*AGREED TEMPORARY RESTRICTION ORDER #K-15-012-BS2*

| RE: | IN THE MATTER OF<br>IVMEDCO FORT WORTH<br>(PHARMACY LICENSE #13332) | BEFORE THE TEXAS STATE<br>BOARD OF PHARMACY |
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On this day came on to be considered by the Disciplinary Panel of the Texas State Board of Pharmacy (Board) the matter of the Petition for Temporary Restriction of pharmacy license number 13332 issued to IVMedco Fort Worth (Respondent), pursuant to § 565.059 of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J.

By letter dated May 15, 2015, the Board gave notice to Respondent of its intent to impose a temporary restriction. This action was taken as a result of an investigation which produced evidence indicating that Respondent may have violated:

> Section 565.002(a)(3) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2013); and
>
> Sections 291.36(9); and 291.133 of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2015), in that allegedly:

## PREVIOUS HISTORY

On or about May 12, 2015, the Disciplinary Panel of the Board entered Temporary Suspension or Restriction Order Without Notice K-15-012-BS1 in the matter of IVMedco Fort Worth. The Order was based on a finding of a continuing threat to public safety due to the allegations described below in the Counts. The Order prohibited IVMedco Fort Worth from engaging in the performance of high-risk sterile compounding for 14 days unless a further order of the Board is entered.

## COUNTS

(1) On or about May 6, 2015, a compliance inspector for the Board 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 floor surfaces 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.

2. 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.

On or about May 26, 2015, the following Board members served as the Disciplinary Panel: Jeanne D. Waggener, R.Ph.; Dennis F. Wiesner, R.Ph.; and Bradley A. Miller, Ph.T.R.. Kerstin Arnold served as General Counsel to the Disciplinary Panel. The Disciplinary Panel of the Board determines that Respondent, by continuing the practice of compounding 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 restricted in accordance with § 565.059 of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J. The Disciplinary Panel of the Board makes this finding based on the evidence and/or information in the above-listed Counts.

Stephen Wells, Corporate Vice-President of IVMedco, Inc., and pharmacist-in-charge of IVMedco Fort Worth, for and on behalf of Respondent, agrees to this Order. Respondent neither admits nor denies the truth of the matters set out in this Order, and understands that any failure to comply with the terms of this Order is a basis for discipline under the Texas Pharmacy Act.

It was finally agreed among the parties that Respondent shall comply with the terms and conditions set forth in the ORDER OF THE BOARD below.

## ORDER OF THE BOARD

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

(1) Respondent's license shall be, and such license is hereby temporarily restricted to prohibit high-risk sterile compounding. 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. Said restriction shall be effective immediately and shall continue in effect until such time as the conditions in paragraph (2) below have been satisfied.

(2) Such restriction described above in Paragraph (1), shall be effective until such time as Respondent requests in writing, and Board staff conducts, an inspection of Respondent's clean room, which in the discretion of Board staff adequately demonstrates compliance with all requirements of Board rules relating to high-risk sterile compounding.

(3) If within one (1) year after the entry of this Order, Respondent fails to request in writing that the restriction described above in Paragraph (1) be stayed, said license issued to Respondent shall no longer be classified as a Class A-S, and Respondent shall be reclassified as a Class A. In the event that said license issued to Respondent is reclassified as a Class A, Respondent shall immediately cease all operation as a sterile compounding pharmacy related to the preparation and distribution of low-risk or medium-risk sterile compounds, including the maintenance or distribution of previously prepared sterile compounds. During any such period of time that Respondent is not licensed as a Class A-S, Respondent shall not operate as a community pharmacy in this state authorized to engage in the compounding of sterile preparations, including low-risk, medium-risk or high-risk preparations.

(4) Respondent shall develop and implement policies and procedures to be used by pharmacy personnel to ensure the following is being conducted relating to compounding sterile preparations:

a. Evaluation and testing of pharmacy staff for on-site media-fill and gloved fingertip/thumb sampling;
b. Regular, on-going cleaning and disinfection of the sterile compounding area with appropriate equipment;
c. Proper garbing and gloving by compounding personnel;
d. Proper storage at appropriate temperatures not exceeding 24 hours at a controlled room temperature in the absence of passing a sterility test, or 3 days at a cold temperature;
e. Assignment of beyond-use dating incorporating use of appropriate literature sources and/or direct testing evidence; and
f. Maintenance of current or updated copies of required library references.

A written report of such policies and procedures shall be submitted to Board staff within ninety (90) days after the entry of this Order.

(5) Respondent shall be responsible for all costs relating to compliance with the requirements of this Order.

(6) Respondent shall allow Board staff to directly contact Respondent on any matter regarding the enforcement of this Order.

(7) 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).

And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 26th day of May, 2015.

Jeanne D. Waggener, R.Ph.
MEMBER, TEXAS STATE BOARD OF PHARMACY

R. Ph.
MEMBER, TEXAS STATE BOARD OF PHARMACY

Ph.TR
MEMBER, TEXAS STATE BOARD OF PHARMACY

APPROVED AS TO FORM AND AGREED TO:

Stephen J. Wells, RPh-P-I-C
Stephen Wells, Corporate Vice-President of IVMedco, Inc.,
For and on behalf of IVMedco Fort Worth

APPROVED AS TO FORM:

Kerstin Arnold, General Counsel
Texas State Board of Pharmacy