

Texas Enforcement Priorities for Sterile Compounding Pharmacies



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Executive Director/Secretary

**FDA's Federal-State Meeting to
Discuss Pharmacy Compounding
March 21, 2014**

Board of Pharmacy Members

- Jeanne D. Waggener, R.Ph.** – President – Waco
- Dennis F. Wiesner, R.Ph.** – Vice President – Austin
- Buford T. Abeldt, Sr., R.Ph.** – Lufkin – Treasurer
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- Alice G. Mendoza, R.Ph.** – Kingsville
- Bradley A. Miller, Ph.T.R.** – Austin
- Phyllis A. Stine** – Abilene
- Joyce Tipton, R.Ph., MBA** – Houston
- Charles F. Wetherbee** – Boerne



2013 Texas Legislative Session

- The Texas Pharmacy Act was amended to specify that:
 - New sterile compounding pharmacies may not open until inspected;
 - Out-of-state sterile compounding must reimburse TSBP or our agent for an inspection;



2013 Texas Legislative Session (cont.)

- The Texas Pharmacy Act was amended to specify that:
 - Existing sterile compounding pharmacies may not renew their registration unless they have:
 - been inspected as specified by the Board in rule; and
 - reimbursed the Board for all expenses incurred by the Board in inspecting the pharmacy, if the pharmacy is located in another state.



2013 Texas Legislative Session (cont.)

- The Texas Pharmacy Act was amended to specify that:
 - A pharmacy that compounds a sterile product must notify the Board:
 - Immediately of any adverse effects reported to the pharmacy or known by the pharmacy to be potentially attributable to a sterile product compounded by the pharmacy; and
 - Not later than 24-hours after the pharmacy issues a recall for a sterile product compounded by the pharmacy.

2013 Texas Legislative Session (cont.)

- TSBP was given additional appropriations to:
 - Hire 7 additional personnel directly related to the inspection of sterile product pharmacies; and
 - Additional funding to test sterile products and/or the environment in sterile compounding pharmacies.



Job #1

- After NECC.
 - Identity of pharmacies that compound sterile products.
 - Revises licensing system to specifically identify those pharmacies that compound sterile products.
 - Conduct priority inspections of known sterile compounding pharmacies.
- After additional funding received in 2013.
 - Additional training of current inspectors; and
 - Hiring and training of new inspectors.

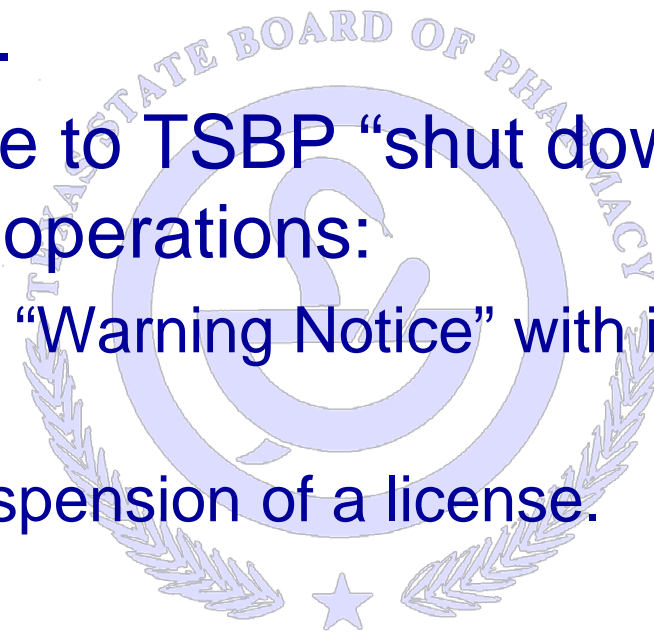
Priorities for Enforcement

- Inspections of Pharmacies that:
 - Compound High Risk Products.
 - Have had previous “poor” history with TSBP.
 - All sterile compounding pharmacies.



Experiences

- As a result of recent inspections, 2-pharmacies were ordered to cease compounding of High-Risk Products.
- Tools Available to TSBP “shut down” compounding operations:
 - Issuance of a “Warning Notice” with immediate due-date.
 - Summary Suspension of a license.



Testing of Compounded Products

SUMMARY OF COMPOUNDED SAMPLE TESTING PROGRAM FY 2009 – FY 2013

	FY2009	FY2010	FY2011	FY2012	FY2013	5-Yr. Avg.
Total # Samples Tested	46	86	37	28	58	51
# Non-Sterile Samples Tested	35	58	27	20	9	29.8
# Potency Failures	6	13	4	2	1	5.2
# Sterile Samples Tested	11	28	10	8	49	21.2
# Potency Failures	1	8	4	1	2	3.2
# Sterility Failures	0	0	0	1**	0	<1
# Fungal Failures*	N/A	N/A	N/A	N/A	0	0
# Endotoxin Failures	0	0	0	0	0	0

*Fungal Testing began in FY2013

**Nasal product

3/21/2014

Thank You!

