

STATE OF MICHIGAN
COURT OF APPEALS

In re COLLEGE PHARMACY.

BUREAU OF PROFESSIONAL LICENSING,

Petitioner-Appellee,

v

COLLEGE PHARMACY,

Respondent-Appellant.

UNPUBLISHED

February 7, 2017

No. 328828

Department of Licensing and
Regulatory Affairs

LC No. 14-028072

Before: BOONSTRA, P.J., and SHAPIRO and GADOLA, JJ.

SHAPIRO, J. (*dissenting*).

I respectfully dissent.

Respondent appeals from a decision of the Board of Pharmacy Disciplinary Subcommittee of the Bureau of Professional Licensing revoking respondent's license to practice in Michigan. I would conclude, given the record before us, that the Board's imposition of the sanction of license revocation was not supported by competent, material, and substantial evidence. Accordingly, I would vacate the Board's order and remand for further proceedings pursuant to MCL 333.16226.

Petitioner issued an administrative complaint against respondent pharmacy on the grounds that it had been subject to administrative penalties in another state, Colorado. MCL 333.17768(2)(d) provides:

[I]n a manner consistent with part 161 [MCL333.16101 et seq], the board may fine, reprimand, or place on probation, a person licensed under this part, or deny, limit, suspend, or revoke a license issued under this part or may order restitution or community service if the board finds that . . . [t]he applicant . . . has had its license or federal registration limited, suspended, or revoked or been subject to any other criminal, civil, or has been subject to any other criminal, civil or administrative penalty.

A hearing was conducted by a hearing examiner (ALJ) who issued a Proposal for Decision on April 10, 2015. The Proposal for Decision, as will be set forth below, contained extensive findings of fact and law none of which are challenged by either party. The hearing examiner did not recommend a specific penalty as such an action is beyond her authority. MCL 333.16231a provides:

(2) The hearing examiner shall determine if there are grounds for disciplinary action The hearings examiner shall prepare recommended findings of fact and conclusions of law for transmittal to the appropriate disciplinary subcommittee. *The hearings examiner shall not recommend or impose penalties.* [Emphasis added.]

The ALJ's conclusions of law read:

The above Findings of Fact establish that Respondent College Pharmacy had administrative penalties imposed against it through Final Orders of the Colorado Board of Pharmacy. Pursuant to the Public Health Code Section 17768(2)(d), this constitutes grounds for action by the Michigan Board of Pharmacy. The Michigan Board of Pharmacy may consider, as mitigation, the above Findings of Fact establishing that the current pharmacy manager of Respondent was specifically approved by the Colorado Board to take over from a previous owner/manager who was in charge when the acts leading to sanctions occurred. Further, the new pharmacy manager has instituted policies and procedures to prevent reoccurrence of problems.

Respondent filed an exception to the ALJ's proposal for decision arguing that no sanctions of any kind were warranted in this case in light of the mitigating factors noted by the ALJ.

The Board of Pharmacy Disciplinary Subcommittee considered the matter at its June 10, 2015 meeting, and its resulting order stated that it "accepted the administrative law judge's Findings of Fact and Conclusions of Law in the Proposal for Decision."¹ The substantive portion of the subcommittee's July 24, 2015 order reads in full:

The Disciplinary Subcommittee of the Michigan Board of Pharmacy (Disciplinary Subcommittee), having reviewed the administrative record, considered this matter at a regularly scheduled meeting held in Lansing, Michigan on June 10, 2015 and accepted the administrative law judge's Findings of Fact and Conclusions of Law in the Proposal for Decision. Therefore,

IT IS ORDERED that for violating section 17768(2)(d) of the Public Health Code, supra, Respondent Pharmacy's license to practice as a

¹ The subcommittee's proceedings are not recorded. Minutes are maintained but as to the instant matter state only that a motion to revoke respondent's license was made and adopted.

pharmacy in the state of Michigan is REVOKED, commencing on the effective date of this Order.

Respondent argues that the decision to impose license revocation as opposed to any of the other available sanctions² should be reversed. We review final orders of disciplinary subcommittees to determine whether they are authorized by law and are supported by competent, material, and substantial evidence on the whole record. *Dep't of Community Health v Risch*, 274 Mich App 365, 370-371; 733 NW2d 403 (2007), and Const 1963, art 6 § 28. Respondent suggests that the subcommittee's decision should be reviewed under an abuse of discretion standard. However, in *Risch*, we considered this issue and concluded that "judicial review of the disciplinary subcommittee's orders is limited to that set forth in Const. 1963, Art. 6 Sec 28, which provides in relevant part:

"All final decisions, findings, rulings and orders of any administrative officer or agency existing under the constitution or by law, which are judicial or quasi-judicial and affect private rights or licenses, shall be subject to direct review by the courts as provided by law. This review shall include, as a minimum, the determination whether such final decisions, findings, rulings and orders are authorized by law; and, in cases in which a hearing is required, whether the same are supported by competent, material and substantial evidence on the whole record." [274 Mich App at 371, quoting Const. 1963, Art. 6 Sec 28.]

The relevant standard of review thus consists of two different determinations. First, was the decision authorized by law and second was it "supported by competent, material, and substantial evidence on the whole record." The first of these is straightforward; the decision is authorized by law. As to the second, it is necessary to review the ALJ's findings of fact, which as noted above, neither party takes exception to:

FINDINGS OF FACT

1. Jerry Gillick R.Ph., has been licensed as a pharmacist in the United States since 1997. In 2005 he moved to Colorado and began working for College Pharmacy. College Pharmacy is licensed in 47 states. In 2009, Mr. Gillick became President and CEO of College Pharmacy[.]
2. On December 18, 2007, Colorado's Board of Pharmacy issued a Stipulation and Final Order. The charges leading to the Final Order involved Board allegations that College Pharmacy had introduced or delivered into interstate commerce a human growth hormone (i.e. "somatropin") that was not approved by the FDA, and offered it for sale through interstate commerce for uses and conditions other than those approved by the FDA for authorized human growth hormones. The

² These include: probation, fine, reprimand, limitation or suspension of license, restitution or community service. MCL 333.17768(2)(d).

Colorado Board also alleged inaccurate or inappropriate reprocessing and repackaging of the somatropin. At the time Thomas Bader was owner of College Pharmacy. The Colorado charging document asserts that Mr. Bader, as the pharmacist manager, was responsible for all operations violations charged against College Pharmacy. As a result of the Final Order, Mr. Bader was directed to transfer all of his shares to an employee stock ownership plan. College Pharmacy was required to submit quarterly reports assuring that any dispensing of human growth hormone was only for FDA approved uses and that dispensing was based on patient-specific orders. The Order also required that the Board approve any pharmacy manager appointed to run College Pharmacy for seven years from the date of the Final Order. (Exhibit 1)

3. Mr. Gillick became the pharmacist in charge (i.e. pharmacy manager) after Mr. Bader relinquished ownership of College Pharmacy. Mr. Gillick has assured compliance with all reporting requirements imposed on College Pharmacy as a result of the 2007 Final Order.
4. Prior to Mr. Gillick taking over as pharmacy manager, a routine audit in May 2008 found that College Pharmacy had purchased and received human growth hormone from a wholesaler that was not registered in Colorado. Further the audit found that an Illinois veterinarian had ordered the human growth hormone listing herself as both the prescribing practitioner and the patient. These two acts were found to be violations of Colorado pharmacy regulations and a violation of the 2007 Stipulation and Final Order that prohibited any further violations of state or federal regulations. (Exhibit 2)
5. When Mr. Gillick took over pharmacy manager responsibilities in 2009, he was not aware that Mr. Bader had entered an agreement to purchase human growth hormone from an unlicensed wholesaler and filled a prescription indicating that a veterinarian was self-prescribing [sic] human growth hormone, because prior to Mr. Gillick assuming managerial responsibilities, there was no system in place to track whether wholesalers were registered in Colorado. Although Mr. Gillick was not involved in the violations found in the May 2008 audit, he assumed responsibility for correcting the College Pharmacy violations, and complying with all conditions of the Colorado Board's disciplinary Orders, when he took over as manager.
6. As a result of the 2008 audit findings, the Colorado Board issued a second Stipulation and Final Order dated April 10, 2009, placing College Pharmacy's registration as a prescription drug outlet in Colorado on probation for seven years, prohibiting the purchase, sale and dispensing of any human growth hormone during probation and requiring more quarterly reports to the Board. (Exhibit 2)

7. In or around December 2012, College Pharmacy entered into an agreement to compound an injectable used in cosmetic procedures called "Tozzi Solution". [sic] The inventor of the solution filed a complaint against College Pharmacy with the Colorado Board. The Board's investigation found that a trial batch of the solution compounded by College Pharmacy was dispensed with a "7-months beyond use" expiration date instead of "365 days beyond-use date" the manufacturer's formula called for. Stability testing by College Pharmacy indicated that the solution had a minimum 2 year stability. The mistaken expiration date assigned to the trial batch did not affect the safety of the batch, rather the expiration period was shorter than it needed to be. Although the Board did not find that College Pharmacy had violated a specific statutory provision or rule, it issued a "letter of admonition" on July 22, 2013, and noted it as a "disciplinary action" in College Pharmacy's permanent record. (Exhibit 3) The July 2013 Colorado letter of admonishment was reported to each of the 47 states where College Pharmacy is licensed, and there has been no disciplinary action in states other than Michigan as a result of the admonishment.
8. After taking over College Pharmacy, and with knowledge of the 2007 and 2009 Colorado Board actions, Mr. Gillick instituted a system to document whether a wholesaler involved in a purchase is licensed in a specific state. In addition there is now a system to track the type of practitioner ordering or prescribing controlled substances. College Pharmacy only fills patient specific prescriptions and no bulk distribution occurs. There have been no product safety allegations filed against College Pharmacy.

Given the statutory limitations on its authority, the ALJ did not make a recommendation as to the proper sanction other than to note that given the violation the Board had "grounds for action" against respondent and that in imposing any sanction, the Board "may consider as mitigation, the above Findings of Fact establishing that the current pharmacy manager of Respondent was specifically approved by the Colorado Board to take over from the previous owner/manager who was in charge when the acts leading to sanctions occurred. Further, the new pharmacy manager has instituted policies and procedures to prevent reoccurrence of problems."

In light of these Conclusions of Law, I find no grounds in the ALJ's report to impose the ultimate penalty of license revocation. Given that the Board adopted and relied upon that report, the Board did not have "substantial evidence" to support the sanction imposed. The serious violations of 2006 and 2008 occurred while respondent was under different ownership and management. The new management was specifically approved by the Colorado Board of Pharmacy, and respondent was placed on probation for a period of seven years. The only violation that occurred thereafter was the 2012 error, which, as found by the ALJ, "did not affect the safety of the [medicine], rather the expiration period was shorter than it needed to be." The Colorado Board of Pharmacy admonished respondent for this violation but took no other action. Respondent reported this discipline to the other 47 states in which it is licensed, and none, other than Michigan, took disciplinary action.

When asked at oral argument why substantial evidence supported the sanction, counsel for the Board took the position that the Board is not required to offer any justification for selecting one sanction over any other and that its sanction decisions are unreviewable except for whether the sanction may be imposed at all. I recognize that the Board has broad discretion and it is not our role to second-guess its choice of sanction where any of several are supported by the evidence. Nevertheless, while the standard of review is very deferential, the Board's actions are, and to comply with due process must be, reviewable by this Court, and, I would not conclude that because the sanction is authorized by law that it is necessarily supported by substantial evidence. Given the Board's position that its choice of sanctions is unreviewable, it has not made an argument why the facts of this case, as found by the ALJ and accepted by the Board, justify the most severe sanction available. Moreover, having accepted the ALJ's findings, it must *consider* the mitigating factors set forth therein. See *Marrs v Board of Medicine*, 422 Mich 688, 694; 375 NW2d 321 (1985).

Given the record before us I would conclude that the Board did not consider the mitigating circumstances in determining the appropriate sanction. I would vacate the disciplinary subcommittee's final order and remand to that body for further consideration pursuant to MCL 333.16226(2).³

/s/ Douglas B. Shapiro

³ Respondent's counsel filed an affidavit with this Court attesting that at the Disciplinary Subcommittee meeting there was no discussion regarding the specific facts of this case and that one of the subcommittee's members "commented that Michigan does not need any additional out-of-state compounding pharmacies." This affidavit is not part of the administrative record, and I do not rely upon it. I reference it however, to suggest that where the most severe sanction is being imposed despite significant mitigating evidence, it would facilitate our review if the Board provided some of its reasoning in its order.