

*TEMPORARY SUSPENSION OR RESTRICTION ORDER #K-15-012-BSI*

RE: IN THE MATTER OF  
IVMEDCO FORT WORTH  
(PHARMACY LICENSE #13332)

BEFORE THE TEXAS STATE  
BOARD OF PHARMACY

On this day came on to be considered by the Disciplinary Panel of the Texas State Board of Pharmacy (Board) the matter of the Temporary Suspension or Restriction of pharmacy license number 13332, issued to IVMedco Fort Worth (Respondent), 3646 Granbury Road, Suite 102, Fort Worth, Texas 76109, pursuant to § 565.059 of the Texas Pharmacy Act (Pharmacy Act), TEX. OCC. CODE ANN., Title 3, Subtitle J. The Disciplinary Panel considered the case during a hearing without notice, and a second hearing with notice of hearing is scheduled within fourteen (14) days of the date of this Order.

Joseph Kemper West, Corporate President of IVMedco, Inc., on behalf of Respondent, did not appear and was not represented by counsel. Caroline K. Hotchkiss represented Board staff. Kerstin E. Arnold served as General Counsel to the Disciplinary Panel. The following Board members served as the Disciplinary Panel: Dennis F. Wiesner, R.Ph.; Joyce A. Tipton, R.Ph., M.B.A.; and Phyllis A. Stine.

The Disciplinary Panel determines that Respondent, by continuation in the operation of the pharmacy engaged in the compounding of high-risk sterile preparations, would constitute a continuing threat to the public welfare, and that pharmacy license number 13332 issued to Respondent shall be temporarily suspended or restricted in accordance with § 565.059 of the Pharmacy Act. The Disciplinary Panel makes this finding based on the following evidence and/or information presented at the May 12, 2015, Hearing on Temporary Suspension or Restriction of License of Respondent:

1. IVMedco Fort Worth, 3646 Granbury Road, Suite 102, Fort Worth, Texas 76109, holds Texas pharmacy license number 13332.

2. Pharmacy license number 13332 issued to IVMedco Fort Worth has been designated by the TSBP as a Class A-S pharmacy license, which allows IVMedco Fort Worth to engage in the compounding of sterile preparations.
3. IVMedco Fort Worth is owned and operated by IVMedco, Inc.
4. The owner of a pharmacy as responsibility for all administrative and operational functions of the pharmacy.
5. A pharmacy is responsible for any violations in the practice of pharmacy by an owner or employee of the pharmacy.
6. The license of IVMedco Fort Worth is current through August 31, 2016.
7. All jurisdictional requirements have been satisfied.
8. On or about May 6, 2015, a compliance inspector for the TSBP performed a partial routine inspection of IVMedco Fort Worth. During the inspection the compliance inspector noted numerous violations relating to IVMedco Fort Worth's compounding of sterile preparations. The compliance inspector noted violations, including, but not limited to, the following:
  - a. Environmental violations, such as porous flooring in the ante-area; lack of hands free access to clean room; walls, fixtures, and ceilings, shelving, counters with cracks and crevices and deterioration, including rust; and failure to have a pressure gauge or velocity meter to monitor pressure differential airflow;
  - b. Personnel evaluations and testing violations, such as failure to have conducted on-site media fill tests, and failure to have a sampling of compounding personnel glove fingertips. In addition, the compliance inspector observed compounding personnel exercise improper hand washing, gloving, and garbing;
  - c. Compounded sterile preparation storage violations, such as storage at room temperature of a sterile preparation in excess of 24 hours;
  - d. Cleaning and disinfecting violations, such as failure to clean and disinfect the pharmacy on a daily basis, and failure to mop per board rules;
  - e. Equipment and supply violations, such as failure to have a temperature-sensing mechanism in the controlled temperature storage space, and use of non-lint free towels.
9. On or about May 6, 2015, at approximately 4:00 p.m., the compliance inspector issued several warning notices in regards to IVMedco Fort Worth. A copy of the warning notices issued were left with Stephen Wells, pharmacist-in-charge of IVMedco Fort Worth. One of the warning notices issued by the compliance inspector was for the immediate cessation of the compounding of high-risk sterile preparations. Mr. Wells

verbally refused to comply with the inspector's issuance of the warning notice for immediate cessation of compounding of high-risk sterile preparations.

Subsequent to any proceedings involving the conduct described above, the Board may take additional disciplinary action on any criminal action taken by the criminal justice system based on the same conduct described in the allegations above. However, Respondent shall be provided all rights of due process should the Board initiate such disciplinary action subsequent to the conclusion of the criminal proceedings.

### **ORDER OF THE BOARD**

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that:

- (1) Pharmacy license number 13332 held by Respondent shall be, and such license is hereby temporarily restricted to prohibit high-risk sterile compounding. Said restriction shall be effective immediately and shall continue in effect for a period of fourteen (14) days unless a further Order of the Board is entered. During the period of restriction, Respondent shall cease all operation as a sterile compounding pharmacy related to the preparation and distribution of high-risk sterile compounds including the maintenance or distribution of previously prepared high-risk sterile compounds during the period said license is temporarily restricted.
- (2) Respondent shall allow Board staff to directly contact Respondent on any matter regarding the enforcement of this Order.
- (3) Failure to comply with any of the requirements in this Order constitutes a violation and shall be grounds for further disciplinary action. The requirements of this Order are subject to the Texas Pharmacy Act, TEX. OCC. CODE ANN., Title 3, Subtitle J (2013), and Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2015).

Passed and approved at the Temporary Suspension or Restriction Hearing of the Disciplinary Panel of the Texas State Board of Pharmacy on the 12th day of May, 2015.

And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 12th day of May, 2015.

  
MEMBER, TEXAS STATE BOARD OF PHARMACY

  
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