COURT OF APPEALS COSHOCTON COUNTY, OHIO FIFTH APPELLATE DISTRICT

ELISE MILLER JUDGES:

Hon. Patricia A. Delaney, P.J. Plaintiff-Appellant Hon. Sheila G. Farmer, J.

Hon. John W. Wise, J.

-VS-

OHIO STATE BOARD OF PHARMACY Case No. 11-CA-9

Defendant-Appellee <u>OPINION</u>

CHARACTER OF PROCEEDING: Appeal from the Court of Common

Pleas, Case No. 2011Cl0050

JUDGMENT: Affirmed

DATE OF JUDGMENT: March 9, 2012

APPEARANCES:

For Plaintiff-Appellant For Defendant-Appellee

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Farmer, J.

- {¶1} Appellant, Elise Miller, became a licensed pharmacist in 1979. She owned and operated two pharmacies, Miller Pharmacy which was a retail pharmacy and Three Rivers which provided specialty infusion products. The pharmacies where right next to each other.
- {¶2} In 2008, the FBI searched Three Rivers and seized many documents. Three Rivers went bankrupt and was closed by the bankruptcy trustee on April 1, 2009.
- In April and May of 2009, two investigators from the Ohio State Pharmacy Board, Louis Mandi and David Gallagher, conducted surprise inspections of the pharmacies. Pursuant to a letter from the Board dated March 10, 2010, appellant was charged with 23 counts of misbranding drugs, adulteration of drugs, and failure to keep accurate records. An administrative hearing before the Board was held on December 8, 2010. At the conclusion of the hearing, the Board revoked appellant's pharmacy license. The decision was made an official order on January 14, 2011.
- {¶4} On January 28, 2011, appellant filed an appeal with the Court of Common Pleas of Coshocton County. By judgment entry filed June 17, 2011, the trial court affirmed the Board's decision.
- {¶5} Appellant filed an appeal and this matter is now before this court for consideration. Assignments of error are as follows:

I

{¶6} "THE TRIAL COURT ERRED IN FAILING TO PROPERLY ADDRESS EACH ASSIGNMENT OF ERROR."

{¶7} "THE TRIAL COURT ERRED IN AFFIRMING THE BOARD'S CONCLUSIONS OF LAW, 2, 11, 13, 14 AND 18-24 AS TO WILLFULNESS."

Ш

{¶8} "THE TRIAL COURT ERRED IN SUMMARILY AFFIRMING THE BOARD'S FINDING NOS. 4, 5, 6 AND 14 AS THERE WAS NO EVIDENCE THAT THESE ITEMS WERE OFFERED FOR SALE AND MS. MILLER HAD ACCESS TO STATE AND FEDERAL DRUG LAWS."

IV

{¶9} "THE TRIAL COURT ERRED IN AFFIRMING THE BOARD'S ADMISSION
OF IRRELEVANT HEARSAY EVIDENCE."

V

{¶10} "THE TRIAL COURT ERRED IN SUMMARILY AFFIRMING THE BOARD'S FINDING NO. 12 AS THERE WAS INSUFFICIENT EVIDENCE OF THE DISPENSING OF BACLOFEN AS LIORESAL."

V١

{¶11} "THE TRIAL COURT ERRED IN AFFIRMING THE BOARD'S REFUSAL TO PRODUCE ITS INVESTIGATIVE FILE AND ALL STATEMENTS PRIOR TO THE HEARING."

{¶12} Appellant claims the trial court erred in failing to address each of her assignments of error raised in her R.C. Chapter 119 appeal. We disagree.

{¶13} "In reviewing an administrative appeal, the common pleas court is not permitted to either try the issues *de novo* or substitute its own judgment for that of the administrative agency.***The role of the common pleas court in an administrative appeal is limited to determining whether the judgment of the administrative agency is support by reliable, probative and substantial evidence and is in accordance with law. See R.C. 119.12; see, also, *Pons v. Ohio State Med. Bd.* (1993), 66 Ohio St.3d 619, 621, 614 N.E.2d 748, 750–751; *In re Williams* (1991), 60 Ohio St.3d 85, 86, 573 N.E.2d 638, 639." *Baughman v. Department of Public Safety Motor Vehicle Salvage* (1997), 118 Ohio App.3d 564, 570. (Citations omitted.)

{¶14} "***'Reliable, probative and substantial evidence has been defined as: (1) "Reliable" evidence is dependable; that is, it can be confidently trusted. In order to be reliable, there must be a reasonable probability that the evidence is true. (2) "Probative" evidence is evidence that tends to prove the issue in question; it must be relevant in determining the issue. (3) "Substantial" evidence is evidence with some weight; it must have importance and value. *Our Place, Inc. v. Ohio Liquor Control Comm.* (1992), 63 Ohio St.3d 570, 571, 589 N.E.2d 1303.' " *Vinci v. Ohio State Board of Pharmacy,* Tuscarawas App. Nos. 2008 AP 08 0052 and 2008 AP 08 0053, 2010-Ohio-451, ¶85.

{¶15} Appellant argues the trial court is somehow required to follow App.R. 12(A)(1)(c) which states, "[u]nless an assignment of error is made moot by a ruling on another assignment of error, decide each assignment of error and give reasons in writing for its decision." However, trial courts are only required to address the standard of R.C. 119.12. Not only did the trial court sub judice address the evidence as being reliable, probative, and substantial to support the Board's findings, it also addressed

evidentiary issues (hearsay) as well as the distinction between Miller Pharmacy and Three Rivers as raised in the appeal.

- {¶16} Upon review, we find no necessity for the trial court to follow the Appellant Rules of Procedure.
 - {¶17} Assignment of Error I is denied.

II, III, V

- {¶18} In these assignments, appellant claims the trial court erred in determining the Board's decision was supported by reliable, probative, and substantial evidence. We disagree.
- {¶19} Specifically, appellant argues the Board's Findings of Fact Nos. 2, 11, 13, 14, and 18-24 were incorrect because there was no showing of willfulness, Findings of Fact Nos. 4, 5, 6, and 14 were incorrect because there was no showing that the mentioned items were offered for sale, and Findings of Fact No. 12, that she dispensed Baclofen as Lioresal, was not supported by sufficient evidence.
- {¶20} " 'On appeal to this Court, the standard of review is more limited. Unlike the court of common pleas, a court of appeals does not determine the weight of the evidence. Rossford Exempted Village School Dist. Bd. of Edn. v. State Bd. of Edn. (1992), 63 Ohio St.3d 705, 707, 590 N.E.2d 1240. In reviewing the trial court's determination [whether] the Board of Review's order was supported by reliable, probative and substantial evidence, this Court's role is limited to determining whether the trial court abused its discretion. Roy v. Ohio State Med. Bd. (1992), 80 Ohio App.3d 675, 680, 610 N.E.2d 562. The term "abuse of discretion" connotes more than an error of law or judgment; it implies that the court's attitude is unreasonable, arbitrary or

unconscionable. *Blakemore v. Blakemore* (1983), 5 Ohio St.3d 217, 219, 450 N.E.2d 1140.' *Id.* at ¶9, ¶10, 450 N.E.2d 1140. An abuse of discretion shows 'perversity of will, passion, prejudice, partiality, or moral delinquency.' *Pons v. Ohio State Med. Bd.* (1993), 66 Ohio St.3d 619, 621, 614 N.E.2d 748." *Vinci,* supra at ¶86.

- {¶21} In *Payne v. Vance* (1921), 103 Ohio St. 59, paragraph three of the syllabus, the Supreme Court of Ohio held, "[w]illful tort involves the element of malice or ill will, but it is not necessary to show actual malice or ill will. It may be shown by indifference to the safety of others after knowledge of their danger, or failure after such knowledge to use ordinary care to avoid injury."
- {¶22} Appellant argues no evidence was presented to establish that she willfully dispensed Kineret, a single-use product, into four different syringes, thereby reducing the effectiveness of the drug. See, Findings of Fact Nos. 2 and 11.
- {¶23} It is uncontested from appellant's own testimony that she took the commercially packed dosages of Kineret containing 100 mg and repackaged the drug into 25 mg dosages as prescribed by a doctor for a juvenile patient. T. at 61-62. Appellant claimed this had been the practice since 2005 and it was approved by the doctor. T. at 63, 73, 75. However, documented proof of such approval of this method was not presented. Appellant claimed to have no records of the approval or the patient's chart because of the FBI search and confiscation of documents and the subsequent bankruptcy and sale of Three Rivers. T. at 75, 95. Appellant admitted to making dispensing errors. T. at 130, 290.
- {¶24} The Board's compliance specialist, Louis Mandi, testified appellant's method was an inappropriate method. T. at 221-222. The single-use dosage can be

administered in lesser amounts at the time of injection by injecting the drug into a sterile vial and then the prescribed amount can be removed by a syringe. T. at 222. Appellant's method compromised the life of the drug from thirty days to four to six hours and exposed it to an unstable environment causing it to congeal or thicken. T. at 221.

{¶25} Appellant disregarded the original packaging and the standard procedures for dispensing the drug and did not have any supporting evidence of approval of her method. We find the trial court did not err in finding this procedure was willful.

{¶26} Appellant argues her failure to have her ID badge on and her failure to have the Drug Laws of Ohio book at hand in Miller Pharmacy was not willful. See, Findings of Fact Nos. 13 and 14. Appellant argued the items were next door at Three Rivers, but also argued she had no control over Three Rivers because the bankruptcy trustee was in control and had shut the place down on April 1, 2009. T. at 267-268. Although technical violations, they were nevertheless violations. These standing alone would not have precipitated the Board's actions, but were part of appellant's "house of cards" when she admitted her life was in chaos. T. at 270.

{¶27} Findings of Fact Nos. 18-24 cover the failure to properly record the dispensing of drugs and keeping patient profiles. Appellant admitted to these errors. T. at 269-272. She attempted to excuse them by arguing her life was in chaos, and she was a small town pharmacist who knew her physicians by voice and first name. T. at 270. She did not state she forgot, she just failed to do it properly. Although all of these claims may very well be true, they are no excuse for failing to comply with the Administrative Code and her own standard of care for her profession.

- {¶28} Based upon appellant's admissions and the facts presented via the testimony of compliance specialists Mandi and Gallagher, we find the trial court was correct in concluding there was substantial credible evidence of willfulness.
- {¶29} Findings of Fact Nos. 4, 5, and 6 found appellant misbranded drugs. The trial court found these findings were supported by reliable, probative, and substantial evidence. When Mr. Mandi first investigated Three Rivers in April of 2009, he found stored in the refrigerator several unmarked intravenous mixtures and containers that he could not identify. T. at 192-193. There were also unidentified syringes in the refrigerator. T. at 193. The drugs were misbranded because there were no labels on them. T. at 195-196; State's Exhibits 7 and 7a.
- {¶30} Appellant was unable to tell Mr. Mandi what was in the containers. T. at 196. Appellant did not deny that they were unmarked, but claimed they were not offered for sale because Three Rivers was closed. T. at 267. This argument is disingenuous because Mr. Mandi and Mr. Gallagher observed activity and persons in Three Rivers at the time of their inspection, and appellant acknowledged compounding drugs there after April 1, 2009. T. at 27, 200-201, 205, 246, 280. We find sufficient evidence of on-going activity and use of Three Rivers after April 2009 to substantiate the fact that unbranded drugs were available for sale.
- {¶31} Appellant argues there was insufficient evidence to establish that she was compounding Baclofen and labeling it Lioresal. See, Findings of Fact No. 12. As testified to by Mr. Mandi and admitted by appellant, if the brand drug is available (Lioresal) it is illegal to compound it from the generic (Baclofen) [R.C. 3715.52(A)(2)]. T. at 218-219. While not admitting to compounding Baclofen, appellant admitted it was

done for those patients who needed more that the branded amount of 2000 mg; however she was unable to support this claim with prescriptions for those patients she claimed needed more than 2000 mg. T. at 34-35. 37-39, 65.

- {¶32} Via the affidavits of Janet Myers who was a technician in the pharmacy in 2008 and Douglas Bolden who was a pharmacist until 2007, there was evidence that appellant oversaw the compounding of Baclofen and labeling it Lioresal. See, Exhibits 3 and 4. Further, Dr. Joseph Poole of the Mt. Vernon Developmental Center provided Mr. Mandi with information that the packaging of Lioresal received from appellant's pharmacy as late as May 13, 2009 was not labeled as the same as the branded Lioresal. T. at 197.
- {¶33} Documents compiled by Mr. Mandi compared the purchase versus dispensing records of Lioresal from the pharmacy for 2008-2009. T. at 208-214; Exhibits 34 and 35. Even assuming some overstocking at the commencement of the analysis, the amounts dispensed far exceeded the amounts purchased. T. at 213, 228. This circumstantial evidence plus the direct evidence from Ms. Myers and Mr. Bolden more than substantiated the charge of illegally compounding Baclofen.
 - {¶34} Assignments of Error II, III, and V are denied.

IV

- {¶35} Appellant claims the Board permitted irrelevant hearsay. We disagree.
- {¶36} The complained of hearsay testimony consisted of the affidavits of Ms. Myers and Mr. Bolden, statements made by Nurse Busdiecker to Mr. Gallagher, and statements made by Dr. Poole to Mr. Mandi.

- {¶37} At the outset, we note the Ohio Rules of Evidence are relaxed in administration proceedings. *Simon v. Lake Geauga Printing Co.* (1982), 69 Ohio St.2d 41. "Statements that would elsewhere be excluded as hearsay will be admissible in an administrative proceeding where they are not inherently unreliable, and may constitute reliable, probative, and substantial evidence." *Vinci,* supra at ¶118.
- {¶38} Evid.R. 401 defines "relevant evidence" as, "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence."
- {¶39} Each of the complained of statements provide evidence of the illegal compounding of Baclofen to Lioresal; therefore, they were clearly relevant to the issue at hand.
 - {¶40} Assignment of Error IV is denied.

VΙ

- {¶41} Appellant claims she was denied her right to discovery as any criminal defendant would be entitled to to prepare an adequate defense. We disagree.
- {¶42} Appellant argues she was entitled to the investigation file that may or may not have included exculpatory evidence.
- {¶43} "It is well settled that the Civil Rules pertaining to discovery do not apply to proceedings conducted pursuant to R.C. Chapter 119.12." *Baughman,* supra at 573; see also *Yoder v. Ohio State Board of Education* (1988), 40 Ohio App.3d 111. We conclude the same would be the case for the Criminal Rules of Procedure.
- {¶44} The Board contends appellant was given every document and a witness list prior to the hearing.

{¶45}	Upon review, we find the arguments herein lack merit.	
{¶46}	Assignment of Error VI is denied.	
{¶47}	The judgment of the Court of Common Pleas of Coshocton County, Ohio	
is hereby affirmed.		
By Farmer, J.		
Delaney, P.J. and		
Wise, J. concur.		
	s/ Sheila G. Farmer	
	s/ Patricia A. Delaney	
	_s/ John W. Wise	
	JUDGES	

IN THE COURT OF APPEALS FOR COSHOCTON COUNTY, OHIO FIFTH APPELLATE DISTRICT

ELISE MILLER	:
Plaintiff-Appellant	
-vs-	: JUDGMENT ENTRY
OHIO STATE BOARD OF PHARMACY	
Defendant-Appellee	: CASE NO. 11-CA-9
For the reasons stated in our	accompanying Memorandum-Opinion, the
judgment of the Court of Common Pleas of	of Coshocton County, Ohio is affirmed. Costs
to appellant.	
	s/ Sheila G. Farmer
	s/ Patricia A. Delaney
	s/ John W. Wise
	JUDGES