

Dutchess Business Services, Inc.; and Legend Pharmaceuticals, Inc. v. Nevada State Board of Pharmacy, 124 Nev. Adv. Op. No. 63 (Sept. 11, 2008)¹

Administrative Law – Agencies

Summary

Appeal from a district Court order denying review of a Nevada State Board of Pharmacy Decision to revoke wholesaler licenses and impose fines.

Disposition/Outcome

Affirmed in part and reversed the district Court's denial of petition for judicial review. Remanded with instructions to remand to the Nevada State Board of Pharmacy to reconsider and reevaluate fines.

Factual and Procedural History

The Nevada State Board of Pharmacy [hereinafter "Board"] licensed Petitioners as pharmaceutical wholesalers. Petitioners purchased pharmaceuticals and resold them to other wholesalers and pharmacies. A three-year period of Petitioners' business dealings with questionable entities formed the basis of an investigation by the Board. In August 2003, the Board filed a Notice of Intended Action and Investigation against the two companies. The accusation alleged that Petitioners: (1) bought and sold adulterated and misbranded prescription drugs; (2) failed to make, maintain, and provide accurate pedigrees; (3) failed to make, keep, and provide accurate records of purchases; and (4) purchased drugs from unlicensed distributors.

Dutchess, and then Legend as its successor company, bought and resold three drugs in question: Lupron, Zoladex, and Serostim. Dutchess bought the three drugs from four wholesalers: Crystal Coast, Genendo, Xenigen, and Rekcus. Legend bought Lupron from Rekcus. Although Crystal Coast was not an authorized distributor of Serostim, it represented itself as such to Dutchess. Part of the shipment received from Crystal Coast contained counterfeit Serostim. Although Dutchess was notified of the counterfeit Serostim, Dutchess never investigated or discovered the questionable distributor status of Crystal Coast. The remaining three distributors also falsely represented their distributor status to Petitioners.

Dutchess failed to keep accurate records for drug pedigrees.² In certain instances, Dutchess kept two sets of pedigrees, one that listed original seller and distributor, and the second a chain of wholesalers who handled the drug in question. In other instances, no records were kept except to note that Dutchess was an authorized distributor.

Petitioners provided only limited shipping records. One record in question showed that some business conducted with Crystal Coast received shipments from Overseas International, an unlicensed wholesaler in Florida. Only three of 29 records were actually shipped from Crystal

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² A drug pedigree is a statement of origin that identifies each prior sale, purchase, or trade of a drug, including the date of those transactions and the names and addresses of all parties to them.

Coast while the remainder was unaccounted for. Lastly, Dutchess maintained a relationship with TAP³ in an attempt to resell Lupron to other wholesalers without having to provide a pedigree.

After a five-day hearing, the Board unanimously held that Petitioners were guilty of 11 violations of Nevada pharmacy law, and fined the companies. Petitioners petitioned for judicial review, which was denied by the district Court but remanded for the Board to reconsider the amount of fines imposed. On remand, the Board reduced the fines. Petitioners now appeal the district Court's denial of their petition for judicial review.

Discussion

Petitioners argue the Board: (1) lacked jurisdiction to discipline them, (2) improperly joined them as defendants causing undue prejudice, (3) deprived them of their due process rights, (4) applied incorrect legal standards and misinterpreted ruling statutes and regulations, (5) acted arbitrarily and capriciously, and (6) impermissibly pierced corporate veils.

Jurisdiction

Petitioners argue because transactions occurred outside of Nevada, the Board lacked jurisdiction to discipline them. Under NRS 639.210⁴, the Board has jurisdiction to discipline Nevada license holders. The Court held that the statutes are plain and unambiguous and as nothing in the statute limits the Board's review to conduct occurring in Nevada, the Board had jurisdiction to discipline and impose penalties on Petitioners.

Joinder

Petitioners argue they were wrongfully joined during the Board hearing because they did not participate in the same transactions that make up the offenses. The Court acknowledged the lack of controlling law in Nevada, noting specifically that NRCP 19⁵ and NRCP 20⁶ are non-binding on adjudicatory proceedings of state agencies, unless expressly adopted by the agency.⁷ The Court held that despite this state of the law, the Board was within its discretion to join Petitioners. Basing its decision on evidence presented, the Court reasoned that because Legend acquired Dutchess in a stock purchase, both companies conducted business at the same facilities, and Legend continued business with Rekcus after Dutchess discontinued operation, the Board did not abuse its discretion. Additionally, Petitioners failed to establish that either suffered undue prejudice, and as such, the Court held that they did in fact not suffer undue prejudice.

Due Process

³ An authorized dealer.

⁴ In relevant part, NEV. REV. STAT. § 639.210(4) provides the Board with authority to discipline a license holder "guilty of unprofessional conduct or conduct contrary to the public interest." In addition, NEV. REV. STAT. 639.210(12) provides the same for any license holder who "has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any of the provisions of this chapter."

⁵ Mandatory joinder of parties

⁶ Permissive joinder of parties

⁷ *Yoder v. Ohio State Bd. Of Education*, 531 N.E.2d 769,770.

Petitioners argue the Board violated their due process rights in three ways: (1) failing to provide adequate notice of charges; (2) finding them guilty of charges not in the accusation; and (3) denying them pre-hearing discovery.

1. Notice of charges

Administrative bodies must follow their own established guidelines and under NRS 639.241⁸, and initiate an administrative hearing process by filing an accusation against the licensee. The accusation must set forth all charges, acts, or omissions, so that the respondent/licensee may be able to form a defense.⁹ The Court held that NRS 639.241 comports with due process, and because Petitioners received the Board's accusation, fully stating the factual bases of the charges against them, due process was not violated.

2. Adjudication of charges in the accusation

The opportunity to form a defense defines due process.¹⁰ Petitioners argue that because the accusation failed to charge Dutchess with providing inaccurate pedigrees, instead of falsely representing itself as an authorized dealer, Dutchess was not on notice and was unable to form a defense. The Court held this argument was without merit because the language in the accusation clearly and unambiguously¹¹ notified Dutchess it was charged with not providing accurate pedigrees, and Dutchess was found guilty of this charge.

3. Pre-hearing discovery

Petitioners argue that they should have been allowed to conduct pre-hearing discovery and the Board been required to produce a witness list. The Court adopted standards from other jurisdictions holding there is no constitutional right, federal or otherwise, allowing pre-hearing discovery in administrative proceedings that would require disclosure of witnesses.¹² Furthermore, Nevada Rules of Civil Procedure do not apply to administrative hearings,¹³ and no discovery provisions are contained in Nevada's Administrative Procedure Act. Therefore, as the Board does not have any established rules for discovery, it is within its discretion to decline to allow it.¹⁴

Conclusions of Law

⁸ NEV. REV. STAT. § 639.241(1).

⁹ NEV. REV. STAT. § 639.241(2).

¹⁰ Nevada St. Apprenticeship v. Joint Appren., 94 Nev. 763, 765 (1978).

¹¹ Specifically, the language in question states "[i]n making and providing pedigrees to wholesalers for sales of Lupron that made and perpetuated the false representation that Dutchess was the authorized distributor for the Lupron. . . violat[ing] . . . NEV. ADMIN. CODE § 639.603. . ."

¹² See Kelly v. U.S. E.P.A., 203 F.3d 519, 523 (7th Cir. 2000); Cimarusti v. Superior Court, 94 Cal. Rptr. 2d 336, 342 (Ct. App. 2000); McClelland v. Andrus, 606 F.2d 1278, 1285 (D.C. Cir. 1979).

¹³ See NEV. RULES CIV. PROC. 1.

¹⁴ See NEV. REV. STAT. § 233.B040(1).

Petitioners argue that the Board reached several conclusions of law by misinterpreting Nevada regulations and applying incorrect legal standards.

1. Strict Liability

First, Petitioners argue the administrative hearing was a quasi-criminal proceeding, and therefore, requirements for imposing criminal liability should apply. The Court rejected Petitioners arguments as baseless and held that the Board was not alleging criminal violations, did not need to apply criminal standards, and used the proper standard to adjudicate Petitioners violations. Then, as a matter of first impression, the Court held NRS 585.520(1)¹⁵ does not contain a knowledge requirement under the plain meaning of the statute. The Court declined to impose a knowledge requirement and held the legislature intended NRS 585.520(1) to be a strict liability statute. Further, the burden of proof would have been on Petitioners to show otherwise.¹⁶ In support of their decision, the Court cited to *United States v. Dotterwich*,¹⁷ and the statute's federal counterpart,¹⁸ holding that section 331 contains no knowledge requirement.

2. "Knew or reasonably should have known"

Petitioners similarly argue the Board improperly applied a "knew or reasonably should have known" standard. The Court rejects this argument holding that the Board did not apply a criminal knowledge or intent standard.

3. Accurate pedigrees

Petitioners argue that NAC 639.603(1)¹⁹ exempts authorized distributor wholesalers from providing full pedigrees. The Board responds that authorized distributor wholesalers are only exempted if the wholesaler is an authorized distributor and did not purchase the drug from another wholesaler.²⁰ The Court agreed with the Board and rejected Petitioners argument that subsections (a) and (b) were distinct exceptions. Petitioners' argument cited to a similar federal statute²¹ however the Court noted the language of that federal statute was distinctly different from the Nevada statute which clearly indicated an intent to deviate from the federal counterpart.

4. Accepting drugs from unlicensed company

¹⁵ NEV. REV. STAT. § 585.520(1) ("The manufacture, sale or delivery, holding or offering for sale of any food, drug, device or cosmetic that is adulterated or misbranded.")

¹⁶ NEV. REV. STAT. § 233.B.135(2).

¹⁷ 320 U.S. 277, 281 (1943).

¹⁸ Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 331(a) (2000).

¹⁹ In relevant part, "each wholesaler shall provide a statement of prior sales identifying each sale of a prescription drug before the prescription drug is sold to another wholesaler or to a pharmacy when supplying prescription drugs if the wholesaler."

²⁰ NEV. ADMIN. CODE § 639.603(1), ("(a) Has not established an ongoing relationship with the manufacturer from whom the prescription drug was purchased; or (b) Purchased the prescription drug from another wholesaler.")

²¹ 21 U.S.C. § 353(e)(1)(A)

Petitioners argue that the Board erred in finding them guilty of accepting drugs from an unlicensed company. They cite two reasons: (1) the statute in place at that time²² did not require intermediary companies to maintain licenses; and alternately (2) even if the company in question (Overseas) was required to maintain a license, Petitioners did not buy from them because they were only the shipping company. The Court accepted this argument and remanded on this singular point for the Board to recalculate fines.

5. Adequate records

Petitioners argue that NAC 639.602 does not require records showing ship from addresses. The Court citing to the plain language²³ rejected the argument holding that the subsections clearly require wholesalers to keep shipping records.

6. Arbitrary and capricious

Petitioners argue that the Board acted arbitrarily and capriciously by (1) not citing to authority when imposing fines, (2) fined Legend for drugs it never handled, (3) fines were excessive given mitigating factors, and (4) the Board cited to a repealed statute to authorize imposing attorneys fees on Petitioners. Taking each argument in turn, the Court first held that because each fine was below \$10,000 as mentioned in the statute, the Board was under no obligation to cite to authority and its actions were not arbitrary and capricious. Second, the Court cited to evidence that the Board specifically fined Legend for only 125 of the 249 mentioned counts, and therefore it did not fine Legend for drugs it never handled. Thereby, the Board's actions were not arbitrary and capricious in this case either. Third, as the mitigating factors argument was the same presented at the administrative hearing, and the Board's decisions regarding fines are entitled to great deference, the Court refused to upset this decision and reconsider the Board's determination. Lastly, because the Board conceded erroneously citing to NRS 639.255²⁴ instead of NRS 622.400(1)(a), the Court refused to upset the correct decision based on a simple oversight. In sum, the Court held that the Board did not act arbitrarily and capriciously.

7. Corporate Veils

Petitioners argue that the Board improperly pierced the corporate veil when it instructed staff to seek payment of the fines from Paul DeBree and Lance Parker, principals of the company. DeBree was president of Dutchess and manager of Legend, while Packer was Dutchess's designated representative. The Court held that the Board did not pierce corporate veils because to do so would require a separate action against DeBree and Packer. Additionally, the Board conceded that while the language in the order was a directive, carrying it out would require a separate action and further legal action.

²² NEV. REV. STAT. § 639.233(1), in relevant part the 2003 version exempted wholesalers or manufacturers whose principal place of business was in another state.

²³ NEV. ADMIN. CODE §§ 639.602(1)(c)-(f) requires "each wholesaler" to "make and maintain a record of its inventory" including "shipping record," "shipping label," and "shipping record evidencing shipment. . . from wholesaler to the purchaser or purchasing wholesaler."

²⁴ Repealed.

Conclusion

The Court concluded by holding: (1) the Board had jurisdiction to discipline Petitioners, (2) was within its discretion to joined Petitioners as defendant and joinder did not cause undue prejudice, (3) Petitioners were not deprived of their due process rights, (4) the Board applied correct legal standards in reaching all but one of its decisions, (5) did not act arbitrarily and capriciously, and (6) did not impermissibly pierce corporate veils. The Court remanded to the district court to remand to the Board to reconsider fines in light of Overseas being exempted from Nevada licensing requirements.