BEFORE THE ALASKA OFFICE OF ADMINISTRATIVE HEARINGS ON REFFERRAL FROM THE ALASKA BOARD OF PHARMACY

| In the Matter of |) | |
|------------------------------|---|----------------------------|
| |) | |
| PHARMACY SOLUTIONS, INC. dba |) | |
| BELLEVUE PHARMACY SOLUTIONS |) | OAH No. 08-0344-PHA |
| |) | Board Case No. 2659-01-001 |

DECISION

I. Introduction

Pharmacy Solutions, Inc. dba Bellevue Pharmacy Solutions ("Bellevue") is a Missouri concern with a multistate business focusing on compounding. It perceives a demand for this specialty service in Alaska and seeks an out-of-state pharmacy registration in this state. The Alaska Board of Pharmacy initially denied Bellevue's application on the basis that one of its three owners and managing officers had been convicted of several felonies related to his pharmacy practice in 1985. Bellevue had admitted the convictions on the face of its application. Bellevue requested an administrative hearing to challenge the denial.

A videoconferenced, recorded hearing took place on September 18, 2008, in which Bellevue offered testimony from its pharmacist-in-charge, two character witnesses, and the individual with the convictions. A licensing examiner testified for the Division of Corporations, Business and Professional Licensing, which serves as staff to the Board. The licensing file on this application and two additional exhibits (Bellevue 2 and 3) were admitted without objection. No evidence was excluded. The administrative law judge took subsequent briefing from the parties on a legal issue, so that the record did not close until January 20, 2009.

As a general matter, an out-of-state registration is a license that the Board may—but is not required to—deny if an owner of the applying pharmacy has ever been convicted of a felony. In challenging the initial denial in this case, Bellevue has the burden to show that it ought to receive the registration. At the hearing, Bellevue made some headway toward making that showing, but it fell short of a fully convincing presentation.

II. Facts

A. Bellevue

Bellevue is a closely-held corporation, one-third of whose shares are held by T. Brock Smith, Peter Hueseman, and Peter Hueseman's son Paul Hueseman. ¹ It operates a pharmacy business on two floors of a large professional building in St. Louis, Missouri. ² Smith serves as Vice President, Secretary, and Pharmacist-in-Charge. ³ Paul Hueseman serves as President and Treasurer, and Peter Hueseman as Chairman of the Board. ⁴ All three are pharmacists. ⁵

Bellevue describes itself as a "hybrid pharmacy." It operates a traditional walk-in pharmacy, where patients visit in person to fill prescriptions of all kinds. It also conducts what it describes as a "niche" business in the area of compounding. This entails preparing medications specially on physicians' orders to create formulations for people who have chemical sensitivities, swallowing difficulties, or other special needs that may not be served by the ready-made preparations of pharmaceutical manufacturers. Additionally, perhaps unrelated to the compounding, Bellevue has a "very large hormone replacement clientele." The compounding and hormone replacement businesses serve customers "from coast to coast."

Bellevue is making a systematic effort to become licensed in all fifty states.⁷ The company has offered no documentation or details regarding the demand for its services in Alaska or regarding the availability of similar services to Alaskans from other providers, but it has reported that Alaska physicians have asked it to become licensed here.⁸

The three shareholders serve distinct functions in the Bellevue organization. Smith, as Pharmacist-in-Charge, supervises a staff of 15 on the first floor of the facility who perform nearly all of the company's dispensing and compounding work. Smith has sole authority to order Schedule II drugs, and only Smith and another dispensing pharmacist named Lee have keys to the locked cabinet in which they are kept. Smith conducts inventory controls and spotchecks to ensure that Schedule III, IV, and V drugs are managed correctly.

Testimony of T. Brock Smith.

² Id

³ *Id.*; Ex. A. at 21.

⁴ Ex. A. at 21.

⁵ Ex. A at 98.

⁶ Testimony of Smith (whole paragraph).

 $^{^{7}}$ Id

⁸ Testimony of Peter Hueseman.

Testimony of Smith (whole paragraph).

Paul Hueseman, the President, works in the second-floor executive offices. ¹⁰ He is the principal business manager for Bellevue. He also spends significant time on clinical evaluation with hemophilia and HIV patients. ¹¹

Board Chairman Peter Hueseman also works in the second-floor executive offices, only "rarely" coming to the first floor to perform dispensing or compounding functions. His specialty is in the consulting area, and in a typical day he may have a hundred phone calls with physicians, patients, and other pharmacists. As a business decision to allocate talent where it can best be used, Peter Hueseman—with a long employment history in pharmaceutical sales—has been assigned the task of building the business through relationships, particularly physician relationships. In theory, Peter Hueseman could change his specialty and go to work in the pharmacy, but this would involve a major management decision and, for business reasons, it is a decision the collective management is unlikely to make.

B. Peter Hueseman's History

Peter Hueseman is the shareholder whose felony convictions have raised a question about the suitability of Bellevue for registration in Alaska. He began his pharmacy career 35 years ago, purchasing his first drug store, a Rexall outlet, shortly after obtaining his professional degree. By the mid-1980s he was operating two Medicine Shoppe franchises in Missouri. The business was not going well.¹⁶

Peter Hueseman began to self-medicate for stress with Dilaudid, a Schedule II narcotic. ¹⁷ In 1985, Peter Hueseman pled guilty to four felonies: two State of Missouri counts for fraudulently adding Dilaudid to legitimate prescriptions for other medications; one federal count for the same misconduct; and one Missouri count for making a false statement on a prescription for Methaqualone, a Schedule I narcotic. ¹⁸ For these crimes, he served nine months in jail with daytime work release, followed by several years of probation. ¹⁹

Testimony of Peter Hueseman.

¹⁰ *Id.*

Testimony of Smith.

Testimony of Peter Hueseman.

¹⁴ *Id*.

Testimony of Smith.

Testimony of Peter Hueseman.

¹⁷ *Id*.

¹⁸ Ex. A at 32-33.

Testimony of Peter Hueseman. He reports that he served five days of continuous jail time, followed by nine months in which he spent his week nights in jail, weekends at home, and workdays on work release. *Id.* The ostensible federal prison sentence was three years, with two-and-a-half suspended. There were five-year probation sentences for the state and federal counts. Ex. A at 63, 66.

At the hearing in this appeal, Mr. Hueseman testified that he falsified two prescriptions in total, and falsified no others during his entire career. The two falsified prescriptions correspond to the two Dilaudid counts in the state criminal action; the federal case, he testified, was a federal charge growing out of one of the same Dilaudid prescriptions. As for the Methaqualone matter, Mr. Hueseman testified that it was essentially "a mistake of paperwork." He said that he had overlooked a 1984 change in which Methaqualone moved from Schedule II, which he was authorized to stock, to Schedule I, for which his pharmacy did not have the necessary permit. He did not remove the item from inventory and, according to him, he therefore "got nailed for having possession of a Schedule I item in the inventory."²⁰

In contrast to this testimony, the documentary record establishes a broader pattern of falsifying prescriptions than Mr. Hueseman is willing to acknowledge today, and a more troubling set of facts regarding the Methaqualone. In a 2002 summary provided to Bellevue's Pharmacist-in-Charge, the U.S. Department of Justice's Drug Enforcement Administration (DEA) described the 1985 events as follows:

In February 1985, an inspection conducted by the Missouri Bureau of Narcotics and Dangerous Drugs revealed that Mr. Hueseman, co-owner and pharmacist of the Medicine Shoppe, 3461 Hampton Avenue, St. Louis, Missouri, diverted Schedule II and Schedule IV controlled substances. Further investigation determined that legitimate prescriptions were altered to include Dilaudid, Percodan, and Valium in handwriting similar to that of Mr. Hueseman. It was also determined that Mr. Hueseman wrote and dispensed fraudulent prescriptions for Dilaudid and Percodan on prescription pads he obtained while employed at the Kirkwood Drug Company in Kirkwood, Missouri. * * *

In 1985, Mr. Hueseman was arrested . . . on two counts of willfully making false statements on prescriptions by unlawfully adding Dilaudid on prescriptions. Subsequent to Mr. Hueseman's arrest, the store's coowner changed the door locks at the Medicine Shoppe to prevent Mr. Hueseman from entering the pharmacy. According to an employee at the time, Mr. Hueseman requested that the employee bring a box of personal belongings to him. The employee found the box and discovered 187 dosage units of various brands of methaqualone, a Schedule I controlled substance, and a "street" price list, which quoted methaqualone at approximately \$13 per tablet. The employee surrendered the box and its contents to the St. Louis Metropolitan Police Department.²¹

Testimony of Peter Hueseman.

Ex. A at 62-63.

The DEA summary indicates that the two instances of falsifying Dilaudid prescriptions to which Peter Hueseman pled guilty were not the only prescriptions he ever falsified, and that the Methaqualone offense was not a mere paperwork error. Bellevue has not supplied any reason to disbelieve the DEA summary, which it used as part of its 2007 application package.

In any event, part of the outcome of one of the court proceedings was that Mr. Hueseman was ordered to surrender his Missouri pharmacy license.²² Apparently not content with a surrender, the Missouri Board of Pharmacy revoked the license after a hearing.²³

Until 1990 or 1991, Mr. Hueseman worked outside the pharmacy industry.²⁴ He completed his criminal probation without violations and completed substance abuse counseling.²⁵ In June of 1990, he took and passed the examination for a Missouri pharmacy license.²⁶ The Missouri Board initially denied his application, but after an appeal the Board granted him a probationary license.²⁷ Hueseman completed the probation successfully, and he now apparently holds unrestricted licenses in Missouri and Illinois.²⁸ He also held a license in Colorado from 1998 to 2003 (initially on a probationary basis), which he permitted to lapse after he moved away from that state.²⁹

In the ten years after regaining licensure, Peter Hueseman worked both as a dispensing pharmacist and in pharmaceutical sales in the St. Louis area and in Colorado Springs. In 2001 he joined with his son and Brock Smith to form Bellevue, and in 2002 he began his present work in the new venture.³⁰

Since Bellevue was formed, there is no evidence that the company or its investors have had any disciplinary problems with licensing authorities. Evidence of the company's local and national reputation is very limited. Bellevue offered two letters of reference from senior pharmacists in St. Louis, both drafted by Bellevue's attorney.³¹ The signers of the letters

Ex. A at 33, \P 5.

²³ *Id.*, ¶ 7.

Testimony of Peter Hueseman.

²⁵ Id

²⁶ Ex. A at 33, ¶ 8.

Ex. A at 33-34.

Testimony of Peter Hueseman.

²⁹ *Id.*; Ex. A at 84-89.

Testimony of Peter Hueseman.

See Bellevue Exhibits 2 and 3 (attached to Bellevue's Notice of Defense). The testimony of James Schmidt indicated that both letters were composed by the attorney.

testified, but their knowledge of Mr. Hueseman's history was not extensive and their testimony was vague.³²

III. Discussion

This case is governed by the Administrative Procedure Act (APA)³³ and by the statutes and regulations governing out-of-state pharmacy registration.³⁴ In general, Bellevue has the burden to prove that it is entitled to the relief it seeks,³⁵ which in this case is to become registered and therefore eligible to make sales to Alaska patients on a "regular" basis.³⁶ As was its obligation under the APA, the Division of Corporations, Business and Professional Licensing has identified the "particular matters that have come to the attention of the [division] . . . that would authorize a denial" of this relief.³⁷ The single matter identified was Peter Hueseman's felony record from 1985.

A. The Board has Broad Discretion to Consider an Applicant's Fitness for Registration.

Registration of an out-of-state pharmacy is a type of license³⁸ that gives businesses elsewhere authority to serve clients in Alaska based primarily on the strength of their licensure in their home jurisdictions.³⁹ The Alaska Legislature established the registration procedure in 1992.⁴⁰ The overall vision of the drafters seems to have been to rely primarily on the home-state authorities to regulate out-of-state pharmacies.⁴¹ In keeping with this philosophy, the registration provision in statute expressly requires only a fairly limited array of information for registration, much of it devoted to ensuring that the pharmacy is in compliance with the pharmacy laws in its own jurisdiction.⁴²

Testimony of James Schmidt and Nicholas Verzino.

The APA, found in AS 44.62, is made applicable by AS 44.62.330(a)(5).

³⁴ See AS 08.01, AS 08.80, and 12 AAC 52.

³⁵ AS 44.62.460(e)(2).

See AS 08.80.158(a), (g). "Regular" means more than two shipments, mailings, or deliveries per year. 12 AAC 52.130(c).

AS 44.62.370(a)(2).

See, e.g., AS 08.01.110(4) (registrations are licenses for purposes of the general licensing chapter). As described in AS 08.80.158, registration fits the common legal understanding of the word "license," which is "[a] permit, granted by an appropriate governmental body, generally for consideration, to a person, firm, or corporation to pursue some occupation or to carry on some business subject to regulation" Black's Law Dict. (5th ed. 1979) at 829.

³⁹ See AS 08.80.158(b); 12 AAC 52.130(b).

sec. 1, ch. 56 SLA 1992).

Memorandum from John Gaguine, Legislative Counsel, to Rep. Curt Menard, Feb. 6, 1990 (Ex. 2 to Division's Supplemental Brief).

See AS 08.80.158(b).

Nonetheless, the legislature has amended AS 08.80 twice in ways that make it clear the Board is not required to defer to out-of-state regulators with respect to registration. First, in 1996 the legislature rewrote AS 08.80.157, and included in it a provision authorizing the Board to "deny . . . the license of a facility or pharmacy" on a variety of additional grounds beyond those listed in the registration statute, including authorization to do so on the basis of "a felony conviction under federal, state, or local law of an owner of the facility or pharmacy." A reading of § 157 alone might leave the impression that it applies only to in-state facilities and pharmacies, but that impression is dispelled by a new definition of "pharmacy" for AS 18.80 that the legislature adopted at the same time. The new definition of "pharmacy" referred to "licensure or registration" of out-of-state pharmacies "under AS 08.80.157(b)," confirming that § 157 encompasses both in-state licenses and out-of-state registrations. Second, the legislature in 2003 amended another provision, AS 08.80.261, to empower the Board to deny a license of any kind if it finds the applicant incapable of engaging in the practice of pharmacy "with reasonable skill, competence, and safety for the public."

The Board's regulation on registration, 12 AAC 52.130, is consistent with this authority. Subsection (b) of the regulation contains a checklist requiring four items: (1) completing an application provided by the department containing certain information; (2) paying the required fee; (3) submitting a certified, true copy of a current, valid facility license where the pharmacy is located; and (4) submitting an inspection report. Subsection (a) indicates that applicants must both "meet the requirements of the checklist" and "meet the qualifications in AS 08.80" to be issued a registration. Alaska Statute 08.80.157(h) and 08.80.261 are among "the qualifications in AS 08.80" applicable to registrants. The Board can therefore deny registration if it comes to the Board's attention that an applicant falls short of the qualifications in one of those provisions.

-

⁴³ AS 08.80.157(h)(2).

AS 08.80.261(a)(7), as amended by § 1, ch 140 SLA 2003 to authorize denial of a license for this reason. An argument can be made that AS 08.80.261 applies only to individual rather than institutional licenses. The argument would be that AS 08.80.157 and AS 08.80.158—the two provisions covering institutional licenses—contain specific provisions (§§ 157(h), 158(d)) that cover when the Board may suspend, revoke, or suspend the particular types of licenses they cover, and these specific provisions control over the more general § 261. No party has pressed this construction in the present case. This decision will not foreclose its consideration in a future case.

B. The Board Is Not Required to Deny Registration to this Applicant.

At the hearing, division licensing examiner Sharon Zinn indicated that she does not believe the Board has ever licensed an entity with an owner having a felony drug conviction, and indicated that she believed it to be in accordance with the Board's "policies" to deny such applications. One of the division's counsel in this case has suggested that Mr. Hueseman's convictions represent "a barrier crime."

To the extent that these remarks may suggest that some involved in the process may have regarded the felony conviction as an automatic disqualifier from all future licensing in Alaska, they require clarification. Although the Board has the authority to refuse a license, including out-of-state registration, on the basis of a prior felony conviction of an owner, it is never required to do so. The statutory chapter on pharmacists and pharmacies says that the Board "may" deny a license for various enumerated reasons, not that it "shall" deny or "may not grant" the license. ⁴⁷ This means that the Board evaluates the conduct and the totality of the circumstances, and makes the decision on the merits of the particular case before it.

The Board has not uniformly considered conviction of a drug-related felony to be a disqualification from licensure. In the *Matter of Larry Dean Payton*, a negotiated memorandum of agreement adopted by the Board in late 2004, the Board renewed Mr. Payton's license with conditions notwithstanding his 2002 conviction in Florida of misdemeanor larceny and felony possession of opium or derivative. The drugs had been stolen from the pharmacy where Payton was employed, and he had ingested some of them while on duty. Although the memorandum of agreement contains only sparse details, it suggests that the Board believed Payton had sufficiently demonstrated rehabilitation to allow him to practice safely. On the other hand, the Board has refused to issue a new pharmacy technician license to an applicant convicted of misdemeanor refusal to submit to chemical testing (after an impaired driving stop), on the basis

OAH No. 08-0344-PHA

Direct examination of Zinn (digital recording file 2 at 47:00).

Division's Supplemental Brief at 3.

AS 08.80.261(a); AS 08.80.157(h). These statutes contrast with licensing statutes for some other professions, which do create mandatory barriers to licensing for some conduct. *See*, *e.g.*, AS 08.64.240(a) ("The [medical] board may not grant a license if"); AS 14.20.020(f) ("The department may not issue a teacher certificate to a person who has been convicted").

In re Payton, No. 2600-04-015 (Board of Pharmacy, December 14, 2004).

that the crime affected the applicant's "ability to safely and competently perform the duties of a pharmacy technician." ⁴⁹

C. Bellevue Has Fallen Short of its Burden.

Although Peter Hueseman's four felonies and the conduct that surrounded them represented extraordinarily serious pharmacy-related misconduct, they occurred a long time ago and he has since satisfied other pharmacy boards that he is safe to practice without restriction. It might be reasonable, therefore, to approach with some optimism the application to register the entity in which he is now a part-owner. Nonetheless, the law is clear that the applicant has the burden to establish that it merits the license it is seeking.⁵⁰

Bellevue's showing at the hearing in its effort to meet this burden was disappointing in several respects. Most disturbingly, Mr. Hueseman inaccurately described his convictions and the surrounding events from the 1980s. He seemed to believe he was free to minimize these events in order to better package his firm's application. Since the crimes at issue were crimes of dishonesty, this lack of forthrightness was particularly unsettling. Second, the company's demonstration of its own and Mr. Hueseman's current standing in the pharmacy community amounted to little more than window-dressing, with nearly identical character references from two individuals who, on cross-examination, proved to have only limited direct knowledge to impart. Third, the company made little effort to demonstrate a specific need for its services in Alaska. Without that demonstration, there is no proven benefit to the public to counterbalance any risk the company may pose.

In order to discharge their statutory duty to protect the safety of the public, Alaska's regulators need to have reasonable certainty that an out-of-state entity seeking registration will operate in an honest and law-abiding manner. The inaccurate or uninformative evidence the company offered at the hearing did not supply enough of that certainty. The present record does not support a recommendation to grant registration to Bellevue to do business in this state.

⁴⁹ In re Coolidge, No. 2656-04-001 (Board of Pharmacy, January 28, 2005).

AS 44.62.460(e)(2).

IV. Conclusion

Pharmacy Solutions, Inc. dba Bellevue Pharmacy Solutions has not met its burden of demonstrating that it meets the qualifications in AS 08.80 applicable to registrants. Its application for registration is therefore denied.

DATED as of this 4th day of February, 2009.

By: Signed

Christopher Kennedy Administrative Law Judge

Adoption

The Alaska Board of Pharmacy adopts this decision as final under the authority of AS 44.64.060(e)(1). Judicial review of this decision may be obtained by filing an appeal in the Alaska Superior Court in accordance with AS 44.62.560 and Alaska R. App. P. 602(a)(2) within 30 days after the date of distribution of this decision.

DATED this 19th day of February, 2009.

By: Signed

Signature

Mary D. Mundell

Name

<u>Chair – Board of Pharmacy</u>

Title

[This document has been modified to conform to technical standards for publication.]