



*Delaney, J.*

{¶1} Appellant Ohio State Board of Pharmacy (“Board”) appeals three judgment entries of the Tuscarawas County Court of Common Pleas, all filed on September 4, 2008, which reversed and vacated the Board’s disciplinary action taken against the pharmaceutical licensure of Appellees SCP, Inc., dba, Strasburg Pharmacy (Case No. 2008 AP 10 0063), Michael T. Dennis, R.Ph. (Case No. 2008 AP 10 0064) and Amy Lynn Froman, R. Ph. (Case No. 2008 AP 10 0065).

{¶2} Because the three cases involve the same facts and the identical assignments of error, they shall be addressed together.

#### STATEMENT OF THE FACTS AND CASE

{¶3} Michael Dennis is the owner and responsible pharmacist at Strasburg Pharmacy, a small independent pharmacy located in Strasburg, Ohio. Amy Lynn Froman is a staff pharmacist at Strasburg Pharmacy. Strasburg Pharmacy is a Terminal Distributor of dangerous drugs under the supervision of Dennis. Dennis, Froman and Strasburg Pharmacy were duly licensed by the Board pursuant to R.C. Chapter 4729, which governs the practice of pharmacy in the State of Ohio.<sup>1</sup>

{¶4} On July 19, 2005, the Board issued separate Notices of Opportunity for Hearing to Appellees. Each Notice was 359 pages long, consisting of 1510 paragraphs alleging wrongdoing. Paragraphs 1 through 755 of the Notice alleged that each Appellee: “did...knowingly sell, conspire to sell, and/or aid and abet the sale of a controlled substance when the conduct was not in accordance with Chapter 3719., 4729., and 4731. of the Ohio Revised Code, to wit: [Appellees] sold the following

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<sup>1</sup> In addition to the statutes, a pharmacist’s responsibilities are detailed in regulations found in Ohio Administrative Code (“OAC”) Chapter 4729-5 and the Board’s Compliance Bulletins.

controlled substances to [the listed patients] when not for a legitimate medical purpose issued by a prescriber acting in the usual course of his professional practice and in compliance with the administrative code rules addressing pain management and violating Rule 4729-5-30 of the Ohio Administrative Code and 21 CFR 1306.04.” Similar violations were alleged in Paragraphs 756 through 1510 of the Notices, except the charges in these paragraphs involved dangerous drugs.

{¶5} An administrative hearing on the charges commenced on November 6, 2006 before the Board. At the beginning of the hearing, the State, without objection, orally requested the removal of thirty-two paragraphs from each Notice. The motion was granted by the Board.

{¶6} The following evidence was adduced at the hearing, which was held over four days.

{¶7} At the hearing, David Gallagher, a compliance agent with the Ohio State Board of Pharmacy, testified that in February of 2003 he began receiving reports from several retail pharmacists in Tuscarawas County about unusual prescription drug activity. Agent Gallagher testified that he learned from the pharmacists that in late 2002, a Dr. Edward DeHaas came to New Philadelphia and opened a pain clinic known as Professional Pain Management of Ohio (“PPMO”). The clinic was located near the off-ramps for Interstate 77. Prior to opening the clinic, Dr. DeHaas sent out mass mailings in Kentucky, West Virginia, and Ohio announcing his opening. He also visited area pharmacies to introduce himself and provided the pharmacy with a letter explaining the nature of his practice. The letter states, “most of our patients come to us as a last resort, with chronic pain which has not responded to surgical intervention, physical

therapy, or other forms of treatment.” Previously, Dr. DeHaas operated a pain management clinic along the Ohio River.

{¶8} Agent Gallagher testified that between mid and late February of 2003, he started receiving telephone calls complaining about PPMO and Dr. DeHaas’s prescriptions. According to Agent Gallagher, four of the calls came from area pharmacies in New Philadelphia indicating, “they were concerned about the practice, the fact that the practice was presenting so many prescriptions for patients who were receiving all the same type of medications, hydrocodone 10 products and carisoprodol 350 milligrams. They were upset or concerned that the patients were coming in groups, multiple patients in the same vehicles, they were concerned because these patients were coming from such long distances in these vehicles, from the Kentucky, West Virginia area, is what I was told. And they wanted to make me aware of these concerns and what they were seeing and that they wanted – I think maybe one or two may have said something about getting – that I need to look into it. These were red flags that they were bringing up to me. Some of them even addressed it in that way.” Hearing Transcript (“T.”) at 31.

{¶9} As a result of his surveillance of the pain clinic, Agent Gallagher learned that customers of the clinic were predominately going to two different pharmacies, one of them being Strasburg Pharmacy, which was a 20-minute drive north of PPMO, just off Interstate 77.

{¶10} Agent Gallagher testified that he went to Strasburg Pharmacy on December 1, 2003 to gather prescription data on prescriptions from PPMO. When he arrived, approximately 20 PPMO patients were waiting in line for prescriptions. He

found on the front counter area numerous bottles of pre-packaged hydrocodone 10mg (also known as Lortab or Lorcet), an opioid derivative pain reliever, and carisoprodol 350mg (also known as Soma or Vicodin), a muscle relaxer, and “an incredible large stock supply” of the drugs. T. at 46, State’s Exhibit 6. He discovered that the pharmacy had filled quite a few of the PPMO prescriptions, and had created pre-printed prescription blanks in order to make it quicker to dispense PPMO drug orders that were being telephoned in by PPMO doctors. T. at 58.

{¶11} Upon reviewing the pharmacy records, Agent Gallagher testified that there were upward of 1,800 PPMO patients that received prescriptions from Strasburg Pharmacy. He discovered that the vast majority of patients were coming from Kentucky (1700 patients) and West Virginia (88 patients) and traveling 8 to 12 hours round-trip for their prescriptions. Appellees began filling PPMO prescriptions in March with 31 prescriptions and increasing each month thereafter to 3,308 prescriptions in October. In less than nine months, the pharmacy had dispensed in excess of 900,000 doses of hydrocodone 10mg and in excess of 400,000 carisoprodol 350mg doses.

{¶12} Exhibit 21, which was compiled from data from the Drug Enforcement Administration, showed that, in 2003, Strasburg Pharmacy was the largest retail purchaser of hydrocodone 10mg tablets in the State of Ohio, with 984,600 dosage products.

{¶13} Agent Gallagher testified that the total profit after wholesale costs made by the pharmacy to be in excess of \$380,000 for the hydrocodone and carisoprodol prescriptions. T. at 65.

{¶14} When asked why the citation issued to Appellees only contained approximately 730 patients, Agent Gallagher responded as follows:

{¶15} “THE WITNESS: I was asked to use the profiles of individuals that met a duration of therapy that’s talked about as being beyond, or for a period of time of 12 weeks; that is talked about in the Medical Board’s Intractable Pain Rule.” T. at 62.<sup>2</sup>

{¶16} Agent Gallagher was questioned about the four different pharmacies that contacted him in February of 2003 with concerns about PPMO. Notarized written statements from the area pharmacists were admitted as State’s Exhibits 2, 3, 4 and 5. Ted Nussbaum with Discount Drug Mart, in his statement (Exhibit 2) stated that he had concerns over numerous patients asking for specific color or tablets Discount Drug had and stated that he “felt this was a sure sign of problems because drug seekers or sellers usually know what they are looking for.” He also voiced concerns over the fact that the patients were coming a long way. Nussbaum stated that he told Dr. DeHaas that he would have to handwrite his prescriptions in the proper format rather than call them in and that Dr. DeHaas gave him a hard time.

{¶17} Brad White, a pharmacist with the Medicine Shoppe, stated in his notarized statement (Exhibit 3) that he was concerned that all of PPMO patients were receiving the exact same drugs in the same strength and under the same directions; that they were from out of state and that he was repeatedly asked by patients for the

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<sup>2</sup> By way of background, intractable or chronic pain is defined as “a state of pain that is determined, after reasonable medical efforts have been made to relieve the pain or cure its cause, to have a cause for which no treatment or cure is possible or for which none has been found. R.C. 4731.052(A). The state medical board has established standards and procedures to be followed by physicians in the diagnosis and treatment of intractable pain, including standards for prescribing dangerous drugs in amounts and combinations that may not be appropriate when treating other medical conditions. R.C. 4731.052(B). These standards are more fully discussed later in this Opinion.

“blues.” He also noted that he observed more than one patient arrive in the same car. The Medicine Shoppe only filled 15 prescriptions before refusing to fill any more.

{¶18} Janine O’Neill, also a pharmacist with the Medicine Shoppe, stated in her notarized statement (Exhibit 4) that shortly after she began filling PPMO prescriptions she noticed that two of Dr. DeHaas’s patients were from Kentucky and rode together in the same car and getting the same two medications filled (Lorocet and Soma). She stated: “This is when I expressed to Brad (pharmacy mgr) that something isn’t right and did not feel comfortable filling his prescriptions. Then more prescriptions came in from patients with KY addresses and that was it for me. Brad called the Board with his concerns and we stopped filling his prescriptions.”

{¶19} Dana Coutts, a pharmacist at Wal-Mart, was the first pharmacist to contact Agent Gallagher in February, 2003. Her concerns were detailed in a notarized statement to the Board (Exhibit 5) and Agent Gallagher summarized those as follows:

{¶20} “THE WITNESS: One of the things that stood with her was that they were frequently calling the doctor’s office to try and get diagnoses and understand what was causing the doctor’s office to prescribe these drugs for these individual patients. She stated that they were also getting, as detailed as possible, patient histories and, as a result, the patients were getting very upset that they were being questioned and talked to, or asked any questions. And she also stated that she had argued with Dr. DeHaas (sic) on the telephone. \* \* \* She did talk early on, in February, about the patients coming in groups, primarily the same type of red-flag complaints. The one that stood out at the time to me was she – her contact, just like Pharmacist Nussbaum, that they

had contacted the Doctor and run into a less than – a situation where the Doctor didn't want to listen to them.”

{¶21} Gallagher also established that although the Board has compliance agents who review pharmacists' records, drug storage, and files, these agents are not pharmacists<sup>3</sup> and therefore lack the power to decide whether there is a legitimate purpose for a given prescription. T. at 148, 151-152. Accordingly, the Board relies upon voluntary compliance from pharmacists.

{¶22} Appellee Dennis was interviewed by the Board's compliance agents at the Strasburg Pharmacy on December 1, 2003 and the interview was audio taped, transcribed and admitted as State's Exhibit 11. Pursuant to R.C. 4729.19, a pharmacist “shall cooperate with federal, state, and local government investigations and shall divulge all information when requested by a government agency.” During his interview, Dennis indicated that all the pre-packaged Lorcet and Soma was for Dr. DeHaas's patients and that was done to get PPMO patients, who seemed to come in a “surge,” out of the store quicker because they were shoplifting. Dennis Transcript (“D.T.”) at 22-23. Dennis also stated he was raising the prices on PPMO prescriptions by \$10 to \$20 to “get some of them not to come here” and provided written notice of the price increases to the customers on November 1st. D.T. at 23-24, 41. He noted the majority paid cash and since none of the PPMO patients ever had any questions about their prescriptions, the pharmacists did not offer to counsel them. Furthermore, Dennis stated that if a patient refuses counseling, the store failed to document it, which Dennis recognized was a legal requirement. Almost all PPMO customers used generic, as

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<sup>3</sup> Agent Gallagher has been employed as a Board compliance agent for 14 years and formerly was a police officer for Jackson Township, Stark County for 9 years.



opposed to name brand, and knew and requested certain color pills such as blue and green, which Dennis noted on the patient prescription and profile. D.T. at 37-38.

{¶23} Dennis stated he did research into pain management and felt that Dr. DeHaas's treatment followed the Medical Board's preference for treatment of intractable pain, which he understood to be pain that can't be cured and which may not have a specific cause. D.T. at 43-44. However, he did not consider PPMO customers to be intractable pain patients. Id. He further stated that 100% of Dr. DeHaas's patients received either hydrocodone or Soma or both and that these customers accounted for approximately 50% of the pharmacy's prescriptions prior to the notice of the price increase. He noted it was "odd" that a single person would pay for two or three people's prescriptions and asked Dr. DeHaas about it, who explained that these patients have a "handler." He stated it was very rare for other doctors to write prescriptions for Lorcet or Soma. D.T. at 77. Dennis stated that the pain treatment regime by Dr. DeHaas was all the same, only the doses varied, he thought, according to the patient's size and their level of pain. D.T. at 80. He understood that these patients did not have much money and couldn't afford more expensive medicine and got the feeling that Dr. DeHaas was trying to keep the price affordable with using something he thought would work.

{¶24} Furthermore, Dennis stated he had not experienced other pain management centers prescribing all the same drug nor had he ever worked at a pharmacy where he prepared vials of prescription drugs beforehand. D.T. at 103-104. He also told the investigators that Froman, who worked about 26 hours a week at the pharmacy, did not indicate to him that she had any major concerns or problems with filling PPMO prescriptions. D.T. at 121.

{¶25} At the hearing, Agent Gallagher testified that he also spoke with Froman on December 4, 2003 and audiotaped the interview, which was transcribed and admitted at the hearing. State's Exhibit 12. Froman stated that Dr. DeHaas visited the pharmacy and others to get the lowest price for his poor patients and subsequently told her the pharmacy was the lowest. However, she revealed that the mark-up charged to PPMO patients was "quite gouging," for example the markup for Soma was \$26.50, compared to the store's usual \$10 over cost, and she "wouldn't do that to my normal customers." Froman Transcript at 14-18.

{¶26} PPMO was closed down on December 16, 2003, after the execution of a search warrant.

{¶27} At the Board's administrative hearing, Robert Kubasak, a registered pharmacist with the State of Ohio who owns two pharmacies, testified as an expert on behalf of the State. He testified that has been a licensed pharmacist since 1973 and was qualified as an expert in the area of pharmacy. Kubasak testified that he was asked by the Board to review records and material involving Strasburg Pharmacy and Appellees. He testified that he was given a printout of all the prescriptions for the year 2003 as well as patient profiles.

{¶28} According to Kubasak, pharmacists are not required to fill the prescriptions submitted to them. T. at 305. Rather, they must determine whether a prescription should be filled in light of any contraindications for the drug and whether there is a legitimate medical purpose for its use. Id. at 292, 305. The "corresponding responsibility" is discussed in various newsletters issued by the Board that set forth dispensing guidelines to assist pharmacists in exercising their professional judgment as

to whether a prescription should be filled. Moreover, absent a legitimate medical reason for its use, a prescription is a “false” prescription and a pharmacist dispensing such a purported prescription is subject to the penalties of law. See, OAC 4729-5-30.

{¶29} The regulatory scheme reflects that pharmacists are the last safety check before a drug reaches a customer, and they therefore have the ultimate responsibility in determining that there is a legitimate purpose for the medication. Specifically, Kubasak discussed patients being treated for intractable pain. He discussed the State Medical Board regulation, OAC 1731-21-02, which governs the utilization of prescription drugs for the treatment of intractable pain. The regulation requires an individualized treatment plan with prescription drug therapy plan “tailored to the individual medical needs of each patient.” Id. He also stated a pharmacist would know that the intractable pain regulation requires an individualized treatment plan. T. at 291. Kubasak opined that PPMO was not in compliance with this regulation because 80 to 90 percent of PPMO patients were receiving the exact same medications for long-term use and the dosages were escalating, not decreasing. T. at 289-290.

{¶30} Kubasak further explained that a pharmacist must follow OAC regulations which requires a pharmacist to: (1) obtain patient data and drug therapy record for a patient profile, OAC 1729-5-18; (2) review that patient profile prior to dispensing any prescription for the purpose of identifying over-utilization or abuse/misuse, OAC 1729-5-20; and (3) personally offer to provide the service of counseling for any prescription, new or refill, and when counseling is refused, the pharmacists shall ensure the refusal is documented in the patient’s or caregiver’s presence, OAC 1729-5-22.

{¶31} In this case, Kubasak opined the Appellees failed to exercise their professional judgment as follows:

{¶32} “The sheer volume of numbers; the patients traveling long distances, everybody getting the same medication. Unbelievable that everybody would get the same medication. Patients paying for it with large dollar amounts; handlers coming in, people coming in to handle them or bring them into the pharmacy. Again, the distances are just, that bothers me immensely.” T. at 306.

{¶33} He further stated:

{¶34} “My conclusion was that they both, Froman and Pharmacist Dennis, not only deviated from acceptable standards of practice, but that they continuously and repeatedly did so by continuing to dispense the prescriptions on a daily basis to Dr. DeHaas. If there’s any kind of professional judgment, if there’s any kind of professional judgment, if they had thought of anything or even looked at this, it would have lead any reasonable pharmacist to conclude that these were not for a legitimate medical purpose. And that they should have questioned every prescription that came in. I think they both failed to fulfill their Corresponding Responsibility as pharmacists. And as far as that goes, they totally failed to do it. That is my opinion. “ T. at 308.

{¶35} Both Dennis and Froman testified at the hearing that they never refused to fill any PPMO prescriptions because Dr. DeHaas was a licensed physician in good standing and it appeared to them that his treatment was consistent with the intractable pain rule based upon information provided by Dr. DeHaas. Dennis further testified that the store profits from PPMO business went to pay down his business and personal

loans, and purchase store stock. Appellees did not present any expert testimony on their behalf.

{¶36} Pursuant to separate Orders mailed on January 11, 2007, the Board revoked the terminal distributor license of Strasburg Pharmacy, but suspended the revocation provided there are no similar violations within the next year; permanently revoked Dennis' pharmacist license and suspended Froman's pharmacist license for a period of three years.

{¶37} In the Orders, the Board stated, in relevant part, as follows:

{¶38} "The Board is cognizant that both rule 4729-5-21 (formerly embodied in rule 4729-5-30) of the Ohio Administrative Code and Section 1306.04 of Title 21 of the Code of Federal Regulations state that a pharmacist has a corresponding responsibility with the prescriber to ensure that a prescription is issued for a legitimate medical purpose by a licensed prescriber in the usual course of professional practice. This is axiomatic in the pharmacy profession. This means that a pharmacist must review every prescription for legitimacy and must then make a professional judgment on whether or not to fill the prescription. Every pharmacist is accountable to this Board and to society for what he knew or should have known due to professional training, experience, licensure, and continuing pharmacy education in pharmacy law. Obviously, the dispensing pharmacist need not review the prescriber's patient chart; rather, the required judgment to be exercised must be based upon the pharmacist's extensive knowledge and training in drug therapy, the pharmacist's knowledge of the patient (obtained through profile information required by rule 4729-5-18 of the Ohio Administrative Code, a review of that profile as required by rule 4729-5-20 of the Ohio

Administrative Code, and other discussions with the patient pursuant to rule 4729-5-22 of the Ohio Administrative Code), and the pharmacist's knowledge of the prescriber's practice, particularly as it elates to other similar practices in the region.

{¶39} “This pharmacist shirked [his/her] responsibilities in this regard, ignoring numerous obvious indicators of illegal prescribing activity on the part of the physicians involved in this case. Some of these indicators include the large numbers of patients who drove very long distances to come to these physicians and this pharmacy and the almost identical treatment of a problem (pain) that requires individualization for treatment dosages and drugs more than any other health-related problem. Individualized treatment for pain is required in all aspects of health care and is specifically stated in rule 4731-21-02 of the [OAC], yet was clearly ignored by this pharmacist. Moreover, it is significant that practically all of the patients from these prescribers paid cash for their prescriptions instead of using insurance as is usually the case for the overwhelming percentage of prescriptions filled today. It is clear that this pharmacist consciously ignored his obligations to the patients simply for monetary gain.”

{¶40} Strasburg Pharmacy (Common Pleas Case No. 2007 AA 01 0041), Dennis (Common Pleas Court Case No. 2007 AA 01 0042) and Froman (Common Pleas Case No. 2007 AA 01 0055) then appealed to the Tuscarawas County Court of Common Pleas. Pursuant to judgment entries, filed on September 4, 2008, the trial court reversed and vacated the Board's Orders in each case, finding that they were not supported by reliable, probative and substantial evidence.

{¶41} The Board timely appealed all cases, and raises the same assignments of error in each case:

{¶42} “I. THE LOWER COURT ERRED WHEN IT FOUND THAT THE BOARD’S ORDER WAS NOT BASED UPON RELIABLE, PROBATIVE AND SUBSTANTIAL EVIDENCE. THE COURT FAILED TO GIVE DUE DEFERENCE TO THE BOARD’S FINDINGS AND CONCLUSIONS.

{¶43} “II. CONSIDERATION BY THE LOWER COURT OF WHETHER OTHER PHARMACIES OR PHARMACISTS WERE ISSUED ADMINISTRATIVE CITATIONS BY THE BOARD WAS PREJUDICIAL AND AN ABUSE OF DISCRETION. APPELLANT’S FOURTEENTH AMENDMENT RIGHTS WERE NOT VIOLATED. (TRIAL COURT’S JUDGMENT ENTRY, SEPTEMBER 4, 2008, P. 9).

{¶44} “III. THE LOWER COURT ERRED AND ABUSED ITS DISCRETION IN FINDING THE TESTIMONY OF THE EXPERT WITNESS DID NOT CONSTITUTE RELIABLE, PROBATIVE AND SUBSTANTIAL EVIDENCE. (TRIAL COURT’S JUDGMENT ENTRY, SEPTEMBER 4, 2008 P. 10).

{¶45} “IV. THE LOWER COURT ABUSED ITS DISCRETION IN FAILING TO FAIRLY CONSIDER THE FACTUAL AND EVIDENTIARY CONCLUSIONS OF THE BOARD, AS INDICATED BY THE LANGUAGE AND STATEMENTS USED AS ITS JUDGMENT ENTRY OF SEPTEMBER 4, 2008. (TRIAL COURT’S JUDGMENT ENTRY, SEPTEMBER 4, 2008, P. 1-13).”

I, III

{¶46} The Board’s first and third assignments of error present interrelated issues and will be addressed together.

{¶47} In the first and third assignments of error, the Board argues that the trial court erred when it found that the Orders were not based upon reliable, probative and

substantial evidence. Specifically, the Board asserts the trial court erred in finding the testimony of Gallagher and Kubasak was not reliable, probative or substantial. We agree.

{¶48} In *Clay v. Licking Cty. Prosecutor*, 5th Dist. No. 02CA00011, 2002-Ohio-4243, we stated in relevant part as follows: “In an administrative appeal pursuant to R.C. 119.12, the trial court reviews an order to determine whether it is supported by reliable, probative and substantial evidence and is in accordance with the law. 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.

{¶49} “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. 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.

{¶50} The Board, in revoking Dennis’ license and suspending Froman’s license, concluded that the pharmacists were guilty of gross immorality as provided in R.C. 4729.16(A)(1), of unprofessional conduct in violation of R.C. 4729.16(A)(2), and of willfully violating, conspiring to violate, attempting to violate, or aiding and abetting the violation of provisions of Chapters 2925 [drug offense] and 3719 [controlled substances] of the Revised Code in violation of R.C. 4729.16(A)(5).

{¶51} For ease of discussion, this Court will simultaneously address the evidence pertaining to all transgressions allegedly committed by Appellees under each of the above divisions of R.C. 4729.16(A).

{¶52} There is sparse Ohio case law regarding the scope of a pharmacist’s “corresponding responsibility” to properly dispense prescription medicine; however, federal courts have developed substantial case law in the context of criminal prosecutions under the federal Controlled Substances Act, 21 USC 841, and implementing regulations, including 21 CFR 1306.04 which is virtually identical to the mandate of OAC 4729-5-30(A) and governs all pharmacists licensed in Ohio.

{¶53} OAC 4729-5-30(A) states, in relevant part: “A prescription, to be valid, must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of his/her professional practice. The responsibility for the proper prescribing is upon the prescriber, but a corresponding responsibility rests with the

pharmacist who dispenses the prescription. An order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties of law." (Emphasis added).

{¶54} In two recent cases decided by the U.S. Court of Appeals for the Fifth Circuit, the court noted that hydrocodone and carisoprodol have a high abuse potential and a high illegal street market value, and are dispensed by "pain management" clinics, some of which operate within the bounds of the law and serve a valuable medical purpose, but "others flood the streets with dangerous, addictive narcotics while preserving some trappings of lawful medical practice." *U.S. v. Brown*, 553 F.3d 768, 773 (5th Cir. 2008); *U.S. v. Armstrong*, 550 F.3d 382, 386 (5th Cir. 2008). In both cases, the convictions of pharmacists, pharmacies and doctors for violations of the federal Controlled Substances Act were upheld when these drugs were not prescribed legitimately at pain management clinics.<sup>4</sup>

{¶55} In addition, the U.S. Court of Appeals for the Sixth Circuit recently discussed the meaning of "corresponding responsibility" as set forth in 21 C.F.R. 1306.04(A), as follows: "The regulation thus requires 'pharmacists [to] use common sense judgment,' which includes paying attention to the 'number of prescriptions issued, the number of dosage units prescribed, the duration and pattern of the alleged treatment,' the number of doctors writing prescriptions and whether the drugs prescribed have a high rate of abuse. *Ralph J. Bertolino Pharmacy, Inc.*, 55 Fed.Reg. 4, 729, 4,730 (DEA Feb.9, 1990). 'When [pharmacists'] suspicions are aroused as

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<sup>4</sup> Likewise, Dr. DeHaas was indicted for federal drug offenses, pled guilty and was imprisoned.

reasonable professionals,' they must at least verify the prescription's propriety, and if not satisfied by the answer they must 'refuse to dispense.' *Id.* see also, *United States v. Henry*, 727 F.2d 1373, 1378-79 (5th Cir. 1984)." *Medicine Shoppe-Jonesborough v. DEA*, 300 Fed. Appx. 409, 412, 2008 WL 4899525 (C.A.6).

{¶56} Based on the foregoing, we find that the trial court abused its discretion in reversing and vacating the Board's Orders with respect to Appellees based on the volume of evidence presented at the Board hearing that Appellees ignored the red flags that were waving in front of them -- the same red flags that caused other pharmacists to voluntarily cease dealing with PPMO. Newsletters issued by the Board to its pharmacists discussed the "corresponding responsibility" of a pharmacist and the factors to consider in determining whether a prescription was legal: whether the patient resided within the area, whether significant numbers of persons appeared with prescriptions for the same drugs from the same prescribers, and whether the pharmacy's purchases of controlled substances increased dramatically.

{¶57} As is discussed in detail above, there was testimony that Appellees were aware that large numbers of PPMO patients were traveling long distances from as far away as Kentucky and West Virginia. Testimony also was adduced that the patients, regardless of age, etc., primarily received the same two medications and paid in cash, which was highly unusual. The pharmacists also admitted that PPMO patients asked for specific colors of pills. In addition, testimony was adduced at the hearing as to the dramatic increases in the number of monthly PPMO prescriptions.

{¶58} Expert testimony indicated the pharmacists abdicated their professional responsibility by indiscriminately selling the same controlled substances to people again

and again, at a significantly increasing rate, and in cash. The volume of prescriptions filled for a single medical practice, as well as the prices charged by Appellees, support the Board's conclusions that Appellees knew that the prescriptions were not issued for a legitimate medical purpose.<sup>5</sup> One of the reasons for requiring that a pharmacist not dispense controlled substances for other than a medical purpose is to place the responsibility upon the trained professional, rather than the layperson, to prevent abuse and potential for drug trafficking.

{¶59} We find the trial court's decision was arbitrary, unconscionable and unreasonable in view of the totality of evidence and in according proper respect for the expertise of the Board.

{¶60} The first and third assignments of error are sustained.

## II.

{¶61} In its second assignment of error, the Board contends the trial court abused its discretion by inferring in its decision that Agent Gallagher and the Board selectively prosecuted Appellees.

{¶62} In this regard, the trial court indicated Agent Gallagher's "testimony fails to explain why, if none of the prescriptions were legitimate, did he select *some* of the

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<sup>5</sup> Courts that have addressed the issue have indicated that medical testimony is not necessary to establish a prescription is issued outside the usual course of professional treatment. See, *U.S. v. Lovern*, -- F.3d ---, 2009 WL 2871538 (10th Cir. 2009)(upholding conviction of pharmacist based upon testimony of other pharmacists and DEA investigator because, given a pharmacist's legal duty not to knowingly fill prescriptions issued outside the usual course of medical practice under 21 C.F.R. 1306.04(A), "it does not strain the imagination to think that some pharmacists might know and be qualified to speak about what it means for a prescription to be consistent or inconsistent with the usual course of medical practice.")

See also, *Armstrong*, supra at 388-389; *U.S. v. Hayes*, 595 F.2d 258, 261, n.6 (5th Cir. 1979) ("the facts of this case show how a pharmacist can know the prescriptions are issued for no legitimate medical purpose without his needing to know anything about medical science."(5th Cir. 1979); *Jones v. State* (1985), 684 S.W.2d 223, 225, citing *Hayes*; *Sloman v. Board of Pharmacy Examiners of the State of Iowa*, (1989) 440 N.W.2d 609, citing *Hayes* and *Jones*; *State of Ohio v. Moss*, 8th Dist. Nos. 623318, 62322 (May 13, 1993), citing *Hayes*.

pharmacists in his territory for prosecution, but *not all* of the pharmacists who filled those prescriptions during the same time frame.”

{¶63} It appears to this Court that the lower court believed Agent Gallagher’s testimony was not reliable or probative because he did not issue administrative citations to each and every pharmacist who filled PPMO prescriptions, albeit at an extremely lower volume than Appellees.

{¶64} "To support a defense of selective or discriminatory prosecution, a defendant bears the heavy burden of establishing, at least prima facie, (1) that, while others similarly situated have not generally been proceeded against because of conduct of the type forming the basis of the charge against him, he has been singled out for prosecution, and (2) that the government's discriminatory selection of him for prosecution has been invidious or in bad faith, i.e., based upon such impermissible considerations as race, religion, or the desire to prevent his exercise of constitutional rights." *W. Chester Twp. Bd. of Trustees v. Speedway Superamerica, LLC*, 12th Dist. No. CA2006-05-104, 2007-Ohio-2844, ¶50, citing *State v. Flynt* (1980) 63 Ohio St.2d 132, 134.

{¶65} As stated earlier, it was the sheer volume of illegitimate prescriptions written by Appellees that formed the basis of underlying administrative action. There is no evidence in the record that a pharmacy or pharmacists doing a comparable amount of PPMO business were excluded from enforcement action by the Board.<sup>6</sup> Therefore,

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<sup>6</sup> This Court also presided over the administrative appeals concerning Board citations issued to two pharmacists, Scott Vinci and Connie Campbell at Dusini Drug, another Tuscarwaras County pharmacy. Similar to the case sub judice, the Board also took action to suspend the licensure of the pharmacists based upon similar allegations involving PPMO prescriptions. About 1,581 PPMO patients filled prescriptions at Dusini Drug during the same 10 month period, similar in volume to Appellees. *Vinci v. Ohio State Pharmacy Board*, Case No. 2008 AP 08 0052; *Campbell v. Ohio State Pharmacy Board*, Case No. 2008 AP 08 0053.

we find it was in error for the trial court to consider the testimony of Agent Gallagher unreliable or not probative on the basis of selective enforcement.

{¶66} The second assignment of error is sustained.

#### IV.

{¶67} The Board, in its fourth assignment of error, argues that the trial court abused its discretion in failing to “fairly consider” the factual findings and conclusions of the Board. It asserts that the language used by the trial court in its decisions show that the decisions were based upon passion, prejudice and partiality. The Board also contends the trial court presented a “very one-sided and slanted view of the facts and testimony presented to the Board” and failed to acknowledge the vast amount of evidence against Appellees.

{¶68} Based upon our disposition of the other assignments of error, we find such assignment of error to be moot.

{¶69} The judgment of the Tuscarawas County Court of Common Pleas is reversed and we reinstate the Decisions and Orders of the Board issued against Appellees.

By: Delaney, J.

Gwin, P.J. and

Edwards, J. concur.

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HON. PATRICIA A. DELANEY

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HON. W. SCOTT GWIN

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HON. JULIE A. EDWARDS

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

|                              |   |   |
|------------------------------|---|---|
| SCP, INC. dba STRASBURG      | : |   |
| PHARMACY,                    | : |   |
| And                          | : |   |
| MICHAEL T. DENNIS, R. PH.,   | : |   |
| And                          | : |   |
| AMY LYNN FROMAN, R. PH.,     | : |   |
|                              | : | JUDGMENT ENTRY  |
| Plaintiffs-Appellees         | : |   |
| -vs-                         | : |   |
|                              | : |   |
| OHIO STATE BOARD OF PHARMACY | : |   |
|                              | : |   |
| Defendant-Appellant          | : | Case Nos. 2008 AP 10 0063,<br>2008 AP 10 0064 and 2008 AP 10 0065 |

For the reasons stated in our accompanying Memorandum-Opinion on file, the judgment of the Tuscarawas County Court of Common Pleas is reversed and the Board's Decisions and Orders are reinstated. Costs assessed to Appellees.

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HON. PATRICIA A. DELANEY

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HON. W. SCOTT GWIN

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HON. JULIE A. EDWARDS