

124 Nev., Advance Opinion 63

IN THE SUPREME COURT OF THE STATE OF NEVADA

DUTCHESS BUSINESS SERVICES,
INC.; AND LEGEND
PHARMACEUTICALS, INC.,
Appellants,
vs.
NEVADA STATE BOARD OF
PHARMACY,
Respondent.

No. 46345

FILED

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Petition for rehearing of Dutchess Business Services v. State Board of Pharmacy, 124 Nev. ___, 184 P.3d 397 (2008) (opinion withdrawn July 17, 2008). Appeal from a district court order denying judicial review of a Nevada State Board of Pharmacy decision. Eighth Judicial District Court, Clark County; Valerie Adair, Judge.

Rehearing granted; affirmed in part, reversed in part, and remanded with instructions.

Chesnoff & Schonfeld and Richard A. Schonfeld and David Z. Chesnoff,
Las Vegas,
for Appellants.

Louis A. Ling, General Counsel, Nevada State Board of Pharmacy, Reno,
for Respondent.

BEFORE THE COURT EN BANC.

OPINION

By the Court, HARDESTY, J.:

On May 29, 2008, this court issued an opinion in this matter affirming in part and reversing in part the district court's order and

remanding with instructions. Subsequently, appellants filed a petition for rehearing of that decision. On July 17, 2008, this court withdrew the prior opinion pending resolution of the petition for rehearing. After reviewing the rehearing petition, as well as the briefs and appendix, we conclude that rehearing is warranted under NRAP 40(c)(2), and we grant the petition for rehearing. We now issue this opinion in place of our prior opinion.

In this case, 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 revoking the wholesalers' licenses for violations of Nevada's statutes and regulations governing the secondary prescription drug market. After a disciplinary hearing, the Board found that appellants Dutchess Business Services, Inc., and its successor company, Legend Pharmaceuticals, Inc., violated numerous sections of the Nevada Revised Statutes and the Nevada Administrative Code; therefore, the Board revoked Dutchess's and Legend's wholesaler's licenses and imposed fines on the entities. Dutchess and Legend appeal on multiple grounds, four of which raise issues of first impression.

Specifically, after addressing the Board's jurisdiction to discipline Dutchess and Legend for conduct that occurred outside of Nevada, we consider the following issues in the context of resolving Dutchess and Legend's appellate contentions: an administrative agency's discretion concerning joinder in an administrative proceeding; an administrative agency's discretion with respect to discovery in an administrative proceeding; whether intent must be proven to render an entity liable for violating NRS 585.520(1), which prohibits "[t]he manufacture, sale or delivery, holding or offering for sale of any food, drug,

device or cosmetic that is adulterated or misbranded”; and whether a wholesaler that has established an ongoing relationship with a pharmaceutical manufacturer must nonetheless provide a pedigree when reselling the prescription drugs under NAC 639.603(1). Concerning an administrative agency’s discretion to decide joinder and discovery issues during an administrative proceeding, we conclude that in the absence of a rule, statute, or regulation governing the type of proceeding before the agency, issues such as joinder and discovery are generally left to the agency’s discretion. With regard to determining liability under NRS 585.520(1), because the plain language of that statute does not require intent for its violation, we conclude that the Board may find that a licensee violated NRS 585.520(1) without proving a licensee’s intent to cause harm or violate the statute. And with respect to NAC 639.603(1)’s pedigree requirement, that regulation plainly requires authorized distributors to provide pedigrees on subsequent sales of prescription drugs if they purchased the drug from another wholesaler, even if the wholesaler has established an ongoing relationship with the pharmaceutical manufacturer. After addressing those issues, we resolve Dutchess and Legend’s remaining contentions.

FACTS

The Board regulates the practice of pharmacy in Nevada. Among its myriad responsibilities, the Board licenses and oversees entities engaged in the buying and selling of pharmaceutical drugs. The Board licensed Dutchess and Legend as pharmaceutical wholesalers in 1998 and 2002, respectively. As pharmaceutical wholesalers, Dutchess and Legend purchased pharmaceuticals from manufacturers, wholesalers, and pharmacies and resold the pharmaceuticals to other wholesalers and pharmacies.

Over a three-year period, Dutchess, and then Legend as Dutchess's successor company, conducted business with a number of questionable entities. Dutchess's and Legend's dealings with these companies formed the basis of an investigation by the Board. As a result of the Board's investigation, in August 2003, the Board filed a Notice of Intended Action and Accusation¹ against Dutchess and Legend. In the accusation, the Board alleged that from 2001 to 2003, Dutchess and Legend bought and sold adulterated and misbranded prescription drugs; failed to make, maintain, and provide accurate pedigrees detailing the sources of the drugs;² failed to make, keep, and provide accurate records of their purchases; and purchased drugs from unlicensed distributors. The following facts are taken from evidence presented to the Board during the five-day hearing it conducted on the charges listed in the accusation.

Dutchess and Legend bought and resold three drugs in particular that form the subject of this action: (1) Lupron, which is used to treat advanced prostate cancer and is manufactured by TAP Pharmaceutical Products, Inc.; (2) Zoladex, which is also used to treat prostate cancer and is manufactured by AstraZeneca; and (3) Serostim,

¹An accusation is a "written statement of the charges alleged." NRS 639.241(2).

²NAC 639.603 requires wholesalers to provide statements of prior sales of drugs, commonly referred to as "pedigrees," which must identify with considerable specificity "each sale of a prescription drug before the prescription drug is sold to another wholesaler or to a pharmacy" under certain conditions.

which is used to treat cachexia³ and is manufactured by EMD Serono, Inc. Dutchess bought and sold multiple shipments of these drugs from three Florida-based wholesalers—Crystal Coast, Inc.; Genendo Purchasing Organization; and Xenigen, Inc.—and one South Carolina-based wholesaler—Rekcus, Inc.

Dutchess bought Lupron, Zoladex, and Serostim from all four wholesalers. Legend bought Lupron from Rekcus. Dutchess's and Legend's purchases from these wholesalers totaled approximately \$8.5 million.

Dutchess's purchases of Serostim from Crystal Coast

Although Crystal Coast represented itself as an authorized distributor of Serostim on the invoices that it sent to Dutchess, it was not an authorized distributor.⁴ Dutchess purchased at least 927 boxes of Serostim from Crystal Coast at prices below the Wholesale Acquisition Cost (WAC),⁵ and 399 of the boxes contained counterfeit Serostim. In late 2000, Serono became aware that counterfeit Serostim was circulating in

³"Cachexia" is a "[c]ondition characterized by extreme weight loss, anemia, wasting of muscles, and weakness; associated with a long-term disease or severe malnutrition." Attorney's Illustrated Medical Dictionary C1 (2002).

⁴According to the Board, an "authorized distributor" is a wholesaler who has an ongoing relationship with a manufacturer pursuant to NAC 639.589. Under NAC 639.589, an "ongoing relationship" is "a continuing business relationship in which a wholesaler distributes a manufacturer's prescription drugs which is established pursuant to NAC 639.594."

⁵The WAC for any given drug is established by each drug company internally and is then published to the marketplace as the price for the drug.

the drug market and sent notification to pharmacists and its customers, including Dutchess. Even though Dutchess received formal notification from Serono and informal notification from its own customers about counterfeit Serostim, Dutchess never asked Crystal Coast to provide invoices to demonstrate Crystal Coast's source of the Serostim. The evidence presented to the Board demonstrated that the person who supplied the counterfeit Serostim to Crystal Coast, before going to federal prison, had apparently conducted a pharmaceutical wholesale business in Florida without a permit, in violation of Florida law. The Board found that these facts should have caused Dutchess to discover the questionable character of Crystal Coast's distributor status.

Dutchess's purchases of Lupron and Zoladex from Genendo, Xenigen, and Rekcus

Genendo and Xenigen both falsely represented that they were authorized distributors of Lupron and Zoladex, and Rekcus falsely represented that it was an authorized distributor of Lupron. Both Dutchess and Legend purchased Lupron at prices below WAC, and Dutchess purchased Zoladex at prices below WAC.

Dutchess's recordkeeping

The record is unclear whether Dutchess conducted business with Cactus RX, another pharmaceutical wholesaler. However, for certain pharmaceutical purchases, Dutchess maintained two sets of pedigrees. One set of pedigrees listed Cactus RX as the original seller and authorized distributor. The other set identified a chain of wholesalers who handled the drug in question before it reached Dutchess, but the Board found that the information identifying that chain had been "crudely redacted." Additionally, Dutchess's records indicate that Dutchess made several

purchases of Serostim from Crystal Coast where no corresponding record of sale of the Serostim was provided.

Dutchess provided only limited shipping records at the hearing. The shipping records that it provided showed that although Dutchess was then conducting business with Crystal Coast, it actually received several shipments from Overseas International, an unlicensed wholesaler in Florida. The Board also found that only 3 of the 29 Crystal Coast transactions for which Dutchess provided shipping records were actually shipped from Crystal Coast's licensed address. Dutchess did not provide any other shipping records for its transactions with Crystal Coast and provided no shipping records for its transactions with Genendo, Xenigen, and Rekcus. Legend also failed to provide shipping records for its transactions with Rekcus.

Dutchess's and Legend's records further provided that, as noted above, Dutchess and Legend purchased Lupron from Crystal Coast, Genendo, Xenigen, and Rekcus. When selling the Lupron to subsequent purchasers, Dutchess and Legend provided pedigrees which indicated that they were authorized distributors of the drug but which did not disclose from whom they had purchased the drug. The Board heard testimony from Barb Tolbert, the manager of customer service for TAP Pharmaceuticals, that Dutchess and Legend were both customers-of-record with TAP.⁶ At the hearing, Paul DeBree, the CEO of Dutchess and

⁶Tolbert testified that TAP uses the terminology, "customer-of-record" to refer to wholesalers whose licenses have been verified and to whom TAP directly sells drugs; she testified that TAP does not use the term "authorized distributor." The parties do not dispute that in this
continued on next page . . .

manager of Legend, testified that Dutchess and Legend obtained and maintained authorized distributor status with TAP so that they could purchase Lupron from wholesalers and then resell the Lupron to other wholesalers without providing a pedigree detailing the prior sales of the Lupron.

Procedural history

After the 5-day hearing on the charges listed in the accusation, the Board unanimously determined that Dutchess and Legend were guilty of 11 violations of Nevada pharmacy law. The Board issued its findings of fact, conclusions of law, and order, in which it revoked Dutchess's and Legend's pharmaceutical wholesaler's licenses, fined Dutchess \$1 million plus fees and costs totaling \$37,609.77, and fined Legend \$371,000 plus fees and costs totaling \$37,609.77.

Dutchess and Legend petitioned for judicial review, and the district court denied the petition in all respects, except that it remanded to the Board for it to reconsider the amount of fines imposed. On remand, the Board issued revised conclusions of law and an order reducing the fines against Dutchess to \$519,750 and the fines against Legend to \$31,250. Dutchess and Legend now appeal the district court's denial of their petition for judicial review.

... continued

circumstance, a customer-of-record is analogous to an authorized distributor.

DISCUSSION

On appeal, Dutchess and Legend argue that the Board (1) lacked jurisdiction to discipline them, (2) improperly joined them as defendants at the administrative hearing causing undue prejudice as a result, (3) deprived them of their due process rights by denying them the right to conduct discovery and by finding them guilty of charges not listed in the accusation, (4) applied incorrect legal standards and misinterpreted certain statutes and regulations, (5) acted arbitrarily and capriciously, and (6) impermissibly pierced their corporate veils to add certain employees as alter egos. After addressing our standard of review, we address each argument in turn.

Standard of review

We review issues pertaining to statutory construction de novo.⁷ We nonetheless defer to an agency's interpretation of its governing statutes or regulations if the interpretation is within the language of the statute.⁸

The Board had jurisdiction to discipline Dutchess and Legend

Dutchess and Legend contend that because each transaction occurred outside Nevada, the Board lacked jurisdiction to discipline them. We disagree.

Dutchess and Legend were both licensed as pharmaceutical wholesalers in the State of Nevada. The Board has jurisdiction to discipline Nevada license holders under NRS 639.210. Specifically, NRS

⁷Torrealba v. Kesmetis, 124 Nev. ___, 178 P.3d 716 (2008).

⁸State, Tax Comm'n v. Nevada Cement Co., 117 Nev. 960, 968-69, 36 P.3d 418, 423 (2001).

639.210(4) authorizes the Board to revoke the license of any holder who is “guilty of unprofessional conduct or conduct contrary to the public interest,” and NRS 639.210(12) authorizes the same for any holder who has “violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any of the provisions of [Chapter 639].” The Board is also authorized to impose fines for each count of an accusation, according to a schedule of fines.⁹ It is well established that when statutory language is plain and unambiguous, we will not look beyond the language to ascertain legislative intent.¹⁰ These statutes are plain and unambiguous. Nothing in NRS 639.210(4) limits the Board’s review of unprofessional conduct to acts occurring solely in the State of Nevada. Licensees who commit acts of unprofessional conduct, whether in this state or elsewhere, violate the public interest of this state in its licensed pharmaceutical wholesalers. Thus, the Board has jurisdiction to discipline and impose penalties on Dutchess and Legend.

The Board properly joined Dutchess and Legend

Dutchess and Legend argue that they were wrongfully joined as defendants at the hearing because they did not participate in the same transactions or series of transactions constituting any of the offenses. That argument is unpersuasive.

Initially, we acknowledge the absence of controlling Nevada law governing joinder of parties in administrative proceedings. Although NRCP 19 and NRCP 20 allow for mandatory and permissive joinder of

⁹NRS 639.255(1)(f).

¹⁰Meridian Gold v. State, Dep’t of Taxation, 119 Nev. 630, 633, 81 P.3d 516, 518 (2003).

parties, respectively, in civil proceedings, NRCP 1 states that Nevada's rules of civil procedure "govern the procedure in the district courts in all suits of a civil nature whether cognizable as cases at law or in equity." Thus, NRCP 19 and NRCP 20 are not binding on a state agency in an adjudicatory proceeding, unless expressly adopted by the agency.¹¹

Notwithstanding the absence of express statutory authority, we determine that the Board was within its discretion to join Dutchess and Legend. Such a determination is within the broad scope of discretion afforded to the Board as an administrative agency.¹² In this case, the Board did not abuse its discretion by joining Dutchess and Legend. Specifically, the evidence showed that Legend acquired Dutchess in a stock purchase, that Legend conducted its operations at the same facilities as Dutchess, and that Legend continued transacting business with Rekus after Dutchess ended its own operations.

We further determine that Dutchess and Legend have failed to establish that either suffered undue prejudice as a result of joinder. Although they allege that the Board penalized Legend for aspects of Dutchess's wrongdoing, as we discuss in greater detail below, the Board did not fine Legend for Dutchess's violations. Dutchess and Legend fail to

¹¹See Yoder v. Ohio State Bd. of Educ., 531 N.E.2d 769, 770 (Ohio Ct. App. 1988) (holding that where state rules of civil procedure "apply to courts of the state," they do not apply to adjudicatory proceedings before state agencies).

¹²See American Beef Packers, Inc. v. U.S. Dep't Agric., 486 F.2d 1048, 1049 (8th Cir. 1973) ("Procedural decisions relating to such matters as pleadings, joinder of parties, and motions to sever, fall well within the administrative agency's discretion.").

claim or establish any other instances of undue prejudice. Accordingly, we conclude that Dutchess and Legend did not suffer undue prejudice resulting from their joinder.

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 in the following three ways: (1) by failing to provide them with adequate notice of the factual basis for the charges in the accusation, (2) by finding them guilty of charges not listed in the accusation, and (3) by denying them the ability to conduct discovery or providing a list of witnesses.

Dutchess and Legend received adequate notice of the charges

Dutchess and Legend argue that their due process rights were violated because the Board failed to notify them of the factual bases for the charges against them. Although proceedings before administrative agencies may be subject to more relaxed procedural and evidentiary rules,¹³ due process guarantees of fundamental fairness still apply.¹⁴ Administrative bodies must follow their established procedural guidelines¹⁵ and give notice to the defending party of "the issues on which

¹³McClelland v. Andrus, 606 F.2d 1278, 1285 (D.C. Cir. 1979); Silverman v. Commodity Futures Trading Com'n, 549 F.2d 28, 33 (7th Cir. 1977).

¹⁴Bivins Constr. v. State Contractors' Bd., 107 Nev. 281, 283, 809 P.2d 1268, 1270 (1991); see also McClelland, 606 F.2d at 1285-86; Silverman, 549 F.2d at 33.

¹⁵McClelland, 606 F.2d at 1285-86.

decision will turn and . . . the factual material on which the agency relies for decision so that he may rebut it.”¹⁶

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. The accusation is required to set forth in writing the charges alleged and the acts or omissions with which the respondent is charged such that the respondent may prepare a defense.¹⁷ The Board must also serve a copy of the accusation on the respondent.¹⁸ The procedure for preparing and serving an accusation set forth in NRS 639.241 comports with minimum standards of due process by ensuring that a party to a hearing before the Board is apprised of the charges against it and the factual predicates for those charges. Because Dutchess and Legend received the Board’s accusation, and it fully stated the factual bases for the charges against them, their due process rights were not violated.

The Board did not adjudicate Dutchess and Legend guilty of charges not listed in the accusation

Dutchess and Legend assert that while the Board found Dutchess guilty of providing inaccurate pedigrees for particular drugs, the closest cause of action listed in the accusation alleged that Dutchess falsely represented itself as an authorized distributor of TAP

¹⁶Bowman Transp. v. Ark.-Best Freight System, 419 U.S. 281, 288-89 n.4 (1974); see also Nevada St. Apprenticeship v. Joint Appren., 94 Nev. 763, 765, 587 P.2d 1315, 1317 (1978).

¹⁷NRS 639.241(2).

¹⁸NRS 639.242(1).

Pharmaceuticals. They argue that because the accusation failed to charge Dutchess with providing inaccurate pedigrees, Dutchess was without notice of the charge and was unable to prepare a defense to it.

Under NRS 639.241(2), the Board is required to give notice in the accusation of the charges alleged:

The accusation is a written statement of the charges alleged and must set forth in ordinary and concise language the acts or omissions with which the respondent is charged to the end that the respondent will be able to prepare his defense. The accusation must specify the statutes and regulations which the respondent is alleged to have violated, but must not consist merely of charges phrased in language of the statute or regulation.

This court has held that, in the context of administrative pleadings, "due process requirements of notice are satisfied where the parties are sufficiently apprised of the nature of the proceedings so that there is no unfair surprise."¹⁹ We explained that it is the opportunity to prepare a defense that defines due process.²⁰

The relevant cause of action in the Board's accusation stated, in pertinent part,

When Dutchess sold the Lupron it had purchased from Crystal Coast, Genendo, Xenigen, and Rekcus to other wholesalers, Dutchess did not show on the pedigrees that the seller was Dutchess' source.

....

¹⁹Nevada St. Apprenticeship, 94 Nev. at 765, 587 P.2d at 1317.

²⁰Id.

Dutchess knew that none of the Lupron it sold had been purchased by Dutchess from TAP Pharmaceuticals and, instead, that all of the Lupron it sold had actually been purchased from Crystal Coast, Genendo, Xenigen, and Rekcus.

....

In 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 where Dutchess had not purchased any of the Lupron from TAP Pharmaceuticals and, instead, had actually purchased the Lupron from Crystal Coast, Genendo, Xenigen, or Rekcus, Dutchess violated . . . NAC 639.603

On this point, the Board concluded that Dutchess had violated NAC 639.603, among other statutes and regulations, by "making and providing pedigrees to pharmaceutical wholesalers for sales of Lupron that made the false representation that Dutchess was the originating [authorized distributor] for the Lupron instead of accurately showing that Dutchess had actually purchased the Lupron from Crystal Coast, Genendo, Xenigen, or Rekcus."

The language in the accusation clearly and unambiguously notified Dutchess that it was charged with failing to provide accurate pedigrees, and the Board found Dutchess guilty of this charge. We thus determine that Dutchess and Legend's argument that the Board adjudicated Dutchess guilty of charges not listed in the accusation is without merit.

Dutchess and Legend do not have a constitutional right to prehearing discovery

Dutchess and Legend argue further that the Board should have permitted prehearing discovery²¹ and been required to produce a witness list. Generally, there is no state or federal constitutional right in administrative proceedings to prehearing discovery that would require disclosure of intended witnesses.²² Furthermore, as discussed, the Nevada Rules of Civil Procedure do not apply to administrative proceedings,²³ and Nevada's Administrative Procedure Act makes no provision for discovery. Thus, the extent to which a party engaged in an administrative hearing before the Board is entitled to discovery is determined by the statutes governing the Board and its adopted regulations.²⁴ The Board has not established any procedures allowing for discovery, and it is within its discretion to decline to do so.²⁵

²¹Dutchess and Legend fail to identify any other prehearing discovery that they requested and that was rejected by the Board.

²²See 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).

²³See NRCP 1 ("These rules govern the procedure in the district courts in all suits of a civil nature.").

²⁴See NRS 233B.040(1) (authorizing administrative agencies to adopt "reasonable regulations" to aid in carrying out their duties).

²⁵See id.

Notwithstanding the Board's decision, due process guarantees of fundamental fairness still apply.²⁶ The fundamental fairness of the Board's proceeding against Dutchess and Legend must be examined in light of the procedural protections made available to Dutchess and Legend by the Board's proceeding. Under NRS 639.246(1), the Executive Secretary of the Board must issue subpoenas on behalf of any party to an action before the Board "for the production of witnesses, documents or papers, in accordance with statutory provisions." Thus, Dutchess and Legend had available to them a procedural mechanism for obtaining any evidence necessary to their defense, and the Board argues, without contradiction from Dutchess or Legend, that it provided subpoenas for all witnesses and evidence that Dutchess and Legend requested. Furthermore, NRS 639.2485(2) provides that "[t]he complaint or other document filed by the Board to initiate disciplinary action and all documents and information considered by the Board when determining whether to impose discipline are public records." Therefore, Dutchess and Legend could subpoena witnesses and had access to any statements of potential witnesses that the Board had considered. Again, Dutchess and Legend do not allege that the Board refused access to witness statements. Thus, because the Board's procedures to subpoena witnesses and provide access to their statements comport with due process guarantees of

²⁶Bivins Constr. v. State Contractors' Bd., 107 Nev. 281, 283, 809 P.2d 1268, 1270 (1991); see also Dixon v. Love, 431 U.S. 105, 115 (1977); McClelland, 606 F.2d at 1285-86; Silverman v. Commodity Futures Trading Com'n, 549 F.2d 28, 33 (7th Cir. 1977).

fundamental fairness, Dutchess and Legend have failed to establish that the Board improperly denied them access to witnesses.

The Board properly reached its conclusions of law

Dutchess and Legend argue that the Board applied an incorrect legal standard and misinterpreted a Nevada regulation in reaching several of its conclusions of law. The Board argues in response that its conclusions are well grounded in Nevada and federal law, that they comport with the plain meaning of the respective statutes and regulations, and that they promote public policy. We conclude that all but one of Dutchess's and Legend's arguments lack merit. We conclude that the remaining complained-of conclusions of law are based on a proper application of the law.

Strict liability under NRS 585.520(1)

Dutchess and Legend argue that the Board improperly applied a strict liability standard when it determined that Dutchess had violated NRS 585.520(1), which prohibits "[t]he manufacture, sale or delivery, holding or offering for sale of any food, drug, device or cosmetic that is adulterated or misbranded."²⁷ According to Dutchess and Legend, the administrative hearing was at least a quasi-criminal proceeding because NRS 585.550 provides for certain criminal penalties. Thus, Dutchess and Legend assert, because the proceeding was criminal in nature, certain requirements for imposing criminal liability should apply. Dutchess and Legend argue specifically that (1) NRS 193.190 requires "a union of act and intention, or criminal negligence to constitute a crime"; (2) in the

²⁷Although Legend argues alongside Dutchess for this proposition, the Board only found Dutchess guilty of violating NRS 585.520(1).

absence of clear legislative intent, there is a strong presumption that a crime requires a culpable mental state; (3) the Board did not present any evidence that the Legislature intended NRS 585.520(1) to be a strict liability statute; (4) the Board's staff presented caselaw during their closing argument that was not applicable to the current case and was therefore prejudicial; and (5) Dutchess had no knowledge that any of the drugs it bought or sold were counterfeit. We reject all of Dutchess and Legend's arguments as meritless and determine that the Board used the proper standard in adjudicating Dutchess guilty of violating NRS 585.520(1).

We address first Dutchess and Legend's contention that the administrative hearing was a quasi-criminal proceeding. Although NRS 585.550 provides for criminal penalties for anyone who violates any provision of Chapter 585, NRS 585.540(1) instructs the Attorney General or district attorney to institute "appropriate proceedings . . . in the proper court" after learning from the agency of a violation of Chapter 585. NRS 585.550 thus enables the Attorney General or district attorney, not the Board, to prosecute criminal violations of Chapter 585. In holding its hearings, the Board was not adjudicating alleged criminal violations and was therefore not bound to apply criminal standards, such as that contained in NRS 193.190, when proceeding against Dutchess and Legend.

We next address, as a matter of first impression, whether NRS 585.520(1) contains a knowledge requirement. NRS 585.520(1) states that "[t]he manufacture, sale or delivery, holding or offering for sale of any food, drug, device or cosmetic that is adulterated or misbranded" is prohibited in Nevada. The plain meaning of the statute is evident by its language—it prohibits the sale or delivery of any drug that has been

adulterated or misbranded. The statute does not contain a knowledge requirement, and we decline to impose such a requirement when none exists. Contrary to Dutchess and Legend's contention, the Board did not bear the burden of establishing that the Legislature intended NRS 585.520(1) to be a strict liability statute because under NRS 233B.135(2) "[t]he burden of proof is on the party attacking or resisting the decision." Because Dutchess and Legend were "attacking or resisting" the Board's decision, they have the burden of proving that the statute contained a knowledge requirement.

That NRS 585.520(1) 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, section 331(a) of the Federal Food, Drug, and Cosmetic Act. Section 331(a) prohibits "[t]he introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded."²⁸ In United States v. Dotterweich, the Supreme Court held that section 331 contains no knowledge requirement: "Such legislation dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing."²⁹ The Court explained that the Federal Food, Drug, and Cosmetic Act was intended to protect consumers, and, although the imposition of liability absent consciousness of wrongdoing may be harsh,

²⁸21 U.S.C. § 331(a) (2000).

²⁹320 U.S. 277, 281 (1943).

Congress determined that the burden was more properly borne by shippers rather than the general public.³⁰

Based on the plain language of NRS 585.520(1), and supported by the Supreme Court's interpretation of the statute's federal counterpart, we conclude that NRS 585.520(1) contains no knowledge requirement and that liability may be imposed under that section absent consciousness of any wrongdoing. The Board did not err by interpreting the statute this way.

Application of a "knew or reasonably should have known" standard in imposing liability for several regulations

Similarly, Dutchess and Legend argue that the Board applied an incorrect knowledge requirement with respect to the parties' violations of NRS 639.210(4) and (12); NAC 639.603; and NAC 639.945(1)(a), (g), (h), and (i). But, as discussed, the Board was not adjudicating Dutchess's and Legend's culpability for alleged criminal violations. Rather, the Board proceeded against Dutchess and Legend pursuant to its administrative authority to discipline license holders for statutory violations.³¹ The Board was therefore not applying criminal knowledge or intent

³⁰Id. Dutchess and Legend also argue that the Board cited prejudicial and inapplicable authority when it referred to several cases, including United States v. Dotterweich, during the hearing. We reject this contention because the cases cited by the Board, Dotterweich, United States v. Park, 421 U.S. 658 (1975), and Triangle Candy Co. v. United States, 144 F.2d 195 (9th Cir. 1944), all discuss the absence of a knowledge requirement in 21 U.S.C. § 331 and are therefore persuasive authority concerning the interpretation of NRS 585.520, the controlling law in the instant case.

³¹See NRS 639.255.

requirements when determining whether the parties' conduct violated the statutes and regulations at issue.

Failing to provide accurate pedigrees

Dutchess and Legend argue that the Board misinterpreted Nevada regulatory law when it determined that Dutchess and Legend violated NAC 639.603 by providing pedigrees on sales of Lupron that did not indicate from whom Dutchess and Legend purchased the drug. Dutchess and Legend contend that NAC 639.603(1) exempts wholesalers that have obtained authorized distributor status with the manufacturer from providing pedigrees with information about prior sales of the drug. The Board responds that NAC 639.603(1) exempts wholesalers from providing information of prior sales on pedigrees only if the wholesaler is an authorized distributor and did not purchase the drug from another wholesaler. We agree with the Board and conclude that Dutchess and Legend were properly found guilty of violating NAC 639.603.

NAC 639.603(1) generally provides the following:

[E]ach 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:

- (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.

The regulation is phrased somewhat awkwardly. It sets forth a requirement that wholesalers that are not authorized distributors, i.e.,

wholesalers that do not have an ongoing relationship with the manufacturer³² or that purchased prescription drugs from other wholesalers, must provide pedigrees with all subsequent sales. If a wholesaler meets the description in either subsection (a) or (b), it must provide a pedigree.

Dutchess and Legend argue that subsections (a) and (b) set forth two distinct exceptions to the pedigree requirement and that satisfaction of either subsection exempts a wholesaler from providing pedigrees on subsequent sales. We disagree. The language of the regulation makes clear that a wholesaler must provide a pedigree if it either is not an authorized distributor or if it purchased the drug from another wholesaler. “The word ‘or’ is typically used to connect phrases or clauses representing alternatives.”³³ The regulation’s use of “or” indicates that the descriptions in the subsections are “in the alternative to, and [are] not conditioned by” the other subsection.³⁴ If the regulation required all wholesalers to provide pedigrees unless either subsection applied, then both subsections would provide separate exceptions to the requirement. That is not the case here, contrary to Dutchess and Legend’s argument. An exception exists only if the wholesaler is both an authorized distributor and purchased the drug from an entity other than another wholesaler.

³²Although NAC 639.603(1) describes “an ongoing relationship with the manufacturer,” the parties do not dispute that this term is analogous to the term “authorized distributor.”

³³Coast Hotels v. State, Labor Comm’n, 117 Nev. 835, 841, 34 P.3d 546, 550 (2001).

³⁴Id.

As indicated, testimony before the Board revealed that Dutchess and Legend were authorized distributors for TAP Pharmaceuticals, the manufacturer of Lupron. But, testimony and documentation also revealed that Dutchess and Legend purchased the Lupron in question from other wholesalers, and not from TAP, before reselling it. So, although Dutchess and Legend were authorized distributors, they were required to provide pedigrees under subsection (b) of NAC 639.603(1) because they purchased the prescription drug from other wholesalers. Therefore, the Board did not err when it concluded that Dutchess and Legend violated NRS 639.603(1) by failing to provide pedigrees on sales of Lupron disclosing the details of prior sales.

Nevertheless, Dutchess and Legend further assert that NAC 639.603 is modeled after the federal statute that likewise sets forth a pedigree requirement. 21 U.S.C. § 353(e)(1)(A) exempts wholesalers who have obtained authorized distributor status from providing pedigrees:

Each person who is engaged in the wholesale distribution of a drug subject to subsection (b) of this section and who is not the manufacturer or an authorized distributor of record of such drug shall, before each wholesale distribution of such drug . . . , provide to the person who receives the drug a statement . . . identifying each prior sale, purchase, or trade of such drug. (Emphasis added.)

However, the language in § 353(e)(1)(A) differs markedly from that in NAC 639.603(1). The federal statute clearly requires all wholesalers, except manufacturers and authorized distributors, to provide pedigrees.³⁵

³⁵See RxUSA Wholesale v. Dept. of Health and Human Serv., 467 F. Supp. 2d 285, 290 (E.D.N.Y. 2006) (finding that a group of pharmaceutical
continued on next page . . .

In contrast to our above comparison of NRS 585.520(1) and its federal counterpart, section 331(a) of the Federal Food, Drug, and Cosmetic Act, here, the federal interpretation of an analogous provision is unpersuasive because the distinct language of the Nevada regulation indicates an intent to deviate from the federal provision. Indeed, the Board counters Dutchess and Legend's argument by stating that when enacting NAC 639.603(1), it intended to prevent the result obtained under the federal provision.

The purpose of requiring a pedigree from wholesalers that meet the descriptions in either subsection (a) or (b) of NAC 639.603(1) is illustrated in a case such as this, when testimony before the Board revealed that Dutchess and Legend maintained authorized distributor status with TAP Pharmaceuticals so they could sell Lupron to other wholesalers without pedigrees, concealing the untrustworthy source of the drug. By requiring wholesalers to provide pedigrees unless they both are an authorized distributor and purchased the drug from an entity other than another wholesaler, NAC 639.603 serves the public policy interest in transparency in the wholesale prescription drug market.

... continued

companies were entitled to a preliminary injunction preventing the implementation of Food and Drug Administration (FDA) regulations that would have required unauthorized distributors "to provide pedigree information for sales all the way back to the manufacturer" because they demonstrated that § 353(e)(1)(A) allowed authorized distributors to sell drugs without pedigrees, and therefore, an unauthorized distributor who purchased drugs from an authorized distributor would be unable to provide the information required by the FDA regulation).

Improperly accepting drugs from an unlicensed company

Dutchess and Legend argue that the Board erred when it determined that Dutchess had violated NRS 639.210(4) and (12)³⁶ and NAC 639.945(1)(g), (h), and (i).³⁷ The Board concluded that Dutchess

³⁶NRS 639.210 provides, in pertinent part:

The Board may suspend or revoke any certificate, license, registration or permit issued pursuant to this chapter, and deny the application of any person for a certificate, license, registration or permit, if the holder or applicant:

....

4. Is guilty of unprofessional conduct or conduct contrary to the public interest;

....

12. Has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy, or has knowingly permitted, allowed, condoned or failed to report a violation of any of the provisions of this chapter or any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy committed by the holder of a certificate, license, registration or permit.

³⁷NAC 639.945 provides, in pertinent part:

1. The following acts or practices by a holder of any license, certificate or registration issued by the Board or any employee of any business holding any such license, certificate or registration are declared to be, specifically but not

continued on next page . . .

violated those provisions when it accepted and sold drugs that were handled and shipped by Overseas International, a company unlicensed in any state, and by accepting and selling drugs from various addresses at which no pharmaceutical wholesaler was licensed. Dutchess and Legend argue that the Board erred for two reasons: (1) the statute governing licensing requirements, NRS 639.233, did not require a company such as 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 purchased drugs from Overseas because Overseas was merely a shipping agent. We agree and conclude that the Board erred in reaching this conclusion of law.

... continued

by way of limitation, unprofessional conduct and conduct contrary to the public interest:

....

(g) Supplying or diverting drugs, biologicals, medicines, substances or devices which are legally sold in pharmacies or by wholesalers, so that unqualified persons can circumvent any law pertaining to the legal sale of such articles.

(h) Performing or in any way being a party to any fraudulent or deceitful practice or transaction.

(i) Performing any of his duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner.

NRS 639.233(1) requires wholesalers who furnish drugs to people in this state to be licensed.³⁸ However, the version of the statute effective in 2003 exempted from the licensing requirement wholesalers or manufacturers whose principal place of business was in another state.³⁹ Therefore, Overseas was not then required to be licensed in Nevada to sell controlled substances to Dutchess. We conclude that the Board erred in determining that Dutchess's conduct in accepting and selling to other wholesalers drugs obtained from Overseas was unprofessional under NRS 639.210(4) and a violation of "regulation[s] relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy" under NRS 639.210(12). Accordingly, on remand from the district court, the Board should recalculate the fines imposed on Dutchess.

Failure to maintain adequate records

Dutchess and Legend argue that the Board erred when it determined that Dutchess had violated NAC 639.602 by failing to maintain and provide to the Board records showing the names and principal addresses of the locations from which prescription drugs were

³⁸NRS 639.233(1) provides:

Any person, including a wholesaler or manufacturer, who engages in the business of wholesale distribution or furnishing controlled substances, poisons, drugs, devices or appliances that are restricted by federal law to sale by or on the order of a physician to any person located within this State shall obtain a license pursuant to the provisions of this chapter.

³⁹NRS 639.233(2) (2002).

shipped to Dutchess. Dutchess and Legend contend that NAC 639.602 does not require such recordkeeping. We reject this argument.

NAC 639.602(1) provides, in pertinent part, that:

Each wholesaler shall make and maintain a record of its inventory and of each transaction relating to the receipt and distribution or other disposition of a prescription drug. The record must include, without limitation:

....

(c) The shipping record, which may be a manifest, shipping label, shipping bill or any similar document, evidencing the shipment of the prescription drug from the supplier to the wholesaler;

....

(f) The shipping record evidencing the shipment of the prescription drug from the wholesaler to the purchaser or purchasing wholesaler.

These subsections clearly require wholesalers to maintain shipping records. As a wholesaler, Dutchess was subject to this requirement. Accordingly, we conclude that the Board did not err by determining that Dutchess violated NAC 639.602 by failing to maintain and provide shipping records.

The Board's orders are not arbitrary and capricious

Dutchess and Legend argue that the Board's original order and the modified order on remand 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 Dutchess and Legend and the revocation of Legend's license are excessive given several mitigating circumstances, and (4) the Board cited

to a repealed statute, NRS 639.255(1)(g), to authorize the imposition of attorney fees on Dutchess and Legend.

If an administrative order is arbitrary or capricious, this court may remand or set aside any part or the entirety of the order.⁴⁰ Nevertheless, having considered Dutchess and Legend's contentions, we conclude that the Board's orders are not arbitrary or capricious.

We address first Dutchess and Legend's claim that the Board's failure to cite to statutory authority renders its imposition of fines arbitrary and capricious. NRS 639.255 allows the Board to impose fines as a method of discipline. NRS 639.255 provides, in pertinent part,

1. The holder of any certificate, license or permit issued by the Board, whose default has been entered or who has been heard by the Board and found guilty of the violations alleged in the accusation, may be disciplined by the Board by one or more of the following methods:

....

(f) Imposition of a fine for each count of the accusation, in accordance with the schedule of fines established pursuant to subsection 3.

....

3. The Board shall, by regulation, establish a schedule of fines that may be imposed pursuant to paragraph (f) of subsection 1. Each fine must be commensurate with the severity of the applicable violation, but must not exceed \$10,000 for each violation.

These provisions permit the Board to fine a licensed wholesaler for every count charged provided that the fine does not exceed

⁴⁰NRS 233B.135(3)(f).

\$10,000 per count. In its order on remand, the Board fined Dutchess \$1,000 each for 399 counts and \$250 for each of the remaining 483 counts, while it fined Legend \$250 each for 125 counts. The Board has the authority, under NRS 639.255, to impose these fines, and its order is not arbitrary and capricious simply because the Board failed to cite to that authority. Dutchess and Legend do not cite to any statute or regulation that requires the Board to cite its statutory authority to impose fines and have not demonstrated that they were prejudiced by the Board's failure to do so. Moreover, Dutchess and Legend have not shown that the Board fined more than \$10,000 per count or that the Board's arithmetic was incorrect.

We next address Dutchess and Legend's contention that the Board fined Legend for Serostim it never handled. The Board cited 249 counts whereby Dutchess and Legend violated Nevada law regarding their purchases of Serostim, Zoladex, and Lupron. However, the Board fined Legend for only 125 of the 249 counts mentioned. This indicates that the Board recognized that Legend bought and sold only Lupron and not Serostim and Zoladex and fined Legend only for drugs that it handled. Dutchess and Legend present no evidence that the 125 counts involve Serostim or Zoladex, and in the absence of any such evidence to the contrary, we conclude that the Board did not fine Legend for Serostim it did not handle.

Turning to Dutchess and Legend's argument that the fines imposed against them and the revocation of Legend's license were excessive given certain mitigating circumstances, we determine that the arguments merely reiterate evidence presented during the hearing. The Board's imposition of fines and revocation of licenses are entitled to great

deference to the extent that they were based upon the Board's interpretation of the evidence and testimony.⁴¹ Therefore, we will not reconsider the Board's determination in this regard.

Finally, we address Dutchess and Legend's contention that the Board's citation to a repealed statute justifying the imposition of attorney fees renders its order arbitrary and capricious. The Board concedes that it inadvertently cited to NRS 639.255 when it should have cited to NRS 622.400(1)(a), which authorizes attorney fees for proceedings such as the administrative hearing. This court will not reverse a correct judgment "simply because it was based on the wrong reason."⁴² We conclude that the Board's order is not arbitrary and capricious merely for its failure to cite to the proper statutory authority. Because NRS 622.400(1)(a) authorizes the Board's imposition of attorney fees,⁴³ we determine that its order is not arbitrary and capricious.

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

Dutchess and Legend argue that the Board impermissibly pierced their corporate veils when, in the last sentence of its order, it instructed Board staff to seek payment of fines owed by Dutchess and Legend from Paul DeBree and Lance Packer personally, principals of

⁴¹SIIS v. Montoya, 109 Nev. 1029, 1031-32, 862 P.2d 1197, 1199 (1993).

⁴²Kraemer v. Kraemer, 79 Nev. 287, 291, 382 P.2d 394, 396 (1963) (citing Nelson v. Sierra Constr. Corp., 77 Nev. 334, 364 P.2d 402 (1961)).

⁴³Under NRS 622.400(1)(a), a regulatory body may recover reasonable attorney fees incurred "as part of its investigative, administrative and disciplinary proceedings" upon the entry of a final order.

Dutchess and Legend. We disagree with Dutchess and Legend's argument.

DeBree was the president and CEO of Dutchess from its inception until March 2003, when Legend assumed all operations from Dutchess. DeBree also served as a manager of Legend from its inception until, presumably, the time when the Board revoked Legend's license. Packer was Dutchess's designated representative.

The Board did not pierce Dutchess's or Legend's corporate veils by including the following language in its order:

Should either Dutchess or Legend fail to timely pay the fine or fees and costs imposed in this Order, Board staff is directed to take whatever legal action it deems necessary and proper to effectuate collection of the sums due. To the extent legally possible, Board staff is directed to seek payment of the unpaid sums from Dutchess and Legend and from Mr. DeBree and Mr. Packer personally.

First, nothing in NRS Chapter 639 suggests that the Board has the authority to pierce the corporate veil or add nonparties as alter egos of the judgment debtor. Second, even if the Board wished to pierce Dutchess's and Legend's corporate veils, it would have to institute a separate action to do so, ensuring that DeBree and Packer received "a full opportunity of notice, discovery, and an opportunity to be heard before potentially being found liable."⁴⁴ The language, as conceded by the Board, was a directive to Board staff regarding further action, but carrying it out would require

⁴⁴Callie v. Bowling, 123 Nev. ___, ___, 160 P.3d 878, 881 (2007).

further legal action. The Board's inclusion of this language in its order does not constitute a judgment against the principals.

CONCLUSION

In conclusion, we reject Dutchess and Legend's following claims on appeal and hold as follows: (1) because Dutchess and Legend held licenses issued by the Board, the Board had jurisdiction under NRS 639.210 to discipline and impose penalties on them even if the acts supporting unprofessional conduct occurred outside the state; (2) as an administrative body, the Board was within its discretion to join Dutchess and Legend in a single action, and neither party was unduly prejudiced by the joinder; (3) Dutchess and Legend were not deprived of due process because they received adequate notice of the charges against them, they were not entitled to conduct discovery, and the Board adjudicated them guilty only of charges listed in the charging document; (4) the Board applied the proper legal standards in reaching all but one of its conclusions of law; (5) the Board's orders are not arbitrary and capricious; and (6) the Board did not pierce either Dutchess's or Legend's corporate veils to impose liability on their principals under an alter ego theory.⁴⁵ However, because we conclude that the statute in effect in 2003, NRS 639.233(2), exempted Overseas International from Nevada's licensing requirements, we conclude that the Board erred in determining that Dutchess violated Nevada law by conducting business with Overseas.

⁴⁵Having considered all of the issues raised by Dutchess and Legend, we conclude that their other claims are without merit and do not warrant reversal of the district court's order.

Accordingly, we reverse the district court's denial of the petition for judicial review and remand to the district court with instructions to remand to the Board. It is unclear from the record what portion of the fines imposed on Dutchess by the Board related to its determination that Dutchess violated Nevada law by conducting business with an unlicensed company. On remand from the district court, the Board should reconsider and recalculate the fines imposed on Dutchess.

Hardesty, J.
Hardesty

We concur:

Gibbons, C.J.

Gibbons

Maupin, J.

Maupin

Parraguirre, J.

Parraguirre

Douglas, J.

Douglas

Cherry, J.

Cherry

Saitta, J.

Saitta