IN THE SUPREME COURT OF IOWA

No. 36 / 06–1747

Filed June 27, 2008

GARVIS G. HOUCK,

Appellant,

vs.

IOWA BOARD OF PHARMACY EXAMINERS,

Appellee.

Appeal from the Iowa District Court for Cerro Gordo County, Bryan H. McKinley, Judge.

Pharmacist appeals from the district court's order affirming a decision of the Iowa Board of Pharmacy Examiners. **AFFIRMED**.

Michael M. Sellers of Sellers Law Office, West Des Moines, for appellant.

Thomas J. Miller, Attorney General, and Scott M. Galenbeck, Assistant Attorney General, for appellee.

HECHT, **Justice**.

A pharmacist compounded and sold a product to a customer without a prescription. The customer filed a complaint with the administrative agency that regulates the conduct of pharmacists, and a sanction was imposed against the pharmacist. In this appeal from the district court's ruling affirming the agency's action, we must decide whether the agency has authority to designate the compounded product as a drug that may be dispensed by a pharmacist only if it has been prescribed by a practitioner. We conclude the agency acted within its broad authority, and therefore affirm the district court's ruling.

I. Factual and Procedural Background.

Garvis Houck is a licensed Iowa pharmacist and the owner-operator of Houck Drug, a licensed Iowa pharmacy in Clear Lake. In 2002 Shirley Meyer consulted Houck about nasal irritation. After offering to supply a product to ease Meyer's symptoms, Houck compounded[1] a nasal spray containing a mixture of: 2-deoxy-d-glucose (an antiviral); dyclonine (an anesthetic); miconazole (an antifungal); methylcellulose (a suspending agent); sodium chloride; and distilled water. Each of these substances was, by itself, a nonprescription drug. Houck sold the compounded product to Meyer in a bottle that was not labeled with a prescription number, a prescriber's name, or a pharmacist's initial on the label. Meyer used the nose drops once, experienced increased nasal irritation, and filed a complaint with the Iowa Board of Pharmacy Examiners ("board").

[1]The Iowa Administrative Code defines "compounding" as "preparing, mixing, assembling, packaging, and labeling a drug or device for an identified patient . . . ." Iowa Admin. Code r. 657—20.2.

The board assigned an investigator, Jacky Devine, to investigate Meyer's complaint.[2] Houck admitted he compounded the nasal spray for Meyer without a prescription based on his experience in compounding some of the same substances for prescribers in the area. While conducting the investigation of the Meyer complaint, Devine found several violations of pharmacy regulations that had been noted in a prior inspection. Houck was unable to produce for Devine forms required to record transactions involving narcotics,[3] a required log for permanent and nonpermanent pharmacist employees, compounding production records bearing the initials of the compounding pharmacist, and a logbook containing the initials of pharmacists who provided customers certain cough syrups containing codeine. Houck had been warned about all of these record-keeping deficits in 2000.

The board filed two charges against Houck based on the investigation of the Meyer transaction and the 2002 inspection: (1) intentional or repeated violation of the board's rules regarding operation of a pharmacy and maintenance of controlled substance records; and (2) unlawful manufacturing and dispensing of a compounded drug without a prescriber's authorization. Following a hearing, the board issued a written decision finding Houck committed the alleged violations and placed Houck and Houck Drug on probation for three years with several conditions. The board specifically ordered

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[2]Devine had investigated for the board a similar complaint against Houck in October of 2000. That complaint also arose as a consequence of Houck's compounding of "over-the-counter" substances without a prescription. Devine found Houck's records to be out of compliance in several particulars with the board's regulations at that time, and warned Houck against compounding and selling substances without a prescription.

[3]Houck later provided Devine with most, but not all, of the missing forms.

Houck to refrain from compounding of any kind without authorization from a prescriber.

Houck sought judicial review in the district court. He contended the regulations prohibiting pharmacists from compounding, without a prescription, substances separately available without a prescription are unconstitutional. Houck also asserted the board lacked authority to issue the regulations, and the board's disciplinary action was not supported by substantial evidence. The district court denied Houck's petition.

II. Scope of Review.

On judicial review of final agency action, we review for errors at law. *Hough v. Iowa Dep't of Pers.*, 666 N.W.2d 168, 170 (Iowa 2003). In determining the appropriate scope of review of an agency's interpretation of a statute, the crucial question for the reviewing court is whether the interpretation of the statute has clearly been vested by a provision of law in the agency's discretion. *See* Iowa Code § 17A.19(10)(*c*), (*l*). If the agency has been clearly vested with interpretive authority, we generally defer to the agency's interpretation, and may grant relief only if the agency's interpretation is "irrational, illogical, or wholly unjustifiable." *Id.* § 17A.19(10)(*l*). If the agency has not been clearly vested with discretion to interpret the statute, "we are free to substitute our judgment de novo for the agency's interpretation and determine if the interpretation is erroneous." *Auen v. Alcoholic Beverages Div.*, 679 N.W.2d 586, 589–90 (Iowa 2004) (citing Iowa Code § 17A.19(10)(*c*)).

The legislature has delegated broad authority to the Board of Pharmacy Examiners for the regulation of the practice of pharmacy in

Iowa. Iowa Code section 147.76 (2007)[4] confers upon the board the authority to "adopt all necessary and proper rules to implement and interpret [chapter 155A]." *See also* Iowa Code § 155A.3(3) (stating the term "board" in chapter 155A refers to the board of pharmacy examiners). We have previously held similar language in other statutes constituted a clear vesting in the agency of the authority to interpret a statute. *Thoms v. Iowa Pub. Employees' Ret. Sys.*, 715 N.W.2d 7, 11 (Iowa 2006) (finding a clear vesting of interpretive authority where a statute directed the agency to "adopt . . . rules . . . and take other action it deems necessary for the administration of the retirement system"); *Auen*, 679 N.W.2d at 590 (holding grant of authority to an agency to adopt rules "necessary to carry out this chapter" clearly vested in the agency authority to interpret a statute); *City of Marion v. Iowa Dep't of Revenue & Fin.*, 643 N.W.2d 205, 207 (Iowa 2002) (holding statute providing "[t]he director shall have the power and authority to prescribe all rules not inconsistent with the provisions of this chapter, necessary and advisable for its detailed administration and to effectuate its purposes," vested authority in the department of revenue and finance to interpret section 422.45(20)). Section 147.76 clearly vests the board of pharmacy examiners with authority to interpret chapter 155A. We will therefore overturn the board's interpretation of that chapter only if it is "irrational, illogical, or wholly unjustifiable." Iowa Code § 17A.19(10)(*l*).

[4]The events giving rise to this case occurred in 2002. Accordingly, the statutes controlling our disposition were codified in the 2001 Iowa Code. Those statutes were renumbered and relocated in the code without substantive change after 2001. The parties have uniformly cited those statutes as they appear in the 2007 Code, and we will do so as well.

We review an agency's factual findings for substantial evidence based on the record viewed as a whole. *Id.* § 17A.19(10)(*f*). Substantial evidence is

> the quantity and quality of evidence that would be deemed sufficient by a neutral, detached, and reasonable person, to establish the fact at issue when the consequences resulting from the establishment of that fact are understood to be serious and of great importance.

Id. § 17A.19(10)(*f*)(1).

We review constitutional claims de novo. *Wright v. Iowa Dep't of Corr.*, 747 N.W.2d 213, 216 (Iowa 2008).

III. Discussion.

A. Board's Authority to Regulate Compounding of Nonprescription Drugs.

1. *Board's authority to define "prescription drugs."* The primary controversy in this case centers on the board's interpretation of Iowa Code section 155A.3(35). This statute defines a "prescription drug" as any of the following:

> *a.* A substance for which federal or state law requires a prescription before it may be legally dispensed to the public.
>
> *b.* A drug or device that under federal law is required, prior to being dispensed or delivered, to be labeled with one of the following statements:
>
> (1) Caution: Federal law prohibits dispensing without a prescription.
>
> (2) Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
>
> (3) Caution: Federal law restricts this device to sale by, or on the order of, a physician.
>
> (4) Rx only.
>
> *c.* A drug or device that is required by any applicable federal or state law *or regulation* to be dispensed on

> prescription only, or is restricted to use by a practitioner only.

Iowa Code § 155A.3(35) (emphasis added). The board has interpreted subsection (*c*) as a positive grant of authority by the legislature to the board to enact regulations requiring that certain drugs be dispensed on prescription only. Relying on such authority, the board enacted rule 20.2, a rule which, in relevant part, prohibits a pharmacist from dispensing compounds consisting of exclusively nonprescription components without a prescription from a practitioner.[5] Iowa Admin. Code r. 657—20.2. Rule 20.2 thus brings a compound made from exclusively nonprescription components within the definition of a "prescription drug" in section 155A.3(35)(*c*). Houck contends section 155A.3(35)(*c*) does not vest the board with the authority to designate as a "prescription drug" a compounded substance consisting of a combination of nonprescription substances.

After carefully reviewing chapter 155A in light of the board's authority to implement and interpret that chapter, we cannot say the board's interpretation of section 155A.3(35)(*c*) as a positive grant of authority to the board to designate all compounded substances as "prescription drugs" is irrational, illogical, or wholly unjustifiable. The plain language of section 155A.3(35)(*c*) clearly evidences legislative intent to identify, at least in part through state administrative rule, those substances which may be dispensed by pharmacists only if prescribed by

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[5]The Iowa Code defines a "practitioner" as

> a physician, dentist, podiatric physician, veterinarian, or other person licensed or registered to distribute or dispense a prescription drug or device in the course of professional practice in this state or a person licensed by another state in a health field in which, under Iowa law, licensees in this state may legally prescribe drugs.

Iowa Code § 155A.3(33).

a practitioner. As we have already noted, the board has been vested with broad authority to adopt rules to "implement and interpret" chapter 155A. Iowa Code § 147.76. The board is the agency charged with administering Iowa Code chapter 124 ("Controlled Substances") and Iowa Code chapter 126 ("Iowa Drug, Device, and Cosmetic Act"). *Id.* §§ 124.101(3), .201, .301; 126.2(3), .17. The board asserts, and Houck does not dispute, that no other state administrative agency is assigned regulatory power over controlled substances or prescription drugs. We conclude the board's interpretation of section 155A.3(35)(*c*) as a statutory authorization to identify prescription drugs by administrative rule is not irrational, illogical, or wholly unjustifiable. It is an interpretation that gives reasonable and logical meaning to the words "or regulation" in the statute. *See T & K Roofing Co. v. Iowa Dep't of Educ.*, 593 N.W.2d 159, 162 (Iowa 1999) (noting interpretations that render a portion of a statute redundant or irrelevant should be avoided).

Houck contends the general assembly enumerated in chapter 124 the list of drugs which may be regulated as "prescription drugs" under chapter 155A. According to Houck, the board's only authority to influence what is a "prescription drug" is its role in recommending to the general assembly the appropriate classification for controlled substances in chapter 124. Iowa Code § 124.201. Chapters 124 and 155A, however, do not narrowly limit the board's authority to regulate prescription drugs in the manner suggested by Houck.

As averred by Houck, chapter 124 lists five categories, or schedules, of "controlled substances." *See generally id.* §§ 124.203–.212. As the term is used in chapter 124, a "controlled substance" is "a drug, substance, or immediate precursor in schedules I through V of division II of this chapter." *Id.* § 124.101(5). The schedules categorize various

substances according to their relative potential for abuse, the degree to which the substance has an accepted medical use, and likelihood that abuse of the substance would lead to psychic or physical dependence. *Id.* § 124.201. Contrary to Houck's assertion, however, chapter 124 does not define "prescription drug"; nor does it purport to present an exhaustive list of substances which may be only dispensed by a pharmacist pursuant to a practitioner's prescription. We find no limitation in chapter 124 on the board's authority to define "prescription drugs."

Our rejection of Houck's contention that chapter 124 limits the board's authority to define "prescription drugs" is strengthened by the careful distinctions drawn by the general assembly in chapter 155A between "controlled substances" and "prescription drugs." A "prescription drug" may be either a "drug" or "device."[6] *Id.* § 155A.3(35)(*c*). A "drug" is any of the following:

> *a.* A substance recognized as a drug in the current official United States Pharmacopoeia and National Formulary, official Homeopathic Pharmacopoeia, or other drug compendium or any supplement to any of them.
>
> *b.* A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals.
>
> *c.* A substance, other than food, intended to affect the structure or any function of the body of humans or other animals.
>
> *d.* A substance intended for use as a component of any substance specified in paragraph "*a*", "*b*", or "*c*".

[6]A "device" is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part or accessory, that is required under federal or state law to be ordered or prescribed by a practitioner." Iowa Code § 155A.3(10). This case does not involve a "device," and we therefore consider only the portion of the statute pertaining to "drugs."

e. A controlled substance.

Id. § 155A.3(13) (emphasis added). As in chapter 124, the term "controlled substance" in chapter 155A refers to the substances or precursors to the substances listed in the chapter 124 schedules. *Id.* § 155A.3(6). Thus, in chapter 155A the terms "drug" and "prescription drug" are not limited to the substances in the controlled substance schedules. Although the legislature has granted the board only the limited authority to recommend to the general assembly substances to be designated as "controlled substances," *id.* § 124.201, no such limitation appears in section 155A.3(35)(*c*) in connection with the board's authority to define "prescription drugs."

2. *Validity of the board's compounding rule.* Having found the board could rationally conclude it had the authority to require a drug to be dispensed by prescription only, we must determine whether the board's compounding rule is irrational, illogical, or wholly unjustifiable. Houck contends the relevant portion of the rule is irrational because it forbids pharmacists, who have special training regarding interactions between drugs, from combining and distributing compounds consisting exclusively of substances available without a prescription while allowing nonpharmacists to do so. We disagree. The board's inclusion of all compounded substances within the definition of "prescription drug" is sufficiently related to the goals of chapter 155A to survive our scrutiny under the applicable deferential standard of judicial review.

Rule 20.2 is properly within the bounds of the board's authority under section 155A.3(35). As noted above, that statute requires a "prescription drug" be a "drug or device." *Id.* § 155A.3(35)(*c*). A "drug" includes "[a] substance, other than food, intended to affect the structure or any function of the body of humans." *Id.* § 155A.3(13)(*c*). The product

compounded by Houck for Meyer easily fits within this definition of "drug." Rule 20.2 promulgated by the board expressly confines the definition of compounding to "preparing, mixing, assembling, packaging, and labeling a *drug or device* for an identified individual patient . . . ." Iowa Admin. Code r. 657—20.2 (emphasis added). Because the rule applies only to compounded "drugs" and "devices," it is firmly within the board's authority to require that drugs or devices be dispensed on prescription only.

A rational and logical connection exists between the rule and the board's duties under chapter 155A. The purpose of chapter 155A is "to promote, preserve, and protect the public health, safety, and welfare through the effective regulation of the practice of pharmacy . . . ." Iowa Code § 155A.2. The board asserts it enacted rule 20.2 in order to draw a bright line between the practice of medicine and the practice of pharmacy. Generally speaking, the practice of medicine involves the intake of patients, diagnosis of illnesses, and prescription of treatment, while the practice of pharmacy primarily consists of preparing and dispensing medications. By requiring the "prescriber/patient/pharmacist" relationship as a prerequisite to the dispensing of compounded drugs by pharmacists, the board has exercised administrative discretion to prohibit pharmacists from diagnosing illnesses and prescribing treatment for their customers—functions traditionally undertaken by doctors. The board could rationally and logically have concluded this exercise of discretion clearly separating the pharmacist function from that of the prescriber advances the health, safety, and welfare of pharmacists' customers.

Our confidence in the conclusion the board's rule is neither illogical nor unreasonable is not diminished by the fact that it does not

preclude nonpharmacists from compounding nonprescription substances. Nonpharmacists are not licensed to dispense drugs, and do not hold themselves out as experts in compounding substances sold to treat health problems suffered by human beings. As a consequence, there is no significant market for the compounding services of nonpharmacists. Pharmacists, on the other hand, are licensed and widely regarded by their customers as experts who reliably dispense drugs manufactured by others or compounded by them. The board could logically and rationally conclude the substantial market for the compounding services of pharmacists justifies regulation, and the nonexistent demand for compounding services by nonpharmacists does not. Furthermore, chapter 155A grants the board no authority to regulate the activities of nonpharmacists.

Houck correctly posits that pharmacists are not prohibited by statute or agency rule from recommending nonprescription medications to customers who describe their symptoms and seek advice. He relies on this fact to support his contention that the board does not truly draw the line between pharmacy and medicine at "diagnosing" and "prescribing." Even if we acknowledge the apparent plausibility of Houck's contention, however, we conclude it does not undermine the board's authority to prohibit compounding of drugs without a prescription or render rule 20.2 irrational. The board could rationally conclude, as it did, that compounding of substances—including "drugs" not enumerated as controlled substances under chapter 124 and consisting entirely of "over-the-counter" components—by pharmacists without a prescription for the treatment of maladies or symptoms presented by customers poses risks to the public health, safety, and welfare. Accordingly, rule 20.2 is not rendered invalid as a consequence of the board's failure to require a

prescription for the dispensing by pharmacists of "over-the-counter" drugs manufactured by others.

3. *Constitutional challenge.* Houck also contends the board's regulation violates the equal protection clauses of the federal and Iowa Constitutions because it unfairly discriminates against pharmacists with respect to compounding of nonprescription substances. *See* U.S. Const. amend. XIV; Iowa Const. art. 1, § 6. Houck is a licensed pharmacist, and is therefore not similarly situated to a non-pharmacist. The legislature may therefore treat him differently than a non-pharmacist. *See In re Det. of Hennings*, 744 N.W.2d 333, 339 (Iowa 2008) (noting dissimilar treatment of persons not similarly situated does not offend equal protection). Because he has failed to demonstrate dissimilar treatment of similarly situated individuals, Houck's equal protection challenge to the board's rule is without merit.

B. Noncompounding Violations. Houck also broadly asserts the factual findings underlying the board's decision to sanction him for the other, noncompounding violations were not supported by substantial evidence. While asserting the board made its findings of fact "based solely on its compliance officer's report regarding arguable and meaningless minor violations" of administrative rules, and that the violations were the result of a "hyper-technical application" of administrative rules, Houck does not actually assail the substantiality of the evidence supporting the facts found by the board. Upon a careful review of the record, we find ample support for the board's finding that Houck engaged in a "pattern of choosing which rules to follow and which rules to ignore." The board's findings are supported by substantial evidence.

C. Sanction. We have previously noted the limited scope of judicial review of sanctions imposed by administrative agencies. When a "licensing board is made up of members of the profession they are licensing, the court should not second guess the board's decision" as to the appropriate sanction. *Burns v. Bd. of Nursing of Iowa*, 528 N.W.2d 602, 605 (Iowa 1995). The pharmacy board is primarily constituted of pharmacists, *see* Iowa Code § 174.14(5), and we see no basis in the record to depart from this sound rule. We accordingly uphold the board's findings that Houck's serial violations of administrative rules warranted the imposition of a three-year probation.

IV. Conclusion.

We find the board could have rationally concluded the general assembly delegated to it the authority to designate drugs compounded by pharmacists as "prescription drugs" to be dispensed only if prescribed by a practitioner. The rule adopted by the board consistent with that authority is not irrational, illogical, or wholly unjustifiable. The board's adoption of that rule and enforcement of it against Houck did not deprive him of equal protection of the law. The board's factual findings are supported by substantial evidence in the record.

AFFIRMED.

All justices concur except Baker, J., who takes no part.