

Dutchess Bus. Servs., Inc. v. Nev. St. Bd. of Pharmacy
124 Nev. Adv. Op. 32
(May 29, 2008)¹

ADMINISTRATIVE LAW – PHARMACY REGULATION

Summary

Two pharmaceutical wholesalers appeal from the district court’s denial of a petition for judicial review of an order by respondent Nevada State Board of Pharmacy (the Board) revoking the wholesalers’ licenses for violations of Nevada’s statutes and regulations governing the secondary prescription drug market. The wholesalers appeal on multiple grounds, three of which raise issues of first impression: (1) an administrative agency’s discretion concerning joinder in an administrative proceeding; (2) an administrative agency’s discretion with respect to discovery in an administrative proceeding; and (3) whether intent must be proven to render an entity liable for violating NRS § 585.520(1).²

Disposition/Outcome

Reversed and remanded to recalculate the imposed fines. In regards to an administrative agency’s discretion to decide joinder and discovery issues during an administrative proceeding, the Court concludes that in the absence of a rule, statute, or regulation governing that proceeding, issues such as joinder and discovery are left to the agency’s discretion. Concerning liability under NRS § 585.520(1), the plain language of the statute does not require intent for its violation, thus the Board may find that the licensee violated the statute without proving its intent to cause harm or violate the statute. As to the multiple other arguments, the Court finds them all to be without merit except one – the Board erred in concluding that a company Dutchess transacted with required a license at the time, and the fines must be accordingly recalculated.

Factual and Procedural History

The Board regulates the practice of pharmacy in Nevada through various responsibilities. It licensed Dutchess and Legend as pharmaceutical wholesalers in 1998 and 2002, respectively. Pharmaceutical wholesalers purchase pharmaceuticals from manufacturers, wholesalers, and pharmacies, and resell the pharmaceuticals to other wholesalers and pharmacies.

Over a three-year period, Dutchess, and then Legend as Dutchess’ successor company, conducted business with several questionable entities. This business formed the basis of the Board’s investigation. In August 2003, the Board filed a Notice of Intended Action and Accusation against Dutchess and Legend, accusing them of buying and selling adulterated and misbranded prescription drugs; failing to make, maintain, and provide accurate pedigrees detailing the sources of the drugs; failing to make, keep, and provide accurate records of their

¹ Summarized by Danielle Tarmu

² NEV. REV. STAT. § 585.520(1) prohibits “[t]he manufacture, sale or delivery, holding or offering for sale of any food, drug, device or cosmetic that is adulterated or misbranded.”

purchases; and purchasing drugs from unlicensed distributors. The three drugs bought and sold by the companies that formed the basis of the Board's action were Lupron (manufactured by TAP Pharmaceutical Products, Inc.), Zoladex (manufactured by AstraZeneca), and Serostim (manufactured by EMD Serono, Inc.). Dutchess dealt with shipments of the drugs from wholesalers Crystal Coast, Inc., Genendo Purchasing Organization, Xenigen, Inc., and Rekcus, and Legend dealt only with Rekcus.

Although Crystal Coast represented itself as an authorized distributor of Serostim, it was not an authorized distributor. Dutchess purchased numerous boxes of Serostim from Crystal Coast at prices below the Wholesale Acquisition Cost ("WAC") and almost half of the boxes were counterfeit Serostim. In late 2000, Serono became aware that counterfeit Serostim was being distributed and notified pharmacists and its customers, including Dutchess. Despite its notification of the counterfeit drug, Dutchess did not ask Crystal Coast to provide invoices to demonstrate its source of Serostim. The Board found that these facts should have caused Dutchess to discover Crystal Coast's questionable distributor status.

Genendo and Xenigen falsely represented they were authorized distributors of Lupron and Zoladex, and Rekcus falsely represented that it was an authorized distributor of Lupron. Dutchess and Legend bought Lupron at prices below WAC, and Dutchess bought Zoladex at prices below WAC. For certain pharmaceutical purchases, Dutchess maintained two sets of pedigrees, one listing Cactus RX³ as the original seller and authorized distributor, and the other set identifying a chain of wholesalers who handled the drug before reaching Dutchess. The Board found that the chain had been "crudely redacted." Dutchess had various other questionable record-keeping practices, such as misrepresenting its sources of drugs to its customers. Dutchess also provided limited, questionable shipping records at the hearing. The records showed that although Dutchess was conducting business with Crystal Coast, it received few of its shipments from Crystal Coast's licensed address and received several shipments from Overseas International, an unlicensed wholesaler. Dutchess did not provide any shipping records for its transactions with Genendo, Xenigen, and Rekcus, and Legend did not provide records for its transactions with Rekcus.

The Board held a hearing on the charges listed in the accusation and unanimously determined that Dutchess and Legend were guilty of 11 violations of Nevada pharmacy law. It revoked the companies' pharmaceutical wholesaler's licenses and fined both companies. Dutchess and Legend petitioned for judicial review and the district court denied the petition in totality, except it remanded it to the Board to reconsider the fines. On remand, the Board reduced the fines, but both companies appeal the district court's denial of their petition.

Discussion

On appeal, Dutchess and Legend argue that the Board (a) lacked jurisdiction to discipline them, (b) improperly enjoined them as defendants at the administrative hearing causing them undue prejudice, (c) deprived them of their due process rights by denying them the right to conduct discovery and finding them guilty of charges not listed in the accusation, (d) applied

³ The record is unclear as to whether Dutchess actually conducted business with the wholesaler Cactus RX.

incorrect legal standards and misinterpreted certain statutes and regulations, (e) rendered its decision without substantial supporting evidence, (f) acted arbitrarily and capriciously, and (g) impermissibly pierced their corporate veils to add certain employees as alter egos.

a. The Board had jurisdiction to discipline Dutchess and Legend

Although the subject transactions occurred outside Nevada, Dutchess and Legend were licensed as pharmaceutical wholesalers in the State of Nevada. NRS § 639.210 gives the Board jurisdiction over Nevada license holders and authorizes it to revoke licenses. NRS § 639.255 authorizes the Board to impose fines for each count of an accusation, according to a schedule of fines. These statutes are plain and unambiguous, thus the Court will not look beyond the language to ascertain legislative intent. Nothing in NRS § 639.210 limits the Board's jurisdiction to acts occurring solely within Nevada. Licensees who commit acts of unprofessional conduct and other acts that breach the statute thus violate the public interest of the state; therefore the Board has jurisdiction to discipline and impose penalties on Dutchess and Legend.

b. The Board properly joined Dutchess and Legend

The companies argue they were improperly joined because they did not participate in the same transactions constituting the offenses, but the Court finds the argument unpersuasive. There is an absence of Nevada law governing joinder of parties in administrative proceedings because NRCP binds only district courts, not state agencies unless the agency expressly adopts the rules. Even so, the Court holds that the Board was within its discretion to join Dutchess and Legend because such a determination is within the broad scope of discretion afforded to the Board as an administrative agency.⁴ The evidence showed that Legend acquired Dutchess in a stock purchase, that Legend and Dutchess both operated at the same facilities, and that Legend continued transactions with Rekcus after Dutchess ended its own operations. The companies also failed to establish that they suffered undue prejudice as a result of joinder. Although they allege that the Board penalized Legend for aspects of Dutchess' wrongdoing, the Board did not fine Legend for Dutchess' violations.

c. The Board did not deprive Dutchess and Legend of their due process rights

Dutchess and Legend argue that the Board violated their due process rights by (1) failing to provide them with adequate notice of the factual basis for the charges in the accusation, (2) finding them guilty of charges not listed in the accusation, and (3) denying them the ability to conduct discovery or providing a list of witnesses.

The companies received adequate notice of the charges. Although proceedings before an administrative agency are more relaxed, guarantees of due process still apply.⁵ Under NRS § 639.241, the Board is required to initiate the administrative hearing process by filing an accusation against the entity whose license it seeks to revoke, setting forth the charges. The Board must also serve a copy of the accusation on the respondent.⁶ These procedural

⁴ See *American Beef Packers, Inc. v. U.S. Dep't Agric.*, 486 F.2d 1048, 1049 (8th Cir. 1973).

⁵ *Bivins Constr. V. State Contractors' Bd.*, 107 Nev. 281, 283, 809 P.2d 1268, 1270 (1991).

⁶ NEV. REV. STAT. § 639.242(1).

requirements comport with minimum standards of due process by ensuring that the respondent is apprised of the charges against it and the factual bases for them. Dutchess and Legend received the Board's accusation, which stated the factual bases for the charges, thus their due process rights were not violated.

The Board did not adjudicate the companies guilty of charges that were not listed in the accusation. The companies asserts that while the Board found Dutchess guilty of providing inaccurate pedigrees, the closest cause of action in the accusation alleged that Dutchess falsely represented itself as an authorized dealer. They argue that this discrepancy failed to provide notice to Dutchess of the charge so Dutchess was unable to defend against it. NRS § 639.241 requires the Board to give notice in the accusation of the alleged charges. Due process requirements are satisfied when the parties are sufficiently apprised of the nature of the proceedings so that there is no unfair surprise and can prepare a defense.⁷ Here, the language in the Board's accusation clearly and unambiguously notified Dutchess that it was charged with failing to provide accurate pedigrees and the Board found the company guilty of this charge. Therefore, the companies' argument that they were found guilty of charges not listed in the accusation is without merit.

Dutchess and Legend do not have a constitutional right to pre-hearing discovery. There is no state or federal constitutional right in administrative proceedings to pre-hearing discovery that would require disclosure of intended witnesses,⁸ as the companies argue. Furthermore, the Nevada Rules of Civil Procedure do not apply to administrative proceedings,⁹ and Nevada's Administrative Procedure Act does not provide for discovery. NRS § 233B.040(1) authorizes administrative agencies to adopt regulations to aid in carrying out their duties. The Board has not established any procedures allowing for discovery and no statutes require it, thus it is within their discretion to decline to do so.

Although the Board has not adopted provisions allowing for discovery, due process guarantees of fundamental fairness still apply. NRS § 639.246(1) requires the Board to issue subpoenas on behalf of any party to an action before the Board to produce witnesses or documents. Therefore, Dutchess and Legend had a procedural mechanism to obtaining evidence necessary to their defense, and do not deny the Board's assertion that it subpoenaed all the evidence Dutchess and Legend requested. Moreover, NRS § 639.2485(2) provides that the complaint and other documents filed by the Board to be public records. Therefore, the companies had access to any statements of potential witnesses that the Board considered. Because the Board's procedures to subpoena witnesses and provide access to their statements comport with due process requirements, the companies failed to establish that the Board improperly denied them access to witnesses.

⁷ Nevada St. Apprenticeship v. Joint Appren., 94 Nev. 763, 765, 587 P.2d 1315, 1317 (1978).

⁸ 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).

⁹ See NRCP 1.

d. The Board properly applied the law

Dutchess and Legend allege that the Board applied an incorrect legal standard in reaching several of its conclusions of law. The Court concludes that all but one of the companies' arguments lack merit.

The companies argue that the Board improperly applied a strict liability standard when it determined that Dutchess had violated NRS § 585.520(1), which prohibits transactions involving adulterated or misbranded foods, drugs, devices, or cosmetics. The companies argue that the administrative hearing was at least a quasi-criminal proceeding, so the requirements for imposing criminal liability should apply. Although NRS § 585.550 provides for criminal penalties, it enables the attorney general or district attorney, not the Board, to prosecute criminal violations of Chapter 585. In holding the hearings, the Board was not adjudicating criminal violations and was therefore not bound to apply criminal standards in the proceeding against Dutchess and Legend. Although the companies further contend that NRS § 585.520 contains a knowledge requirement, this argument is contrary to the plain meaning of the statute. The statute's language prohibits the sale or delivery of adulterated or misbranded drugs, with no mention of a knowledge requirement. That the statute does not contain a knowledge requirement is further supported by the United States Supreme Court's interpretation of NRS § 585.520(1)'s federal counterpart in section 331(a) of the Federal Food, Drug, and Cosmetic Act. In *United States v. Dotterweich*, the Court held that section 331 did not contain a knowledge requirement.¹⁰ The Court explained that the Act was intended to protect consumers, and although imposing liability without consciousness of wrongdoing may be harsh, the burden was more properly borne by shippers rather than the general public.¹¹ Based on the plain language of NRS § 585.520(1) and the Supreme Court's interpretation of its federal counterpart, the Court holds that NRS § 585.520(1) does not contain a knowledge requirement. Therefore, the Board did not err by interpreting the statute as such.

Dutchess and Legend similarly argue that the Board applied an incorrect knowledge requirement with respect to the parties' violations of various other statutes and regulations. As discussed above, however, the Board was not adjudicating the companies' culpability for alleged criminal violations. It was acting on its authority under NRS § 639.255 to discipline license holders for statutory violations; therefore the Board was not applying criminal knowledge or intent requirements when it was determining whether the companies violated the statutes and regulations.

Dutchess and Legend argue that the Board erred when it determined that Dutchess had violated NRS § 639.210(4) and (12) and NAC 639.945(1)(g), (h), and (i) when it transacted with Overseas International. The companies argue that the Board erred because (1) NRS § 639.233 did not require a company like Overseas to maintain a license at the time its transactions with Dutchess took place, and (2) even if Overseas was required to maintain a license, Dutchess never bought drugs from Overseas because Overseas was merely a shipping agent. The Court agrees with this agreement and concludes that the Board erred in reaching this conclusion of law.

¹⁰ 320 U.S. 277, 281 (1943).

¹¹ Id.

While NRS § 639.233(1) requires wholesalers who furnish drugs to people to be licensed, in 2003 the statute exempted from the licensing requirements those wholesalers or manufacturers whose principal place of business was in another state.¹² Therefore, Overseas was not then required to be licensed in Nevada to sell controlled substances to Dutchess, and the Board erred in ruling that Dutchess' transactions were unprofessional under NRS § 639.210(4) and violating regulations under NRS § 639.210(12). Accordingly, on remand from the district court, the Board should recalculate the fines imposed on Dutchess.

Dutchess and Legend argue that the Board erred when it determined that Dutchess violated NAC § 639.602 when it failed to maintain and provide records to the Board showing the names and addresses of the locations from which drugs were shipped to Dutchess. However, this regulation clearly requires wholesalers to maintain shipping records and as a wholesaler, Dutchess was subject to this requirement. Accordingly, the Board made no error in its conclusion.

e. The Board's orders are not arbitrary and capricious

The companies argue that the Board's orders are arbitrary and capricious because (1) the Board did not cite to authority to justify its imposition of fines, (2) the Board fined Legend for Serostim that it never handled, (3) the fines against the companies and the revocation of Legend's license are excessive given mitigating circumstances, and (4) the Board cited to a repealed statute to authorize the imposition of attorney fees on the companies. In regards to the first argument, NRS § 639.255 allows the Board to impose fines on a licensed wholesaler as a method of discipline for every count charged, as long as the fine does not exceed \$10,000 per count. The Board's fines were within these limits, and its order was not arbitrary or capricious because it failed to cite to the statute.

As to the second argument, the Board fined Legend for only 125 of the 249 counts mentioned, which indicates that the Board recognized that Legend bought and sold only Lupron and not Serostim and Zoladex, and fined Legend only for drugs it handled. In regards to the third argument, it merely reiterates evidence presented during the hearing. The Board's imposition of fines and revocation of licenses are entitled to great deference, therefore the Court will not reconsider the Board's determination. As to the final argument, the Board admits it inadvertently cited to NRS § 639.255 when it should have cited NRS § 622.400(1)(a), which authorizes attorney fees for administrative hearings. The Court will not reverse a correct judgment simply because it was based on the improper statutory authority, and thus the order is not arbitrary and capricious.

f. The Board did not pierce Dutchess' and Legend's corporate veils

The companies argue that the Board impermissibly pierced their corporate veils when, in its order, it instructed Board staff to seek payment of the fines from Paul DeBree and Lance Packer, employees of the companies. The Court disagrees. Nothing in NRS Chapter 639 suggests that the Board has authority to pierce the corporate veil. Moreover, if the Board wished to pierce the veils, it would have to institute a separate action to do so. The order's language was

¹² NRS 639.233(2) (2002).

a directive to the Board staff regarding further action, and the Board does not have a valid judgment against the principals by way of including this language in the order.

Conclusion

The Court holds that (1) because the companies held licenses issued by the Board, the Board had jurisdiction under NRS § 639.210 to discipline them even though the business transactions took place out of state; (2) as an administrative body, the Board was within its discretion to join Dutchess and Legend and neither party was unduly prejudiced; (3) the companies received adequate notice of the charges against them; (4) in administrative proceedings, there is no due process right to discovery and the companies were not entitled to conduct discovery; (5) the Board adjudicated the companies guilty of charges listed in the accusation; (6) the Board applied the proper legal standards in all but one of its conclusions of law; (7) the Board's orders are not arbitrary and capricious; and (8) the Board did not pierce the companies' corporate veil. Because the statute in effect in 2003 exempted Overseas from Nevada's licensing requirements, the Board erred in determining that Dutchess violated Nevada law by conducting business with Overseas. The Court reverses the district court's denial of the petition for judicial review and remands it to recalculate the fines imposed on Dutchess according to this ruling.