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STATE OF WISCONSIN BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST FINAL DECISION AND ORDER WITH VARIANCE

MARVIN MOORE,
RESPONDENT.DHA Case No. SPS-15-0026
DLSC Case No. 12 PHM 035000440?

BACKGROUND

On October 19, 2015, Administrative Law Judge Jennifer Nashold (ALJ), Division of Hearings and Appeals, issued a Proposed Decision and Order (PDO) in the above-referenced matter. The PDO ordered the Respondent to be reprimanded, to complete nine hours of continuing education approved by the Board within six months after issuance of the final decision and order, and to pay forty percent (40%) of the recoverable costs in this matter. The PDO was mailed to all parties. On November 6, 2015, the Division of Legal Services and Compliance (Division) filed objections to both the level of discipline imposed and the assessed costs, instead requesting suspension or revocation of the Respondent's license and one hundred percent (100%) of assessable costs of the investigation and proceeding. On November 13, 2015, the Respondent, via his Attorney, filed Respondent's Response to the Division's Objections to the PDO, asserting that the ALJ's imposition of a reprimand with continuing education requirement was unduly severe and without merit and that the ALJ's assessment of costs was sufficiently severe, if not excessive. On November 18, 2015, the Pharmacy Examining Board (Board) met to consider the merits of the PDO and the stated objections. The Board voted to approve the PDO with variance. The PDO is attached hereto and incorporated in its entirety into this Final Decision and Order with Variance (Order).

VARIANCE

Pursuant to Wis. Stat. §§ 440.035(1) and 450.03, the Board is the regulatory authority and final decision maker governing disciplinary matters of those credentialed by the Board. The matter at hand is characterized as a class 2 proceeding pursuant to Wis. Stat. § 227.01(3)(b). The Board may make modifications to a PDO, in a class 2 proceeding, pursuant to Wis. Stat. § 227.46(2), provided the Board's decision includes an explanation of the basis for each variance.

In the present case, the Board adopts the PDO in its entirety except for the following variances:

1. In the section entitled, "<u>DISCUSSION</u>" under the subsection entitled, "<u>Alleged</u> <u>Violations</u>," found on page eight (8) of the PDO, the Board makes the following amendment to reflect the correct citation for violation number three (3), to read "Wis. Admin. Code § Phar 10.03(1) and (13)."

- 2. In the section entitled, "<u>CONCLUSIONS OF LAW</u>" found on page eleven (11), paragraph three (3) of the PDO, the Board makes the following amendment to reflect the correct citation for violation number three (3), to read "Wis. Admin. Code § Phar 10.03(1) and (13)."
- 3. All references to forty percent (40%) of costs found in the PDO sections entitled "<u>CONCLUSIONS OF LAW</u>," on page eleven (11), and "<u>ORDER</u>" on page twelve (12), are removed, and seventy-five (75%) of costs is substituted in its place.
- 4. In the section entitled "<u>DISCUSSION</u>" under the subsection entitled "<u>Costs</u>," found on pages ten (10) and eleven (11) of the PDO, the Board removes the subsection in its entirety and substitutes the following subsection.

<u>Costs</u>

The Board has authority to assess all or part of the costs for disciplinary proceedings, taking into account the particular facts of each case. Wisconsin Statute § 440.22(2) states, in relevant part:

In any disciplinary proceeding against a holder of a credential in which the department or an examining board, affiliated credentialing board or board in the department orders suspension, limitation or revocation of the credential or reprimands the holder, the department, examining board, affiliated credentialing board or board may, in addition to imposing discipline, assess all or part of the costs of the proceeding against the holder.

The Board is not required to go through any particular analysis when determining whether to assess all or part of the costs of this proceeding against the Respondent. Nevertheless, guidance can be found in *Noesen v. State Department of Regulation & Licensing, Pharmacy Examining Board*, 2008 WI App 52, ¶¶ 30-32, 311 Wis. 2d 237, 751 N.W.2d 385. In *Noesen*, the Court opined:

Under Wis. Stat. § 440.22(2), the Board may, in its discretion, "assess all or part of the costs of the proceeding" against the licensee if the Board takes disciplinary action as a result. We give due weight to the Board's exercise of discretion. Wis. Stat. § 227.57(10). In reviewing the exercise of discretion, we look to determine whether the decision maker examined the relevant facts, applied the proper standard of law, and reached a reasonable conclusion. *Doersching*, 138 Wis. 2d at 328.

In addition to the above mandatory authority, in previous orders, the Board has considered the following non-mandatory factors to aid in determining if all or part of the costs should be assessed against a Respondent:

- 1. The number of counts charged, contested, and proven;
- 2. The nature and seriousness of the misconduct;

- 3. The level of discipline sought by the parties;
- 4. The respondent's cooperation with the disciplinary process;
- 5. Prior discipline, if any;
- 6. The fact that the Department of Safety and Professional Services (DSPS) is a "program revenue" agency; and
- 7. Any other relevant circumstances.

In the Matter of Disciplinary Proceedings against Elizabeth Buenzli-Fritz (LS 0802183 CHI). In considering these factors, the Board has the discretion to give each factor the weight appropriate given present circumstances. In this case, the Board finds that the imposition of seventy-five (75%) of the costs is warranted.

The Division charged the Respondent with four counts, each of which was contested. The Division proved that the Respondent violated the most significant counts charged, under Wis. Stat. § 450.11(7)(f) and Wis. Admin. Code § Phar 10.03(1) and (13). Those counts were serious in nature, warranting a reprimand and nine hours of continuing education approved by the Board. While all four of the charged counts stemmed from the same conduct by the Respondent, ultimately only three of the four counts were proven. Accordingly, it is appropriate to assess costs to the Respondent for those violations that were in fact substantiated and proven.

The DSPS is a program revenue agency, meaning that DSPS is funded by the revenue received from all licensees. This is a fact that weighs heavily into the calculation of the appropriate amount of costs to be borne by the Respondent. As a program revenue agency, any costs not paid by the Respondent are shared by all other pharmacy profession licensees. Therefore, the Board gives serious consideration as to whether the costs associated with this action should be paid by the Respondent or shared by other non-culpable licensees.

The Respondent's lack of prior discipline, appearance at required conferences and proceedings, and admission to substantial facts are significantly outweighed by the other factors discussed herein. Logically, had the Respondent not engaged in the conduct at hand, none of these costs would have ever been incurred.

Based on all of the above, it is appropriate for the Respondent to bear seventy-five (75%) of the costs associated with this matter.

Dated at Madison, Wisconsin this **25** day of November, 2015.

PHARMACY EXAMINING BOARD By: A Member of the Board



Before The State Of Wisconsin DIVISION OF HEARINGS AND APPEALS

In the Matter of Disciplinary Proceedings Against Marvin Moore, R.Ph., Respondent DHA Case No. SPS-15-0026 DLSC Case No. 12 PHM 035 0004402

PROPOSED DECISION AND ORDER

The parties to this proceeding for purposes of Wis. Stat §§ 227.47(1) and 227.53 are:

Marvin Moore, R.Ph., by

Attorney Andrew J. Krajnek Kaminski & Pozorski 846 North 8th Street P.O. Box 609 Manitowoc, WI 54221-0609

Wisconsin Pharmacy Examining Board P.O. Box 8366 Madison, WI 53708-8366

Department of Safety and Professional Services, Division of Legal Services and Compliance, by

Attorney James E. Polewski Department of Safety and Professional Services Division of Legal Services and Compliance P.O. Box 7190 Madison, WI 53707-7190

PROCEDURAL HISTORY

These proceedings were initiated on March 2, 2015, when the Department of Safety and Professional Services (Department), Division of Legal Services and Compliance (Division), filed and served a formal Complaint on Respondent Marvin Moore (Respondent). The Division's Complaint alleged that, in packaging, selling and distributing authorized generic atorvastatin as

brand-name Lipitor, Respondent violated Wis. Stat. §§ 450.13(1) and 450.11(7)(f), and engaged in unprofessional conduct as defined by Wis. Admin. Code § Phar 10.03(1) and (13).

Pursuant to a notice issued on March 23, 2015, a telephone prehearing conference was held on April 6, 2015, at which a contested case hearing was scheduled. Consistent with a scheduling order issued on April 6, 2015, a contested case hearing was held on June 9, 2015, at which Mitchell Adams testified for the Division, Respondent testified on his own behalf, and documentary evidence was received from both parties. At the close of the evidence, the parties requested briefing, and a briefing schedule was set. Following a briefing order issued on June 22, 2015, the Division submitted its Closing Argument and proposed Findings, Conclusions, and Order on July 31, 2015; Respondent submitted his Argument on September 11, 2015, and the Division filed its Reply Argument on September 25, 2015.

FINDINGS OF FACT

1. Respondent Marvin Moore, R.Ph. (DOB May 11, 1978), is licensed in the State of Wisconsin to practice pharmacy, having license number 13645-40. This license was granted on June 28, 2002, and is current through May 31, 2016. In addition to completing pharmacy school, Respondent underwent three years of community pharmacy business training, with a residency program in 2002-2003, and an apprenticeship from 2003-2005. (Complaint, \P 1; Answer, \P 1; Hrg. Tr., p. 77)

2. During April and May 2012, Respondent owned and operated Lakeshore Apothecary, d/b/a The Medicine Shoppe Pharmacy in Two Rivers, Wisconsin. (Complaint, ¶ 3; Answer, ¶ 3)

3. Atorvastatin is an authorized generic form of Lipitor, a brand-name drug manufactured by Pfizer for the control of cholesterol levels in human patients. (Complaint, \P 4; Answer, \P 4)

4. An "authorized generic" form of a brand-name drug has the identical active and inactive ingredients as the brand-name drug, and may be made by the manufacturer of the brand-name drug at precisely the same time as the brand-name drug, on precisely the same equipment by precisely the same people. At the time an authorized generic leaves the manufacturing facility, it differs from the brand-name drug made at the same time only in packaging, distribution, and price. (Complaint, ¶ 5, Answer, ¶ 5)

5. During April and May of 2012, Respondent intentionally packaged, dispensed and sold authorized generic atorvastatin as Lipitor. During the time Respondent engaged in this conduct, he did not stock Lipitor in the pharmacy. (Complaint, ¶ 7; Answer, ¶ 7; Div. Ex. 4, p. 3; Hrg. Tr., pp. 22, 69, 76)

6. In April and May of 2012, a tablet of atorvastatin was indistinguishable from a tablet of Lipitor of the same dose, but carried a lower wholesale and retail price than the brand-name Lipitor. (Complaint, \P 6; Answer, \P 6)

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7. At hearing, Respondent testified that "there would be no cost savings in these prescriptions that I dispensed" because "[p]atients paid a co-pay," and that the business practices at issue had "no bearing on the co-pay that the patient would pay." The reason the co-pay would not be affected, according to Respondent, is because Medicaid publishes a preferred drug list each month indicating what the preferred drugs are, generic or brand-name, and the co-pays varied for that reason. Respondent further explained that under the Medicaid billing process, if he would have run a claim through for a generic product during a time that Medicaid required brand-name as its preferred product, the claim would not have gone through as a paid claim, and as a result, the patients would have paid more. (Hrg. Tr., pp. 81, 85, 88, 91)

8. Billing records Respondent submitted to the Department generally show that either Lipitor or atorvastatin was purchased during a given month, rather than both products being purchased within the same month. A comparison between the prices of the two products between months generally shows a higher payment for Lipitor than for atorvastatin. (Div. Ex. 5)

9. Mitchell Adams was an employee of the Medicine Shoppe in May of 2012. At the time of his employment there, he had been a pharmacist for approximately one year. (Hrg. Tr., pp. 16-17, 46)

10. On May 16, 2012, Adams spoke with Respondent regarding the practice of selling atorvastatin as Lipitor. Respondent poured the atorvastatin on a counting tray, telling Adams that it looked the same as Lipitor, was made the same, and was the same product as Lipitor. Adams stated that the bottle was atorvastatin. Respondent stated that he purchases atorvastatin at a cheaper price but that it was the same medication. Respondent indicated that the Lipitor was approximately \$400 per bottle and that the atorvastatin was approximately \$308 per bottle. Adams told Respondent that he believed it was fraud because they were dispensing a product that is mislabeled. (Div. Ex. 1; Hrg. Tr., pp. 25-26, 28, 47-48, 82)¹

11. Adams emailed Respondent on May 17, 2012, informing Respondent he would no longer be working at The Medicine Shoppe. (Div. Ex. 1; Hrg. Tr., pp. 16-17)

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¹ The Division repeatedly states in its post-hearing briefs that, during this conversation, Respondent told Adams that the conduct at issue might be insurance fraud. The Division further asserts that Respondent "admits" that he made this statement to Adams. (Div. Reply Argument, p. 1). The Division does not cite any support in the record for its assertion that Respondent admits to having made this statement to Adams, and I was unable to locate any such admission. With regard to whether Respondent made such a statement to Adams, I note that although Adams' complaint to the Division (Div. Ex. 1) states that Respondent made this statement to him, in testifying to their conversation at hearing, Adams never referenced such a statement. Instead, Adams testified that he told Respondent that he thought it was fraud. (Hrg. Tr., pp. 25-28) Likewise, no testimony was elicited from Respondent with respect to this alleged statement, although he too testified regarding their conversation. In addition, in a letter to the Department, Respondent states that when questioned by a relief pharmacist on the appropriateness of his practice, he informed the pharmacist that he would research the issue and in the meantime would stop stocking the authorized generic product. (Ex. 1, p. 1, Ex. 3, p. 1) I conclude that the hearsay regarding this statement contained in Division Exhibit 1 is not sufficiently reliable evidence in view of the fact that it was not corroborated in any of the hearing testimony by the two people engaged in the conversation. Therefore, I make no finding with respect to whether or not Respondent told Adams that Respondent's conduct might be insurance fraud. See also Gehin v. Wisconsin Group Insurance Board, 2005 WI 16, 278 Wis. 2d 111, 692 N.W.2d 572.

12. Respondent responded to Adams by email, stating, "Well, this particular example isn't one that would put a patient at risk. When I reflect on it you are right in that it just isn't the right thing to do." He further stated, "I've made plenty of mistakes and poor decisions in my life, and I'm sure I'll make many more. I try to learn something from each one. This particular situation is a good slap in the face to get me back to where I want to be. By the way, since our discussion last Wednesday I did begin to stock 'brand' once again." He also informed Adams that he had a "ton of respect for [him] as a person and as a pharmacist." (Hrg. Tr., pp. 44, 76)

13. In late May of 2012, Respondent stopped selling atorvastatin as Lipitor and began restocking Lipitor. Although he believed there was no distinction at all between the authorized generic and the brand product and that his practice of selling authorized generic atorvastatin as Lipitor complied with industry requirements, he acknowledged that it was a "gray area" and wanted to adopt the more "conservative" approach. (Div. Ex. 2, p. 2; Div. Ex. 3, p.1; Hr. Tr., pp. 69, 93)

14. On May 17, 2012, Adams filed a Medicare fraud complaint on-line, at the website oig.hhs.gov, which is a website for the U.S Department of Health and Human Services (HHS), Office of Inspector General (OIG). Adams also filed a complaint with the Department on May 18, 2012. (Div. Ex. 1, p. 1; Hrg. Tr., pp. 16-17, 41-43, 50)

15. At some point after May of 2012, an audit was conducted with respect to the Medicare fraud complaint for the time period of approximately January through October of 2012. As part of the audit, Respondent provided the investigating agency with numerous records, including records regarding Lipitor and the authorized generic atorvastatin. The audit was closed without requiring any corrective action on Respondent's part and without imposing any penalty or sanction against Respondent. The audit was conducted after Respondent had changed his practice to stop selling authorized generic atorvastatin as Lipitor. (Hrg. Tr., pp. 50, 71-72, 92-93)

16. Respondent testified that nothing on the label of any of his prescriptions was false. (Hrg. Tr., p. 71)

17. An authorized generic medication comes to market under the original patent of the brand-name manufacturer. In contrast, before a regular generic enters the market it has to go through an Abbreviated New Drug Application (ANDA), wherein the generic company must show that its medication provides a similar effect as the original brand maker's product. An authorized generic product does not have to go through the ANDA process. Authorized generics are issued under the same NDA as the brand product. Authorized generic products also appear the same as the brand product whereas regular generics can vary in appearance from the brand product, including in size, color and imprints on the tablets. (Resp. Ex. 2, p. 127; Resp. Ex. 4, p. 135; Hrg. Tr., pp. 57-59, 61)

18. Respondent conducted research on the issue involved in this case when he became aware that the authorized generic was on the market. (Hrg. Tr., p. 62)

19. "The Orange Book" is a document issued by the federal Food and Drug Administration (FDA) which lists brand-name medications and all of the generic medications that may be substituted for brand-name medications. Its official title is "Approved Drug Products with Therapeutic Equivalence Evaluations," but it is known as The Orange Book due to the orange cover of the original print version. The Orange Book does not list authorized generics. This is because the FDA considers the authorized generic to be the same as the brand product. (Resp. Ex. 1; Resp. Ex. 2, p. 126-127; Hrg. Tr., pp. 59, 61-64, 79-80)

20. A 2008 article entitled, "PRN's Q & A on: The FDA Orange Book," contained in an on-line pharmacy industry publication, "P.R.N. Newsletter," states:

Authorized generics are actually original brand-name drugs re-labeled as generics through a variety of arrangements between innovator companies and their subsidiaries, licensees, or contract manufacturers. This practice also creates an issue for pharmacists because the Orange Book does not list authorized generics. The stated reason for this practice is that the FDA does not consider these products generics. Since they are manufactured under the original, approved New Drug Application (NDA) submitted for the brand-name drug, the FDA considers authorized generics to be identical to the brand.

It further states: "Indeed, a reasonable argument could be made that authorized generics may even be dispensed on prescriptions marked 'dispense as written' (DAW) by the prescriber, at a cost savings to the patient, since they are, in fact, identical drugs." (Resp. Ex. 2, p. 127; Div. Ex. 2, pp. 1-2; Hr. Tr., p. 63)

21. A 2006 article entitled, "New Law Reins in 'Authorized Generics' Despite Generic Industry Court Losses, But Leaves Several Ambiguities," contained in a pharmacy industry publication states: "An authorized generic is like any other generic drug marketed in the United States insofar as being equivalent to the brand-name drug (since it is, in fact, the same drug)." The article further states, "Authorized generics have been marketed as generic drugs for purposes of selling them at a discount off the brand-name drug price. . . ." (Resp. Ex. 3, pp. 131, 134, Hrg. Tr., pp. 64-65)

22. A major insurance provider in the industry, Blue Cross Blue Shield of Oklahoma, states, "An authorized generic exists when a pharmaceutical manufacturer sells a drug under both a brand-name and a generic label. Since authorized generics are considered brand products by the FDA, the authorized generic does not have to go through the same rigorous ANDA approval process required by a true generic." (Resp. Ex. 4, p. 135; Hrg. Tr., p. 66)

23. In July of 2012, Respondent reversed all claims that involved dispensing the authorized generic atorvastatin in place of Lipitor and refunded all monies paid for these claims from both patients and third parties. (Div. Ex. 3, p. 1; Div. Ex. 5)

24. The Medicine Shoppe is one of only three pharmacies in the United States to be accredited, and the only accredited pharmacy in Wisconsin. Accreditation is based on approximately 120 different quality measures and best practices and ensures that the pharmacy is

doing the best it can to provide patient care. Adams testified that, with the exception of this incident, he had "great respect for the store," that it is "nationally known," and that it was the "best store [he'd] ever been at for counseling, taking care of the patients." (Hrg. Tr., pp. 40-41, 74)

DISCUSSION

Burden of Proof

The burden of proof in disciplinary proceedings is on the Division to show by a preponderance of the evidence that the events constituting the alleged violations occurred. Wis. Stat. § 440.20(3); see also Wis. Admin. Code § HA 1.17(2). To prove by a preponderance of the evidence means that it is "more likely than not" that the examined action occurred. See State v. Rodriguez, 2007 WI App. 252, ¶ 18, 306 Wis. 2d. 129, 743 N.W.2d 460, citing United States v. Saulter, 60 F.3d 270, 280 (7th Cir. 1995).

Alleged Violations

Wis. Stat. § 450.13(1)

The Division first alleges that Respondent violated Wis. Stat. § 450.13(1), which states:

450.13 Using drug product equivalent in dispensing prescriptions.

(1) DRUG PRODUCT OR EQUIVALENT TO BE USED. Except as provided in sub. (2), a pharmacist shall dispense every prescription using either the drug product prescribed or its drug product equivalent, if its drug product equivalent is lower in price to the consumer than the drug product prescribed, and shall inform the consumer of the options available in dispensing the prescription. In this section, "drug product equivalent" means a drug product that is designated the therapeutic equivalent of another drug product by the federal food and drug administration.

The Division asserts that Respondent failed to pass the financial benefit that he derived from selling authorized generic atorvastatin² as Lipitor onto the consumer. While that may be true, Wis. Stat. § 450.13(1) does not require that a pharmacist pass any financial benefit on to a consumer. Rather, Wis. Stat. § 450.13(1) requires pharmacists to (1) "dispense every prescription using either the drug product prescribed or its drug product equivalent," if the drug product equivalent is lower in price to the consumer than the drug product prescribed; and (2) "to inform the consumer of the options available in dispensing the prescription."

The Division also argues that Respondent dispensed a "drug product equivalent" to customers and that, contrary to the requirements of Wis. Stat. § 450.13(1), he failed to inform the customers of the lower priced drug product equivalent.

 $^{^{2}}$ Whenever the term atorvastatin is used in the discussion section of this decision, it refers to authorized generic atorvastatin, even if not expressly stated.

Respondent argues that he dispensed "the drug product prescribed" because an authorized generic product is the same as a brand-name product. Alternatively, he argues that even if they are not the same, then the authorized generic is clearly a drug product equivalent since it is chemically identical to the brand-name drug product. Respondent also states that the record is silent as to whether he failed to "inform the consumer of the options available in dispensing the prescription" and that therefore the Division has not met its burden of establishing a violation of Wis. Stat § 450.13(1).³

The evidence of record does not establish that Respondent dispensed a "drug product equivalent" under Wis. Stat. § 450.13(1) rather than a "drug product prescribed." As set forth above, the phrase "drug product equivalent" is specifically defined in Wis. Stat. § 450.13(1) as "a drug product that is designated the therapeutic equivalent of another drug product by the federal food and drug administration." I am bound by this statutory definition in analyzing whether Respondent's conduct constituted a violation of Wis. Stat. § 450.13(1). The record does not establish that the FDA has designated atorvastatin as the "therapeutic equivalent" of Lipitor. Therapeutic equivalents are listed in the FDA's Orange Book. Authorized generics such as atorvastatin do not appear in the Orange Book because they are considered brand products by the FDA. (See Findings of Fact 19-22)

The Division contends that, pursuant to Wis. Stat § 450.13(1), Respondent was required to inform customers of the less expensive "drug product equivalent" atorvastatin. However, because the Division has not shown that atorvastatin was a "drug product equivalent" under the definition contained in that statute, it has not established a violation of Wis. Stat. § 450.13(1).⁴

<u>Wis. Stat. § 450.11(7)(f)</u>

The Division next asserts that Respondent violated Wis. Stat. § 450.11(7)(f), which states: "No person may willfully affix any false or forged label to a package or receptacle containing prescription drugs."

Respondent argues that the Division has not met its burden of establishing this violation because Respondent testified that there was no false information contained on the labels and the Division failed to elicit any testimony or provide other evidence establishing what information was contained on the labels. However, the Division relies on the fact that Respondent has previously admitted in his Answer to the Complaint and his discovery responses that during April and May of 2012, he intentionally packaged, dispensed and sold authorized generic atorvastatin as Lipitor. This admission, particularly that Respondent "packaged" atorvastatin as Lipitor, demonstrates that whatever labels were placed on the products during this time period conveyed to the consumer that the product within the container was Lipitor, not atorvastatin. Therefore, the question is whether that information was "false."

³ Respondent also stresses that, with respect to Adams' Medicare fraud complaint, an audit was conducted, which resulted in no action being taken against Respondent and no request that he change his practices. However, this information is not accorded much weight as the record is devoid of any information as to why the government took no action. Moreover, at the time the audit occurred, Respondent had already changed the practice at issue.

⁴ In light of this conclusion, I need not consider Respondent's alternative argument that the Division failed to show what communication he had with customers.

Respondent's statement that the labels contained no false information appears to be based on his position that authorized generic atorvastatin is the same product as Lipitor. It is true that the atorvastatin at issue is identical to Lipitor in ingredients; is under the same patent and made by the same manufacturer, on the same equipment and at the same time as Lipitor, and looks the same as Lipitor. It is also true that the FDA considers an authorized generic and brand product to be the same product, and that the authorized generic differs from the brand drug only in name, packaging, distribution, and price.

However, the fact that they have different names and that atorvastatin carries a lower wholesale and retail price than Lipitor means that they are not the same product for labeling purposes. Thus, I conclude that a label is "false" when it leads the consumer to believe that the product is brand-name Lipitor rather than authorized generic atorvastatin. By labeling atorvastatin in this manner, Respondent violated Wis. Stat. § 450.11(7)(f).

Wis. Admin. Code § Phar 10.03(1) and (3)

The Complaint filed by the Division also alleges a violation of Wis. Admin. Code § Phar 10.03(1) and (3), which states:

Phar 10.03 Unprofessional conduct. The following, without limitation because of enumeration, are violations of standards of professional conduct and constitute unprofessional conduct in addition to those grounds specified under s. 450.10 (1), Stats.:

(1) Administering, dispensing, supplying or obtaining a drug other than in legitimate practice, or as prohibited by law;

(13) Exercising undue influence on or taking unfair advantage of a patient in the promotion or sale of services, drugs or other products for the financial gain of the pharmacist or a third party[.]

Because Respondent dispensed a drug in violation of Wis. Stat. § 450.11(7)(f), he also violated Wis. Admin Code § Phar 10.03(1), which prohibits dispensing a drug other than in legitimate practice or as prohibited by law.

In addition, the Division established that Respondent violated Wis. Admin. Code \S Phar 10.03(13) by taking "unfair advantage" of patients for his own financial gain. The unfair advantage taken by Respondent is that he led patients to believe that they were receiving brandname Lipitor when they were not, and also subjected them to the higher Lipitor price even though they were receiving atorvastatin. Moreover, the unfair advantage was for Respondent's financial gain as Respondent has admitted that he paid less for atorvastatin than he would have for Lipitor and that atorvastatin had a lower retail price.

In so concluding, I reject Respondent's argument that the Division failed to show that customers would have paid less for atorvastatin than they did for atorvastatin sold as Lipitor. Respondent admitted in his Answer to the Complaint that during the relevant time period, April and May of 2012, atorvastatin carried a lower wholesale *and retail* price than brand-name

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Lipitor. However, at hearing, Respondent testified that his business practices had no bearing on the co-pays paid by customers because Medicaid publishes a preferred drug list each month indicating what the preferred drugs are -- generic or brand-name -- and co-pays vary for that reason. Respondent's testimony is insufficient to contradict his admission and other evidence showing that customers paid a higher price for Lipitor during that time period than they would have for atorvastatin. Significantly, the record does not establish that during April and May of 2012, all of Respondent's customers were Medicaid recipients or were otherwise subject to copays, nor does the record show that Medicaid listed brand-name Lipitor as its preferred drug during that time.

In addition, Respondent's billing records contained in Exhibit 5 overwhelmingly show a higher price paid for Lipitor than for atorvastatin. Finally, I note that the pharmacy industry publications quoted in Findings of Fact 20 and 21, above, refer to selling authorized generics at a discount to the consumer.

Thus, I determine that Respondent's admission and evidence of record is sufficient to establish that atorvastatin would have been lower in price to Respondent's customers than Lipitor during the relevant time period. I therefore further conclude that by packaging, selling and distributing atorvastatin as Lipitor, Respondent took "unfair advantage" of his customers for his own financial gain.

Discipline

The three purposes of discipline are: (1) to promote the rehabilitation of the licensee; (2) to protect the public from other instances of misconduct; and (3) to deter other licensees from engaging in similar conduct. *State v. Aldrich*, 71 Wis. 2d 206, 237 N.W.2d 689 (1976).

The Division recommends that Respondent's license to practice pharmacy be revoked, or, in the alternative, that it be indefinitely suspended until the Wisconsin Pharmacy Examining Board (Board) is satisfied that Respondent may practice honestly and competently. As a final alternative, the Division recommends that Respondent's license be limited, paired with a stayed suspension, permitting Respondent to practice only in a situation where he is not permitted any supervisory status. Under this option, the Division states, Respondent would be prohibited from having any ownership interest in the pharmacy where he works.

In light of his argument that the Division failed to establish any violations, Respondent requests that no discipline be imposed. Alternatively, he requests that if any violation is found, an administrative warning be issued, along with a requirement that Respondent take nine credits of continuing legal education.

Based on the factors in *Aldrich*, I conclude that it is most appropriate to reprimand Respondent and require him to complete nine credits of continuing education requirements approved by the Board.

Such discipline is both necessary and sufficient to advance Respondent's rehabilitation, to protect the public and deter others from engaging in such conduct. The conduct in this case

occurred over a relatively short period of time, April and May of 2012, and involved what appears to be a novel issue, the extent to which authorized generic drugs may be treated as brand drugs. Relying on industry literature showing that the FDA viewed authorized generics as brand products, Respondent determined that he could, at a profit to him, substitute atorvastatin for Lipitor without informing the consumers of that substitution. When confronted by his employee, Respondent discontinued the practice, taking what he deemed to be a more "conservative" approach in this "gray area." Although the Division is correct that Respondent would likely have continued this practice for a longer period of time had his employee not confronted him and resigned in protest, it is also true that when confronted, Respondent almost immediately expressed what appears to be sincere remorse for his actions in an email to his employee and changed his practice. Shortly thereafter, he also voluntarily refunded the customers who purchased atorvastatin as Lipitor. He has been cooperative in all respects in this proceeding.

I also note that Respondent has had no prior discipline and, in fact, appears to otherwise have been an exemplary pharmacist running an outstanding pharmacy. In addition to his pharmacy degree, Respondent had three years of community pharmacy business training, with a residency program in 2002-2003, and an apprenticeship from 2003-2005. Moreover, the Medicine Shoppe, which he owns and operates, is one of only three pharmacies in the United States -- and the only pharmacy in Wisconsin -- to be accredited. Accreditation is based on approximately 120 different quality measures and best practices and ensures that the pharmacy is doing the best it can to provide patient care. Even Adams testified that, with the exception of this incident, he had great respect for the store, that it is nationally known, and that it was the best store he had worked at in terms of counseling and taking care of patients.

However, Respondent did violate provisions governing his profession, including affixing a false label on drug products and taking unfair advantage of customers. Although patients were not placed in danger, they were misled and received a less expensive product while paying for a higher priced product. Thus, an administrative warning, which is not a matter of public record, would be insufficient under the circumstances here. A reprimand, along with continuing education requirements, is a more appropriate response to this conduct.

<u>Costs</u>

The Division has the authority to assess costs pursuant to Wis. Stat. § 440.22. With respect to imposition of costs, factors to consider include: (1) the number of counts charged, contested and proven; (2) the nature and seriousness of the misconduct; (3) the level of discipline sought by the prosecutor; (4) the cooperation of the respondent; (5) any prior discipline; and (6) the fact that the Department is a program revenue agency, funded by other licensees. See In the Matter of Disciplinary Proceedings against Elizabeth Buenzli-Fritz, Order No. LS 0802183 CHI (Aug. 14, 2008).

The Division requests that full costs be imposed on Respondent, whereas Respondent request that no costs be imposed on him. Neither request is justified under the facts of this case and the factors set forth in *Buenzli-Fritz*. Instead, I conclude that imposition of forty percent of the costs on Respondent is appropriate. In terms of the number of counts charged, contested, and proven, I note that the Division's Complaint involved one type of misconduct over a relatively short period of time which resulted in a violation of three of the four provisions cited by the Division. The nature and seriousness of the conduct is discussed in the discipline section above, and can be summarized as serious but not extremely so, considering that it did not endanger patients and considering the FDA's determination that authorized generics are considered brand drugs and not included in the FDA's Orange Book containing a list of generic products. Also, Respondent has had no prior discipline and has been entirely cooperative in these proceedings, appearing at all required conferences and hearings, filing required documents in a timely manner and admitting to substantial facts up front which avoided litigation on those issues.

With respect to the discipline recommended by the Division, I note that the Division's recommendation is quite severe. Because it is unjustifiably so, however, I do not give it much weight in determining costs, particularly as a much lesser form of discipline, a reprimand and continuing education, was imposed instead. However, it is also significant that none of these proceedings would have been necessary had Respondent complied with the law in all respects and that any costs not borne by Respondent would have to be paid by those members of the pharmacy profession who have not engaged in such misconduct.

Accordingly, Respondent is assessed 40 percent of the costs of these proceedings.

CONCLUSIONS OF LAW

1. The Division did not meet its burden of establishing by a preponderance of the evidence that Respondent violated Wis. Stat. 450.13(1) by failing to inform the consumer of a lower priced drug product equivalent, atorvastatin.

2. The Division met its burden of establishing by a preponderance of the evidence that Respondent violated Wis. Stat. § 450.11(7)(f) by willfully affixing a false label to a package or receptacle containing prescription drugs.

3. The Division met its burden of establishing by a preponderance of the evidence that Respondent engaged in unprofessional conduct under Wis. Admin. Code § Phar 10.03(1) and (3) by dispensing atorvastatin other than in the course of legitimate practice or as prohibited by law and by taking unfair advantage of a patient in the sale of drugs for Respondent's financial gain.

4. The facts of record and the criteria delineated in *Aldrich* warrant that Respondent be reprimanded and be required to complete nine hours of continuing education approved by the Board.

5. Imposition of forty percent of the costs of these proceedings on Respondent is justified under the facts of this case and the Department's prior decision in *Buenzli-Fritz*.

<u>ORDER</u>

For the reasons set forth above, IT IS ORDERED that:

1. Respondent is REPRIMANDED.

2. Respondent shall complete, within six months after issuance of the final decision and order in this matter, nine hours of continuing education approved by the Board.

3. Respondent shall pay forty percent of the recoverable costs in this matter in an amount to be established, pursuant to Wis. Admin. Code § SPS 2.18. After the amount is established, payment shall be made by certified check or money order payable to the Wisconsin Department of Safety and Professional Services and sent to:

Department Monitor Department of Safety and Professional Services Division of Legal Services and Compliance P.O. Box 7190 Madison, WI 53707-7190

4. The terms of this Order are effective the date the Final Decision and Order is signed by the Board.

5. IT IS FURTHER ORDERED that the above-captioned matter is hereby closed as to Respondent Marvin Moore.

Dated at Madison, Wisconsin on October 19, 2015.

STATE OF WISCONSIN DIVISION OF HEARINGS AND APPEALS 5005 University Avenue, Suite 201 Madison, Wisconsin 53705 Telephone: (608) 266-7709 FAX: (608) 264-9885 Bv: ifer E. Nashold Administrative Law Judge

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