Secretary and all immediate trading partners that the repackager has reason to believe may have received the illegitimate product of such determination not later than 24 hours after making such determination.

"(iii) RESPONDING TO A NOTIFICATION.—Upon the receipt of a notification from the Secretary or a trading partner, a repackager shall identify all illegitimate product subject to such notification that is in the possession or control of the repackager, including any product that is subsequently received, and shall perform the activities described in subparagraph (A).

"(iv) TERMINATING A NOTIFICATION.—Upon making a determination, in consultation with the Secretary, that a notification is no longer necessary, a repackager shall promptly notify immediate trading partners that the repackager notified pursuant to clause (ii) that such notification has been terminated.

"(v) RECORDS.—A repackager shall keep records of the disposition of an illegitimate product for not less than 6 years after the conclusion of the disposition.

"(C) REQUESTS FOR VERIFICATION.—Beginning 5 years after the date of enactment of the Drug Supply Chain Security Act, upon receiving a request for verification from an authorized manufacturer, wholesale distributor, or dispenser that is in possession or control of a product they believe to be repackaged by such repackager, a repackager shall, not later than 24 hours after receiving the verification request or in other such reasonable time as determined by the Secretary, based on the circumstances of the request, notify the person making the request whether the product identifier, including the standardized numerical identifier, that is the subject of the request corresponds to the product identifier affixed or imprinted by the repackager. If a repackager responding to a verification request identifies a product identifier that does not correspond to that affixed or imprinted by the repackager, the repackager shall treat such product as suspect product and conduct an investigation as described in subparagraph (A). If the repackager

has reason to believe the product is an illegitimate product, the repackager shall advise the person making the request of such belief at the time such repackager responds to the verification request.

"(D) ELECTRONIC DATABASE.—A repackager may satisfy the requirements of paragraph (4) by developing a secure electronic database or utilizing a secure electronic database developed or operated by another entity. The owner of such database shall establish the requirements and processes to respond to requests and may provide for data access to other members of the pharmaceutical distribution supply chain, as appropriate. The development and operation of such a database shall not relieve a repackager of the requirement under subparagraph (C) to respond to a verification request submitted by means other than a secure electronic database.

"(E) VERIFICATION OF SALEABLE RETURNED PRODUCT.—Beginning 5 years after the date of enactment of the Drug Supply Chain Security Act, upon receipt of a returned product that the repackager intends to further distribute, before further distributing such product, the repackager shall verify the product identifier for each sealed homogeneous case of such product or, if such product is not in a sealed homogeneous case, verify the product identifier on each package.

"(f) DROP SHIPMENTS.—

"(1) IN GENERAL.—A wholesale distributor that does not physically handle or store product shall be exempt from the provisions of this section, except the notification requirements under clauses (ii), (iii), and (iv) of subsection (c)(4)(B), provided that the manufacturer, repackager, or other wholesale distributor that distributes the product to the dispenser by means of a drop shipment for such wholesale distributor includes on the transaction information and transaction history to the dispenser the contact information of such wholesale distributor and provides the transaction information, transaction history, and transaction statement directly to the dispenser.

"(2) CLARIFICATION.—For purposes of this subsection, providing administrative services, including processing of orders and payments, shall not by itself, be construed as being involved in the handling, distribution, or storage of a product.".

SEC. 203. ENHANCED DRUG DISTRIBUTION SECURITY.

Section 582, as added by section 202, is amended by adding at the end the following:

"(g) ENHANCED DRUG DISTRIBUTION SECURITY.—

"(1) IN GENERAL.—On the date that is 10 years after the date of enactment of the Drug Supply Chain Security Act, the following interoperable, electronic tracing of product at the package level requirements shall go into effect:

"(A) The transaction information and the transaction statements as required under this section shall be exchanged in a secure, interoperable, electronic manner in accordance with the standards established under the guidance issued pursuant to paragraphs (3) and (4) of subsection (h), including any revision of such guidance issued in accordance with paragraph (5) of such subsection.

"(B) The transaction information required under this section shall include the product identifier at the package level for each package included in the transaction.

"(C) Systems and processes for verification of product at the package level, including the standardized numerical identifier, shall be required in accordance with the standards established under the guidance issued pursuant to subsection (a)(2) and the guidances issued pursuant to paragraphs (2), (3), and (4) of subsection (h), including any revision of such guidances issued in accordance with paragraph (5) of such subsection, which may include the use of aggregation and inference as necessary.

"(D) The systems and processes necessary to promptly respond with the transaction information and transaction statement for a product upon a request by the Secretary (or other appropriate Federal or State official) in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product shall be required.

"(E) The systems and processes necessary to promptly facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer, as applicable, shall be required—

"(i) in the event of a request by the Secretary (or other appropriate Federal or State official), on account of a recall or for the purposes of investigating a suspect product or an illegitimate product; or

"(ii) in the event of a request by an authorized trading partner, in a secure manner that ensures the protection of confidential commercial information and trade secrets, for purposes of investigating a suspect product or assisting the Secretary (or other appropriate Federal or State official) with a request described in clause (i).

"(F) Each person accepting a saleable return shall have systems and processes in place to allow acceptance of such product and may accept saleable returns only if such person can associate the saleable return product with the transaction information and transaction statement associated with that product.

"(2) COMPLIANCE.—

"(A) INFORMATION MAINTENANCE AGREEMENT.—A dispenser may enter into a written agreement with a third party, including an authorized wholesale distributor, under which the third party shall confidentially maintain any information and statements required to be maintained under this section. If a dispenser enters into such an agreement, the dispenser shall maintain a copy of the written agreement and shall not be relieved of the obligations of the dispenser under this subsection.

"(B) ALTERNATIVE METHODS.—The Secretary, taking into consideration the assessment conducted under paragraph (3), shall provide for alternative methods of compliance with any of the requirements set forth in paragraph (1), including—

"(i) establishing timelines for compliance by small businesses (including small business dispensers with

25 or fewer full-time employees) with such requirements, in order to ensure that such requirements do not impose undue economic hardship for small businesses, including small business dispensers for whom the criteria set forth in the assessment under paragraph (3) is not met, if the Secretary determines that such requirements under paragraph (1) would result in undue economic hardship; and

"(ii) establishing a process by which a dispenser may request a waiver from any of the requirements set forth in paragraph (1) if the Secretary determines that such requirements would result in an undue economic hardship, which shall include a process for the biennial review and renewal of any such waiver.

"(3) ASSESSMENT.—

"(A) IN GENERAL.—Not later than the date that is 18 months after the Secretary issues the final guidance required under subsection (h), the Secretary shall enter into a contract with a private, independent consulting firm with expertise to conduct a technology and software assessment that looks at the feasibility of dispensers with 25 or fewer full-time employees conducting interoperable, electronic tracing of products at the package level. Such assessment shall be completed not later than 8½ years after the date of enactment of the Drug Supply Chain Security Act.

"(B) CONDITION.—As a condition of the award of the contract under subparagraph (A), the private, independent consulting firm shall agree to consult with dispensers with 25 or fewer full-time employees when conducting the assessment under such subparagraph.

"(C) CONTENT.—The assessment under subparagraph (A) shall assess whether—

"(i) the necessary software and hardware is readily accessible to such dispensers;

"(ii) the necessary software and hardware is prohibitively expensive to obtain, install, and maintain for such dispensers; and

"(iii) the necessary hardware and software can be integrated into business practices, such as interoperability with wholesale distributors, for such dispensers.

"(D) PUBLICATION.—The Secretary shall—

"(i) publish the statement of work for the assessment under subparagraph (A) for public comment prior to beginning the assessment;

"(ii) publish the final assessment for public comment not later than 30 calendar days after receiving such assessment; and

"(iii) hold a public meeting not later than 180 calendar days after receiving the final assessment at which public stakeholders may present their views on the assessment.

"(4) PROCEDURE.—Notwithstanding section 553 of title 5, United States Code, the Secretary, in promulgating any regulation pursuant to this section, shall—

"(A) provide appropriate flexibility by—

"(i) not requiring the adoption of specific business systems for the maintenance and transmission of data;

"(ii) prescribing alternative methods of compliance for any of the requirements set forth in paragraph (1) or set forth in regulations implementing such requirements, including—

"(I) timelines for small businesses to comply with the requirements set forth in the regulations in order to ensure that such requirements do not impose undue economic hardship for small businesses (including small business dispensers for whom the criteria set forth in the assessment under paragraph (3) is not met), if the Secretary determines that such requirements would result in undue economic hardship; and

"(II) the establishment of a process by which a dispenser may request a waiver from any of the requirements set forth in such regulations if the Secretary determines that such requirements would result in an undue economic hardship; and

"(iii) taking into consideration—

"(I) the results of pilot projects, including pilot projects pursuant to this section and private sector pilot projects, including those involving the use of aggregation and inference;

"(II) the public meetings held and related guidance documents issued under this section;

"(III) the public health benefits of any additional regulations in comparison to the cost of compliance with such requirements, including on entities of varying sizes and capabilities;

"(IV) the diversity of the pharmaceutical distribution supply chain by providing appropriate flexibility for each sector, including both large and small businesses; and

"(V) the assessment pursuant to paragraph (3) with respect to small business dispensers, including related public comment and the public meeting, and requirements under this section;

"(B) issue a notice of proposed rulemaking that includes a copy of the proposed regulation;

"(C) provide a period of not less than 60 days for comments on the proposed regulation; and

"(D) publish in the Federal Register the final regulation not less than 2 years prior to the effective date of the regulation.

"(h) GUIDANCE DOCUMENTS.—

"(1) IN GENERAL.—For the purposes of facilitating the successful and efficient adoption of secure, interoperable product tracing at the package level in order to enhance drug distribution security and further protect the public health, the Secretary shall issue the guidance documents as provided for in this subsection.

"(2) SUSPECT AND ILLEGITIMATE PRODUCT.—

"(A) IN GENERAL.—Not later than 180 days after the date of enactment of the Drug Supply Chain Security Act, the Secretary shall issue a guidance document to aid

trading partners in the identification of a suspect product and notification termination. Such guidance document shall—

"(i) identify specific scenarios that could significantly increase the risk of a suspect product entering the pharmaceutical distribution supply chain;

"(ii) provide recommendation on how trading partners may identify such product and make a determination on whether the product is a suspect product as soon as practicable; and

"(iii) set forth the process by which manufacturers, repackagers, wholesale distributors, and dispensers shall terminate notifications in consultation with the Secretary regarding illegitimate product pursuant to subsections (b)(4)(B), (c)(4)(B), (d)(4)(B), and (e)(4)(B).

"(B) REVISED GUIDANCE.—If the Secretary revises the guidance issued under subparagraph (A), the Secretary shall follow the procedure set forth in paragraph (5).

"(3) UNIT LEVEL TRACING.—

"(A) IN GENERAL.—In order to enhance drug distribution security at the package level, not later than 18 months after conducting a public meeting on the system attributes necessary to enable secure tracing of product at the package level, including allowing for the use of verification, inference, and aggregation, as necessary, the Secretary shall issue a final guidance document that outlines and makes recommendations with respect to the system attributes necessary to enable secure tracing at the package level as required under the requirements established under subsection (g). Such guidance document shall—

"(i) define the circumstances under which the sectors within the pharmaceutical distribution supply chain may, in the most efficient manner practicable, infer the contents of a case, pallet, tote, or other aggregate of individual packages or containers of product, from a product identifier associated with the case, pallet, tote, or other aggregate, without opening each case, pallet, tote, or other aggregate or otherwise individually scanning each package;

"(ii) identify methods and processes to enhance secure tracing of product at the package level, such as secure processes to facilitate the use of inference, enhanced verification activities, the use of aggregation and inference, processes that utilize the product identifiers to enhance tracing of product at the package level, including the standardized numerical identifier, or package security features; and

"(iii) ensure the protection of confidential commercial information and trade secrets.

"(B) PROCEDURE.—In issuing the guidance under subparagraph (A), and in revising such guidance, if applicable, the Secretary shall follow the procedure set forth in paragraph (5).

"(4) STANDARDS FOR INTEROPERABLE DATA EXCHANGE.—

"(A) IN GENERAL.—In order to enhance secure tracing of a product at the package level, the Secretary, not later than 18 months after conducting a public meeting on the

interoperable standards necessary to enhance the security of the pharmaceutical distribution supply chain, shall update the guidance issued pursuant to subsection (a)(2), as necessary and appropriate, and finalize such guidance document so that the guidance document—

"(i) identifies and makes recommendations with respect to the standards necessary for adoption in order to support the secure, interoperable electronic data exchange among the pharmaceutical distribution supply chain that comply with a form and format developed by a widely recognized international standards development organization;

"(ii) takes into consideration standards established pursuant to subsection (a)(2) and section 505D;

"(iii) facilitates the creation of a uniform process or methodology for product tracing; and

"(iv) ensures the protection of confidential commercial information and trade secrets.

"(B) PROCEDURE.—In issuing the guidance under subparagraph (A), and in revising such guidance, if applicable, the Secretary shall follow the procedure set forth in paragraph (5).

"(5) PROCEDURE.—In issuing or revising any guidance issued pursuant to this subsection or subsection (g), except the initial guidance issued under paragraph (2)(A), the Secretary shall—

"(A) publish a notice in the Federal Register for a period not less than 30 days announcing that the draft or revised draft guidance is available;

"(B) post the draft guidance document on the Internet Web site of the Food and Drug Administration and make such draft guidance document available in hard copy;

"(C) provide an opportunity for comment and review and take into consideration any comments received;

"(D) revise the draft guidance, as appropriate;

"(E) publish a notice in the Federal Register for a period not less than 30 days announcing that the final guidance or final revised guidance is available;

"(F) post the final guidance document on the Internet Web site of the Food and Drug Administration and make such final guidance document available in hard copy; and

"(G) provide for an effective date of not earlier than 1 year after such guidance becomes final.

"(i) PUBLIC MEETINGS.—

"(1) IN GENERAL.—The Secretary shall hold not less than 5 public meetings to enhance the safety and security of the pharmaceutical distribution supply chain and provide for comment. The Secretary may hold the first such public meeting not earlier than 1 year after the date of enactment of the Drug Supply Chain Security Act. In carrying out the public meetings described in this paragraph, the Secretary shall—

"(A) prioritize topics necessary to inform the issuance of the guidance described in paragraphs (3) and (4) of subsection (h); and

"(B) take all measures reasonable and practicable to ensure the protection of confidential commercial information and trade secrets.

"(2) CONTENT.—Each of the following topics shall be addressed in at least one of the public meetings described in paragraph (1):

"(A) An assessment of the steps taken under subsections (b) through (e) to build capacity for a unit-level system, including the impact of the requirements of such subsections on—

"(i) the ability of the health care system collectively to maintain patient access to medicines;

"(ii) the scalability of such requirements, including as it relates to product lines; and

"(iii) the capability of different sectors and subsectors, including both large and small businesses, to affix and utilize the product identifier.

"(B) The system attributes necessary to support the requirements set forth under subsection (g), including the standards necessary for adoption in order to support the secure, interoperable electronic data exchange among sectors within the pharmaceutical distribution supply chain.

"(C) Best practices in each of the different sectors within the pharmaceutical distribution supply chain to implement the requirements of this section.

"(D) The costs and benefits of the implementation of this section, including the impact on each pharmaceutical distribution supply chain sector and on public health.

"(E) Whether electronic tracing requirements, including tracing of product at the package level, are feasible, cost effective, and needed to protect the public health.

"(F) The systems and processes needed to utilize the product identifiers to enhance tracing of product at the package level, including allowing for verification, aggregation, and inference, as necessary.

"(G) The technical capabilities and legal authorities, if any, needed to establish an interoperable, electronic system that provides for tracing of product at the package level.

"(H) The impact that such additional requirements would have on patient safety, the drug supply, cost and regulatory burden, and timely patient access to prescription drugs.

"(I) Other topics, as determined appropriate by the Secretary.

"(j) PILOT PROJECTS.—

"(1) IN GENERAL.—The Secretary shall establish 1 or more pilot projects, in coordination with authorized manufacturers, repackagers, wholesale distributors, and dispensers, to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution supply chain. Such projects shall build upon efforts, in existence as of the date of enactment of the Drug Supply Chain Security Act, to enhance the safety and security of the pharmaceutical distribution supply chain, take into consideration any pilot projects conducted prior to such date of enactment, including any pilot projects that use aggregation and inference, and inform the draft and final guidance under paragraphs (3) and (4) of subsection (h).

"(2) CONTENT.—

"(A) IN GENERAL.—The Secretary shall ensure that the pilot projects under paragraph (1) reflect the diversity of the pharmaceutical distribution supply chain and that the pilot projects, when taken as a whole, include participants representative of every sector, including both large and small businesses.

"(B) PROJECT DESIGN.—The pilot projects under paragraph (1) shall be designed to—

"(i) utilize the product identifier for tracing of a product, which may include verification of the product identifier of a product, including the use of aggregation and inference;

"(ii) improve the technical capabilities of each sector and subsector to comply with systems and processes needed to utilize the product identifiers to enhance tracing of a product;

"(iii) identify system attributes that are necessary to implement the requirements established under this section; and

"(iv) complete other activities as determined by the Secretary.

"(k) SUNSET.—The following requirements shall have no force or effect beginning on the date that is 10 years after the date of enactment of the Drug Supply Chain Security Act:

"(1) The provision and receipt of transaction history under this section.

"(2) The requirements set forth for returns under subsections (b)(4)(E), (c)(1)(B)(i), (d)(1)(C)(i), and (e)(4)(E).

"(3) The requirements set forth under subparagraphs (A)(v)(II) and (D) of subsection (c)(1), as applied to lot level information only.

"(l) RULE OF CONSTRUCTION.—The requirements set forth in subsections (g)(4), (i), and (j) shall not be construed as a condition, prohibition, or precedent for precluding or delaying the provisions becoming effective pursuant to subsection (g).

"(m) REQUESTS FOR INFORMATION.—On the date that is 10 years after the date of enactment of the Drug Supply Chain Security Act, the timeline for responses to requests for information from the Secretary, or other appropriate Federal or State official, as applicable, under subsections (b)(1)(B), (c)(1)(C), and (e)(1)(C) shall be not later than 24 hours after receiving the request from the Secretary or other appropriate Federal or State official, as applicable, or in such other reasonable time as determined by the Secretary based on the circumstances of the request.".

SEC. 204. NATIONAL STANDARDS FOR PRESCRIPTION DRUG WHOLESALE DISTRIBUTORS.

(a) AMENDMENTS.—

(1) REQUIREMENT.—Section 503(e) (21 U.S.C. 353(e)) is amended by striking paragraphs (1), (2), and (3) and inserting the following:

"(1) REQUIREMENT.—Subject to section 583:

"(A) IN GENERAL.—No person may engage in wholesale distribution of a drug subject to subsection (b)(1) in any State unless such person—

"(i)(I) is licensed by the State from which the drug is distributed; or

"(II) if the State from which the drug is distributed has not established a licensure requirement, is licensed by the Secretary; and

"(ii) if the drug is distributed interstate, is licensed by the State into which the drug is distributed if the State into which the drug is distributed requires the licensure of a person that distributes drugs into the State.

"(B) STANDARDS.—Each Federal and State license described in subparagraph (A) shall meet the standards, terms, and conditions established by the Secretary under section 583.

"(2) REPORTING AND DATABASE.—

"(A) REPORTING.—Beginning January 1, 2015, any person who owns or operates an establishment that engages in wholesale distribution shall—

"(i) report to the Secretary, on an annual basis pursuant to a schedule determined by the Secretary—

"(I) each State by which the person is licensed and the appropriate identification number of each such license; and

"(II) the name, address, and contact information of each facility at which, and all trade names under which, the person conducts business; and

"(ii) report to the Secretary within a reasonable period of time and in a reasonable manner, as determined by the Secretary, any significant disciplinary actions, such as the revocation or suspension of a wholesale distributor license, taken by a State or the Federal Government during the reporting period against the wholesale distributor.

"(B) DATABASE.—Not later than January 1, 2015, the Secretary shall establish a database of authorized wholesale distributors. Such database shall—

"(i) identify each authorized wholesale distributor by name, contact information, and each State where such wholesale distributor is appropriately licensed to engage in wholesale distribution;

"(ii) be available to the public on the Internet Web site of the Food and Drug Administration; and

"(iii) be regularly updated on a schedule determined by the Secretary.

"(C) COORDINATION.—The Secretary shall establish a format and procedure for appropriate State officials to access the information provided pursuant to subparagraph (A) in a prompt and secure manner.

"(D) CONFIDENTIALITY.—Nothing in this paragraph shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

"(3) COSTS.—

"(A) AUTHORIZED FEES OF SECRETARY.—If a State does not establish a licensing program for persons engaged in the wholesale distribution of a drug subject to subsection

(b), the Secretary shall license a person engaged in wholesale distribution located in such State and may collect a reasonable fee in such amount necessary to reimburse the Secretary for costs associated with establishing and administering the licensure program and conducting periodic inspections under this section. The Secretary shall adjust fee rates as needed on an annual basis to generate only the amount of revenue needed to perform this service. Fees authorized under this paragraph shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

"(B) STATE LICENSING FEES.—Nothing in this Act shall prohibit States from collecting fees from wholesale distributors in connection with State licensing of such distributors.".

(2) WHOLESALE DISTRIBUTION.—Section 503(e) (21 U.S.C. 353(e)), as amended by paragraph (1), is further amended by adding at the end the following:

"(4) For the purposes of this subsection and subsection (d), the term 'wholesale distribution' means the distribution of a drug subject to subsection (b) to a person other than a consumer or patient, or receipt of a drug subject to subsection (b) by a person other than the consumer or patient, but does not include—

"(A) intracompany distribution of any drug between members of an affiliate or within a manufacturer;

"(B) the distribution of a drug, or an offer to distribute a drug among hospitals or other health care entities which are under common control;

"(C) the distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act, except that, for purposes of this paragraph, a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

"(D) the dispensing of a drug pursuant to a prescription executed in accordance with subsection (b)(1);

"(E) the distribution of minimal quantities of drug by a licensed retail pharmacy to a licensed practitioner for office use;

"(F) the distribution of a drug or an offer to distribute a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

"(G) the purchase or other acquisition by a dispenser, hospital, or other health care entity of a drug for use by such dispenser, hospital, or other health care entity;

"(H) the distribution of a drug by the manufacturer of such drug;

"(I) the receipt or transfer of a drug by an authorized third-party logistics provider provided that such third-party logistics provider does not take ownership of the drug;

"(J) a common carrier that transports a drug, provided that the common carrier does not take ownership of the drug;

"(K) the distribution of a drug, or an offer to distribute a drug by an authorized repackager that has taken ownership or possession of the drug and repacks it in accordance with section 582(e);

"(L) salable drug returns when conducted by a dispenser;

"(M) the distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user (referred to in this subparagraph as a 'medical convenience kit') if—

"(i) the medical convenience kit is assembled in an establishment that is registered with the Food and Drug Administration as a device manufacturer in accordance with section 510(b)(2);

"(ii) the medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Comprehensive Drug Abuse Prevention and Control Act of 1970;

"(iii) in the case of a medical convenience kit that includes a product, the person that manufacturers the kit—

"(I) purchased such product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

"(II) does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and

"(iv) in the case of a medical convenience kit that includes a product, the product is—

"(I) an intravenous solution intended for the replenishment of fluids and electrolytes;

"(II) a product intended to maintain the equilibrium of water and minerals in the body;

"(III) a product intended for irrigation or reconstitution;

"(IV) an anesthetic;

"(V) an anticoagulant;

"(VI) a vasopressor; or

"(VII) a sympathomimetic;

"(N) the distribution of an intravenous drug that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

"(O) the distribution of an intravenous drug used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

"(P) the distribution of a drug that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

"(Q) the distribution of medical gas, as defined in section 575;

"(R) facilitating the distribution of a product by providing solely administrative services, including processing of orders and payments; or

"(S) the transfer of a product by a hospital or other health care entity, or by a wholesale distributor or manufacturer operating at the direction of the hospital or other health care entity, to a repackager described in section 581(16)(B) and registered under section 510 for the purpose of repackaging the drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the drug remains with the hospital or other health care entity at all times.".

(3) THIRD-PARTY LOGISTICS PROVIDERS.—Section 503(e) (21 U.S.C. 353(e)), as amended by paragraph (2), is further amended by adding at the end the following:

"(5) THIRD-PARTY LOGISTICS PROVIDERS.—Notwithstanding paragraphs (1) through (4), each entity that meets the definition of a third-party logistics provider under section 581(22) shall obtain a license as a third-party logistics provider as described in section 584(a) and is not required to obtain a license as a wholesale distributor if the entity never assumes an ownership interest in the product it handles.".

(4) AFFILIATE.—Section 503(e) (21 U.S.C. 353(e)), as amended by paragraph (3), is further amended by adding at the end the following:

"(6) AFFILIATE.—For purposes of this subsection, the term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—

"(A) one business entity controls, or has the power to control, the other business entity; or

"(B) a third party controls, or has the power to control, both of the business entities.".

(5) STANDARDS.—Subchapter H of chapter V, as added by section 202, is amended by adding at the end the following:

"SEC. 583. NATIONAL STANDARDS FOR PRESCRIPTION DRUG WHOLESALE DISTRIBUTORS.

"(a) IN GENERAL.—The Secretary shall, not later than 2 years after the date of enactment of the Drug Supply Chain Security Act, establish by regulation standards for the licensing of persons under section 503(e)(1) (as amended by the Drug Supply Chain Security Act), including the revocation, reissuance, and renewal of such license.

"(b) CONTENT.—For the purpose of ensuring uniformity with respect to standards set forth in this section, the standards established under subsection (a) shall apply to all State and Federal licenses described under section 503(e)(1) (as amended by the Drug Supply Chain Security Act) and shall include standards for the following:

"(1) The storage and handling of prescription drugs, including facility requirements.

"(2) The establishment and maintenance of records of the distributions of such drugs.

"(3) The furnishing of a bond or other equivalent means of security, as follows:

"(A)(i) For the issuance or renewal of a wholesale distributor license, an applicant that is not a government owned and operated wholesale distributor shall submit a surety bond of $100,000 or other equivalent means of security acceptable to the State.

"(ii) For purposes of clause (i), the State or other applicable authority may accept a surety bond in the amount of $25,000 if the annual gross receipts of the previous tax year for the wholesaler is $10,000,000 or less.

"(B) If a wholesale distributor can provide evidence that it possesses the required bond in a State, the requirement for a bond in another State shall be waived.

"(4) Mandatory background checks and fingerprinting of facility managers or designated representatives.

"(5) The establishment and implementation of qualifications for key personnel.

"(6) The mandatory physical inspection of any facility to be used in wholesale distribution within a reasonable time frame from the initial application of the facility and to be conducted by the licensing authority or by the State, consistent with subsection (c).

"(7) In accordance with subsection (d), the prohibition of certain persons from receiving or maintaining licensure for wholesale distribution.

"(c) INSPECTIONS.—To satisfy the inspection requirement under subsection (b)(6), the Federal or State licensing authority may conduct the inspection or may accept an inspection by the State in which the facility is located, or by a third-party accreditation or inspection service approved by the Secretary or the State licensing such wholesale distributor.

"(d) PROHIBITED PERSONS.—The standards established under subsection (a) shall include requirements to prohibit a person from receiving or maintaining licensure for wholesale distribution if the person—

"(1) has been convicted of any felony for conduct relating to wholesale distribution, any felony violation of subsection (i) or (k) of section 301, or any felony violation of section 1365 of title 18, United States Code, relating to product tampering; or

"(2) has engaged in a pattern of violating the requirements of this section, or State requirements for licensure, that presents a threat of serious adverse health consequences or death to humans.

"(e) REQUIREMENTS.—The Secretary, in promulgating any regulation pursuant to this section, shall, notwithstanding section 553 of title 5, United States Code—

"(1) issue a notice of proposed rulemaking that includes a copy of the proposed regulation;

"(2) provide a period of not less than 60 days for comments on the proposed regulation; and

"(3) provide that the final regulation take effect on the date that is 2 years after the date such final regulation is published.".

(b) AUTHORIZED DISTRIBUTORS OF RECORD.—Section 503(d) (21 U.S.C. 353(d)) is amended by adding at the end the following:

"(4) In this subsection, the term 'authorized distributors of record' means those distributors with whom a manufacturer

has established an ongoing relationship to distribute such manufacturer's products.".

(c) EFFECTIVE DATE.—The amendments made by subsections (a) and (b) shall take effect on January 1, 2015.

SEC. 205. NATIONAL STANDARDS FOR THIRD-PARTY LOGISTICS PROVIDERS; UNIFORM NATIONAL POLICY.

Subchapter H of chapter V, as amended by section 204, is further amended by adding at the end the following:

"SEC. 584. NATIONAL STANDARDS FOR THIRD-PARTY LOGISTICS PROVIDERS.

"(a) REQUIREMENTS.—No third-party logistics provider in any State may conduct activities in any State unless each facility of such third-party logistics provider—

"(1)(A) is licensed by the State from which the drug is distributed by the third-party logistics provider, in accordance with the regulations promulgated under subsection (d); or

"(B) if the State from which the drug distributed by the third-party logistics provider has not established a licensure requirement, is licensed by the Secretary, in accordance with the regulations promulgated under subsection (d); and

"(2) if the drug is distributed interstate, is licensed by the State into which the drug is distributed by the third-party logistics provider if such State licenses third-party logistics providers that distribute drugs into the State and the third-party logistics provider is not licensed by the Secretary as described in paragraph (1)(B).

"(b) REPORTING.—Beginning 1 year after the date of enactment of the Drug Supply Chain Security Act, a facility of a third-party logistics provider shall report to the Secretary, on an annual basis pursuant to a schedule determined by the Secretary—

"(1) the State by which the facility is licensed and the appropriate identification number of such license; and

"(2) the name and address of the facility and all trade names under which such facility conducts business.

"(c) COSTS.—

"(1) AUTHORIZED FEES OF SECRETARY.—If a State does not establish a licensing program for a third-party logistics provider, the Secretary shall license the third-party logistics provider located in such State and may collect a reasonable fee in such amount necessary to reimburse the Secretary for costs associated with establishing and administering the licensure program and conducting periodic inspections under this section. The Secretary shall adjust fee rates as needed on an annual basis to generate only the amount of revenue needed to perform this service. Fees authorized under this paragraph shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation.

"(2) STATE LICENSING FEES.—

"(A) STATE ESTABLISHED PROGRAM.—Nothing in this Act shall prohibit a State that has established a program

to license a third-party logistics provider from collecting fees from a third-party logistics provider for such a license.

"(B) NO STATE ESTABLISHED PROGRAM.—A State that does not establish a program to license a third-party logistics provider in accordance with this section shall be prohibited from collecting a State licensing fee from a third-party logistics provider.

"(d) REGULATIONS.—

"(1) IN GENERAL.—Not later than 2 years after the date of enactment of the Drug Supply Chain Security Act, the Secretary shall issue regulations regarding the standards for licensing under subsection (a), including the revocation and reissuance of such license, to third-party logistics providers under this section.

"(2) CONTENT.—Such regulations shall—

"(A) establish a process by which a third-party accreditation program approved by the Secretary shall, upon request by a third-party logistics provider, issue a license to each third-party logistics provider that meets the requirements set forth in this section;

"(B) establish a process by which the Secretary shall issue a license to each third-party logistics provider that meets the requirements set forth in this section if the Secretary is not able to approve a third-party accreditation program because no such program meets the Secretary's requirements necessary for approval of such a third-party accreditation program;

"(C) require that the entity complies with storage practices, as determined by the Secretary for such facility, including—

"(i) maintaining access to warehouse space of suitable size to facilitate safe operations, including a suitable area to quarantine suspect product;

"(ii) maintaining adequate security; and

"(iii) having written policies and procedures to—

"(I) address receipt, security, storage, inventory, shipment, and distribution of a product;

"(II) identify, record, and report confirmed losses or thefts in the United States;

"(III) correct errors and inaccuracies in inventories;

"(IV) provide support for manufacturer recalls;

"(V) prepare for, protect against, and address any reasonably foreseeable crisis that affects security or operation at the facility, such as a strike, fire, or flood;

"(VI) ensure that any expired product is segregated from other products and returned to the manufacturer or repackager or destroyed;

"(VII) maintain the capability to trace the receipt and outbound distribution of a product, and supplies and records of inventory; and

"(VIII) quarantine or destroy a suspect product if directed to do so by the respective manufacturer, wholesale distributor, dispenser, or an authorized government agency;

"(D) provide for periodic inspection by the licensing authority, as determined by the Secretary, of such facility warehouse space to ensure compliance with this section;

"(E) prohibit a facility from having as a manager or designated representative anyone convicted of any felony violation of subsection (i) or (k) of section 301 or any violation of section 1365 of title 18, United States Code relating to product tampering;

"(F) provide for mandatory background checks of a facility manager or a designated representative of such manager;

"(G) require a third-party logistics provider to provide the applicable licensing authority, upon a request by such authority, a list of all product manufacturers, wholesale distributors, and dispensers for whom the third-party logistics provider provides services at such facility; and

"(H) include procedures under which any third-party logistics provider license—

"(i) expires on the date that is 3 years after issuance of the license; and

"(ii) may be renewed for additional 3-year periods.

"(3) PROCEDURE.—In promulgating the regulations under this subsection, the Secretary shall, notwithstanding section 553 of title 5, United States Code—

"(A) issue a notice of proposed rulemaking that includes a copy of the proposed regulation;

"(B) provide a period of not less than 60 days for comments on the proposed regulation; and

"(C) provide that the final regulation takes effect upon the expiration of 1 year after the date that such final regulation is issued.

"(e) VALIDITY.—A license issued under this section shall remain valid as long as such third-party logistics provider remains licensed consistent with this section. If the Secretary finds that the third-party accreditation program demonstrates that all applicable requirements for licensure under this section are met, the Secretary shall issue a license under this section to a third-party logistics provider receiving accreditation, pursuant to subsection (d)(2)(A).

"SEC. 585. UNIFORM NATIONAL POLICY.

"(a) PRODUCT TRACING AND OTHER REQUIREMENTS.—Beginning on the date of enactment of the Drug Supply Chain Security Act, no State or political subdivision of a State may establish or continue in effect any requirements for tracing products through the distribution system (including any requirements with respect to statements of distribution history, transaction history, transaction information, or transaction statement of a product as such product changes ownership in the supply chain, or verification, investigation, disposition, notification, or recordkeeping relating to such systems, including paper or electronic pedigree systems or for tracking and tracing drugs throughout the distribution system) which are inconsistent with, more stringent than, or in addition to, any requirements applicable under section 503(e) (as amended by such Act) or this subchapter (or regulations issued thereunder), or which are inconsistent with—

"(1) any waiver, exception, or exemption pursuant to section 581 or 582; or

"(2) any restrictions specified in section 582.

"(b) WHOLESALE DISTRIBUTOR AND THIRD-PARTY LOGISTICS PROVIDER STANDARDS.—

"(1) IN GENERAL.—Beginning on the date of enactment of the Drug Supply Chain Security Act, no State or political subdivision of a State may establish or continue any standards, requirements, or regulations with respect to wholesale prescription drug distributor or third-party logistics provider licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards and requirements applicable under section 503(e) (as amended by such Act), in the case of a wholesale distributor, or section 584, in the case of a third-party logistics provider.

"(2) STATE REGULATION OF THIRD-PARTY LOGISTICS PROVIDERS.—No State shall regulate third-party logistics providers as wholesale distributors.

"(3) ADMINISTRATION FEES.—Notwithstanding paragraph (1), a State may administer fee collections for effectuating the wholesale drug distributor and third-party logistics provider licensure requirements under sections 503(e) (as amended by the Drug Supply Chain Security Act), 583, and 584.

"(4) ENFORCEMENT, SUSPENSION, AND REVOCATION.—Notwithstanding paragraph (1), a State—

"(A) may take administrative action, including fines, to enforce a requirement promulgated by the State in accordance with section 503(e) (as amended by the Drug Supply Chain Security Act) or this subchapter;

"(B) may provide for the suspension or revocation of licenses issued by the State for violations of the laws of such State;

"(C) upon conviction of violations of Federal, State, or local drug laws or regulations, may provide for fines, imprisonment, or civil penalties; and

"(D) may regulate activities of licensed entities in a manner that is consistent with product tracing requirements under section 582.

"(c) EXCEPTION.—Nothing in this section shall be construed to preempt State requirements related to the distribution of prescription drugs if such requirements are not related to product tracing as described in subsection (a) or wholesale distributor and third-party logistics provider licensure as described in subsection (b) applicable under section 503(e) (as amended by the Drug Supply Chain Security Act) or this subchapter (or regulations issued thereunder).".

SEC. 206. PENALTIES.

(a) PROHIBITED ACT.—Section 301(t) (21 U.S.C. 331(t)), is amended—

(1) by striking "or" after "the requirements of section 503(d),"; and

(2) by inserting ", failure to comply with the requirements under section 582, the failure to comply with the requirements under section 584, as applicable," after "in violation of section 503(e)".

(b) MISBRANDING.—Section 502 (21 U.S.C. 352), as amended by section 103, is further amended by adding at the end the following:

"(cc) If it is a drug and it fails to bear the product identifier as required by section 582.".

SEC. 207. CONFORMING AMENDMENT.

(a) IN GENERAL.—Section 303(b)(1)(D) (21 U.S.C. 333(b)(1)(D)) is amended by striking "503(e)(2)(A)" and inserting "503(e)(1)".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on January 1, 2015.

SEC. 208. SAVINGS CLAUSE.

Except as provided in the amendments made by paragraphs (1), (2), and (3) of section 204(a) and by section 206(a), nothing in this title (including the amendments made by this title) shall be construed as altering any authority of the Secretary of Health and Human Services with respect to a drug subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)) under any other provision of such Act or the Public Health Service Act (42 U.S.C. 201 et seq.).

Speaker of the House of Representatives.

Vice President of the United States and President of the Senate.

TASK FORCE ON MEDICAL DEVICE DISTRIBUTION

SEPTEMBER 29, 2015 · MEETING AGENDA

Meeting Location:
Louisiana Board of Drug and Device Distribution
12091 Bricksome Avenue, Suite B
Baton Rouge, LA 70816

Meeting Time:
9:30 AM to Noon

AGENDA ITEMS

I.	Welcome	George Lovecchio Executive Director, LBDDD Chairman, Task Force
II.	Facilitated Deliberation of Task Force	Rudy Gomez Partner, SSA Consultants Task Force Facilitator
III.	Next Steps	Rudy Gomez Partner, SSA Consultants Task Force Facilitator
IV.	Adjournment	George Lovecchio Executive Director, LBDDD Chairman, Task Force

ABOUT THE TASK FORCE ON MEDICAL DEVICE DISTRIBUTION

Senate Resolution (SR) 177 of the 2015 Louisiana Legislative Session created the Task Force on Medical Device Distribution "to review existing regulation and propose revisions of regulations and the elimination of duplicate regulations while remaining focused on the protection of the health and safety of Louisiana citizens."

Task Force on Medical Device Distribution

SEPTEMBER 29, 2015

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Agenda

I. Welcome
II. Facilitated Discussion of Task Force
III. Next Steps
IV. Adjournment

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Specific Recommendations for Consideration

- To propose that DHH conduct/assist FDA in the inspection processes that are required for Louisiana device manufacturers and obtain information and training necessary to do so. The inspection process shall be limited to the manufacturing portion of the FDA process. [APPROVED]
- To propose if DHH declines the responsibility of Louisiana device manufacturers inspection, the LBDDD shall be required to facilitate an FDA Device Manufacturer inspection as required by the FDA and obtain the training and credentials necessary to do so. [APPROVED]
- To affirm the LBDDD's current rule 301K Licensing renewal (Residence License) and 309 Storage and handling requirements for legend drugs and devices. [APPROVED]
- To amend the LBDDD's current rule on exemption of samples of drugs as stated within 105.A.6 to include "drugs and devices." [APPROVED]
- To affirm the LBDDD's current law on legend drug and legend device distributors. La.R.S. Chapter 54 of Title 37. [APPROVED]

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Specific Recommendations for Consideration

- Legend device and legend drug manufacturers must follow state distribution laws and rules as they pertain to distribution if the manufacturer acts in a distribution role. [APPROVED]
- To propose a state workshop to be conducted by NABP (all member states) for more compatible legend device distribution laws. [APPROVED]
- Legend device licensing requirement shall be for saleable items only and does not include instruments or samples not withstanding any other safety guidelines or requirements. [APPROVED]
- Exemption licensing legend device trunk stock for an agent or employee of the manufacturer of the legend device. The storage requirements of the legend device product must be maintained as explained in the laws and rules of the LBDDD and the State of Louisiana. [NOT APPROVED]

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Specific Recommendations for Consideration

- Exemption for legend device licensing in transit with a courier, agent, or employee of the manufacturer of the legend device. In the event of an emergency, natural disaster, or state of emergency, legend devices could be stored in an unlicensed facility subject to the review of the LBDDD. [APPROVED]
- LBDDD to monitor and implement rules consistent with the guidelines published by DSCSA, which is expected later this year. [APPROVED]
- To propose exemptions for licensing by the LBDDD for standalone software or medical software applications currently regulated by FDA. [APPROVED]

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Next Steps

- SSA will begin drafting the report for Task Force review based approved recommendations
- Next Task Force Meeting
  - December 1, 2015 9:00 AM till 4:00 PM at LBDDD office

6

Adjournment

7

Appendices

Appendix D – AdvaMed Letter to Task Force dated November 17, 2015

701 Pennsylvania Avenue, Ste. 800
Washington, DC 20004–2654
Tel: 202 783 8700
Fax: 202 783 8750
www.AdvaMed.org

AdvaMed
Advanced Medical Technology Association

November 17, 2015

George Lovecchio, Chair
Louisiana Board of Drug and Device Distributors
Baton Rouge, LA

Dear Mr. Lovecchio:

As the Task Force on Medical Device Distribution nears the end of its study, I want to thank you for your efforts to examine issues around the distribution of devices in Louisiana.

AdvaMed continues to believe that the same level of state oversight of pharmaceutical distribution is inappropriate for medical device distribution, which is significantly different and doesn't pose the same risk of harm to patients. As the attached paper explains, the federal Food and Drug Administration (FDA) has robust statutory and regulatory authority over all aspects of device manufacturing, distribution, and post-market oversight and enforcement, including the ability to inspect distribution facilities and records.

While we are glad that John Crenshaw, with Johnson & Johnson, was able to represent the industry on the task force, it is regrettable that overall task force members' recommendations were influenced by their background in drug distribution and ignorance of device distribution. For example, it is unnecessary over-regulation to require licensure of commercial rental units used by company representatives to store a modest supply of devices. Devices, stored in this manner, are often those referred to as physician preference items (PPI). PPI are those devices that have characteristics that differentiate them from alternatives and often require specialized training to use or implant them. Generally, it is not feasible for hospitals to maintain an extensive inventory of these devices. Unlike pharmaceuticals, there is virtually no risk of PPI devices being diverted and harming patients by being used outside of a physician's care. Therefore, we request that the task force recommend exempting from licensure devices kept in short-term rental units.

However, we strongly support the committee's plan to recommend exempting from licensure medical devices in transit with a courier, agent, or manufacturer's employee; allowing devices to be stored in an unlicensed facility in emergency situations; and exempting stand-alone medical

software or medical software applications. Often, there are instances where a courier or device company representative must transport a device from one facility to another, or from a company storage facility to a health care facility for trauma surgery, or because a facility does not have the appropriate device on hand. This exemption recognizes that these transactions are appropriate and do not pose a risk to patients.

We appreciate you considering our concerns and look forward to continuing to work with you.

Sincerely,

Thomas E. Tremble
Vice President, State Government Relations

cc: Senator Fred Mills
John Crenshaw

FDA Regulation of Medical Devices and State Registration and Licensure

Medical devices are heavily regulated by the federal Food and Drug Administration (FDA), which has oversight over all aspects of device manufacturing, distribution, and even post-market oversight and enforcement, including the ability to inspect distribution facilities and records. Fewer than twenty-five states choose to add additional distribution regulation for devices. In many cases, state registration or licensing of device distribution came from states broadly expanding their domain over prescription drugs to include devices as well. However, state regulation of devices is often duplicative of federal requirements and therefore can be confusing and unnecessary. Efforts should be made to minimize duplication of federal requirements, and avoid having drug-specific provisions apply to devices.

FDA Device Regulation

Premarket Requirements

- Exempt devices**.** Many medical devices, such as bandages, are exempt from premarket review because they pose little risk to patients and can be marketed once the manufacturer registers the device with the federal Food and Drug Administration (FDA).

- 510(k) Notification. Under the 510(k) section of the statute, if a moderate risk device is similar to a device already on the market and does not present new questions of safety and effectiveness, the manufacturer can bring it to market once FDA has reviewed evidence providing it is substantially similar to an existing device.

- Pre-Market Approval. Primarily high-risk devices, not eligible for the 510(k) process, go through the pre-market approval process, which requires submission of clinical studies demonstrating the device's safety and effectiveness.

Manufacturing

Once a product is cleared for market the manufacturer must abide by Good Manufacturing Practices (GMPs) and the Quality Systems Regulation (QSR) which requires manufacturers to have a quality system in place for different stages in the life of a device, including the design, manufacture, installation and servicing. Under QSR, the FDA holds manufacturers responsible for the quality of the product and processes, including ensuring that quality procedures are met by suppliers, contractors, and consultants.

Post-Market Requirements

The FDA has numerous regulations imposing requirements for device manufacturers once a device has been cleared for market. The Agency has oversight of a wide range of activities relating to device marketing and use, including problems that may develop with the device. The major areas of post-market oversight are:

- Registration, Listing and Inspection. Owners of establishments involved in the production and distribution of device must annually register with the FDA, as well as list the devices they

manufacture and th4e activities performed at those facilities. FDA conducts inspections of manufacturing facilities to determine compliance with GMPs.

- Labeling-These rules pertain to all labels and other printed materials accompanying the device. All devices must conform to general requirements for labeling. Some devices must include informational literature, patient release forms, and information on performance testing.

- Adverse Event Reporting The Medical Device Reporting (MDR) regulation stipulates how manufacturers report to FDA significant adverse events involving medical devices. The MDR process enables FDA to monitor issues and work with manufacturers to quickly address them.

- Medical Device Tracking. FDA has the authority to require device manufacturers to track certain devices through the distribution chain. Tracking allows the company to quickly notify patients if there is a need for notifications or recalls due to potential risks.

- The Sentinel Initiative and Unique Device Identifier (UDI) . The FDA is expanding its Sentinel Initiative, originally intended to track drug safety issues, to include medical devices. The Unique Device Identifier system has the potential, when fully implemented, to enhance various aspects of device distribution and safety, including improving handling of recalls and reducing counterfeiting.

State Medical Device Regulations

State regulations designed to apply to prescription drugs should not apply to devices, which include hip and knee implants, surgical tools, cardiac stents, and diagnostic equipment; all of which are inherently different from pharmaceuticals. State law should recognize these differences as well as the robust federal regulatory system that is in place. In most cases, these devices are designated as "prescription only" not because they pose a danger to consumers, but because they must be provided by a physician. In particular, state regulations should:

- Limit duties of medical device manufacturers to providing the state with a listing of in-state facilities and a copy of the company's FDA registration;
- Exclude device company executives from providing fingerprints or criminal background checks;
- Exclude from the distributor definition, a device company representative or agent providing device samples or loaner devices to providers; and
- Exclude from the distributor definition, device company representatives or agents who do not take ownership of the device.

Appendices

Appendix E – Task Force Meeting: Tuesday, December 1, 2015 Materials

TASK FORCE ON MEDICAL DEVICE DISTRIBUTION

DECEMBER 1, 2015 · MEETINGS MATERIALS

Meetings Location:
Louisiana Board of Drug and Device Distribution
12091 Bricksome Avenue, Suite B
Baton Rouge, LA 70816

Meetings Time:
December 1, 2015
9:00 AM to 4:00 PM

Material Packet Contents

- December 1, 2015 Meeting Agenda
- AdvaMed letter dated November 17, 2015
- Draft task force report

NOTE: For the purposes of this final report, the meeting minutes from the following task force meetings are included with this materials set.

- September 28, 2015
- September 29, 2015
- December 1, 2015

These minutes have not been formally received by the task force and have been compiled by the task force facilitator, SSA Consultants.

ABOUT THE TASK FORCE ON MEDICAL DEVICE DISTRIBUTION

Senate Resolution (SR) 177 of the 2015 Louisiana Legislative Session created the Task Force on Medical Device Distribution "to review existing regulation and propose revisions of regulations and the elimination of duplicate regulations while remaining focused on the protection of the health and safety of Louisiana citizens."

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AGENDA ITEMS

I.	Welcome	George Lovecchio Executive Director, LBDDD Chairman, Task Force
II.	Agenda Review	Rudy Gomez Partner, SSA Consultants Task Force Facilitator
III.	Review and Discussion of AdvaMed Letter	Rudy Gomez Partner, SSA Consultants Task Force Facilitator
IV.	Review and Approval of Task Force Report	Rudy Gomez Partner, SSA Consultants Task Force Facilitator
V.	Next Steps	Rudy Gomez Partner, SSA Consultants Task Force Facilitator
VI.	Adjournment	George Lovecchio Executive Director, LBDDD Chairman, Task Force

LUNCH PROVIDED

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Task Force on Medical Device Distribution in Louisiana

Senate Resolution No. 177
2015 Regular Session

Report of Findings and Recommendations to the Louisiana Legislature

12/1/2015

DRAFT

"…shall review existing regulations and propose revisions of regulations and the elimination of duplicate regulations related to the distribution of medical devices while remaining focused on the protection of the health and safety of Louisiana citizens."
Senate Resolution No. 177, 2015 Regular Session

Introduction

Senate Resolution 177 (SR 177) by Senator Mills, enacted during the 2015 regular session of the Louisiana Legislature, directed the Louisiana Board of Drug and Device Distributors to create the Task Force on Medical Device Distribution for the purpose of investigating "existing regulations and propose revisions of regulations and the elimination of duplicate regulations related to the distribution of medical devices while remaining focused on the protection of the health and safety of Louisiana Citizens."[1]

SR 177 specified five members of the committee, and these members were authorized to select designees to serve on the task force. SR 177 further specified that the Executive Director of the Louisiana Board of Drug and Device Distributors (or his designee) would serve as the task force chairperson, and that the task force members would serve without compensation.

Any official action by the task force would require a quorum (a simple majority of the total membership) of the task force present and an affirmative vote of a majority of the quorum present and voting.

The task force was charged to conduct its first meeting on or before September 1, 2015 and to complete its work by submitting a report of its findings and recommendations to the Louisiana Legislature no later than December 15, 2015. The authority of the task force terminates upon submission of the report to the legislature. A copy of SR 177 is provided in *Appendix A* of this document.

This document is the final report of the Task Force on Medical Device Distribution. It includes a listing of the task force members, a summary description of the task force's activities, copies of the task force meeting materials, and the task force's findings and recommendations – all submitted respectfully for review and consideration by the Louisiana Legislature.

The task force members extend a special thank you to Senator Mills for authoring SR 177, and the members of the task force also express their gratitude to the Louisiana Legislature for the opportunity to serve as part of this important study effort.

[1] SR 177 of the 2015 Louisiana Legislative Session

Table of Contents

Appendices

Executive Summary

Senate Resolution 177 (SR 177) by Senator Mills, enacted during the 2015 regular session of the Louisiana Legislature, created the Task Force on Medical Device Distribution for the purpose of investigating "existing regulations and propose revisions of regulations and the elimination of duplicate regulations related to the distribution of medical devices while remaining focused on the protection of the health and safety of Louisiana Citizens."[2]

SR 177 specified five stakeholder members of the committee. The task force conducted a total of five meetings in the late summer and fall of 2015 the last of which was held on December 1, 2015. All meetings were scheduled to last approximately four hours and each member of the task force was offered an open opportunity to present information, evidence, and arguments relevant to the issue before the task force.

The information, evidence, and arguments presented by individual committee members were discussed and debated by the task force but member votes were not taken to either accept or reject any of the arguments presented.

Task Force Recommendations

After completion of all presentations and discussions the task force the following eleven recommendations to the Louisiana Legislature were offered (by motion) and approved by the task force:

1. The task force recommends that the Louisiana Department of Health and Hospitals (DHH) collaborate with the federal Food and Drug Administration (FDA) to provide or assist in providing inspection processes required for Louisiana device manufacturers. DHH would need to obtain necessary information and training required to competently fulfill this role. This new inspection role for DHH would be limited to the manufacturing portion of the FDA's inspection processes.
2. The task force recommends that should DHH decline the new inspection responsibility described in recommendation number one above, the LBDDD should provide or assist in providing inspection processes required for Louisiana device manufacturers. LBDDD would need to obtain necessary information and training required to competently fulfill this role. This new inspection role for LBDDD would be limited to the manufacturing portion of the FDA's inspection processes.

[2] SR 177 of the 2015 Louisiana Legislative Session

3. The task force affirms the LBDDD's current rule for licensing renewal for Residence License (section 301.K) and the current rule for storage and handling requirements for legend drugs and devices (section 309).

4. The task force recommends amending the LBDDD's current rule on the exemption of drug samples, as stated within section 105.A.6, to read as "drugs and devices."

5. The task force affirms the LBDDD's current law on legend drug and legend device distributors as stated within Louisiana Revised Statute Chapter 54 of Title 37.

6. The task force affirms that legend device and legend drug manufacturers must follow state distribution laws and rules if the manufacturer acts in a distribution role.

7. The task force encourages the National Association of Boards of Pharmacy (NABP) to develop and conduct a workshop with all state members focused on the development of more compatible legend device distribution laws.

8. The task force affirms that the legend device licensing requirement shall be for saleable items only and does not include instruments or samples not withstanding any other safety guidelines or requirements.

9. The task force recommends the exemption for legend device licensing in transit with a courier, agent, or employee of the manufacturer of the legend device – in the event of an emergency, natural disaster, or state of emergency, legend devices could be stored in an unlicensed facility subject to the review of the LBDDD.

10. The task force recommends the LBDDD monitor the pending federal Drug Supply Chain Security Act (DSCSA) and implement Louisiana rules consistent with the guidelines published by DSCSA.

11. The task force recommends an LBDDD licensing exemption for standalone software or medical software applications currently regulated by the FDA.

Task Force Membership

SR 177 states the task force shall include the following members:

1. The secretary of the Department of Health and Hospitals, or her designee.
2. The president of the Louisiana Senate, or his designee.
3. The speaker of the Louisiana House of Representatives, or his designee.
4. The executive director of the Louisiana Board of Drug and Device Distributors, or his designee.
5. A representative of the Advanced Medical Technological Association.

Figure 1 includes a roster of the individuals that served on the task force as specified members or designees.

Figure 1. Task Force Members/Designees

Organizations Listed in Legislation:	Designee Name:
Louisiana Department of Health and Hospitals	Evonna Sue Fontenot, R.Ph.
Louisiana Senate	Claire Defelice
Louisiana House of Representatives	Jacob Dickson
Louisiana Board of Drug and Device Distributors	George Lovecchio
Advanced Medical Technological Association	John Crenshaw

Add bio summaries of each member/designee here – three or four line bio.

Task Force Activities

SR 177 created the Task Force on Medical Device Distribution and charged the Louisiana Board of Drug and Device Distributors (LBDDD) with the responsibility of administering the work of the task force. LBDDD engaged the services of SSA Consultants (SSA), a Baton Rouge-based management consulting firm to assist the board in the fulfillment of these responsibilities.

SSA managed all task force meeting logistics (scheduling, materials management, communications, facility arrangements, etc.), served as the independent facilitator of the task force's meetings, and drafted the task force's report of findings and recommendations (this report).

The task force agreed to and completed a total of four meetings, including:

1. Monday, August 31, 2015
2. Monday, September 28, 2015
3. Tuesday, September 29, 2015
4. Tuesday, December 1, 2015

Each of these four meetings lasted approximately four hours and was facilitated by SSA. The following is a summary of activity for each meeting.

Task Force Meeting: Monday, August 31, 2015

The agenda of the first meeting was focused on initial introductions of the task force members, opening statements by task force members, establishing the task force's meeting schedule and agenda outlines for each meeting. Additionally, the task force members discussed the items for further review in regards to their legislative charge.

A copy of all materials from this committee meeting (agenda, presentation materials set, and meeting minutes) is provided in *Appendix B* of this document.

Task Force Meeting: Monday, September 28, 2015

The agenda of the second meeting was focused on task force member presentations offering information about the specific functions of the LBDDD and addressing the relevant interface between state and federal regulations. A total of five presentations were developed and presented during this task force meeting.

The first presentation (by task force member John Crenshaw) focused on the definition of medical devices and the current initiatives and regulations acted upon by the federal Food and Drug Administration (FDA). The second presentation (by task force member George Lovecchio)

described the current relevant license types available in Louisiana today. Mr. Lovecchio also presented statistics on total numbers of active licenses and their impact on the state of Louisiana. The third presentation (by invited task force guest Trion Horgan of Stryker Orthopaedics) demonstrated current distribution models being utilized by the manufacturers and distributors of medical devices to supply clients.

The fourth presentation (by task force member Claire Defelice) detailed how inspections are currently handled by the LBDDD through a comprehensive look at the individual areas of inspection. The fifth presentation (by task force member George Lovecchio) reviewed the current enabling legislation (H.R. 3204-13) of the LBDDD's authority to carry out inspections and their overall duty to protect the people of Louisiana.

All presentations were followed by facilitated discussion.

A copy of all materials from this committee meeting (agenda, presentation materials set, and meeting minutes) is provided in *Appendix C* of this document.

Task Force Meeting: Tuesday, September 29, 2015

The agenda of the third meeting was focused on facilitated deliberations by the task force that included discussion and consideration of specific recommendations offered by individual task force members. Each recommendation offered (by motion) was discussed and debated and voted upon. A total of 12 recommendations were offered for consideration by the task force members and 11 recommendations were approved by a majority vote of the task force. One recommendation – requesting an exemption for legend device trunk stock – was offered for consideration by the task force members but the motion did not carry.

A copy of all materials from this task force meeting (agenda, presentation materials set, and meeting minutes) is provided in *Appendix C* of this document.

Task Force Meeting: Tuesday, December 1, 2015

The agenda of the fifth meeting included a review of the task force's draft report of findings and recommendations. The agenda also included review of written letter from the Advanced Medical Technology Association (AdvaMed) commenting on the work of the task force. A copy of the AdvaMed letter is provided in *Appendix D* of this document.

Suggested changes to the draft report were presented and discussed. Changes to the draft report were voted upon and approved changes were included in a final document that was approved by a vote of the task force.

A copy of all materials from this task force meeting (agenda, presentation materials set, and meeting minutes) is provided in *Appendix E* of this document.

Task Force Recommendations

After completion of all task force presentations and discussions the following eleven recommendations to the Louisiana Legislature were offered (by motion) and approved by the task force:

1. The task force recommends that the Louisiana Department of Health and Hospitals (DHH) collaborate with the federal Food and Drug Administration (FDA) to provide or assist in providing inspection processes required for Louisiana device manufacturers. DHH would need to obtain necessary information and training required to competently fulfill this role. This new inspection role for DHH would be limited to the manufacturing portion of the FDA's inspection processes.

2. The task force recommends that should DHH decline the new inspection responsibility described in recommendation number one above, the LBDDD should provide or assist in providing inspection processes required for Louisiana device manufacturers. LBDDD would need to obtain necessary information and training required to competently fulfill this role. This new inspection role for LBDDD would be limited to the manufacturing portion of the FDA's inspection processes.

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TASK FORCE ON MEDICAL DEVICE DISTRIBUTION

SEPTEMBER 28, 2015 · MEETING MINUTES

Meeting Location:
Louisiana Board of Drug and Device Distribution
12091 Bricksome Avenue, Suite B
Baton Rouge, LA 70816

Meeting Time:
9:30 AM to 4:00 PM

AGENDA ITEMS

I. Welcome – 9:36 AM

George Lovecchio
Executive Director, LBDDD
Chairman, Task Force

George Lovecchio, Task Force Chairman and Executive Director of the Louisiana Board of Drug and Device Distribution (LBDDD), and Rudy Gomez, Task Force Facilitator and Partner with SSA Consultants, welcomed task force members and public members to the second meeting of the Task Force on Medical Device Distribution.

II. Agenda Review

Rudy Gomez
Partner, SSA Consultants
Facilitator, Task Force

Rudy Gomez, Task Force Facilitator, reviewed the agenda and the schedule for the day, including task force presentations. He also reviewed the meeting material provided to task force members. The August meeting minutes were included in the material set for the members' review and approval.

Task force members then introduced themselves and the organization they represented for the record.

Task force members present for the meeting included:

1. Jacob Dickson; designee for Louisiana House of Representatives
2. Claire Defelice; designee for Louisiana Senate
3. George Lovecchio; designee for Louisiana Board of Drug and Device Distributors
4. John Crenshaw; designee for Advanced Medical Technological Association

Not present at this point in the meeting (but would join later) was the fifth task force member, Evonna Sue Fontenot, R.Ph. who is the designee for the Louisiana Department of Health and Hospitals.

A quorum of the task force was established by the members present.

III. Presentation – 9:45 AM

John Crenshaw
Director, U.S. Distribution
Johnson & Johnson Health Care Systems Inc.
Member, Task Force

John Crenshaw, task force member, provided information to the task force on the federal Food and Drug Administration (FDA) inspection process, the unique device identification (UDI) system, the 21st Century Cures Act, and the Drug Quality and Security Act (DQSA). He also provided information on the national trends legend drug and device manufacturers are seeing in the industry. A copy of his presentation materials was provided in the meeting material set. Following the presentation, task force members engaged in a question and answer session about the information presented.

The task force then took a break from 10:40 AM to 10:55 AM.

IV. Presentation – 10:55 AM

George Lovecchio
Executive Director, LBDDD
Chairman, Task Force

George Lovecchio, task force member, provided information to the task force on the Louisiana Board of Drug and Device Distribution (LBDDD) including the types of licensure, approval process, general timeline for licensure issuance, and scope of authority. The LBDDD is focused on the distribution of legend devices. A copy of his presentation was provided in the meeting material set. Task force members were free to ask questions throughout the presentation.

Lovecchio then introduced the types of distribution models that exist. To discuss the Type I distribution model and how it operates day-to-day, Trion Horgan, Branch Operations Manager with Stryker Orthopaedics, was invited to present to the task force members. A copy of his presentation was provided in the meeting material set. Horgan also displayed several examples of legend devices his company distributes. Task force members asked clarifying questions as needed during the presentation. These were primarily focused on understanding the distribution process for a legend medical device as it moves between the office to the hospital.

Lovecchio resumed his presentation with a description of Type II and III distribution models. It is estimated approximately 80% of orthopedic devices are in the Type II distribution model. The LBDDD's authority is for the distribution of legend devices and ensuring the health and safety of citizens of Louisiana who are the end users of the legend devices. Important that the legend devices are handled appropriately as they move through the distribution model. For example, some legend devices have a maximum temperature stipulated by the manufacturer. A copy of his presentation was provided in the meeting material set. Task force members were free to ask questions throughout the presentation.

The task force members were interested in understanding the LBDDD exemptions for legend devices in transit. For example, a sales rep who is transporting a legend device from one location to another (e.g., a storage unit to a hospital) would not need a license because the legend device is in transit. The LBDDD does not allow overnight storage of legend devices in home or cars for safety reasons. The LBDDD has offered a storage solution for sales rep who are in the field. One is a storage unit that meets state regulation (e.g., temperature monitoring, secure site, pest controlled, etc.) which would receive a license and be subject to annual inspection. Another option is to utilize a shipping service (like FedEx or UPS) who would hold the legend device for pick-up.

V. Lunch – 12:00 PM to 12:45 PM

The task force took a lunch break. Lunch was provided by the LBDDD.

VI. Presentation – 12:45 PM — George Lovecchio, Executive Director, LBDDD, Chairman, Task Force

After the lunch break, Lovechhio resumed his presentation with a review of license types and the ability of the LBDDD to sort, track, and report on its licensees. It is expected in November there will be updates to the federal guidelines. The LBDDD, in anticipation of the updates, made the necessary changes to its legislation during the 2015 Louisiana Legislative Session. Lovecchio also discussed the quick turnaround time from application to issuance of a license and it is one of the performance metrics for the office. The LBDDD has worked with the FDA to make suggestions to eliminate duplication where possible, such as the home state background checks.

The LBDDD has not expanded the scope of its authority and remains focused on its mission to protect the health and safety of the public. Nor is it the LBDDD's intent to delay or impede business operations or prevent patient access to life-saving care. Thus, the LBDDD has an emergency use clause. A copy of his presentation was provided in the meeting material set. Task force members were free to ask questions throughout the presentation.

Task Force member discussion included the LBDDD's participation in emergency planning operations and the anticipated federal guideline changes. In particular, the LBDDD is currently working through the Louisiana rule promulgation process with the goal of updated rules published by November 2016 and in effect by 2017. Louisiana is ahead of the curve in terms of the anticipated changes with other model states including California and Florida.

Next, Claire Defelice with Medi-Chest, Inc. and a task force member reviewed the inspection checklist used by the LBDDD, which is available online and from the LBDDD staff. Licensees are subject to an annual inspection by the LBDDD. A copy of her presentation was provided in the meeting material set. Task force members were free to ask questions throughout the presentation.

The task force took a break from 1:36 PM to 1:48 PM.

VII. Presentation – 1:48 PM — George Lovecchio, Executive Director, LBDDD, Chairman, Task Force

The task force meeting resumed after the break. Task force member Sue Fontenot joined the meeting at this point. The task force asked Lovecchio to discuss the most common violations found during the inspection process. Common violations included: temperature violations, unverified source, and cleanliness. Each inspection report is presented to the Board and kept on file at the Board office. The LBDDD made the investment to upgrade its technology and now have a digital version of the inspection report available immediately. Task force members were free to ask questions throughout the presentation.

Each licensee is subject to an annual inspection. More frequent inspections may be necessary if a violation is found. LBDDD does have the authority to quarantine in the field. The LBDDD rules dictate the violation notice and response process. A violation can elevate to a hearing for formal action if appropriate.

Lovecchio next reviewed the National Association Boards of Pharmacy VAWD program, which is a verification process. It is a costly and evolving program which is more focused on the legend drugs versus the legend devices. A copy of his presentation was provided in the meeting material set.

The final component of Lovecchio's presentation included a review of state vs. federal regulations. See the material set for presentation material including a report by JASOS comparing state and federal regulations. The states and the FDA work together to ensure the safety of the public with the states covering the distribution network while the FDA covers the manufacturing process. The research paper was authored by the JASOS firm in Florida who specialized in regulatory consulting.

The task force discussion began regarding the industry's interest in streamlining the process for clarity and consistency to easily understand requirements at the federal level and the at state level, especially if working in multiple states. The LBDDD's focus was to ensure the safety and health of Louisianans through the legend device distribution supply chain. The National Uniformity Act offers great promise to help create consistency across all settings. The LBDDD is supportive of those efforts and is working to align itself with the federal regulation. The meeting material set included a copy of the Drug Quality and Security Act as requested at the last task force meeting.

VIII. Next Steps – 2:53 PM

Rudy Gomez
Partner, SSA Consultants
Facilitator, Task Force

Gomez discussed with the task force members the next steps for the task force. The meeting scheduled for September 29, 2015 is to deliberate and create consensus on the task force's recommendations. The meeting is scheduled from 9:30 AM to 12:00 PM at the LBDDD office. The meeting goal is to have a sense of recommendations approved by the Task Force. SSA will then develop a draft report for circulation to the task force members. The last meeting is to edit and approve the report which will then be submitted to the Louisiana Legislature as outlined in Senate Resolution 177.

IX. Public Comment – 3:02 PM

Rudy Gomez
Partner, SSA Consultants
Facilitator, Task Force

The task force then opened the floor for public comment. There was none offered.

X. Adjournment

George Lovecchio
Executive Director, LBDDD
Chairman, Task Force

The Chairman opened the floor for a motion to adjourn the meeting. John Crenshaw made the motion and it was seconded by Jacob Dickson. There were no objections to the adjournment of the meeting.

These minutes have not been formally received by the task force and have been compiled by the task force facilitator, SSA Consultants.

ABOUT THE TASK FORCE ON MEDICAL DEVICE DISTRIBUTION

Senate Resolution (SR) 177 of the 2015 Louisiana Legislative Session created the Task Force on Medical Device Distribution "to review existing regulation and propose revisions of regulations and the elimination of duplicate regulations while remaining focused on the protection of the health and safety of Louisiana citizens."

TASK FORCE ON MEDICAL DEVICE DISTRIBUTION

SEPTEMBER 29, 2015 · MEETING AGENDA

Meeting Location:
Louisiana Board of Drug and Device Distribution
12091 Bricksome Avenue, Suite B
Baton Rouge, LA 70816

Meeting Time:
9:30 AM to Noon

AGENDA ITEMS

I. Welcome – 9:30 AM

George Lovecchio
Executive Director, LBDDD
Chairman, Task Force

George Lovecchio, Executive Director for Louisiana Board of Drug and Device Distribution (LBDDD) and Chairman of the task force, called the task force meeting to order and welcomed members to the meeting. Task force members then introduced themselves and the organization they represented for the record.

Task force members present for the meeting included:

1. Jacob Dickson; designee for Louisiana House of Representatives
2. Claire Defelice; designee for Louisiana Senate
3. George Lovecchio; designee for Louisiana Board of Drug and Device Distribution
4. John Crenshaw; designee for Advanced Medical Technological Association
5. Evonna Sue Fontenot, R.Ph.; designee for the Louisiana Department of Health and Hospitals

A quorum was established with the task force members present.

Rudy Gomez, Partner with SSA Consultants and facilitator of the task force, reviewed the meeting agenda and outlined the goals for the day.

II. Facilitated Deliberation of Task Force – 9:40 AM

Rudy Gomez
Partner, SSA Consultants
Facilitator, Task Force

Task force members were invited to offer recommendations for discussion and consideration by the task force. The task force members had a discussion about the presentations offered in the September 28, 2015 task force meeting. An initial discussion of potential recommendations followed the discussion. Gomez offered a process suggestion to the task force members, to see all recommendations offered for consideration and then vote on each recommendation.

Lovecchio made a motion to have all recommendations offered for task force consideration and then the task force would vote on each recommendation individually.

John Crenshaw, designee for Advanced Medical Technological Association (AdvaMed), seconded the motion. There were no objections to the motion and it was unanimously accepted by the task force.

The task force took a short break from 10:04 AM to 10:08 AM

The task force resumed their discussion of potential recommendations after the break with each task force member participating and offering their thoughts. Gomez offered a process suggestion to the task force members for consideration. Each task force member write their recommendation for SSA to add to a slide for task force consideration. The task force members agreed to this suggestion and worked on their recommendation wording until 11:45 AM.

All recommendations were added to the meeting slide show (and provided in the meeting material set as an appendix to the final report). The task force was asked to consider each recommendation individually and vote to accept the principle of the recommendation.

The task force agreed SSA Consultants (SSA) may change the wording of the approved recommendation when developing the report for ease of readability but may not change the intent or principle of the approved recommendations. SSA will circulate the draft report for the task force members' review in advance of the next meeting. At the last meeting of the task force, members will make any final edits to the report content and vote to adopt the final report.

The following recommendations were considered and voted on by the task force members.

- To propose that DHH conduct/assist the FDA in the inspection processes that are required for Louisiana device manufacturers and obtain information and training to do so. The inspection process shall be limited to the manufacturing portion of the FDA process.
    - Crenshaw made the motion to accept the recommendation which was seconded by Jacob Dickson, designee for the Louisiana House of Representatives. The recommendation was accepted unanimously by the task force.
- To propose if DHH declines the responsibility of Louisiana device manufacturers inspection, the LBDDD shall be required to facilitate an FDA Device Manufacturer inspection as requested by the FDA and obtain the training and credentials necessary to do so.
    - Dickson made the motion to accept the recommendation which was seconded by Crenshaw. The recommendation was accepted unanimously by the task force.
- To affirm the LBDDD's current role in 301K licensing renewal (Residence License) and 309 Storage and Handling requirements for legend drugs and devices.

    - Some discussion around the need for additional clarification on definitions of terms included in these two sections. Sue Fontenot R.Ph., designee for the Louisiana Department of Health and Hospitals, made the motion to accept the recommendation which was seconded by Clair Defelice, designee for Louisiana Senate. The recommendation received a four to one vote in favor of accepting the recommendation with Crenshaw voting against the recommendation.
- To amend the LBDDD's current rule on exemption of samples of drugs as stated within 105.A.6 to include "drugs and device."
    - Defelice made the motion to accept the recommendation which was seconded by Crenshaw. The recommendation was accepted unanimously by the task force.
- To affirm the LBDDD's current law on legend drugs and legend devices distributers (La R.S. Chapter 54 of Title 37).
    - Dickson made a motion to accept the recommendation which was seconded by Defelice. The recommendation was accepted unanimously by the task force.
- Legend device and legend drug manufacturers must follow state distribution laws and rules as they pertain to distribution if the manufacturer acts in a distribution manner.
    - Dickson made a motion to accept the recommendation which was seconded by Defelice. The recommendation was accepted unanimously by the task force.
- To propose a state workshop be conducted by NABP (all member states) for more compatible legend device distribution laws.
    - Fontenot made a motion to accept the recommendation which was seconded by Defelice. The recommendation was accepted unanimously by the task force.
- Legend device licensing requirement shall be for saleable items only and does not include instruments or samples, notwithstanding other applicable safety requirements and guidelines.
    - Dickson made a motion to accept the recommendation which was seconded by Crenshaw. The recommendation was accepted unanimously by the task force.
- Exemption licensing legend device trunk stock for an agent or employee of the manufacturer of the legend device. The storage requirements of the legend device product must be maintained as explained in the laws and rules of the LBDDD and the state of Louisiana.
    - Crenshaw made a motion to accept the recommendation. There was no second to the motion and the motion failed to carry.
- Exemption for legend device licensing in transit with a courier, agent, or employee of the manufacturer of the legend device. In the event of an emergency, natural disaster, or state of emergency, legend devices could be stored in an unlicensed facility subject to the review of the LBDDD.

  - Some discussion was held regarding goods in transit which addressed by the Louisiana Department of Transportation and Development (DOTD) rules for goods in transit. Crenshaw made a motion to accept the recommendation which was seconded by Defelice. The recommendation was accepted unanimously by the task force.
- LBDDD to monitor and implement rules consistent with the guidelines published by DSCSA, which is expected later this year.
  - Dickson made a motion to accept the recommendation which was seconded by Fontenot. The recommendation was accepted unanimously by the task force.
- To propose exemption for licensing by LBDDD for standalone software or medical software application currently regulated by the FDA.
  - Crenshaw made a motion to accept the recommendation which was seconded by Dickson. The recommendation was accepted unanimously by the task force.

III. Next Steps – 1:10 PM

Rudy Gomez
Partner, SSA Consultants
Facilitator, Task Force

Gomez reminded the task force members of the next steps including circulation of the draft report to task force members in advance of the next meeting, which is scheduled for December 1, 2015 from 9:00 AM to 4:00 PM at the LBDDD office in Baton Rouge. At the next meeting, task force members would offer any edits to the report language to create the final report. The task force would then vote to accept the report and submit to the Louisiana Legislature as directed in Senate Resolution 177.

IV. Public Comment – 1:12 PM

Rudy Gomez
Partner, SSA Consultants
Facilitator, Task Force

The task force then opened the floor for public comment. There was no offered.

V. Adjournment – 1:15 PM

George Lovecchio
Executive Director, LBDDD
Chairman, Task Force

The Chairman opened the floor for a motion to adjourn the meeting. Defelice made the motion which was seconded by Fontenot. There were no objections to the adjournment of the meeting.

These minutes have not been formally received by the task force and have been compiled by the task force facilitator, SSA Consultants.

TASK FORCE ON MEDICAL DEVICE DISTRIBUTION

DECEMBER 1, 2015 · MEETING MINUTES

Meeting Location:
Louisiana Board of Drug and Device Distribution
12091 Bricksome Avenue, Suite B
Baton Rouge, LA 70816

Meeting Time:
9:00 AM to 4:00 PM

AGENDA ITEMS

I. Welcome – 9:16 AM

George Lovecchio
Executive Director, LBDDD
Chairman, Task Force

George Lovecchio, Task Force Chairman, called the meeting to order. Rudy Gomez, Partner with SSA Consultants and Task Force Facilitator, asked each member to introduce themselves for the record and the organization they represent on the task force.

Task force members present for the meeting included:

1. Jacob Dickson; designee for Louisiana House of Representatives
2. Claire Defelice; designee for Louisiana Senate
3. George Lovecchio; designee for Louisiana Board of Drug and Device Distribution
4. John Crenshaw; designee for Advanced Medical Technological Association (AdvaMed)
5. Evonna Sue Fontenot, R.Ph.; designee for the Louisiana Department of Health and Hospitals

A quorum was established with the task force members present.

II. Agenda Review – 9:18 AM

Rudy Gomez
Partner, SSA Consultants
Facilitator, Task Force

Rudy Gomez reviewed the agenda for the day with the Task Force members.

III. Review and Discussion of AdvaMed Letter – 9:20 AM

Rudy Gomez
Partner, SSA Consultants
Facilitator, Task Force

John Crenshaw, the designee for AdvaMed, provided a summary of the letter to the task force members. The task force members then engaged in a discussion about the letter and its request for the task force to consider an additional recommendation exempting short-term storage units. Task force members also discussed the medical device space and logistics of moving product from device representatives to appropriate medical

settings (i.e., hospitals). Task fForce members appreciated AdvaMed's input and the opportunity to engage in the discussion.

IV. Review and Approval of Task Force Report – 10:00 AM Rudy Gomez
Partner, SSA Consultants
Facilitator, Task Force

Gomez reviewed the report layout and content with the task force members. Task force members were then asked to review the content of the report and offered edits to the report content.

The task force took a break from 10:28 AM to 10:39 AM

SSA will conduct a final proof reading and final format review of the report. John Crenshaw will follow-up with AdvaMed to address typo in AdvaMed attachment and resubmit to the Task Force for inclusion to the report. The Chairman asked for any additional edits to the report, particularly in relation to the AdvaMed. With the edits to the report

The task force recognizes the FDA has authority over the manufacturers – in the steps to bring items to market and post-market regulations. The FDA is the ultimate power that drives compliance with those manufacturers.

Jacob Dickson, designee for the Louisiana House of Representative, made a motion to accept the report as amended at the meeting which was seconded by Sue Fontenot, R.Ph, designee for the Louisiana Department of Health and Hospitals. The motion was unanimously accepted by the task force.

V. Next Steps – 10:52 AM Rudy Gomez
Partner, SSA Consultants
Facilitator, Task Force

There are a few remaining steps for SSA – final proofing, etc. Then SSA will circulate by email to the task force members. The report will then be delivered to the Louisiana Legislature as directed by the SR 177 in advance of the December 15, 2015 deadline.

The Task Force will not be able to formally adopt the minutes from the September meetings as this is the last meeting and will be marked accordingly.

Copies will be submitted to the Legislature in hard copy format and electronic format. George Lovecchio will work with Senator Mills, author of the legislation, to determine next steps with the Legislature, if any.

George Lovecchio can also draft a letter on behalf of the task force to each of the entities connected to the recommendations (i.e., DHH) and provide them a copy of the report, which is a public document.

VI. Adjournment – 11:10 AM

George Lovecchio
Executive Director, LBDDD
Chairman, Task Force

George Lovecchio, Chairman of the task force, expressed his appreciation to the task force members for their time and commitment to the task force and its important work to protect the citizens of Louisiana.

The Chairman opened the floor for a motion to adjourn the meeting. Dickson made the motion and it was seconded by Claire Defelice, designee for the Louisiana Senate. There were no objections to the adjournment of the meeting.

LUNCH PROVIDED FOR TASK FORCE MEMBERS BY LOUISIANA BOARD OF DRUG AND DEVICE DISTRIBUTION

These minutes have not been formally received by the task force and have been compiled by the task force facilitator, SSA Consultants.

ABOUT THE TASK FORCE ON MEDICAL DEVICE DISTRIBUTION

Senate Resolution (SR) 177 of the 2015 Louisiana Legislative Session created the Task Force on Medical Device Distribution "to review existing regulation and propose revisions of regulations and the elimination of duplicate regulations while remaining focused on the protection of the health and safety of Louisiana citizens."