

IN THE MATTER OF

* BEFORE THE

MELWOOD PHARMACY

* MARYLAND STATE

PERMIT NO. P01278

* BOARD OF PHARMACY

RESPONDENT

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* * * * *

FINAL DECISION AND ORDER

Background

On April 6, 1999, the Maryland State Board of Pharmacy (the "Board") issued a notice of intent to summarily suspend the pharmacy permit held for Melwood Pharmacy, Permit No. P01278 ("Pharmacy"), held by Behrooz Goodarzi ("Pharmacist"). The Pharmacy was given an opportunity for a hearing to show cause as to why the Board should not issue an unexecuted order that would have suspended the pharmacy permit due to the imminent threat to the public health created by dangerous practices at the pharmacy. (See the Board's unexecuted order attached as Exhibit #1 hereto and incorporated by reference herein). A show cause hearing before a panel of the Board was held on April 13, 1999. This show cause hearing was limited to oral argument, some testimony by the Pharmacist, and an examination of the inventory prepared by the Division of Drug Control inspector, Catherine. Putz, based upon her observations of the Pharmacy on March 24, 1999 and March 30, 1999. (State's Exhibits 2 and 3).

On April 21, 1999, the Board issued an Order for Summary Suspension of Pharmacy Permit, finding that there was probable cause to believe that the pharmacy practices at the Pharmacy endangered the public health, safety, and welfare, requiring emergency action authorized by Md. Code Ann., State Gov't Art., §10-226(c). The Board gave the Pharmacy an opportunity for a prompt evidentiary hearing on the propriety of continuing the Order for Summary Suspension of Pharmacy

Permit. That hearing was held on May 12, 1999, and May 19, 1999. On May 20, 1999, the Board issued an Interim Order Pending Final Decision and Order, finding that sufficient evidence was presented at the hearing to justify continuation of the summary suspension order. This Final Order and Decision is being issued to formally present the Board's findings of fact and conclusions of law in support of its decision to continue in effect the summary suspension of the Pharmacy's permit.

Summary of Exhibits and Pertinent Witness Testimony

A. Exhibits

State's Exhibit 1 - Division of Drug Control Inspection Report - undated.

State's Exhibit 2 - Division of Drug Control Pharmacy Inspection Report - 3/24/99.

State's Exhibit 3 - Division of Drug Control Inspection Report - 3/30/99.

State's Exhibit 4 - Division of Drug Control Pharmacy Inspection Report - 6/20/95.

State's Exhibit 5 - Division of Drug Control Pharmacy Inspection Report - 6/23/98.

State's Exhibit 6 - Division of Drug Control Pharmacy Inspection Report - 6/18/96.

State's Exhibit 7 - Transcript of Show Cause Hearing, 4/13/99.

State's Exhibit 8 - Withdrawn.

State's Exhibits 9 through 15 - Photographs of box of drugs in Melwood Pharmacy.

State's Exhibit 16 - Blank Drug Enforcement Administration ("DEA") Form 41

(Registrant's Inventory of Drugs Surrendered).

State's Exhibit 17A - Letter to Kathy Putz [sic] from Paul Champagne, CVS - 5/12/99

State's Exhibit 17B - Letter to Kathy Putz [sic] from Paul Champagne, CVS - 5/12/99

elaborating on first letter sent on the same day.

State's Exhibit 18A - Letter dated 2/4/99 from Rite Aid to Pharmacy Board and

Division of Drug Control regarding continuing education to be held by Rite Aid.

State's Exhibit 18B - Continuing education certificate issued to Catherine S. Putz on
3/24/99.

State's Exhibit 19 - Permit renewal applications for Melwood Pharmacy - 11/15/97, 11/4/93,
11/3/92, 10/27/98, 11/7/94, 11/4/95.

Respondent's Exhibit A - Letter to Norene Pease, Executive Director, Board of Pharmacy
from David Dorin, M.D. - 4/30/99.

Respondent's Exhibit B - Letter to Board from Delbert L. Perkins, M.D. - 5/3/99.

Respondent's Exhibit C - Letter to Board from David Stover, D.D.S. - 4/29/99.

Respondent's Exhibit D - Return Goods Policies

Respondent's Exhibit E - Curriculum Vitae of Bertram A. Nicolas, Jr.

Respondent's Exhibit F - One Box Return Manufacturers Return Goods Policies

Respondent's Exhibit G - Credit memos from McKesson

Respondent's Exhibit H - Brief Curriculum Vitae of Nicholas C. Lykos

Respondent's Exhibits P1 through P5 - Photographs of Melwood Pharmacy

B. Summary of Pertinent Witness Testimony

Catherine Putz, Division of Drug Control inspector, testified that in response to an anonymous complaint that the Pharmacist was dispensing outdated drugs, she inspected the Pharmacy on March 24, 1999, and March 30, 1999, and found approximately 450 outdated products on the pharmacy shelves (T. 40, 77, 96). She observed that the Pharmacy had no visible system in place to identify drugs that were about to expire. (T. 46). She also observed the presence of

unlabeled medications without any name, expiration date, or lot number. (T. 46). In addition, she observed drug products where the labels had been pasted over the bottle so that the expiration date and lot number could not be seen. (T. 47). In all, she observed 17 bottles of unlabeled drugs containing no expiration dates or lot numbers. (T. 50).

Ms. Putz observed a soda bottle on the pharmacy shelves that contained Zyrtec, a prescription liquid medication. (T. 45, 75-76). She stated that the Pharmacist was not aware that he should destroy outdated Controlled Dangerous Substances ("CDS"), and she provided him with a DEA form 41 for that purpose. (T. 49-50, 99-100). She noted her observations in her inspection reports. (Exhibits 2 and 3). She recalled that her visit with the Pharmacist was "very friendly." (T. 40).

Jack Freedman, Chief, Division of Drug Control, testified that he had personally found outdated drugs on the pharmacy shelves when he accompanied Ms. Putz to her return inspection on March 30, 1999. (T. 18). Robert Chang, Deputy Chief, Division of Drug Control, testified that the Pharmacist mentioned a couple times that Ms. Putz was very nice and that he had thanked her for removing the outdated products from the shelves and stated that she had really helped him out by doing so. (T. 146). Other Division of Drug Control inspectors, Harold Jones and Lawrence Friedman, testified regarding their observations in previous inspections of the Respondent Pharmacy.

Stanton Brown testified regarding his observations while working as a relief pharmacist for the Respondent on March 30, 1999, including his observation that Ms. Putz had pulled outdated drugs from the pharmacy shelves. (T. 122, 140). Vincent Savarino, Rite Aid Regional Pharmacy Acquisition Specialist, testified regarding the reasons why Rite Aid decided not to buy the Respondent Pharmacy. Paul Champagne, CVS Operations Manager, testified that it is the policy of CVS not to sell drugs to other pharmacies.

Yahya Sari, M.D., David Dorin, M.D., and Vicki Beckham, a nurse who is employed by Dr. Durin, all testified regarding the quality of pharmaceutical services provided by the Respondent to their patients. Hossein Ejtemai, a pharmacist and long-time friend of the Pharmacist, testified regarding his observations of the Pharmacy, and regarding Mr. Ejtemai's practices with regard to the disposition of outdated drug products. Two patients of the Respondent Pharmacy, Elizabeth Snider and Arnold Cave, testified regarding the quality of pharmaceutical services they had received from the Respondent.

Donna Huff, a cashier employed by the Respondent Pharmacy, testified that when Ms. Putz came to the Pharmacy on March 24, 1999, she had an arrogant attitude and snapped at the Pharmacist, saying "We'll see about that, I have a meeting tonight with Rite Aid" in her conversation with the Pharmacist. (T. 382, 388). While Ms. Huff testified that Ms. Putz took drugs out of boxes on the floor (T. 352), she was not definite in her recollection, stating "I couldn't say" when asked "did [Ms. Putz] take things out of those boxes and put them on the counter and count them?" (T. 353-54).

The Respondent's expert witnesses, Bertram Nicholas and Nicholas Lykos, both testified that in their opinion it was not incompetent for the Pharmacist to keep outdated drugs in the pharmacy. (T. 434, 579). However, they both admitted that it was not a good pharmacy practice to keep outdated drugs on the pharmacy shelves because it increased the chances that a dispensing error would occur. (T. 446-47, 451, 454-55, 572, 581, 587).

The Pharmacist denied that he had numerous products without lot numbers or expiration dates. (T. 484-86). He claimed that only one item had a price sticker covering the expiration date and lot number. (T. 492-93). He testified that there were only 362 outdated pharmaceutical products

contained in Ms. Putz's report, rather than the 525 noted in the Board's Summary Suspension Order. (T. 555). The Pharmacist claimed that most of these outdated drugs were taken from boxes he had placed on the floor of the pharmacy and in his office, not from the pharmacy shelves. (T. 488, 494-95, 554, 558). He stated his belief that having an outdated product on the shelf is not holding that product for sale, and claimed that he checks the expiration date of every medication prior to dispensing it. (T. 509). He admitted pouring Zyrtec syrup into a soda bottle and defended that practice, but insisted he does not use soda bottles when dispensing liquid medications. (T. 481-83, 535-36).¹ He claimed that Ms. Putz referred to herself as the "Jack Kevorkian for pharmacy," and that she stated "I don't care if my co-worker [sic] did not know how to do their job. I will do my job." (T. 518). However, he admitted he had told Robert Chang that Ms. Putz had been helpful and that he appreciated her help in removing outdated drugs from the shelf. (T. 544).

FINDINGS OF FACT

Based upon the testimony and documentary evidence presented at the evidentiary hearing, the Board finds that the following facts are true:

1. At all times relevant, the Respondent operated as a pharmacy in the State of Maryland.
2. At all times relevant, the Respondent operated as Melwood Pharmacy at 9644 Marlboro Pike, Upper Marlboro, Maryland 20072 (the "Pharmacy").
3. At all times pertinent hereto, Behrooz Goodarzi, P.D. (The "Pharmacist"), a licensed pharmacist in the State of Maryland, has held the pharmacy permit for the pharmacy.

¹ At the show cause hearing the Pharmacist vigorously defended this practice and stated that he would dispense medications that had been poured into a soda bottle. However, at the evidentiary hearing he said that he has since changed his mind and would no longer dispense medications contained in soda bottles. (T. 552-54)

4. Acting on an anonymous complaint that expired drugs had been dispensed at the Pharmacy (T. 77), the Division of Drug Control performed an inspection on March 24, 1999, at the Melwood Pharmacy. A follow-up inspection was performed on March 30, 1999.

5. Upon inspection on March 24, 1999 (State's Exhibit 2), the following was found:

- a) Liquid medication was stored in a soda bottle (T. 45);
- b) There were numerous products without lot number or expiration dates (T. 46, 50);
- c) There were approximately 450 outdated products dating as far back as 1987 (T. 96);
- d) The Pharmacist was not aware that he should destroy outdated CDS, and DEA form 41 was provided to him (T. 99-100); and
- e) There were expiration dates and lot numbers covered by pasted-on labels. (T. 47, Exhibit 2).

6. The following is a list of outdated products by category², found at the Pharmacy on March 24 through 30, 1999: electrolyte supplements, anti-psychotics, anti-hypertensive, antibiotics, antitussives, antihistamines, acid blockers, circulation medications, Antibuse, pain relievers, Alzheimer management medications, tranquilizers, diuretics, prenatal vitamins, medications for the control of obsessive compulsive disorders, anti-inflammatory creams, steroidal, antigout products, acne lotion, saliva substitute, progesterone, antibiotic acne liquid, aspirin/codeine products, antivirals, calcium channel blockers, pain relievers, expectorants, enemas, anti-inflammatory medications, sleep aids, pediculacide, UTI medications, vitamins, urinary antiseptics, antinausea,

² State's Exhibits 2 and 3 are the inventories of March 24, 1999, and March 30, 1999, prepared by C. Putz of the Division of Drug Control and signed by the Pharmacist.

anti-ulcer, mobility agents, anticoagulants, thyroid supplements, anti-depressants, muscle relaxants, tuberculosis drugs, antiarrhythmic heart medications, antidiabetics, asthma medications, oral contraceptives, ear anti-infectives, potassium supplements, anti-miasthenics, antiseizure products, bulk hormones for compounding, laxatives, Schedule III³ cough suppressant/expectorants, Schedule III pain relievers, Schedule IV tranquilizers, and Doral, a Schedule IV sedative. In addition to the above, these categories of pediatric specific medications were found: expectorant/decongestants, numerous antibiotics, cough/cold preparations, asthma and pain relievers. A bottle of Diethylstilbesterol, with an expiration date of May, 1994 was also found on the shelf of the Pharmacy. Diethylstilbesterol is no longer on the market.

7. At the show cause hearing the Pharmacist defended his practice of putting liquid medications such as Zyrtec syrup into soda bottles despite the risk of contamination. (4/13/99 T. 50). At the evidentiary hearing the Pharmacist continued his defense of this practice. (T. 535-36). However, for the first time at the evidentiary hearing, he claimed that would no longer dispense medications from a soda bottle. (T. 552-54).

8. At the show cause hearing the Pharmacist claimed that he never had a chance to get rid of the outdated drugs and admitted that he had no system to flag outdated drugs. (4/13/99 T. 54). At the show cause hearing he claimed that he has since changed his practices since the inspection so that on each day he now pulls all outdated drugs off the pharmacy shelves. (4/13/99 T. 53). He further stated that he now keeps his containers upside down or sideways when they are drawing near

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Some of the products previously listed are scheduled drugs.

to the expiration date. (4/13/99 T. 53).⁴ Catherine Putz, Division of Drug Control inspector, testified that she did not notice any bottles put on their side, or that any other flagging techniques were in use at the pharmacy. (T. 46).

9. At the show cause hearing the Pharmacist claimed there were only 362 bottles of outdated products rather than 525. (4/13/99 T. 39). He admitted that "maybe" some of these outdated products had been on the shelf. (4/13/99 T. 41). At the evidentiary hearing the Pharmacist also admitted that some of these outdated medications were on the pharmacy shelves, although he believed they were only recently expired, and that the majority of the outdated medications were in empty boxes on the floor and in his office. (T. 488, 494-95, 554, 558). The Board finds that it is most likely that many of these bottles were on the shelves and contained outdated drugs as reported by the inspector. Outdated pharmaceutical products can cause substantial harm to patients and the Board finds that there was no valid reason to possess these products in such numerous quantities and for such long periods of time, and to keep such products on the pharmacy shelves. To possess these numerous quantities of outdated pharmaceutical products on the pharmacy shelves either shows extreme incompetence or an intent to dispense these outdated products. In either event, emergency action is required to protect the public.⁵

⁴ At the evidentiary hearing the Pharmacist denied he made these statements at the show cause hearing. (T. 499). However, his testimony at the show cause hearing was as follows:

Q: But they were flagged somehow that they were going to be going out of date soon ?

A: No, because it's not something that has a light on it that you see. You really don't. I mean, as I said, the best way any pharmacist really knows what is out of date when I actually go in the shelf and pick up the medication and dispense it. (4/13/99 T. 54).

⁵ The Board is especially troubled by the presence of such outdated pharmaceutical products as pediatric medications, antibiotics, anti-hypertensives, antiarrhythmic heart

laws that are designed to protect the public health, emergency action is legitimate based solely upon those observations. The evidentiary hearing was held to give the Respondent an opportunity to contest the accuracy of those observations and to challenge the credibility of the inspectors.

After hearing the testimony of all the witnesses and observing their demeanor while testifying, the Board believes the version of events testified to by Catherine Putz, an inspector for the Division of Drug Control, who observed great quantities of outdated drugs on the Respondent pharmacy's shelves. Furthermore, Jack Friedman, Chief, Division of Drug Control, also testified that he personally removed outdated drugs from the shelves on March 30, 1999. (T. 18). In addition, Stanton Brown, relief pharmacist for the Respondent on March 30, 1999, testified that he observed Ms. Putz removing drugs from the pharmacy shelves. (T. 122, 140). The Board finds Ms. Putz's testimony to be credible and to be corroborated by the testimony of other witnesses. The Board does not find to be credible the Pharmacist's testimony that most of these outdated medications were in boxes. (T. 488).

Ms. Putz made a detailed list of outdated drugs she had found on the shelves on March 24, 1999. (T. 40-42). She stated that she had taken approximately 450 outdated drugs off the shelf, which she stated was an "extraordinary amount." (T. 96-97). She noticed the soda bottle containing Zyrtec on the Pharmacist's shelf. (T. 45). She also noticed pharmaceutical products on the pharmacy shelves that had no name, expiration date, or lot number, which she characterized as, and the Board agrees, a "cardinal sin of pharmacy" due to the resulting danger to the public. (T. 46) She described her visit with the Pharmacist as "very friendly" and related that they had discussed his family and his previous soccer playing days. (T. 40). In fact, the Pharmacist thanked her for her help and for taking the outdated drugs off the shelf. (T. 92, 146, 544). She said her activities as an investigator

10. The Board, in its professional and administrative expertise, finds that it violates the standards of pharmacy practice to keep outdated pharmaceutical products on pharmacy shelves next to current products and that such a practice endangers the health of patients who are more likely to receive outdated drugs due to the increased potential for the erroneous dispensing of outdated drugs. Every pharmacist witness, including the Pharmacy's own expert witnesses, testified that it is a commonly accepted standard pharmacy practice to remove outdated drugs from the pharmacy shelves.⁶ (T. 35, 61-63, 118, 131-32, 161-62, 240-41, 244, 285, 290-91, 434-35, 446, 451, 454-55, 572, 581, 588).

11. Because the Pharmacy is being operated in an incompetent manner that exposes the public to the grave dangers of outdated drugs, the Board finds that emergency action is necessary to protect the public health, safety, and welfare.

OPINION

Under State Gov't Art., §10-226(c), the Board possesses emergency powers to protect the public from imminent harm when it learns of information giving it probable cause to believe that immediate intervention is required to protect the public health. Because the Board must rely on the observations of its agents who inspect pharmacies to ensure their continued compliance with the

medications, anti-psychotics, antivirals, progesterone, oral contraceptives, thyroid supplements, tuberculosis drugs, and medications used to control obsessive-compulsive disorders.

⁶ The Board rejects the Pharmacy's argument that standards for pharmacy practice must be contained in statutes or regulations. Every pharmacist has a duty to practice pharmacy competently. *See Health Occ. Art., §12-313(b)(20)* (A pharmacist is subject to discipline for professional, physical, or mental incompetence). More importantly, when dangerous practices come to the Board's attention, the Board has a responsibility to take emergency action under State Government Article, §10-226(c) in order to protect the public from dangerous pharmacy practices which fail to meet commonly accepted minimum standards for safe pharmacy practice.

were not intended to be punitive and that she considered herself to be more of a teacher and a helper to pharmacists, and that most pharmacists are happy to take her advice. (T. 92).

Ms. Putz testified that outdated drugs present a danger to the public health because they lose their potency. (T. 61-62). She further testified that she would not dispense Zyrtec that had been poured from a cracked medication bottle into a soda bottle because of the possibility that glass and other adulterants that may have gotten in through the crack. (T. 83). Contrary to the Pharmacist's claim, she denied that she took any outdated drugs out of boxes, and stated: "I took nothing out of a box on the floor" (T. 66), "I took every single expired drug off the shelf" (T. 67), and "I took nothing from his counter. I took nothing out of any box. I only took from the shelves." (T. 77). She admitted she had no evidence that the Pharmacist had dispensed an outdated drug. (T. 63).⁷ She denied telling the Pharmacist that she was "the Dr. Kevorkian of the Pharmacy Board." (T. 69-70). She denied telling the Pharmacist that a hearing before the Board would be a good experience and would help him to become a better pharmacist. (T. 93). She denied saying "we'll see about that," when the Pharmacist said he had discussed a job with Rite Aid. She also denied talking with representatives of Rite Aid about her experience with the Pharmacist and the Respondent pharmacy. Finally, she denied that she told the Pharmacist that the other inspectors for Drug Control did not

⁷Of course, without eyewitness testimony, it would be nearly impossible to prove actual dispensing of expired drugs, even according to the Respondent's own witness, pharmacist Hossein Ejtemai. (T. 289). This is precisely why the Maryland Food, Drug, and Cosmetic Act prohibits not only the dispensing of outdated drugs [which are decomposed substances due to their lack of potency, *see* Health-General Art., §§21-216(b)(1) and 21-256(1)], but also prohibits the holding of these drugs for sale. Health-General Art., §21-102(a)(1). *See also* *Blanton v. United States*, 428 F.Supp. 360, 362 (D. D.C. 1977) (Outdated drug was of "unknown effectiveness" and consequently "was in effect, a 'new drug' without FDA approval and must be presumed dangerous.").

know their job, but that she was going to do it. (T. 400-401).

The Board does not find Donna Huff's testimony to be credible. Ms. Huff was a biased witness whose job was at stake pending the outcome of these proceedings. She also admitted that the Respondent did not withhold Social Security or Medicare contributions from her wages, providing additional reasons to view her testimony as biased and unreliable. (T. 379). Furthermore, she could not remember whether Ms. Putz had taken drugs out of boxes rather than off the pharmacy shelves. (T. 353-54)

The Pharmacist also claimed there were only 362 outdated products contained in Ms. Putz's report, rather than the 525 noted in the Board's Summary Suspension Order. (T. 555). However, even if there were *only* 362 as claimed by the Pharmacist, there still would be no legitimate reason to keep on the pharmacy shelves ready to be dispensed to patients this huge amount of outdated drugs, especially given the fact that many of them had been expired for a period of years, not weeks. In addition, Cathy Putz testified that the Pharmacist removed approximately 100 additional outdated drugs from the pharmacy shelves. (T. 41). The presence of numerous drugs on pharmacy shelves ready to be dispensed that have long since expired presents a danger to the public requiring the immediate suspension of the Respondent's pharmacy permit.

This conclusion is also supported by the testimony of the Respondent's own expert witnesses, Bertram Nicholas and Nicholas Lycos. Bertram Nicholas testified that outdated drugs were "adulterated" under the Health-General Article (T. 450), that the existence on pharmacy shelves of five hundred bottles of outdated drugs dating as far back as ten years would not be typical of pharmacies (T. 451), and that the chance of dispensing an outdated drug "certainly is there." (T. 454-55). Mr. Nicholas further agreed that the chance of dispensing an outdated drug is higher than

if there are no outdated drugs. (T. 451-452). Regarding outdated drugs, he testified that "it's not a good idea to have them on the shelf with your other medications" (T. 446), and that "[l]eaving them there and being unaware of it is not a good practice." (T. 447).

Nicholas Lykos testified that it was not wise to keep outdated drugs on the pharmacy shelves and that they should be pulled from the pharmacy shelves. (T. 572). In fact, he admitted that as a matter of routine practice, he pulls medications from the shelves when they are expired. (T. 582-83). With pride, he noted that Division of Drug Control inspectors had failed to find any expired drugs in his pharmacy, despite an inventory of 8,000 to 10,000 drugs on the shelves. (T. 580-81). He also agreed with the statement that he would not expect a prudent pharmacist to have hundreds of outdated drugs on the shelves that had expired a year or so earlier. (T. 581). Finally, he agreed that leaving outdated drugs on the pharmacy shelves increased the chances for error. (T. 587).

It is clear from the testimony of all the pharmacists and experts who testified that a basic standard of pharmacy practice is to pull outdated drugs from the pharmacy shelves and not to merely check the expiration date of each bottle prior to dispensing the drugs. This practice is obviously followed by pharmacists in order to reduce the risk of erroneously dispensing dangerously outdated drugs. The Pharmacy Board, in its professional and administrative expertise, finds that outdated drugs must be taken off the shelves to reduce the risk of dispensing outdated drugs. It is very disturbing that the Pharmacist openly advocates for the contrary practice. The Board believes that the Pharmacist's unsafe pharmacy practices demonstrate that he should not hold a pharmacy permit. The Board will not wait for a patient to be hurt prior to intervening to stop such unsafe practices.

CONCLUSIONS OF LAW

Based upon the foregoing Findings of Fact and Opinion, the Board finds that the public health, safety and welfare imperatively requires emergency action pursuant to Md. Code Ann., State Gov't Art., § 10-226(c)(1).

ORDER

Based upon the foregoing Findings of Fact, Opinion, and Conclusions of Law, it is this 19 day of May, 1999, by a majority of the quorum of the Board, hereby

ORDERED that the Respondent's pharmacy permit continue to be summarily suspended pursuant to Md. Code Ann., State Gov't Art., §10-226(c). And be it further

ORDERED that this a **FINAL ORDER** and as such is a public document pursuant to § 10-611 *et seq.* of the State Government Article, Annotated Code of Maryland. And be it further

ORDERED that the Board shall continue to hold the original display permit no. P01278 for Melwood Pharmacy already in its possession.

8/16/99
Date

W. Irving Lottier, Jr.
W. Irving Lottier, Jr. P.D.
Secretary, Board of Pharmacy

IN THE MATTER OF

* BEFORE THE

MELWOOD PHARMACY

* MARYLAND STATE

PERMIT NO. P01278

* BOARD OF PHARMACY

RESPONDENT

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**BOARD'S RULINGS ON REQUESTS FOR REHEARING
AND CLAIM FOR LITIGATION EXPENSES UNDER S.G. §10-224**

For the reasons set forth below, the Board denies the Respondent's Request for Rehearing and claim for ligation expenses under S.G. §10-224.

Pursuant to the hearing regulations adopted by the Board and published in the Code of Maryland Regulations ("COMAR") 10.34.01.05, the Pharmacy has requested a rehearing of the matters that led the Board to issue an order dated April 21, 1999, summarily suspending the pharmacy permit, no. P01278. The Board's order was issued following a show cause hearing held pursuant to Md. Code Ann., State Gov't Art., §10-226(c). The Board subsequently held an evidentiary hearing on May 12, 1999, and May 19, 1999, regarding whether the summary suspension order should remain in effect. This evidentiary hearing was additional process not required under S.G. §10-226(c) but that was granted to give the Pharmacy the opportunity to address the Board's concerns through the introduction of evidence and the cross-examination of prosecution witnesses.

COMAR 10.34.01.05 does not apply to this matter as claimed by the Pharmacy. The Board's authority to summarily suspend the Pharmacy permit is derived from S.G. §10-226(c), and only those hearing provision referred to in that statute apply in this matter. S.G. §10-226(c) was enacted to enable licensing agencies to take swift action when a licensee's practices threaten the public health and welfare. Such a legislative policy would be stymied were COMAR 10.34.01.05 applied to this

matter because its application would prevent the Board from acting to protect the public in a timely manner as mandated by the legislature because its order would be automatically stayed until final disposition of the matter.

In addition, COMAR 10.34.01.05 was only meant to apply to those hearings held under the Maryland Pharmacy Act, Md. Code Ann., Health Occ. Art. ("H.O."), §12-315. The sole statutory reference for these regulations is H.O. §12-312, which section was the precursor to current H.O. §12-315. By the express terms of H.O. §12-315, its hearing provisions apply to any action under §12-313." As has been stated herein, the Board's action of summarily suspending the Pharmacy's permit was taken under its authority pursuant to S.G. §10-226(c) in order to protect the public health from imminent danger, not pursuant to its authority to discipline licensees under H.O. §12-313. Given the emergency status of these proceedings brought pursuant to S.G. §10-226(c), the provisions of H.O. §§12-313 and 12-315 simply do not apply to this matter.

This conclusion is further supported by a reading of the text of COMAR 10.34.01, which refers to the requirement that all parties be given at least twenty days notice before the hearing. Such a notice requirement is wholly inconsistent with the need for immediate action to summarily suspend a licensee who is imminently endangering the public health. The Board shall not, and indeed cannot, give its hearing regulations such a broad reading so as to eviscerate the timely enforcement of S.G. §10-226(c). Such an interpretation would have the practical effect of invalidating the Board's application of §10-226(c) to pharmacists and pharmacies, an absurd result that could not possibly have been intended by the General Assembly. Thus, the Board shall deny the Respondent's request

for a rehearing of this matter under COMAR 10.34.01.05.⁸

Respondent's claim for litigation expenses is also denied. To be eligible for litigation expenses under S.G. §10-224(c), a small business claimant must demonstrate the existence of three facts: (1) an action must be initiated against the claimant by an agency as part of its administrative or regulatory function; (2) the action must be initiated without substantial justification or in bad faith; and (3) the action must not result in an adjudication of liability of the small business claimant or a determination of noncompliance, violation, infringement, deficiency, or breach on the part of the business or nonprofit organization. It is self-evident that the third fact cannot be demonstrated by the Pharmacy because its pharmacy practices have been found by the Board to have presented an imminent danger to the public health and safety, requiring the summary suspension of the Respondent's pharmacy permit under S.G. §10-226(c). The Board also believes that the second fact cannot be demonstrated as this action was clearly initiated with substantial justification and not in bad faith.

⁸ At the hearing Respondent claimed that the notice of this matter given by the Board was deficient because it allegedly failed to list all pertinent statutory and regulatory sections, potential penalties, and what was required to obtain a hearing. (T. 9). These claims are simply incorrect. The Board notified Respondent that it intended to issue a summary suspension order under authority of the summary suspension statute, S.G. §10-226(c) [in the notice the identical predecessor statute, S.G. §10-405, was mistakenly cited], because the practices at the Pharmacy endangered the public health, safety, and welfare. See Board's Ruling on Response to Charges and Motion to Dismiss dated April 21, 1999 and contained within the Board's Order for Summary Suspension of Pharmacy Permit issued on the same date. The potential penalty of summary suspension was obvious. Finally, the notice stated that the Board would hold a hearing within thirty days after receiving the Respondent's written request for an evidentiary hearing, which hearing was in fact timely held.

For all the foregoing reasons, the Pharmacy's request for rehearing and claim for litigation expenses is denied.

5/15/99
Date

W. Irving Lottier, Jr.
W. Irving Lottier, Jr., P.D.
Secretary, Board of Pharmacy

NOTICE OF RIGHT TO APPEAL

Pursuant to Md. Code Ann., Health Occ. Art., §12-316, you have a right to take a direct judicial appeal. A petition for appeal shall be filed within thirty days of your receipt of this Final Order and shall be made as provided for judicial review of a final decision in the Maryland Administrative Procedure Act, Md. Code Ann., State Gov't Art., §§10-201, *et seq.*, and Title 7, Chapter 200 of the Maryland Rules.