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**BEFORE THE DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSING
OF THE DEPARTMENT OF COMMERCE
OF THE STATE OF UTAH**

IN THE MATTER OF THE LICENSES OF :

STAPLEY PHARMACY : **STIPULATION AND ORDER**
TO ACT AS A PHARMACY :
AND TO DISPENSE :
CONTROLLED SUBSTANCES :
IN THE STATE OF UTAH :

AND .

DEE EVAN STAPLEY, R.PH., : Case No DOPL 2005-194
TO ACT AS A PHARMACIST AND TO :
DISPENSE CONTROLLED SUBSTANCES :
IN THE STATE OF UTAH :

Stapley Pharmacy ("Respondent," "Respondent Stapley Pharmacy") and the
Division of Occupational and Professional Licensing of the Department of Commerce of
the State of Utah (the "Division") stipulate and agree as follows

1 Respondent Stapley Pharmacy is represented in the above-entitled matter
by attorney Phillip S Ferguson and, by and through Respondent Dee Evan Stapley,

signs this Stipulation with the advice of counsel

2 Respondent Stapley Pharmacy admits the jurisdiction of the Division over Respondent and over the subject matter of this action

3 Respondent Stapley Pharmacy is licensed in the State of Utah to act as a Class A Pharmacy (License No 5683021-1703) and to dispense controlled substances (License No 5683021-8913) Respondent Stapley Pharmacy was so licensed at all times material to the above-entitled action

4 In or about 1979, Respondent Dee Evan Stapley purchased the Bateman Pharmacy in St George, Utah

5 In or about 1989, the Bateman Pharmacy entered into an agreement with two branch pharmacies, the Brian Head Medical Clinic Branch Pharmacy, Brian Head, Utah, and the Zion Canyon Medical Clinic Branch Pharmacy, Springdale, Utah In said 1989 agreement, the Bateman Pharmacy agreed to become the parent pharmacy and to provide pharmacy services for the two branch pharmacies

6 In 2004, Respondent Dee Evan Stapley surrendered the pharmacy license for the Bateman Pharmacy and submitted an application to the Division to license the pharmacy under the name of the Stapley Pharmacy In said application for licensure, Respondent Stapley and Respondent Stapley Pharmacy did not designate the Brian Head Medical Clinic Branch Pharmacy or the Zion Canyon Medical Clinic Branch Pharmacy as branch pharmacies for Stapley Pharmacy Respondent Stapley Pharmacy currently acts as and at all times material to the above-entitled action, has acted as the parent pharmacy for the Brian Head Medical Clinic Branch Pharmacy and the Zion Canyon Medical Clinic Branch Pharmacy without licensure to do so

7 Respondent Dee Evan Stapley is currently and was at all times material to the above-entitled action, (a) the owner and Pharmacist-in-Charge of Respondent Stapley Pharmacy and (b) the Supervising Pharmacist of the Brian Head Medical Clinic Branch Pharmacy and the Zion Canyon Medical Clinic Branch Pharmacy. In these capacities, Respondent Dee Evan Stapley is authorized to act for and to enter into binding agreements on behalf of Respondent Stapley Pharmacy

although not the current

was so at all times

related to this matter

8 A Petition and Notice of Agency Action have been filed and served upon Respondent Dee Evan Stapley and Respondent Stapley Pharmacy in the above-entitled case

9 In and about 2006 and 2007 and subsequent to the filing of the Petition and Notice of Agency Action in the above-entitled matter, the Division conducted an inspection of the Brian Head Medical Clinic Branch Pharmacy and the Zion Canyon Medical Clinic Branch Pharmacy. The inspection produced evidence supporting allegations that Respondent Dee Evan Stapley, Respondent Stapley Pharmacy, the Brian Head Medical Clinic Branch Pharmacy, and the Zion Canyon Medical Clinic Branch Pharmacy failed to comply with the laws and rules regulating parent and branch pharmacies in the State of Utah

10 Respondent Stapley Pharmacy acknowledges that, prior to the entry of the Order which is based on this Stipulation, Respondent is entitled to the issuance of an Amended Petition and a Notice of Agency Action that would include, in addition to the allegations of the original Petition, allegations that Respondent Dee Evan Stapley, Respondent Stapley Pharmacy, the Brian Head Medical Clinic Branch Pharmacy, and the Zion Canyon Medical Clinic Branch Pharmacy failed to comply with the laws and

rules regulating parent and branch pharmacies in the State of Utah

11 Respondent Stapley Pharmacy acknowledges that Respondent is entitled to a hearing on such Amended Petition before the Utah State Board of Pharmacy (the "Board"), or other Division presiding officer, at which time Respondent Stapley Pharmacy may present evidence on behalf of Respondent Dee Evan Stapley. Respondent Stapley Pharmacy, the Brian Head Medical Clinic Branch Pharmacy, and/or the Zion Canyon Medical Clinic Branch Pharmacy, present witnesses on behalf of Respondents and/or said branch pharmacies, and confront adverse witnesses

12 Respondent Stapley Pharmacy waives the issuance of such Amended Petition and Notice of Agency Action

13 Respondent Stapley Pharmacy waives the right to a hearing on any such Amended Petition and any other rights to which Respondent Stapley Pharmacy may be entitled in connection with said hearing

14 Respondent Stapley Pharmacy admits the following acts, practices, and omissions pertaining to the compounding of pharmaceuticals at the Stapley Pharmacy

- a In or about 2004 and 2005, Respondent Stapley and Pharmacy Technicians employed by Respondent Stapley Pharmacy compounded drugs on prescriptions issued by physicians
- b Included among these pharmaceutical preparations were bags of Meperidine solution ("Demerol Paks"), which were to be administered to patients intravenously by analgesic pump for the control of post-surgical pain. In and between December 1998 and March 2005, Respondent Stapley and staff of Respondent Stapley Pharmacy compounded and dispensed approximately 323 Demerol Paks. Demerol Paks, if compounded with amounts of Meperidine in excess of therapeutic levels, are potentially lethal
- c Respondent Stapley and Respondent Stapley Pharmacy failed to prepare and maintain a policy and procedure manual for the

compounding, dispensing, and delivery of sterile pharmaceutical prescription drug orders including lot numbers of the components used in compounding sterile prescriptions in violation of Utah Admin Code R156-17a-618(2) (2004) and Utah Admin Code R156-17b-614(3) (2005) Said conduct constitutes unprofessional conduct pursuant to Utah Code Ann § 58-1-501(2)(a) (West 2004 and Supp 2006)

- d Respondent Stapley and Respondent Stapley Pharmacy failed to document appropriate training of Pharmacy Technicians including, but not limited to, the compounding of pharmaceutical preparations, in violation of Utah Admin Code R156-17a-610(7) (2004), Utah Admin Code R156-17b-614(3) (2005), and Utah Admin Code R156-17b-603(6) (2005) Said conduct constitutes unprofessional conduct pursuant to Utah Code Ann § 58-1-501(2)(a) (West 2004 and Supp 2006)
- e Respondent Stapley and Respondent Stapley Pharmacy failed to *prepare and enforce written procedures to double-check* compounding accuracy, in violation of Utah Admin Code R156-17a-610(7) (2004) and Utah Admin Code R156-17b-614(3) (2005) Said conduct constitutes unprofessional conduct pursuant to Utah Code Ann § 58-1-501(2)(a) (West 2004 and Supp 2006)
- f Respondent Stapley and Respondent Stapley Pharmacy, by failing to provide adequate supervision of Pharmacy Technicians, permitted Pharmacy Technicians to engage in conduct outside the scope of practice for their license classification Said conduct constitutes unprofessional conduct pursuant to Utah Code Ann § 58-17a-502(8) (West 2002), repealed and re-enacted as Utah Code Ann § 58-17b-502(8) (West 2004) (effective July 1, 2004), Utah Code Ann § 58-1-501(1)(c) (West 2004 and Supp 2006), and Utah Code Ann § 58-1-501(2)(a) (West 2004 and Supp 2006)
- g Respondent Stapley and staff of Respondent Stapley Pharmacy compounded and dispensed Demerol Paks to Patient L A and Patient C G (names withheld to protect confidentiality) Respondent Stapley and Respondent Stapley Pharmacy cannot identify the individual who prepared these prescriptions Both patients died subsequent to the use of these Demerol Paks with toxic levels of Meperidine in their systems Respondent Stapley and Respondent Stapley Pharmacy have no documentation to support that the Demerol Paks were prepared in conformity with prescription orders

15 Respondent Stapley Pharmacy admits that, in and between 2004 and 2006, Respondent Stapley, Respondent Stapley Pharmacy, the Brian Head Medical Clinic Branch Pharmacy, and the Zion Canyon Medical Clinic Branch Pharmacy engaged in the following acts, practices, and omissions

- a Respondent Stapley and Respondent Stapley Pharmacy failed to submit to the Division an application for the designation of the Brian Head Medical Clinic Branch Pharmacy and the Zion Canyon Medical Clinic Branch Pharmacy as branch pharmacies for Stapley Pharmacy, in violation of Utah Admin Code R156-17a-311(2), (3) and (4) (2004), Utah Admin Code R156-17b-614a(2), (3), and (4) (2005), Utah Code Ann § 58-1-501(1)(a) and (d) (West 2004 and Supp 2006), and Utah Code Ann § 58-1-501(2)(a) (West 2004 and Supp 2006)
- b Respondent Stapley and Respondent Stapley Pharmacy sold pre-filled bottles of prescription medications including controlled substances to the Brian Head Medical Clinic Branch Pharmacy and the Zion Canyon Medical Clinic Branch Pharmacy. The medical clinic staff then sold the pre-filled bottles to clinic patients and billed patient insurers. The medical clinic staff were not licensed to practice pharmacy. Respondent Stapley Pharmacy and Respondent Stapley, by selling prescription medications to the medical clinics, enabled medical clinic staff to engage in the practice of pharmacy when they were not licensed to do so. Based upon the foregoing, Respondent Stapley and Respondent Stapley Pharmacy engaged in conduct in violation of Utah Code Ann § 58-17b-502(13) (West 2004 and Supp 2006), Utah Code Ann § 58-1-501(1)(d) (West 2004 and Supp 2006), and Utah Code Ann § 58-1-501(2)(a) (West 2004 and Supp 2006)
- c Respondent Stapley and Respondent Stapley Pharmacy failed to maintain hard copies of prescriptions for medications dispensed from the branch pharmacies and failed to maintain records documenting and accounting for the disposition of medications dispensed from the branch pharmacies, in violation of Utah Code Ann § 58-17b-611(1) (West 2004), Utah Admin Code R156-17a-607(2) (2004), Utah Admin Code R156-17b-612(4) (2005), and Utah Code Ann § 58-1-501(2)(a) (West 2004 and Supp 2006)
- d Respondent Stapley and Respondent Stapley Pharmacy failed to remove outdated prescription drugs from the Zion Canyon Medical

Clinic Branch Pharmacy, in violation of Utah Admin Code R156-17b-614(1)(e) (2005) and Utah Code Ann § 58-1-501(2)(a) (West Supp 2006)

- e Respondent Stapley, as Pharmacist-in-Charge, failed to report to the Controlled Substance Database information pertaining to controlled substances dispensed from the branch pharmacies, in violation of Utah Code Ann § 58-37-7 5(4) (West 2004 and Supp 2006) and Utah Code Ann § 58-1-501(2)(a) (West 2004 and Supp 2006)
- f Respondent Stapley and Respondent Stapley Pharmacy failed to document the "beyond use date" on the prescription labels of pre-filled bottles of medications delivered to the branch pharmacies, in violation of Utah Code Ann § 58-17b-602(5)(h) (West 2004 and Supp 2006) and Utah Code Ann § 58-1-501(2)(a) (West 2004 and Supp 2006)
- g Respondent Stapley and Respondent Stapley Pharmacy permitted the branch pharmacies to distribute medications to patients with prescription labels providing false information as to the prescribing practitioner and the date that the medications were dispensed, in violation of Utah Code Ann § 58-17b-602(5)(c) and (e) (West 2004 and Supp 2006) and Utah Code Ann § 58-1-501(2)(a) and (h) (West 2004 and Supp 2006)

16 Respondent Stapley Pharmacy agrees that, pursuant to Utah Admin Code R156-1-102(7) (2007) and Utah Code Ann § 58-1-401(2) (West 2004), an Order that constitutes disciplinary action against Respondent Stapley Pharmacy's licenses to act as a Class A Pharmacy and to dispense controlled substances shall be entered in this matter as follows

- a Respondent Stapley Pharmacy's licenses shall be placed on probation for a period of three (3) years. The period of probation shall commence on the effective date of this Stipulation and Order, which is the date that the Division Director signs the Order. During the period of probation, Respondent Stapley Pharmacy shall be subject to all of the following terms and conditions. If the Board or Division later deems any of the terms and conditions unnecessary, such deletions may be made by an amended order issued unilaterally by the Division.

- b Respondent Stapley Pharmacy's Pharmacist-in-Charge shall meet with the Board at its first scheduled meeting after the effective date of the Order. Thereafter, the Pharmacist-in-Charge shall meet with the Board and Division on a quarterly basis and shall, at each quarterly meeting, present to the Board for inspection and review copies of all prescriptions filled for patients at the branch pharmacies during each respective quarter.

- c If at any time during the period of probation Respondent Stapley Pharmacy acts or agrees to act as a parent pharmacy for any branch pharmacy including, but not limited to, the Brian Head Medical Clinic Branch Pharmacy and/or the Zion Canyon Medical Clinic Branch Pharmacy, Respondent Stapley Pharmacy shall comply with the following terms and conditions:
 - (1) Within thirty (30) days of the effective date of this Stipulation and Order, Respondent Stapley Pharmacy shall submit a complete application to the Division for designation of the Brian Head Medical Clinic Branch Pharmacy and the Zion Canyon Medical Clinic Branch Pharmacy as branch pharmacies of Respondent Stapley Pharmacy.

 - (2) Prior to acting as the parent pharmacy for any branch pharmacy other than the Brian Head Medical Clinic Branch Pharmacy and the Zion Canyon Medical Clinic Branch Pharmacy, Respondent Stapley Pharmacy shall submit a complete application to the Division for designation of said pharmacy(s) as branch pharmacy(s). Respondent shall not act as a parent pharmacy for any such pharmacy(s) unless and until the Division approves Respondent's application.

 - (3) During the first meeting with the Board subsequent to the effective date of the Order herein and during the first meeting with the Board subsequent to the approval of any application for designation of branch pharmacy(s), the Pharmacist-in-Charge shall submit to the Division and Board the following:
 - (a) proposed policy and procedure manuals for Respondent Stapley Pharmacy and the branch pharmacy(s), and

 - (b) proposed formularies for the branch pharmacy(s)

 - (4) Respondent Stapley Pharmacy and its branch pharmacies

shall comply with policy and procedure manuals and formularies approved by the Division and Board

- (5) Respondent Stapley Pharmacy shall oversee the appropriate operations of its branch pharmacy(s) in accordance with Utah Admin Code R156-17b-614a and the laws and rules governing the practice of pharmacy and shall obtain periodic independent audits of the operations of the branch pharmacy(s). The audits shall be conducted in accordance with the schedule provided in Paragraph 16(g) below
- d During the period of probation, Respondent Stapley Pharmacy shall cease and desist from compounding Meperidine solutions and "Demerol Paks "
 - e Respondent Stapley Pharmacy shall cease and desist from compounding other sterile pharmaceuticals until Respondent Stapley Pharmacy demonstrates the following to the satisfaction of the Division and Board
 - (1) compliance with all orders and federal and state laws, rules, regulations applicable to the practice of pharmacy and the compounding and dispensing of legend and controlled substances including, but not limited to, USP-NF Chapters 795 and 797 and Utah Code Ann § 156-17b-614, and
 - (2) compliance with all check points identified in the most current version of the Division's Pharmacy Compounding Inspection Report for Sterile and Non-Sterile Preparations
 - f Respondent Stapley Pharmacy shall obtain periodic independent audits of the prescriptions filled by Respondent Stapley Pharmacy to determine the compliance of Respondent Stapley Pharmacy with the requirement that it cease and desist from compounding sterile pharmaceuticals and to check for inconsistencies. The audits shall be conducted in accordance with the schedule provided in Paragraph 16(g) below
 - g Respondent Stapley Pharmacy shall, within three (3) months of the effective date of the Stipulation and Order herein, obtain initial independent audits of the Stapley Pharmacy and its branch pharmacy(s) as required in Paragraph 16(c) and (f). Subsequent to the initial audits, Respondent Stapley Pharmacy shall obtain independent audits of Stapley Pharmacy and its branch pharmacy(s) every six (6) months thereafter

- h Respondent Stapley Pharmacy, within three (3) months of the effective date of the Stipulation and Order herein and every six (6) months thereafter, shall, at the direction of the Division and Board, submit a sterile pharmaceutical compounded at Stapley Pharmacy with a copy of the prescription order to a laboratory approved by the Division and Board, for confirmation of the identity, strength, quality, and purity of the component ingredients
- i Before Respondent Stapley Pharmacy shall be released from probation, a Division investigator shall conduct an inspection and make a finding that Respondent Stapley Pharmacy and its branch pharmacy(s), if any, are in full compliance with the terms and conditions of this Stipulation and Order and with all laws and rules governing the practice of pharmacy
- j Respondent Stapley Pharmacy shall comply with all federal and state laws, rules, regulations, and orders pertaining to Respondent's practice of pharmacy and the dispensing of legend and controlled substances
- k Failure of Respondent Stapley Pharmacy to pay for any expenses related to this Stipulation and Order shall be considered a violation of the terms and conditions of this Stipulation and Order
- l Respondent Stapley Pharmacy shall maintain a current license at all times during the period of this Stipulation and Order and failure to maintain a current license constitutes a violation of this Stipulation and Order

17 The terms and conditions of this Stipulation and Order become effective immediately upon the approval of this Stipulation and the signing of the Order by the Division Director. Respondent Stapley Pharmacy must comply with all of the terms and conditions of this Stipulation immediately following the Division Director's signing of the Order herein. Respondent Stapley Pharmacy shall complete all of the terms and conditions contained in the Stipulation and Order in a timely manner. If a time period for completion of a term or condition is not specifically set forth in the Stipulation and Order, Respondent Stapley Pharmacy agrees that the time period for completion of that term or

condition shall be set by the Board. Failure to complete a term or condition in a timely manner shall constitute a violation of the Stipulation and Order.

18 If Respondent Stapley Pharmacy violates any term or condition of this Stipulation and Order, the Division may take action against Respondent Stapley Pharmacy, including imposing appropriate sanctions, in the manner provided by law. Such sanctions may include revocation or suspension of Respondent Stapley Pharmacy's licenses or other appropriate sanctions.

19 Respondent Stapley Pharmacy acknowledges that the Director of the Division is not required to accept the terms of this Stipulation and Order, and, if the Director does not so accept, this Stipulation and Order shall be null and void, except that the Division and Respondent Stapley Pharmacy waive any claim of bias or prejudice they might have with regard to the Director by virtue of his having reviewed this Stipulation, and this waiver shall survive such nullification.

20 Respondent Stapley Pharmacy acknowledges that this Stipulation and Order, if adopted by the Director of the Division, will be classified as a public document and may be released to other persons and entities.

21 Respondent Stapley Pharmacy acknowledges that Respondent Stapley Pharmacy enters into this Stipulation and Order knowingly and voluntarily and that no promise or threat has been made by the Division, or any of its members, officers, agents, or representatives, to induce Respondent Stapley Pharmacy to enter into this Stipulation and Order.

22 Respondent Stapley Pharmacy acknowledges that this Stipulation constitutes the entire agreement between the parties and supersedes and cancels any

and all prior negotiations, representations, understandings, or agreements between the parties regarding the subject matter of this Stipulation and Order. There are no verbal agreements which modify, interpret, construe, or affect this Stipulation.

23 Respondent Dee Evan Stapley, for Respondent Stapley Pharmacy, has read each and every paragraph contained in this Stipulation and Order. Respondent Dee Evan Stapley, for Respondent Stapley Pharmacy, understands each and every paragraph contained in this Stipulation and Order. Respondent Dee Evan Stapley, for Respondent Stapley Pharmacy, has no questions about any paragraph or provision contained in this Stipulation and Order.

RESPONDENT STAPLEY PHARMACY

COUNSEL FOR RESPONDENT

BY *Dee Evan Stapley*
DEE EVAN STAPLEY
Owner
Respondent Stapley Pharmacy

BY *Phillip S. Ferguson*
PHILLIP S. FERGUSON

DATE *3/1/2008*

DATE *1 March 2008*

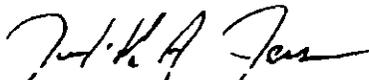
STATE OF UTAH)
COUNTY OF *SALT LAKE*)^{SS}

The foregoing document, Stipulation and Order, was acknowledged before me this *1ST* day of *MARCH*, 2008, by Dee Evan Stapley

Mark L. Anderson
NOTARY PUBLIC



MARK L SHURTLEFF
UTAH ATTORNEY GENERAL

BY 
JUDITH A JENSEN
Assistant Attorney General
Counsel for the Division
DATE *March 3, 2008*

DIVISION OF OCCUPATIONAL &
PROFESSIONAL LICENSING

BY 
DIANA BAKER
Bureau Manager
DATE *3/3/08*

ORDER

The Director of the Division of Occupational and Professional Licensing, having read the foregoing Stipulation, being fully advised, and good cause appearing,

IT IS HEREBY ORDERED that the terms and conditions of the Stipulation above, in the matter of the licenses of Stapley Pharmacy to act as a Class A Pharmacy and to dispense controlled substances in the State of Utah, are approved by the Division of Occupational and Professional Licensing and constitute my Findings of Fact and Conclusions of Law in this matter. The issuance of this Order is a disciplinary action pursuant to Utah Admin Code R156-1-102(7) and Utah Code Ann § 58-1-401(2). The terms and conditions of the Stipulation are hereby incorporated into this Order and constitute my final Order in this case.

DATED this 3 day of *March*, 2008

DIVISION OF OCCUPATIONAL AND
PROFESSIONAL LICENSING


F. DAVID STANLEY
Director