

**COURT OF COMMON PLEAS, FRANKLIN COUNTY, OHIO
CIVIL DIVISION**

Douglas B. Karel, M.D. :
Appellant, : **CASE NO. 11CVF 07 9151**
-vs- : **JUDGE RICHARD SHEWARD**
State Medical Board of Ohio, :
Appellee. :

DECISION AND ENTRY

SHEWARD, JUDGE,

This matter comes before this Court upon an appeal pursuant to R.C. § 119.12 from a July 13, 2011 Order of the State Medical Board of Ohio (hereinafter the “Board”). The Board approved the Proposed Order of the Hearing Officer permanently revoking appellant’s license to practice medicine. See July 13, 2011 Entry of Order. The record certified by the Board can be summarized as follows:

On March 9, 2011 the Board issued to appellant a *Notice of Opportunity for Hearing and Notice of Immediate Suspension* proposing to take action against his Ohio medical license. The Board notified the appellant that it intended to determine whether to take disciplinary action against his certificate based on allegations that included:

From around November 2007 through March 2011, Dr. Karel undertook the care of 16 patients identified on a confidential Patient Key to whom he prescribed controlled substances and other drugs of abuse;

a comparison of alleged aspects of Dr. Karel’s practice with a “constellation of certain criteria and conduct” of “pill mill” facilities as described in the Final Report of the Ohio Prescription Drug Abuse Task Force demonstrates that many apply to his medical practice;

Dr. Karel treated patients with controlled substances who have been convicted or arrested for drug-related crimes or other criminal offenses;

information provided by a *locum tenens* physician concerning her observations of the office where Dr. Karel practiced;

allegations that he had refused to answer a Board investigator's questions after having cooperated initially;

Dr. Karel had altered the medical records for one patient;

Dr. Karel lives in northern Ohio but works in southern Ohio;

Dr. Karel has no hospital privileges or malpractice insurance;

Dr. Karel has patients sign a statement that they are not seeking care as part of an investigation; and

many, if not most, area pharmacies will not honor his prescriptions for controlled substances.

The Board further alleged that Dr. Karel's acts, conduct and/or omissions constitute the following:

"[f]ailure to maintain minimal standards applicable to the selection or administration of drugs, or failure to employ acceptable scientific methods in the selection of drugs or other modalities for treatment of disease, "as those clauses are used in Section 4731.22(B)(2), Ohio Revised Code;

"[s]elling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes or a plea of guilty to, a judicial finding of guilt of, or a judicial finding of eligibility for intervention in lieu of conviction of, a violation of any federal or state law regulating the possession, distribution, or use of any drug," as those clauses are used in Section 4731.22(B)(3), Ohio Revised Code; and/or

"[c]ommission of an act that constitutes a felony in this state, regardless of the jurisdiction in which the act was committed," as that clause is used in Section 4731.22(B)(10), Ohio Revised Code, to wit: Section 2921.12, Ohio Revised Code, Tampering with Evidence.

See June 16, 2011 Report and Recommendation; see also R.C. 4731.22(B)(2), (B)(3), and (B)(10).

The record establishes that on March 11, 2004, the appellant entered into a Probationary Consent Agreement with the Board based upon his violation of R.C. 4731.22(B)(18). In 2002 and again in 2003, the appellant submitted to psychiatric evaluations which each concluded that he did

not suffer from a mental illness. In the consent agreement, Dr. Karel was reprimanded and placed on probation for at least one year with requirements that included continued cognitive behavioral therapy. On February 11, 2005, the Board released the appellant from probation. See June 16, Report and Recommendation; see also State's Exhibit 36.

In his June 16, 2011 Report and Recommendation the hearing examiner made the following

FINDINGS OF FACT:

1(a) From 1996 through 2005 or 2006, Douglas B. Karel, M.D. practiced neurology in Lima, Ohio. In 2005 or 2006, after a job opportunity in another state fell through, Dr. Karel found himself without a position. As a result, he worked as a *locum tenens* physician and practiced one day a week at a pain management practice in Waverly, Ohio. In 2007, he left the practice in Waverly and began working full-time at a pain management practice in South Point, Ohio. Shortly thereafter, the practice moved to Wheelersburg, Ohio, which is located in Scioto County. Dr. Karel continued to practice pain management in Wheelersburg until his license was summarily suspended by the Board on March 9, 2011.

1(b) From about November 2007 until March 2011, Dr. Karel undertook the care of Patients 1 through 16, identified on a Confidential Patient Key, to whom he prescribed controlled substances and/or drugs of abuse in the course of his medical practice.¹

1(c) The State presented convincing evidence that Dr. Karel inappropriately prescribed large amounts of controlled substances to Patients 3,4,5,7,8,9,12,14, 15, and 16 in a manner that was below the minimal standard of care applicable to the selection of drugs and/or without a legitimate medical purpose. Examples of such conduct include the following: failure to perform or document performing adequate diagnostic work-ups with respect to patients' pain complaints, a lack of individualized treatment planning to treat patients suffering from various pain complaints, and failure to or document performing adequate patient histories and physical examinations to the extent that patients' safety was put at risk. Moreover, in the case of Patient 9, an employee, and Patient 16, Dr. Karel issued prescriptions for controlled substances without documenting those prescriptions in the patients' charts. Furthermore, Dr. Karel admitted during his testimony that a former practice where he worked from 2007 through May 2009 "is a true pill mill." His efforts to backtrack from that comment were unconvincing. Finally, Dr. Karel prescribed large amounts of narcotics to one patient, Patient 5, who was two weeks late for his visit, and documented nothing concerning withdrawal symptoms or possible lack of need for such medication.

Dr. Karel noted that he performs frequent pill counts and urine drug screens on his patients. However, the evidence showed, with respect to urine drug screens, that when the screens failed to match the medications being prescribed in the cases Patient 9 and Patient 12, nothing was done.

¹ Patients 1, 3, 9 and 10 are the appellant's entire office staff and thus, his employees. See Tr. 56-58, see also State's Exhibits 19 and 35.

Moreover, with respect to urine to pill counts, in the case of Patient 6, which concerns only Dr. Karel's former practice at the Medical Office, misinformation was included on the progress notes concerning the pharmacy where Patient 6 filled his prescriptions.

Dr. Karel also offered evidence that he refuses to accept about one-third of the patients who come to him due to problems with those patients, and dismisses about one-third of the patients he sees once he discovers they are problematic. It is good that Dr. Karel does that, but Dr. Parran offered persuasive testimony that there is also a downside to that situation. The numbers mean that about 50 percent of the patients who come to Dr. Karel's practice are addicts. Dr. Parran testified that addicts talk with each other and "flock" to a practice that prescribes large amounts of controlled substances with relatively little evaluation.

2. On October, 1, 2010, the Ohio Prescription Drug Abuse Task Force, which was established to address Ohio's prescription drug abuse epidemic, issued its Final Report to the Governor. The Taskforce Report identified a set of criteria that characterize "pill mill" facilities, often disguised as independent pain-management centers, some of which apply to Dr. Karel's practice:

- (a) The Task Force Report states that the highest annual average death rates due to unintentional drug overdose occurred primarily in the state's southern region, which includes Scioto county, causing the city and county health commissioners in Scioto County to declare a public health emergency in January 2010. Dr. Karel's practice is located in Scioto County.
- (b) The Task Force Report states that "pill mills" open and shut down quickly in order to evade law enforcement. Dr. Karel has had three different practice locations since commencing practice in Scioto County 2007. He moved June 2009 when he left one practice, moved from another practice in June or July 2009 after being locked out of the building, and moved again approximately ten months later when better office space became available. All of these moves took place in Wheelersburg, a small community of 7000 residents. Accordingly, the evidence is insufficient to support a finding that Dr. Karel had moved "in order to evade law enforcement." Dr. Karel provided explanations for each move that rebut that allegation.
- (c) The Task Force Report states that "pill mills" do not accept insurance and operate as cash-only businesses. Dr. Karel does not accept private insurance, Medicaid or Medicare, and only accepts cash at his practice, usually charging \$200 per visit.
- (d) The Task Force Report states that "pill mills" treat pain with prescription medications only. Dr. Karel treats his patients with controlled substance medication, and he does not offer other treatments modalities such as trigger point injections. In fact, during a February 15, 2011, interview with Board investigators, when asked what percentage of his patients receive a prescription for controlled substances, Dr. Karel answered, "They all do."

Additionally, Dr. Karel has four employees at his practice, and he prescribes controlled substances to all of them.

- (e) The Task Force Report states that "Pill mills" have the presence of security guards. Dr.

Karel has a male employee, identified as Patient 1, whose job includes working as a security guard. Dr. Karel told board investigators that this employee carries a TASER [stun gun] in the office, but later testified that was not correct, that the employee carries pepper spray.

- (f) Further, Dr. Karel prescribes controlled substances to Patient 1, including OxyContin, Oxycodone, and Alprazolam. Notably, Patient 1 has the following criminal history:
- (i) On November 16, 1990, in the Scioto County Common Pleas Court, Patient 1 was found guilty of Burglary, an aggravated felony of the second degree, in violation of Section 2911.12(A), Ohio Revised Code, and was sentenced to five to fifteen years of incarceration, which was stayed, and Patient 1 was placed on five years probation. On June 23, 1993, after finding that Patient 1 had violated the conditions of his probation, the court revoked Patient 1's probation and sentenced him to five to fifteen years of incarceration.
 - (ii) On March 28, 1991, in the Portsmouth Municipal Court, Patient 1 was found guilty of two misdemeanor counts of Assault, in violation of Section 537.03, Codified Ordinances of Portsmouth, Ohio.
 - (iii) On December 21, 1993, Patient 1 was found guilty in the Scioto County Common Pleas Court, Ohio, of felony Escape, in violation of Sections 2921.34(A) and (C)(2)(b), Ohio Revised Code, and was sentenced to, among other things, two to ten years of incarceration.
 - (iv) On February 24, 2005, in the Scioto County Common Pleas Court, Patient 1 was found guilty of felony Aggravated Trafficking in Drugs, to wit: OxyContin, in violation of Section 2925.03(C)(1)(a), Ohio Revised Code, and was sentenced to five years of community control. Subsequently, on December 17, 2009, the court found that Patient 1 had violated community control after testing positive for opiates, including Oxycodone and Methadone, and after being untruthful to police and probation officers regarding his prescriptions.
- (g) Although not specifically identified as a criterion in the Task Force Report, approximately 40 to 45 percent of Dr. Karel's patients come from out-of-state, primarily with complaints of lower back and neck pain. Because Wheelersburg is on the Ohio River close to the border with Kentucky, and is not far from West Virginia, it does not seem that unusual that he would have a number of patients who reside in those states.

3. In addition to Patient 1, other patients identified on the Confidential Patient Key who have received prescriptions for controlled substances (Patients 2, 7, 8, 11, 13, 14, and 15) have criminal arrests and/or convictions for illicit drug use, abuse and/or possession, or other criminal behavior; for example:

On January 6, 2009, in the Portsmouth Municipal Court, Patient 2 was found guilty of misdemeanor Possessing Drug Abuse Instruments, in violation of Section 2925.12, Ohio Revised Code.

On October 20, 2009, in the Scioto County Common Pleas Court, Patient 2 was charged with felony Aggravated Possession of Controlled Substances, to wit: OxyContin, in violation of Sections 2925.11(A) and (C)(1)(a), Ohio Revised Code. After failing to appear for a scheduled proceeding on that matter, a bench warrant was issued for Patient 2, and, on December 22, 2009, Patient 2 was charged with felony Failure to Appear, in violation of Sections 2937.29 and 2937.99, Ohio Revised Code.

Further, prescription records show that Dr. Karel has recently authorized the following prescriptions for controlled substances to Patient 2:

Date of Prescription	Medication	Quantity
11/24/10	Oxycodone 15 mg	90
11/24/10	Oxycodone 30 mg	120
11/24/10	Xanax 2 mg	30
11/24/10	OxyContin 80mg	90
12/23/10	Xanax 2 mg	30
12/23/10	Oxycodone 30mg	120
12/24/10	Oxycodone 20mg	70
12/24/10	OxyContin 40 mg	180
1/20/11	Xanax 2 mg	30
1/20/11	Oxycodone 30 mg	120
1/20/11	OxyContin 80 mg	90
1/27/11	Oxycodone 15mg	100

4. A *locum tenens* physician covered Dr. Karel's practice at the Medical Office from May 11, 2009, through June 11, 2009, during Dr. Karel's medical absence. This physician stated that she initiated a transfer request within three days of working at the Medical Office because it was "a drug mill," and expressed fear for her personal safety due to retaliation from the patients. This physician reported that all patients, including some who showed up from as far away as Florida, came to the practice with the expectation of receiving a prescription for narcotics. Further, after this physician began to discharge patients in response to inappropriate urine screen results, including presence of illicit drugs, she was admonished by the owner of the clinic, who is not a physician, for "ruining her business." Thereafter, this physician reported that Dr. Karel contacted her and informed her that he did not believe that marijuana in a patient's urine was significant and that she should probably not terminate patients from the pain practice because they tested positive for marijuana.

5. On February 15, 2011, Dr Karel was interviewed by Board investigators. Dr. Karel answered the investigators' questions at first. Partway through the interview, Dr. Karel stated that he needed to speak with an attorney. He left the room and made a telephone call. After speaking with his attorney, Dr. Karel returned and indicated that, on the advice of counsel, he would not answer any more questions. A Board investigator read Dr. Karel the remainder of the questions that they were going to ask him so that Dr. Karel could advise his attorney what they were looking for.

6(a) The evidence is insufficient to support a finding that, on or about March 31, 2010, during a

previous interview with a Board investigator, Dr. Karel informed the investigator that he did not obtain vital signs or listen to the heart/lungs of patients returning for the follow-up visits for back pain because it was unnecessary, and that medical charts subsequently subpoenaed from Dr. Karel by the Board contained this information. It seems very unlikely that Dr. Karel would have attempted to fool a Board investigator into thinking that Dr. Karel did **not** obtain vital signs or listen to the heart and lungs when, in fact, he really did, as evidence by the patient charts. The Hearing Examiner believes that this must have been a miscommunication.

6(b) During the March 31, 2010 interview, the medical chart for one of Dr. Karel's employees, Patient 3, was reviewed by Dr. Karel in the presence of a Board investigator, and appeared to the investigator to contain only about six or eight pages; nonetheless, when the chart was produced to the Board in response to a subpoena *duces tecum*, it consisted of approximately 77 pages, around 65 pages of which pre-date the March 31, 2010 interview. However, evidence was presented during the hearing that Dr. Karel had said something during the interview that gave the investigator the impression that the chart was incomplete, and that Dr. Karel gave the chart to an employee to find the missing information. Subsequently, after the file was returned to Dr. Karel, it was not reviewed again by either Dr. Karel or the investigator. Furthermore, State's Exhibit 3, which is a copy of Patient 3's chart, does not appear to have been a slim chart with numerous pages hastily created at the same time and added to it; rather, its contents appear to be legitimate.

6(c) Additionally, in between the time when Dr. Karel was served with a subpoena *duces tecum* on or about May 5, 2010, and the time he provided the patient record for Patient 3 on or about May 26, 2010, approximately seven pages of pharmacy profiles for Patient 3, all dated May 10, 2010, were added to Patient 3's medical chart.

7. The Board alleged that additional facts concerning Dr. Karel's practice situation are atypical from standard medical practice. The evidence is sufficient to find the following:

- (a) Although Dr. Karel works in southern Ohio, he continues to reside in northern Ohio, and maintains a second address in Wheelersburg close to his office.
- (b) Dr. Karel has no clinical privileges at any hospital.
- (c) Dr. Karel does not have malpractice insurance, and his patients sign a form stating that they have been informed of that fact.
- (d) Each of the patient charts presented at hearing for Patients 3,4,5,7,8,9,12,14,15, and 16 contains a prepared written statement, signed by the patient, stating, among other things, "I am not seeking care from Douglas B. Karel, M.D. as part of an ongoing investigation."
- (e) Dr. Karel acknowledged at hearing that many, if not most, pharmacies in his area will not honor prescriptions he issues for controlled substances.

In his June 16, 2011 Report and Recommendation, the hearing examiner set forth the following CONCLUSIONS OF LAW:

1. The acts, conduct, and/or omissions of Douglas B. Karel, M.D., as described in Findings of Fact 1(b), 1(c), 7(d), and 7(e), collectively constitute “[f]ailure to maintain minimal standards applicable to the selection or administration of drugs, or failure to employ acceptable scientific methods in the selection or administration of drugs, or failure to employ acceptable scientific methods in the selection of drugs or other modalities for treatment of disease,” as those clauses are used in Section 4731.22(B)(2), Ohio Revised Code.
2. Dr. Karel’s acts, conduct, and/or omissions as described in Findings of Fact 1(b), 1(c), 7(d), and 7(e), collectively constitute “[s]elling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes * * *,” as that clause is used in Section 4731.22(B)(3), Ohio Revised Code.
3. For the reasons set forth below, the evidence is insufficient to support a conclusion that Dr. Karel’s acts, conduct, and/or omissions as described in Findings of Fact 2 and 2(a) through 2(g), individually and/or collectively, constitute “[f]ailure to maintain minimal standards applicable to the selection or administration of drugs, or failure to employ acceptable scientific methods in the selection of drugs or other modalities for treatment of disease,” as those clauses are used in Section 4731.22(B)(2), Ohio Revised Code; and/or “[s]elling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes * * *,” as that clause is used in Section 4731.22(B)(3), Ohio Revised Code.

Finding of Fact 2 and its subparagraphs outline criteria that the Ohio Prescription Drug Abuse Task Force reported are commonly found in connection with “pill mills.” However, there is no evidence whether such criteria, individually or in combination, could apply to a legitimate medical practice. Moreover, some of the criteria, such as being located in Scioto County, are far too inclusive. It is though all physicians who practice in Scioto County have one strike against them. Accordingly, Finding of Fact 2 and its subparagraphs do not constitute violations of Sections 4731.22(B)(2) and/or (B)(3), Ohio Revised Code.

4. For the reasons set forth below, the evidence is insufficient to support a conclusion that Dr. Karel’s acts, conduct, and/or omissions as described in Findings of Fact 2(f), 2(f)(i) through 2(f)(iv), and 3, individually and/or collectively, constitute “[f]ailure to maintain minimal standards applicable to the selection or administration of drugs, or failure to employ acceptable scientific methods in the selection of drugs or other modalities for treatment of disease,” as those clauses are used in Section 4731.22(B)(2), Ohio Revised Code; and/or “[s]elling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes * * *,” as that clause is used in Section 4731.22(B)(3), Ohio Revised Code.

These Findings of Fact concern Dr. Karel's prescribing of controlled substances to patients with criminal records. Some of the patients named in Finding of Fact 3 had committed very minor offenses. To conclude that these findings violate the Ohio Medical Practices Act as alleged would place a burden on all Ohio physicians to perform criminal background checks on patients who receive controlled substances. Moreover, it would potentially deprive citizens with minor criminal records from receiving necessary medical treatment. As a matter of public policy, this should not occur. Such a change to the regulatory landscape should be reserved for the Board's rule-making process where such changes can be narrowly tailored to address a problem. Accordingly, Findings of Fact 2(f), 2(f)(i) through 2(f)(iv), and 3 do not constitute violations of Sections 4731.22(B)(2) and/or (B)(3), Ohio Revised Code.

5. For the reasons set forth below, the evidence is insufficient to support a conclusion that Dr. Karel's acts, conduct, and/or omissions as described in Finding of Fact 4, individually and/or collectively, constitute "[f]ailure to maintain minimal standards applicable to the selection or administration of drugs, or failure to employ acceptable scientific methods in the selection or administration of drugs or modalities for treatment of disease," as those clauses are used in Section 4731.22(B)(2), Ohio Revised Code; and/or "[s]elling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes * * *," as that clause is used in Section 4731.22(B)(3), Ohio Revised Code.

Finding of Fact 4 details the observations of a *locum tenens* physician who filled in for Dr. Karel at Dr. Karel's former practice. These observations do not support the violations alleged because all of the observations referenced in the finding took place in Dr. Karel's absence. In fact, the physician testified that she had not seen anything amiss during the two days that she shadowed Dr. Karel. Accordingly, Finding of Fact 4 does not constitute violations of Sections 4731.22(B)(2) and/or (B)(3), Ohio Revised Code.

6. For the reasons set forth below, the evidence is insufficient to support a conclusion that Dr. Karel's acts, conduct, and/or omissions as described in Finding of Fact 5, individually and/or collectively, constitute "[f]ailure to maintain minimal standards applicable to the selection or administration of drugs or other modalities for treatment of disease," as those clauses are used in Section 4731.22(B)(2), Ohio Revised Code; and/or "[s]elling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes * * *," as that clause is used in Section 4731.22(B)(3), Ohio Revised Code.

Finding of Fact 5 concerns Dr. Karel speaking with his attorney partway through an interview with Board investigators and then, upon the advice of counsel, refusing to answer any more questions. Dr. Karel simply exercised his right to speak to counsel and to refuse to answer questions. This potentially could have violated Section 4731.22(B)(34), Ohio Revised Code, which requires licensees to cooperate in Board investigations, but that offense was not charged. It does not violate Sections 4731.22(B)(2) and/or (B)(3), Ohio Revised Code.

7. The evidence is insufficient to support a conclusion that Dr. Karel's act, conduct, and/or omissions as described in Findings of Fact 6(a) and 6(b), individually and/or collectively, constitute "[f]ailure to maintain minimal standards applicable to the selection or administration of drugs, or failure to employ acceptable scientific methods in the selection of drugs or other modalities for treatment of disease," as those clauses are used in Section 4731.22(B)(2), Ohio Revised Code; "[s]elling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes * * *," as that clause is used in Section 4731.22(B)(3), Ohio Revised Code; and/or "[c]ommission of an act that constitutes a felony in this state, regardless of jurisdiction in which the act was committed," as that clause is used in Section 4731.22(B)(10), Ohio Revised Code, to wit: Section 2921.12, Ohio Revised Code, Tampering with Evidence.
8. For the reasons set forth below, the evidence is insufficient to support a conclusion that Dr. Karel's acts, conduct, and/or omissions as described in Finding of Fact 6(c), individually and/or collectively, constitute "[f]ailure to maintain minimal standards applicable to the selection of administration of drugs, or failure to employ acceptable scientific methods in the selection of drugs or other modalities for treatment of disease," as those clauses are used in Section 4731.22(B)(2), Ohio Revised Code; and/or "[s]elling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes * * *," as that clause is used in Section 4731.22(B)(3), Ohio Revised Code.

The evidence establishes that Dr. Karel added a pharmacy profile to his chart for Patient 3 after the Board had subpoenaed that chart. However, the pages of that document are each dated appropriately, and there does not appear to have been any attempt to alter the pre-existing documents in the chart. Accordingly, Finding of Fact 6(c) does not constitute violations of Sections 4731.22(B)(2) and/or (B)(3), Ohio Revised Code.

9. For the reasons set forth below, the evidence is insufficient to support a conclusion that Dr. Karel's acts, conduct, and/or omissions as described in Finding of Fact 6(c), individually and/or collectively, constitute "commission of an act that constitutes a felony in this state, regardless of the jurisdiction in which the act was committed," as that clause is used in Section 4731.22(B)(10), Ohio Revised Code, to wit: Section 2921.12, Ohio Revised Code, Tampering with Evidence.

The evidence establishes that Dr. Karel added a pharmacy profile to his chart for Patient 3 after the Board had subpoenaed that chart. However, the pages of that document are each dated appropriately, and there does not appear to have been any attempt to alter the pre-existing documents in the chart. Adding those pages to the chart after it had been subpoenaed was not a good idea, but it does not rise to the level of Tampering with Evidence. Accordingly, Finding of Fact 6(c) does not constitute violation of Section 4731.22(B)(10), Ohio Revised Code.

10. Maintaining a residence in Lima, Ohio, while maintaining a second residence close to a practice in Wheelersburg, Ohio, does not violate the Medical Practices Act. Neither

does a lack of hospital privileges. Moreover, not having malpractice insurance and having patients sign a form stating that they are aware of that fact actually follows the requirements of Section 4731.143(A), Ohio Revised Code. Accordingly, the evidence is insufficient to support a conclusion that Dr. Karel's acts, conduct, and/or omissions as described in Findings of Fact 7(a) through 7(c), individually and/or collectively, constitute "[f]ailure to maintain minimal standards applicable to the selection of drugs or other modalities for treatment of disease," as those clauses are used in Section 4731.22(B)(2), Ohio Revised Code; and/or "[s]elling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes * * *," as that clause is used in Section 4731.22(B)(3), Ohio Revised Code.

As the rationale for the proposed order, the hearing examiner stated that "Dr. Karel's conduct in repeatedly making large amounts of narcotics and other controlled substances available to patients with relatively little examination or scrutiny deserves the severest sanction." See June 16, 2011 Report and Recommendation.

On July 13, 2011 the Board voted to approve and adopt the June 16, 2011 Report and Recommendation and permanently revoked appellant's license to practice medicine in the state of Ohio. Thereafter, appellant filed a timely appeal. The appellant has not set forth any assignments of error in his brief. Thus, this Court will review the record to determine if the appellee's July 13, 2011 Order is supported by reliable, probative and substantial evidence and is in accordance with law. See R.C. 119.12.

STANDARD OF REVIEW

R.C. § 119.12 sets forth the standard of review a common pleas court must follow when reviewing an administrative appeal. R.C. 119.12 provides in pertinent part:

The court may affirm the order of the agency complained of in the appeal if it finds, upon consideration of the entire record and such additional evidence as the court has admitted, that the order is supported by reliable, probative and substantial evidence and is in accordance with law.

In *Our Place* the Ohio Supreme Court provided the following definition of reliable, probative and substantial evidence 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 Comm. (1992), 63 Ohio St. 3d 570, 571.

Once the common pleas court has determined that the administrative agency's order is supported by reliable, probative and substantial evidence, the court must then determine whether the order is in accordance with law. See R.C. § 119.12. The reviewing court cannot substitute its judgment for the agency's decision where there is some evidence supporting the decision. See *Harris v. Lewis* (1982), 69 Ohio St. 2d 577, 579; see also *University of Cincinnati v. Conrad* (1980), 63 Ohio St. 2d 108.

Moreover, the common pleas court has no authority to modify a penalty that the agency was authorized to, and did impose, on the ground that the agency abused its discretion. When reviewing a Medical Board's order, courts must accord due deference to the Board's interpretation of the technical and ethical requirements of its profession. See *Coniglio v. State Med. Bd. of Ohio*, 2007 Ohio 5018.

LAW AND ARGUMENT

Dr. Theodore V. Parran, Jr., M.D. testified as an expert on behalf of the appellee. There was testimony regarding his background and credentials. See also State's Exhibit 17. He testified that he treats patients who suffer from intractable pain and that he prescribes the appropriate controlled substances to treat them. Tr. 466-467. Dr. Parran assisted the Board in the drafting of the Ohio Administrative Code rules concerning the treatment of intractable pain. He noted that he reviewed copies of the medical records of Patients 1 through 16. Dr. Parran also reviewed the state laws regarding the prescribing of opiates.

The evidence supports that the steps that must be taken to provide proper care of patients with chronic intractable pain are as follows:

A thorough history and physical examination

Verification or establishment of a clear diagnosis

Documentation of an adequate workup involving multiple steps

Assessment of functional capacity and impairment, and demonstration of impaired function

In Ohio, a consultation with a physician who specializes in treatment of the organ system or part of the body involved in the chronic intractable pain syndrome. The purpose of the consultation is to verify the presence or absence of the chronic intractable pain.

An individualized treatment plan that is adjusted over time based upon data obtained during ongoing monitoring of the patient.

Tr. 584-587; see State's Exhibit 17; see also R.C. 4731.052.

Dr. Parran emphasized the need for patient information from the onset and stated that the more information that was available to the physician at the initial visit, the more accurate and confident the physician would be in prescribing appropriate medication and dosages.

Summarily, Dr. Parran criticized appellant since there was no legitimate basis for the prescriptions and no documented evidenced medical rationale for prescribing Schedule II narcotic drugs such as Oxycontin and Oxycodone. See State's Exhibit 17. Dr. Parran found that it was the typical case that no adequate physical exams were conducted and no neurologic exams documented on appellant's patients. He found that the physical exam notes listed in the patient records "have exactly the same words written in exactly the same place in the physical exam as every single patient visit I looked at." Tr. 495-496, 523-524. Dr. Parran testified that in many of the patient charts he reviewed he "didn't find in the physical exam or in the studies that were in the chart, established clinical scientific reason for, you know, high doses of Schedule II drugs in this patient."

Tr. 522. Many of the patients, including Patient 14, had minimal testing reports in their record and some showed negative or normal results. But Dr. Karel still prescribed Schedule II narcotics such as Oxycontin and Oxycodone without evidence to do so. Tr. 550.

Dr. Parran also stated that he was astonished to find forms in the patient's records wherein the appellant had his patients sign these forms stating that "I am not seeking care from Douglas Karel as part of an ongoing investigation." See State's Exhibit 5; Tr. 143-145, 505-506. Dr. Parran stated that no legitimate medical practice would require patients to sign a form stating that they are not part of an investigation against this doctor and that it just illustrates that the appellant was not conducting a legitimate medical practice. Dr. Parran testified that the appellant was writing prescriptions for drugs for anyone who gave him \$200. Tr. 181. Thus, based on his review of 16 of the appellant's patients, Dr. Parran concluded that the appellant failed to employ minimal standards applicable to the selection/administration of drugs or failed to employ acceptable scientific methods in the selection or administration of drugs. Dr. Parran opined that the appellant was furnishing or prescribing drugs for other than a legitimate and therapeutic purpose with little or no attempt made to provide any treatment alternatives to his patients.

Patient 3

Patient 3 is a female born in 1968. She is an employee of the appellant. Her first visit to Tri-State Primary Care was July 22, 2009. Although the appellant testified that he had previously treated Patient 3 for an extended period of time at the Medical Office, her chart from the Medical Office is not included in the record. See Tr. 56, 107; State's Exhibit 3. Dr. Karel acknowledged that he had not documented a complete history for Patient 3. Tr. 117-118. Dr. Parran testified:

[M]y opinion was that the prescribing was done in a way that was inconsistent with the standards of care in the community, and inconsistent with a – with the use – legitimate medical purpose, and inconsistent with using appropriate care and scientific method in the selection of controlled drugs.

See Tr. 541.

The hearing examiner found that Dr. Ross's calculations of the amount of oxycodone that the appellant prescribed for Patient 3 was incorrect and that he failed to address the benzodiazepines that Dr. Karel prescribed to Patient 3. See June 16, 2011 Report and Recommendation. Patient 3 acknowledged that she spent around \$18,000.00 per year for OxyContin. Tr. 811-813.

Patient 4

Patient 4 is a male born in 1973 who visited appellant on September 21, 2009. The appellant testified that he treated Patient 4 when he practiced at Medical Office/Greater Medical Advance and after repeated requests, those medical records were never sent to him. Patient 4's chart includes a photocopy of his State of Ohio non-driver ID card. Patient 4's urine drug screen report tested positive for oxycodone and opiates. Patient 4 was discharged from Tri-State Primary Care after two visits. Dr. Parran testified that the appellant failed to follow proper procedures in his discharging of Patient 4 and in his opinion, the appellant violated the minimal standard applicable to the selection and administration of drugs to Patient 4. In his opinion, Dr. Parran testified that the appellant had prescribed drugs for other than legitimate therapeutic purposes. Tr. 498-501. The appellant testified that he could not do an extensive history due to time constraints because of the many patients that he saw every day. Tr. 118 and 224.

Patient 5

Patient 5 is a male born in 1976 and visited appellant on July 16, 2009. Patient 5 also saw the appellant previously at the Medical Office. Patient 5's chart includes a photocopy of his Ohio non-driver ID card. See State's Exhibit 5. Although Patient 5 had been a patient of the appellant for approximately two years, Patient 5 was discharged about two months after the appellant began

seeing him at Tri-State Primary Care. Tr. 145-146; see State's Exhibit 5. Dr. Parran testified that the appellant's selection and administration of drugs in his treatment of Patient 5:

was done in a manner that was inconsistent with the acceptable standard of care in Ohio and the usual course of medical practice, and that it was done in a way that was unsafe, and, therefore, for other than legitimate medical purpose.

Tr. 511.

Patient 7

Patient 7 is a male born in 1963. He saw the appellant on July 23, 2009. Patient 7 had an extensive list of medical problems which included hepatitis B and C. See State's Exhibit 7. Dr. Parran explained why it was dangerous that the appellant prescribed OxyContin 20 mg #90 and oxycodone 30 mg #90 to Patient 7 on July 23, 2009. Tr. 516-517. He stated that for a patient with bad lung disease and an extensive prior history of addiction, a prescription in that amount of Schedule II opiates was clinically dangerous and demonstrates disregard for the health and safety of the patient. Tr. 516-517. Moreover, the hearing examiner found that Dr. Ross's description of the appellant's adjustment in dosing frequency was incorrect. See June 16, 2011 Report and Recommendation; see also State's Exhibits 7 and 17.

Patient 8

Patient 8 is a female born in 1962 and first visited with appellant for treatment on July 29, 2009. See State's Exhibit 8. Dr. Parran testified that he was unable to find documentation in Patient 8's chart that established a clinical, scientific basis for prescribing high doses of Schedule II medications. Dr. Parran testified that in his opinion the appellant's treatment of Patient 8 fell below the minimal standards applicable to the selection and administration of medication, and that drugs were prescribed for other than legal and legitimate therapeutic purposes. Tr. 522; see State's Exhibit 8.

Dr. Ross testified that the appellant was obligated to maintain Patient 8 on her prior medications until such time as her prior records and/or analyses were available. Dr. Ross’s testimony depicts that “[A]pparently there was only one visit” in regard to Patient 8. See Respondent’s Exhibit B at 11. However, Patient 8’s chart demonstrates that he saw the appellant monthly from July 2009 through May 2010 for a total of ten (10) visits.

Patient 9

Patient 9 is a female born in 1979 and is employed by the appellant. Her first patient visit to appellant was on July 17, 2009. See State’s Exhibit 9. Patient 9’s medical record includes an OARRS² report, dated March 19, 2010, indicating that the appellant had issued the following prescriptions to Patient 9 that were not documented in the records for the Medical Office or Tri-State Primary Care:

Fill Date	Medication	Quantity	Refills
6/11/09	alprazolam 222mg	9	0
7/9/09	alprazolam 2mg	20	0
8/3/09	alprazolam 2mg	30	0
12/30/09	alprazolam 2mg	30	0

See State’s Exhibits 9 and 9A.³

The record demonstrates that Patient 9 submitted to seven urine drug screens on the following dates: July 17, August 14, September 11, and November 10, 2009; and January 24, March 24, and April 22, 2010. None of these drug screens yielded a positive result for benzodiazepines. See State’s Exhibit 9. Dr. Parran noted that Xanax is the most commonly abused benzodiazepine in the United States. Tr. 527. He testified that:

[W]riting a prescription for a controlled drug to a patient without documenting it in the chart is inconsistent with the—the standard of care in the community, and it’s—and especially

² OARRS refers to the Ohio Automated Rx Reporting System. It is a database of controlled substance prescriptions filled by pharmacies in Ohio, and is searchable by prescriber or patient.

³ Alprazolam is a generic name for Xanax.

when adding a benzodiazepine like Xanax which markedly increases the risk of accidental overdose.

Tr. 526.

When asked why Xanax increases the risk of accidental overdose, Dr. Parran stated: Benzodiazepines are sedative-hypnotic. They sedate the brain. Opiates also sedate the brain. The combination of benzodiazepines and opiates is dangerous.

Tr. 526.

Dr. Parran testified that Xanax should have registered a positive result as a benzodiazepine on Patient 9's urine screens. Tr. 527-528. When asked his opinion of the appellant's treatment of Patient 9, Dr. Parran testified:

My opinion was that the controlled drug prescribing to this patient of both the opiates, Schedule II opiates, and benzodiazepines were done in a manner which was not supported by sound clinical and scientific data. It was done in a way that was inconsistent with the standard of care in the usual course of practice and [was] for other than legitimate medical purpose.

Tr. 527-528.

Although Dr. Ross correctly stated that the appellant prescribed methadone to Patient 9 at her initial visit and several visits thereafter, he failed to mention that the appellant had prescribed oxycodone 15mg twice per day at the initial visit, and on ten subsequent occasions, prescribed oxycodone 30 mg twice per day. In addition, Dr. Ross failed to mention the prescriptions for Xanax. See State's Exhibits 9 and 17.

Patient 12

Patient 12 is a female born in 1976. She first sought treatment from the appellant on July 10, 2009. On September 3, 2009, the appellant referred Patient 12 to physical therapy. See State's Exhibit 12. Dr. Parran noted that a September 29, 2009 urine drug screen yielded a negative result for benzodiazepines although Patient 12 had been prescribed Valium 10 mg at her previous visit on September 3, 2009, and had been instructed to take one tablet every other day. Dr. Parran further

testified that the appellant did not address this issue in the progress notes or factor it in the patient's care after that point. Dr. Parran stated:

When prescribing dangerous drugs, especially * * * when it's potent Schedule II opiates plus the benzodiazepines, which we've already established are potentially dangerous in combination with opiates, when there is an inconsistency in the medical record, it's something that needs to be squared.

Tr. 533.

Additionally, Dr. Parran testified that the appellant's selection and administration of drugs to Patient 12:

was done in a way that was inconsistent with the usual course of medical practice, inconsistent with the acceptable standards, and done in a way that was for other than legitimate medical purpose.

Tr. 535.

Dr. Ross opined that the appellant's treatment of Patient 12 was "modified based on non-response to therapy. See Respondent's Exhibit B. However, there is nothing in the record to support Dr. Ross's statement. The record substantiates that there did not appear to be any modification of the appellant's treatment of Patient 12 aside from an occasional increase in medication. Moreover, there is no mention in the chart concerning Patient 12's response or non-response to physical therapy. Most troubling is that there are no records stating that Patient 12 was ever seen by a physical therapist. See State's Exhibits 12 and 17.

Patient 14

Patient 14 is a male born in 1978. He first sought treatment from the appellant on July 15, 2009. See State's Exhibit 14. Based on Patient 14's record and medical history, Dr. Parran testified as follows:

My conclusion regarding the prescribing of Schedule II substances to this patient is that the prescribing of controlled drugs to this patient was done in a manner which was inconsistent with the usual standard of care in the community, the usual course of medical practice, and it

was done in a way that was dangerous to the health and safety of the patient, and, therefore, for certainly no legitimate medical purpose.

Tr. 544-545.

Dr. Ross's report erroneously states that the appellant prescribed Suboxone to Patient 14. There is nothing in Patient 14's chart, or Dr. Parran's report, for that matter that supports that assertion. See State's Exhibits 14 and 17.

Patient 15

Patient 15 is a male born in 1971. Patient 15 had been treated by the appellant at the Medical Office/Greater Medical Advance from September 24, 2007 through April 22, 2009. His first visit to the appellant at Tri-State Primary Care was July 16, 2009. Patient 15 presented with an Ohio non-driver ID card. See State's Exhibit 15.

Dr. Parran testified that he could find no evidence of a legitimate medical purpose for the appellant prescribing an increase of Patient 15's oxycodone from 45 tablets per month to 60 tablets per month at Patient 15's August 13, 2009 visit. Tr. 549. Also on August 13, 2009, the appellant prescribed 220 milligrams per day of oxycodone for Patient 15. Again, Dr. Parran testified that he could find no evidence of a legitimate medical purpose for prescribing to this patient. Furthermore, Dr. Parran testified that the appellant's treatment of Patient 15 fell below the minimal standard applicable to the selection and administration of drugs to this patient. See State's Exhibit 15.

Dr. Ross opined that the appellant initially treated Patient 15 with NSAIDS and steroids. See Respondent's Exhibit B. However, there is nothing in Patient 15's medical charts from the Medical Office or Tri-State Primary Care to support Dr. Ross's assertion that the appellant treated Patient 15 with NSAIDS and steroids. See State's Exhibit 15. With respect to any prescribing of NSAIDS or steroids to Patient 15, Dr. Parran's report states, in part, "old records of ER visits reporting CLBP and no medications with tox screen positive for opiates—treated with NSAIDS and

steroids[.]” See State’s Exhibit 17. The “old” emergency room visits referenced by Dr. Parran occurred in 2001, several years before Patient 15 was seen by the appellant. See State’s Exhibit 17.

Patient 16

Patient 16 is a male born in 1969. He presented with a Kentucky non-driver ID card to Tri-State Primary Care on July 28, 2009. On that July 28, 2009 visit, the appellant prescribed methadone 10mg #360 and oxycodone 30 mg #60. Dr. Parran testified:

I’ve seen patients in methadone maintenance programs on this amount of methadone. I’ve seen patients in hospice care on this amount of methadone. I’ve seen a rare chronic pain patient on this amount of methadone, but with—but—but not with this kind of medical record.

Tr. 551-552.

In addressing the issue of the second undocumented July 28, 2009 prescription, the oxycodone 30 mg #30, Dr. Parran stated:

My concern is that he—when prescribing Schedule II opiates, arguably the most dangerous medicines a physician is licensed to prescribe in the practice of medicine, to—to not document what prescriptions are being given to a patient is absolutely inconsistent with the standard of care in our community.

Tr. 554.

When asked his opinion concerning the appellant’s treatment of Patient 16, Dr. Parran testified:

My opinion was the prescribing was done in a way which was inconsistent with the usual standard of care in the community, inconsistent with the usual course of medical practice, and—and was dangerous, and, therefore, inconsistent with a legitimate medical purpose.

Tr. 556.

Dr. Ross opined that Patient 16 suffered from “failed low back syndrome.” However, the Appellant did not document Patient 16’s condition as such. See State’s Exhibit 16.

LEGAL ANALYSIS

Appellant does not set forth specific assignments of error, as such, in his brief. However, he asserts several arguments. First, the appellant asserts that the Board utilized unfair tactics by labeling Dr. Karel's medical practice as a "pill mill." "Profiling" is a term most commonly used in criminal law describing circumstances wherein individuals are arrested or detained solely on the basis of their appearance or other identifiable traits. Clearly, that term is not applicable to an administrative investigation of a state licensee and the appellant has not provided any case law to support this allegation.

The record demonstrates that the Board was conducting an investigation of Dr. Karel as far back as March 31, 2010. Tr. 243-250. It wasn't until much later, on October 1, 2010, that the Ohio Prescription Drug Task Force ("Task Force") released its report listing the criteria of a "pill mill." It is ironic that Dr. Karel makes this argument since he himself referred to his former place of employment as a "pill mill." Tr. 188. Moreover, there was no reversible error regarding Kimberly Anderson's testimony since the hearing examiner did not rely on evidence regarding "pill mill" criteria. See June 16, 2011 Report and Recommendation, Findings of Fact 2 and Conclusions of Law 2. See *Gelesh v. State Medical Board of Ohio*, 2010-Ohio-4378.

The appellant asserts that the Board erred by failing to rule upon and/or sustain the appellant's motion to strike, motion for more definite statement, and motion to dismiss. The appellant asserts that the Board erred by setting forth facts about his practice which met the Task Force's criteria of a pill mill. However, the hearing examiner was clear in his June 16, 2011 Report and Recommendation that he did not rely on these facts in concluding that the appellant violated the law. See June 16, 2011 Report and Recommendation, Findings of Fact 2 and Conclusions of Law 2. See *Gelesh v. State Medical Board of Ohio*, 2010-Ohio-4378. Thus, the Board made the correct

rulings on the appellant's motion to strike, motion for a more definite statement and motion to dismiss.

R.C. 4731.052(C) provides:

When a treating physician diagnoses an individual as having intractable pain, the physician may treat the pain by managing it with dangerous drugs in amounts or combinations that may not be appropriate when treating other medical conditions. **The physician's diagnosis shall be made after having the individual evaluated by one or more other physicians who specialize in the treatment of the area, system, or organ of the body perceived as the source of the pain.** The physician shall maintain a record of all of the following:

- (1) Medical history and physical examination of the individual;
- (2) The diagnosis of intractable pain, including signs, symptoms and causes;
- (3) The plan of treatment proposed, the patient's response to the treatment, and any modification to the plan of treatment;
- (4) The dates on which dangerous drugs were prescribed, furnished, or administered, the name and address of the individual to or for whom the dangerous drugs were prescribed, dispensed, or administered, and the amounts and dosage forms for the dangerous drugs prescribed, furnished, or administered;
- (5) A copy of the report made by the physician or the physician to whom referral for evaluation was made under this division.

Based on a review of the evidence, appellant did not come close to complying with R.C. 4731.052 or O.A.C. 4731-21-02. In order to be within the parameters of R.C. 4731.052, appellant must have complied with each and every one of the steps necessary in order to have properly diagnosed and then treated an individual with chronic intractable pain. Appellant himself admitted that all or nearly all of the patients who sought treatment from him either at GMA, the Medical Office or Tri-State received prescription narcotics. Tr. 65. The evidence is overwhelming that appellant did not comply with this statute and therefore cannot seek its protections.

The statutory scheme in R.C. Chapter 4731 et seq. authorizes the Board to engage in rulemaking and conduct adjudicatory proceedings, among other purposes. The Board's disciplinary authority is established in R.C. 4731.22.

The record is replete with examples of appellant falling below the minimal standard of

conduct, such as his inappropriate (or non-existent) diagnosis and treatment of these patients, his inappropriate prescribing of controlled substances and/or dangerous drugs in dangerous amounts without any verification of the patient's past dosage; his sloppy, conflicting and incomplete medical records and notes, and his failure to obtain prior medical records, and obtain or document testing, workups and consultations on these patients. Again, these are just examples of a few, among many other infractions, that were proven at the hearing.

The Board is authorized by R.C. 4731.22 to discipline appellant for these various aspects of providing inadequate patient care since appellant's conduct fell below the level of minimal standards of patient care. The evidence overwhelmingly proves, among other things, that appellant failed to maintain minimal standards applicable to the selection and/or prescribing of drugs, and that he failed to document and maintain thorough medical records for these patients. Thus, there is no *premise* that these patients truly had a diagnosis of chronic intractable pain since appellant did not record or support, by documents or verification or otherwise, that any of these patients truly had a diagnosis of chronic intractable pain. See R.C. 4731.052 and O.A.C. 4731-21-02. Clearly, the Board properly disciplined the appellant for violating R.C. 4731.22(B)(2) since the record is replete with evidence that supports these charges.

Appellant argues that the Board erred by adopting the hearing examiner's "flawed analysis" regarding the credibility of the expert witnesses. Expert medical testimony is not mandatory in a medical disciplinary proceeding where the issue is whether a physician's conduct falls below a reasonable standard of medical care. See *Arlen v. State Medical Board of Ohio* (1980), 61 Ohio St. 2d 168; see also *Reed v. State Medical Board of Ohio* (2005), 162 Ohio App. 3d 429. Thus, the Board in this case did not have to rely on the experts' testimony, or the hearing examiner's interpretation of it, since it was perfectly capable of determining on its own whether appellant fell

below a reasonable standard of patient medical care.

In this case, Dr. Parran was well qualified to testify regarding the standard of care issues before the Board. He is Board certified in internal medicine with a subspecialty in addiction medicine. He treats patients in a clinical setting who may or may not have addiction issues. He was a member of the state taskforce that developed the Board's rules concerning intractable pain. Thus, his testimony was relevant regarding the standard of care for similarly situated practitioners in the medical community. Thus, there was a succinct basis for the Board to rely on the credibility of Dr. Parran and also rely on its own expertise, over the testimony of appellant and his expert witness, Dr. Ross, as it did in this case.

The hearing examiner, in his June 16, 2011 Report and Recommendation stated the following in regard to the appellant's expert, Dr. Ross's testimony:

No one is perfect. An occasional , relatively small factual error in an expert's report or testimony may not significantly diminish that expert's credibility as a witness. This is not the case with Dr. Ross. He made a small error with respect to Patient 7, and his miscalculation of Patient 3's dosages could be overlooked in the absence of other significant mistakes. However, his gross factual errors with respect to Patients 8, 9, 12, 14, and 15 are, in the Hearing Examiner's experience, unique. Making his error-fraught report even more unusual, Dr. Ross chose to refer to Dr. Parran's opinions in such strident and disparaging terms as "egregiously flawed and biased," "irrational," and "contemptible." This is simply astonishing.

Given the numerous factual errors in Dr. Ross's report, all of which favor Dr. Karel, it is reasonable to conclude that, at best, Dr. Ross did not review, or give careful review to, the patient charts, and based his opinions on self-induced misinformation. At worst, he was intentionally trying to mislead the finder of fact. Accordingly, Dr. Ross is deemed to be a non-credible and unreliable witness, and his report and testimony are accorded no weight.

The appellant asserts that the hearing examiner failed to summarize and the Board failed to consider or account for the testimony of the six pharmacists and one Ohio Board of Pharmacy employee who testified during the hearing. To the contrary, the hearing examiner's June 16, 2011 Report and Recommendation addressed the subject of pharmacies that honored and did not honor

the appellant's prescriptions for controlled substances. See June 16, 2011 Report and Recommendation, paragraphs 277 through 281; see also State's Exhibit 41A; see Tr. 71, 782-788, 979-1100, 1340-1341. However, the focus of this Court's review is the appellant's conduct in regard to R. C. 4731.22(B)(2) and not whether a pharmacy did or not honor the prescriptions for controlled substances that the appellant prescribed for his patients.

The Board's primary mission is to protect the public against unscrupulous medical practices. The Board is comprised of twelve members: nine physicians and three non-physician public members. Each board member is appointed by the Governor and serves a five-year term. Thus, a majority of the Board's members are experts in their own right since they are doctors and already possess the specialized knowledge needed to determine the acceptable standard of general medical practice. See *Arlen v. The State Medical Board of Ohio* (1980), 61 Ohio St. 2d 168; see also *In re Williams* (1991), 60 Ohio St. 3d 85, 87.

This Court concludes that a majority of the Board members themselves possess the expertise necessary to determine if the appellant fell below the minimum standards of practice and all other matters regarding appellant's conduct that were before the Board.

This court concludes that the conduct of appellant, as set forth in the Hearing Examiner's Findings of Fact and Conclusions of Law and as supported by the record, supports that there is reliable, probative and substantive evidence that appellant violated R.C. 4731.22(B)(2). Therefore, appellant's arguments are not well-taken and are hereby **OVERRULED**.

DECISION

Based on the foregoing, and upon a review of the record, this court concludes that there is reliable, probative and substantial evidence supporting the July 13, 2011 Order of the State Medical Board of Ohio. Moreover, this court concludes that the Board's Order is in accordance with law. The Board's July 13, 2011 Order is hereby **AFFIRMED**.

Rule 58(B) of the Ohio Rules of Civil Procedure provides the following:

(B) Notice of filing. When the court signs a judgment, the court shall endorse thereon a direction to the clerk to serve upon all parties not in default for failure to appear notice of the judgment and its date of entry upon the journal. Within three days of entering the judgment on the journal, the clerk shall serve the parties in a manner prescribed by Civ. R. 5(B) and note the service in the appearance docket. Upon serving the notice and notation of the service in the appearance docket, the service is complete. The failure of the clerk to serve notice does not affect the validity of the judgment or the running of the time for appeal except as provided in App. R. 4(A).

THE COURT FINDS THAT THERE IS NO JUST REASON FOR DELAY. THIS

IS A FINAL APPEALABLE ORDER. Pursuant to Civil Rule 58, the Clerk of Court shall serve upon all parties notice of this judgment and its date of entry.

It is so ordered.

Copies to:
James McGovern, Esq.
Graff and Associates
604 East Rich Street
Columbus, Ohio 43215
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Michael DeWine, Esq.
Kyle Wilcox, Esq.
Office of the Attorney General
Health and Human Services Section
State Office Tower
30 East Broad Street, 26th Floor
Columbus, Ohio 43215-3400
Counsel for Appellee

Franklin County Court of Common Pleas

Date: 01-20-2012
Case Title: DOUGLAS B KAREL MD -VS- OHIO STATE MEDICAL BOARD
Case Number: 11CV009151
Type: DECISION/ENTRY

It Is So Ordered.



Judge Richard S. Sheward

IN THE COURT OF COMMON PLEAS
FRANKLIN COUNTY, OHIO

DOUGLAS B. KAREL, M.D. :
101 Timberfield Drive :
Lima, OH 45807 :

Appellant.

VS.

STATE MEDICAL BOARD OF OHIO :
30 East Broad Street, 3rd Floor :
Columbus, OH 43215 :

Appellee.

CASE NO.

JUDGE

CATEGORY I

11CVF

915

STATE MEDICAL BOARD
OF OHIO
2011 JUL 25 PM 1:27

NOTICE OF APPEAL

Appellant, Douglas B. Karel, M.D., through his undersigned counsel, hereby gives notice of his appeal of the attached Order of the State Medical Board of Ohio (dated July 13, 2011), which was mailed July 15, 2011. The State Medical Board of Ohio's order is not supported by reliable, probative and substantial evidence and is not in accordance with law.

This Notice of Appeal is being filed with the State Medical Board of Ohio and with the Franklin County Court of Common Pleas.

RESPECTFULLY SUBMITTED.

~~JAMES M. ARG GOVERN~~ 0061709
GRAFF & ASSOCIATES
604 East Rich St.
Columbus, OH 43217
(614) 228-5800 (614) 228-8811 fax
Counsel for Douglas B. Karel, M.D.

FILED
COMMON PLEAS COURT
FRANKLIN CO. OHIO
2011 JUL 25 PM 1:37
CLERK OF COURTS-CV

2011 AUG -1 PM 3:49
STATE MEDICAL BOARD
OF OHIO

CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that a true and accurate copy of the foregoing was served upon the following.

Kyle Wilcox, Esq.
Assistant Attorney General
Health and Human Services Section
30 East Broad Street, 26th Floor
Columbus, OH 43215

by fax this 25th day of July, 2011.



JAMES M. MCGOVERN

0061709

2011 JUL 25 PM 1:27

STATE MEDICAL BOARD
OF OHIO

STATE MEDICAL BOARD
OF OHIO
2011 AUG -1 PM 3:49

State Medical Board of Ohio

30 E. Broad Street, 3rd Floor, Columbus, OH 43215-6127

Richard A. Whitehouse, Esq.
Executive Director

(614) 466-3934
med.ohio.gov

July 13, 2011

Douglas B. Karel, M.D.
101 Timberfield Drive
Lima, OH 45807

RE: Case No. 11-CRF-023

Dear Doctor Karel:

Please find enclosed certified copies of the Entry of Order; the Report and Recommendation of R. Gregory Porter, Esq., Hearing Examiner, State Medical Board of Ohio; and an excerpt of draft Minutes of the State Medical Board, meeting in regular session on July 13, 2011, including motions approving and confirming the Report and Recommendation as the Findings and Order of the State Medical Board of Ohio.

Section 119.12, Ohio Revised Code, may authorize an appeal from this Order. Such an appeal must be taken to the Franklin County Court of Common Pleas.

Such an appeal must be commenced by the filing of a Notice of Appeal with the State Medical Board and the Franklin County Court of Common Pleas. The Notice of Appeal must set forth the Order appealed from and state that the State Medical Board's Order is not supported by reliable, probative, and substantive evidence and is not in accordance with law. The Notice of Appeal may, but is not required to, set forth the specific grounds of the appeal. Any such appeal must be filed within fifteen (15) days after the mailing of this notice and in accordance with the requirements of Section 119.12, Ohio Revised Code.

THE STATE MEDICAL BOARD OF OHIO



Lance A. Talmage, M.D.
Secretary

LAT:jam
Enclosures

CERTIFIED MAIL NO. 91 7199 9991 7030 3311 5290
RETURN RECEIPT REQUESTED

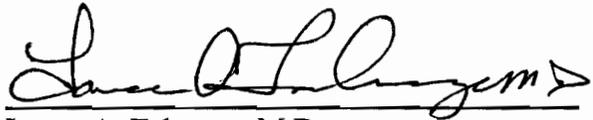
CC: James M. McGovern, Esq.
CERTIFIED MAIL NO. 91 7199 9991 7030 3311 5306
RETURN RECEIPT REQUESTED

Mailed 7-15-11

CERTIFICATION

I hereby certify that the attached copy of the Entry of Order of the State Medical Board of Ohio; Report and Recommendation of R. Gregory Porter, State Medical Board Hearing Examiner; and excerpt of draft Minutes of the State Medical Board, meeting in regular session on July 13, 2011, including motions approving and confirming the Findings of Fact, Conclusions and Proposed Order of the Hearing Examiner as the Findings and Order of the State Medical Board of Ohio; constitute a true and complete copy of the Findings and Order of the State Medical Board in the matter of Douglas B. Karel, M.D., Case No. 11-CRF-023, as it appears in the Journal of the State Medical Board of Ohio.

This certification is made by authority of the State Medical Board of Ohio and in its behalf.



Lance A. Talmage, M.D.

Secretary

(SEAL)

July 13, 2011

Date

BEFORE THE STATE MEDICAL BOARD OF OHIO

IN THE MATTER OF

*

*

CASE NO. 11-CRF-023

DOUGLAS B. KAREL, M.D.

*

ENTRY OF ORDER

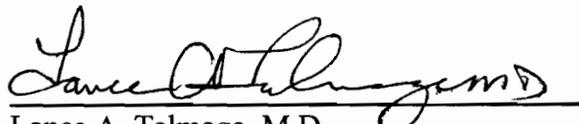
This matter came on for consideration before the State Medical Board of Ohio on July 13, 2011.

Upon the Report and Recommendation of R. Gregory Porter, State Medical Board Hearing Examiner, designated in this Matter pursuant to R.C. 4731.23, a true copy of which Report and Recommendation is attached hereto and incorporated herein, and upon the approval and confirmation by vote of the Board on the above date, the following Order is hereby entered on the Journal of the State Medical Board of Ohio for the above date.

It is hereby ORDERED that:

The certificate of Douglas B. Karel, M.D., to practice medicine and surgery in the State of Ohio shall be PERMANENTLY REVOKED.

This Order shall become effective immediately upon the mailing of the notification of approval by the Board.


Lance A. Talmage, M.D.
Secretary

(SEAL)

July 13, 2011

Date

2011 JUN 16 PM 2: 16

BEFORE THE STATE MEDICAL BOARD OF OHIO

In the Matter of

*

Case No. 11-CRF-023

Douglas B. Karel, M.D.,

*

Hearing Examiner Porter

Respondent.

*

REPORT AND RECOMMENDATION

Basis for Hearing

In a Notice of Summary Suspension and Opportunity for Hearing dated March 9, 2011, the State Medical Board of Ohio [Board] notified Douglas B. Karel, M.D., that, pursuant to Section 4731.22(G), Ohio Revised Code, the Board had summarily suspended his certificate to practice medicine and surgery in Ohio. Moreover, the Board notified Dr. Karel that it intended to determine whether to take disciplinary action against his certificate based on allegations that included:

- from around November 2007 through around March 2011, Dr. Karel undertook the care of 16 patients identified on a confidential Patient Key to whom he prescribed controlled substances and other drugs of abuse;
- a comparison of alleged aspects of Dr. Karel's practice with a "constellation of certain criteria and conduct" of "pill mill" facilities as described in the Final Report of the Ohio Prescription Drug Abuse Task Force demonstrates that many apply to his medical practice;
- Dr. Karel treated patients with controlled substances who have been convicted or arrested for drug-related crimes or other criminal offenses;
- information provided by a *locum tenens* physician concerning her observations of the office where Dr. Karel practiced;
- allegations that he had refused to answer a Board investigator's questions after having cooperated initially;
- Dr. Karel had altered the medical records for one patient;
- Dr. Karel lives in northern Ohio but works in southern Ohio;
- Dr. Karel has no hospital privileges or malpractice insurance;
- Dr. Karel has patients sign a statement that they are not seeking care as part of an investigation; and
- many, if not most, area pharmacies will not honor his prescriptions for controlled substances.

The Board further alleged that Dr. Karel's acts, conduct, and/or omissions constitute the following:

- "[f]ailure to maintain minimal standards applicable to the selection or administration of drugs, or failure to employ acceptable scientific methods in the selection of drugs or other modalities

for treatment of disease,” as those clauses are used in Section 4731.22(B)(2), Ohio Revised Code;

- “[s]elling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes or a plea of guilty to, a judicial finding of guilt of, or a judicial finding of eligibility for intervention in lieu of conviction of, a violation of any federal or state law regulating the possession, distribution, or use of any drug,” as those clauses are used in Section 4731.22(B)(3), Ohio Revised Code; and/or
- “[c]ommission of an act that constitutes a felony in this state, regardless of the jurisdiction in which the act was committed,” as that clause is used in Section 4731.22(B)(10), Ohio Revised Code, to wit: Section 2921.12, Ohio Revised Code, Tampering with Evidence.

Finally, the Board advised Dr. Karel of his right to request a hearing, and received his written request on April 6, 2011. (State’s Exhibits [St. Exs.] 41A, 41B)

Appearances

Mike DeWine, Attorney General, and Kyle C. Wilcox and Melinda R. Snyder, Assistant Attorneys General, for the State of Ohio. James M. McGovern, Esq., on behalf of Dr. Karel.

Hearing Dates: May 3, 4, 5, 6, and 9, 2011

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PROCEDURAL MATTER

Per discussion at hearing, the Respondent submitted a post-hearing document entitled Proffered Testimony of Richard Whitehouse. The document was marked Respondent’s Exhibit P, sealed from public disclosure, and will be held as proffered material.

PAGINATION OF STATE’S EXHIBITS

Many of the State’s exhibits display two page numbers at the bottom of each page. In this report, the page numbers labeled “Medical Board” were used, not the larger number in the bottom right corners, because the larger number is cut off on some pages and does not appear on all the exhibits.

SUMMARY OF THE EVIDENCE

All exhibits and the transcript, even if not specifically mentioned, were thoroughly reviewed and considered by the Hearing Examiner prior to preparing this Report and Recommendation.

Background

1. Dr. Karel testified that he obtained his undergraduate degree from the State University of New York at Albany in 1975. In 1977, Dr. Karel began his medical education at the University of Liege, Faculty of Medicine, in Liege, Belgium. Dr. Karel testified that it took him approximately eight years to complete his medical education because he was seriously injured in an automobile accident that cost him approximately three years of schooling. In 1985, he obtained his medical degree from the University of Liege, Faculty of Medicine.

Some time later, in 1994,¹ Dr. Karel entered a neurology residency at VA Wadsworth/UCLA in Los Angeles, California, which he completed in 1996. (Hearing Transcript [Tr.] at 31-33)

2. Dr. Karel testified that he is not board certified. Shortly after completing his residency, Dr. Karel attempted the certification examination for the American Board of Psychiatry and Neurology, but did not pass. He has not sat for the exam since then. (Tr. at 33)

Dr. Karel's 2004 Consent Agreement

3. Effective March 11, 2004, Dr. Karel entered into a Probationary Consent Agreement with the Board, based upon violation of Section 4731.22(B)(18), Ohio Revised Code. From 2000 through around September 2003, Dr. Karel had been making inappropriate social comments and offensive humorous remarks to patients and hospital staff. He submitted to a psychiatric evaluation in 2002 and the evaluating psychiatrist concluded that Dr. Karel did not suffer from any mental illness, but “a significant head injury he sustained in 1976 may contribute to his persistent inappropriate remarks, and that cognitive behavioral therapy might increase his awareness of his behavior.” He initiated such therapy shortly thereafter. Subsequently, in 2003, Dr. Karel submitted to another psychiatric evaluation which resulted in a determination that he does not suffer from a mental illness. In the consent agreement, Dr. Karel was reprimanded and placed on probation for at least one year with requirements that included continued cognitive behavioral therapy. On February 11, 2005, the Board released Dr. Karel from probation. (St. Ex. 36; Ohio eLicense Center, <<https://license.ohio.gov/Lookup/SearchDetail.asp?ContactIdnt=2982792&DivisionIdnt=78&Type=L>>, accessed May 18, 2011)

Dr. Karel's Work History, 1996 through mid-2009

4. Dr. Karel entered private practice in 1996 in Lima, Ohio, where he practiced neurology. He had privileges at two hospitals, St. Rita's Medical Center and Lima Memorial Hospital. Around 2005 or 2006, he obtained another neurology position in Pennsylvania. He applied for and received a Pennsylvania medical license. He informed his patients and hospitals in advance that he was leaving. However, Dr. Karel testified, “[T]hree or four days before I was going to start the position, I was unable—different factors came into play; I was unable to go to Pennsylvania.” (Tr. at 34-35, 37, 50)

After his position in Pennsylvania fell through, Dr. Karel had difficulty finding another position. He testified:

I went without any consistent work for a year-and-a-half to two years. Then I was—had a couple of part-time positions, [*locum tenens*] positions, first in a chiropractic clinic in a town near Hamilton, Ohio. I forgot the name. And then I had another place in Waverly, Ohio.

¹ The hearing record is unclear about Dr. Karel's activities between 1985 and 1994.

Following that—I took three days initially, I did—I was there for approximately one day a week for approximately one year’s time. And after that, I was suddenly told one day [by my employer] that I should not return the next week.

(Tr. at 35) Dr. Karel further testified the practice in Waverly had been a pain clinic. Moreover, Dr. Karel testified that he had lost the Waverly position in summer 2007. Finally, Dr. Karel testified, “[My employer] never gave me any reason whatsoever” for the termination. (Tr. at 35-36, 39-40)

5. Dr. Karel testified that, after he was asked to leave the practice in Waverly:

[O]ne-and-a-half to two weeks after that, I was called by one of the people who I had worked with at that clinic that there was another person who was interested in somebody full-time in South Point, Ohio. So I jumped at the opportunity and moved to—and started working at South Point.

(Tr. at 36)

Dr. Karel testified that South Point is on the Ohio River between Ashland, Kentucky, and Huntington, West Virginia. The practice was called Southern Pain Management. He further testified that he began working in South Point in August 2007 and worked there until September 2007, at which time the owners of the practice moved the practice to Wheelersburg, Ohio,² and renamed it the “Medical Office.” Dr. Karel testified that he continued working for the Medical Office until May 2009, when he took a leave of absence for a hip operation. (Tr. at 38-42; St. Ex. 14A at 169)

6. Dr. Karel testified that both Southern Pain Management and the Medical Office had been owned by Claude “Sonny” Hamilton and Mr. Hamilton’s daughter, Tammy Neuman. Dr. Karel further testified that neither Mr. Hamilton nor Ms. Neuman had any medical training. (Tr. at 42)
7. Dr. Karel testified that, around March 2009, Sonny Hamilton was murdered. Dr. Karel further testified:

And at that point, his daughter, who then took over the practice, was initially going to relinquish the practice and sell it to me. She reneged on that.

And as far as I could tell, the entire atmosphere and the entire chain of events in the office changed radically. And that’s one of the reasons I decided to leave there.

(Tr. at 211-212)

² Wheelersburg is about six miles away from Portsmouth, Ohio. (Tr. at 814)

8. Shortly thereafter, in May 2009, Dr. Karel had hip surgery, and the Medical Office hired a *locum tenens* physician to cover for him. However, Dr. Karel did not return to the Medical Office following his recovery from hip surgery. Instead, he opened his own medical practice in Wheelersburg. Dr. Karel testified that changes at the Medical Office following Mr. Hamilton's death were part of the reason why he decided not to return. (Tr. at 41-43, 141, 211-212)
9. In June or July 2009, after Dr. Karel left the Medical Office, the owners of the Medical Office changed the practice's name to Greater Medical Advance. (St. Ex. 14A at 90, 92)

Dr. Karel's Practice Following the Medical Office -- Tri-State Primary Care

10. Dr. Karel testified that, following his hip surgery, he had opened a pain clinic at 8308B Ohio River Road in Wheelersburg with a man whom he had believed to be his business partner. Dr. Karel noted that his partner was not a physician. After about two weeks, however, the partner locked Dr. Karel out of the building. Dr. Karel testified, "He refused to pay me the second week. He refused to share the money that we had gathered together. Then he put locks and chains on the door so that I could not get into the office." (Tr. at 43-44) Moreover, Patient 3, an employee of Dr. Karel's, testified that Dr. Karel's partner had used an assumed name. (Tr. at 804-806)
11. Dr. Karel testified that in July 2009, after being locked out, he had opened his own pain clinic, Tri-State Primary Care, at 7997 Ohio River Road in Wheelersburg, about a one-half mile away. Dr. Karel testified that he remained at that location for 10 or 11 months, but that the building was in poor condition. When he had the opportunity, he moved back to the office space he had occupied previously, 8308B Ohio River Road, which he testified is in a modern building with reliable heat, air conditioning, and plumbing. Dr. Karel further testified that he continued to practice there until March 2011 when the Board summarily suspended his license. (Tr. at 44-48, 57-58, 68-69, 1309-1312)

March 9, 2011, Notice of Summary Suspension and Opportunity for Hearing

12. Daniel S. Zinsmaster testified that he is employed as an Enforcement Attorney with the Board. Mr. Zinsmaster further testified that, in that capacity, he had coordinated an investigation of Dr. Karel. The investigation culminated in the Board issuing a Notice of Summary Suspension and Opportunity for Hearing [Notice] on March 9, 2011. (Tr. at 300-301; St. Ex. 41A)
13. Mr. Zinsmaster described in detail the process involved in issuing the order for summary suspension of Dr. Karel's license. Mr. Zinsmaster testified that he assembled evidence identified in a March 7, 2011, memo to file and presented information to the Secretary and the Supervising Member of the Board. Mr. Zinsmaster further testified that, after considering the evidence identified in his memo, the Secretary and the Supervising Member determined that clear and convincing evidence existed that Dr. Karel had violated

Sections 4731.22(B)(2), (B)(3), and (B)(10), Ohio Revised Code, and that Dr. Karel's continued practice presented a danger of immediate and serious harm to the public. Consequently, the Notice was forwarded to the full Board for consideration at the Board's March 9, 2011, meeting. The Board voted to issue the Notice, and it was thereafter served on Dr. Karel and his counsel. (St. Exs, 40, 41A; Tr. at 302-304, 326)

Dr. Karel's Residence

14. Dr. Karel testified that his primary residence is in Lima, Ohio, and that he has lived in Lima for 14 or 15 years. He also has a second residence in Wheelersburg. (Tr. at 29-30, 51-52, 1337-1338)

Hospital Privileges

15. Dr. Karel testified that, since he left Lima and began practicing in southern Ohio, he has not held any hospital privileges. Dr. Karel noted that the closest hospital to Wheelersburg is Southern Ohio Medical Center [SOMC] in Portsmouth, Ohio. He stated that, about four or five years ago, he had applied for a neurology position at SOMC but was not even granted an interview. Dr. Karel believes that SOMC was not interested in him because of his consent agreement with the Board. He has not since applied for clinical privileges at that facility. (Tr. at 49-50, 1338-1339)

Patient Intake Process at Tri-State Primary Care; Subsequent Urine Drug Screens and Pill Counts

16. Dr. Karel testified that he used "a rather strict selection process" at Tri-State Primary Care. He testified that prospective patients must complete an application and that only about 50 percent of patient applicants are accepted. Dr. Karel further testified that his practice does not accept walk-in patients, unlike the Medical Office where he had previously worked. Moreover, Dr. Karel testified that he runs OARRS and KASPER reports on new patients.³ Additionally, all patients must have a relevant MRI and medical records are obtained directly from the office, lab, or hospital where they are kept; Dr. Karel testified that he does not accept any records brought in by the patient.⁴ Finally, Dr. Karel testified that "we have a considerably decreased [patient] load compared to virtually any other pain clinic because of the selection which I take." (Tr. at 65-69, 1284)
17. Dr. Karel testified that, after a patient is accepted, they are subjected to periodic pill counts and urine drug screens. (Tr. at 19)

³ OARRS refers to the Ohio Automated Rx Reporting System. It is a database of controlled substance prescriptions filled by pharmacies in Ohio, and is searchable by prescriber or patient. KASPER is the name of a similar database in Kentucky. (Tr. at 1114-1118)

⁴ Later in the hearing, Dr. Karel testified that new patients "will have to present with their previous medical records, where they've been seen, what they are—what has been stated or assessed in their regard." (Tr. at 1285)

18. Patient 3, an employee of Dr. Karel's, testified that each patient must provide a contact number where that patient can be reached. Patient 3 further testified that, when a patient is selected for a pill count or urine drug screen, the patient is contacted by telephone in the morning. If the office leaves a message and they do not return the call, they are dismissed. If the patient is reached, he or she must appear by 2:00 that afternoon. If they do not appear, unless they can provide an acceptable reason, such as a statement from an employer, which is followed up by a phone call to that employer by Dr. Karel's office, the patient is dismissed. Moreover, Patient 3 testified that they provide a short time frame to appear because, if the patient is short on his or her pills, or has not been taking the medication, they do not want to give the patient a chance to obtain more pills or ingest the medication to get it into his or her system. (Tr. at 773-774)

Expert Witness – Theodore Parran, Jr., M.D.

19. Theodore V. Parran, Jr., M.D., testified as an expert on behalf of the State. Dr. Parran obtained his medical degree in 1982 from the Case Western Reserve University School of Medicine [CWRU] in Cleveland, Ohio. From 1982 through 1985, Dr. Parran participated in an internship and residency in internal medicine at Baltimore City Hospital, Johns Hopkins University School of Medicine, in Baltimore, Maryland. From 1985 through 1986, Dr. Parran was Chief Medical Resident in that program. Dr. Parran was certified by the American Board of Internal Medicine in 1986, and was certified in Addiction Medicine by the American Society of Addiction Medicine in 1994. From 1984 through 1988, Dr. Parran was licensed to practice medicine in Maryland, and from 1988 through the present, he has been licensed to practice medicine in Ohio. (Tr. at 465-466; St. Ex. 39)

Dr. Parran testified that, after completing his residency, he joined the faculty at Baltimore City Hospital and Johns Hopkins University. Then, in 1988, he relocated to Cleveland where he has worked at St. Vincent Charity Hospital and as a faculty member at CWRU. (Tr. at 466)

20. Dr. Parran testified that he spends approximately 60 percent of his patient care time in addiction medicine, and 40 percent in internal medicine. Dr. Parran further testified that he has experience in pain management. Dr. Parran testified that he currently treats patients with pain management issues and serves as a consultant to "other services and clinics in the evaluation and recommendations in the management of" pain. Dr. Parran estimated that he spends approximately 10 percent of his time with patients where the only issue is pain management. Dr. Parran testified that approximately 40 percent of his practice entails patients whose pain management is a significant issue but not the primary or sole issue. (Tr. at 467-468) Moreover, with respect to his training in the area of pain management, Dr. Parran testified:

I've received a lot of training in the area of pain management having to do with continuing medical education, when I was a resident. And during my chief residency there certainly weren't any pain management fellowships at that time. In fact, there really weren't even addiction fellowships at that time.

And, subsequently, I've developed and—and created continuing medical education courses in the area of chronic pain management that have been offered throughout the State of Ohio. And I am currently the medical director of a series of courses with support from the Federal Center for Substance Abuse Treatment, which offers one-day courses throughout the nation on how to aggressively and appropriately treat chronic intractable pain.

(Tr. at 469) Dr. Parran added: "I am the course director, I am a member of the development committee, and the lead—lead educator in those courses. We've taught those courses in, oh, I think seven different states at this point." (Tr. at 469-470) Finally, Dr. Parran testified that he teaches those courses through his affiliation with CWRU and the Federal Center for Substance Abuse Treatment. (Tr. at 470)

21. Dr. Parran testified that, in his practice, he prescribes controlled substances for the treatment of chronic pain, including narcotics. (Tr. at 470)
22. Dr. Parran testified that, in April 2011, the Department of Neurology at the Cleveland Clinic Foundation invited him "to give neurology grand rounds, the grand rounds presentations for all of their residents, fellows, and attendings in the department of neurology on the prudent and appropriate prescribing of opiates in the management of chronic pain." (Tr. at 473)
23. When asked if he has dealt with the issue of "pill mills," Dr. Parran replied:

The pill mill is a term that's come up recently. I've had a lot of experience working in—working both educating about and consulting with investigators regarding the investigation of physicians' prescribing practices to try to consider whether or not those prescribing practices are a part of the usual course of medical practice or outside the usual course. And so that's where my experience is.

(Tr. at 558-559)

24. Dr. Parran testified that he had been asked by the Board to review patient records of Dr. Karel. Dr. Parran reviewed "a summary sheet of an investigation of the physician's practice" and 13 medical records from Dr. Karel's practice.⁵ (Tr. at 475; St. Ex. 17)
25. Dr. Parran testified that, during his review of the patient records, he was contacted by someone from the Board and asked if he could provide at least a partial report by March 4, 2011. Dr. Parran advised that he could have only about half of the patient records finished by that time, and provided that report as requested. Mr. Zinsmaster met with the Board's Secretary

⁵ Two of the patient's whose records Dr. Parran reviewed are not named as patients in this matter. (St. Exs. 17 and 35)

and Supervising Member on March 7, 2011, and the Board issued its Notice on March 9, 2011. Later, in an addendum to his report dated March 10, 2011, Dr. Parran provided his opinions concerning the remainder of the patient records. Dr. Parran's initial report and addendum are identified as State's Exhibit 17. (Tr. at 302-304, 326, 480-481, 626-631)

Expert Witness – David Ross, M.D.

26. David B. Ross, M.D., testified as an expert witness on behalf of Dr. Karel. Dr. Ross obtained his medical degree in 1979 from the University of Miami School of Medicine in Miami, Florida. From 1979 until 1980, Dr. Ross interned at that same institution. From 1980 through 1984, he participated in and completed a neurology residency at the Longwood Area Training Program, Harvard Medical School, in Boston, Massachusetts. From 1982 through 1983, he served as chief resident. Following completion of his residency, Dr. Ross "did a year of academic medicine at the University of Miami," then entered private practice in southeast Florida. He was certified by the American Board of Psychiatry and Neurology, and he is board-eligible in electromyography. He is licensed to practice medicine in Florida. (Respondent's Exhibits [Resp. Exs.] A, B)

Dr. Ross' April 27, 2011, report states:

My academic background was in biochemistry, neurobiology, and a special interest in neuromuscular disease. Upon entering private practice, my interests gravitated toward the problems of neurotrauma. I have gradually focused my practice on the issues behind the complaints of post-traumatic neurocognitive deficits and pain.

(Resp. Ex. A)

27. Dr. Ross testified concerning his current activities:

I've been increasingly interested in the problem of pain management, I left my group practice, I became a solo practitioner to work on that problem and to find solutions to the current epidemic. I invented a technique that I will refer to as NP3, [which] helps evaluate the emotional versus physical versus social issues underlying pain complaints.

For that technique, I won an award from Modern Marvels, History Channel and Time Magazine for one of the Best Inventions in the World 2006. What is not reflected on my CV because I haven't really had a chance to update it is that I've been giving presentations on equipment and on approaches to this problem in a wide variety of venues, including academic ones such as at Johns Hopkins, Harvard, Mayo Clinic, University of Miami, to professors at University of Louisville.

I have had conversations with medical directors, and presentations with medical directors of Travelers, the regional medical director of Liberty Mutual, medical director of Broadspire, I've talked to CEOs of companies, including—and medical schools.

This is where I dedicate my life right now. Outside of my private practice, all of my spare time is on this project.

(Tr. at 826-827)

28. Dr. Ross further testified that he has lived for 27 years in Broward County, Florida, which he described as “one of the epicenters of the pill mill controversy.” (Tr. at 827)
29. Dr. Ross testified that he first became familiar with Dr. Karel about five or six years ago. At that time, Dr. Ross was looking for a partner, and that he “interviewed and talked seriously with Dr. Karel for several months.” Ultimately, Dr. Karel could not easily move to Florida, so that ended their relationship. However, Dr. Ross testified that he has since had a couple conversations with Dr. Karel around 2005 or 2006, wherein Dr. Karel expressed interest in Dr. Ross' project. The next time Dr. Ross heard from Dr. Karel was when Dr. Ross was asked to testified as an expert witness in this matter. (Tr. at 830-831)

Dr. Ross testified that he can remain an impartial expert witness because there is no friendship or closeness with Dr. Karel that could impact Dr. Ross' opinion in favor of Dr. Karel. (Tr. at 832)

30. Dr. Ross testified with respect to his report that he had had only about two weeks to prepare during a time when he was very busy with other matters. Dr. Ross further testified:

I approached this with first trepidation because it's not my habit to bias towards the kind of practice Dr. Karel has.

When * * * the other issues of unfair treatment [were explained to me], I agreed to look at it. Literally, I was shocked by what I think is, by and large, a witch hunt. I, therefore, agreed to take it on * * *.

(Tr. at 836)

31. Dr. Ross testified that, in preparation for his testimony, he had reviewed all of the exhibits that the State intended to present, including Dr. Parran's report, the Notice, and KASPER and OARRS reports. (Tr. at 834)
32. In his report, Dr. Ross referred each of the patients by their initials. (Resp. Ex. B) Each patient relevant to this matter has a unique set of initials, which makes it easy to identify each patient based upon their initials. (St. Ex. 35)

Records for Patients 1 through 16

33. During the course of Dr. Karel's practice at the Medical Office and/or Tri-State Primary Care, he undertook the care of Patients 1 through 16 and prescribed controlled substances to each of those patients. (St. Exs. 1-16)
34. Four of the patients are Dr. Karel's employees: Patients 1, 3, 9, and 10. They are Dr. Karel's entire office staff. (Tr. at 56-58; St. Ex. 19 at 7; St. Ex. 35)
35. The presentation of patient records and prescription records in this matter is complicated:
 - With respect to Patients 1, 2, 10, and 11, no medical records were presented, only pharmacy records and/or copies of prescriptions.
 - With respect to Patients 3, 4, 5, 7, 8, 12, 13, and 16, only medical records from Tri-State Primary Care were presented. However, as set forth elsewhere in this report, all of those patients except Patient 12 had been seen previously by Dr. Karel at the Medical Office.
 - With respect to Patients 9, 14, and 15, medical records from both Tri-State Primary Care and the Medical Office were presented.
 - With respect to Patient 6, the *only* records presented are from the Medical Office because Patient 6 was never seen at Tri-State Primary Care.

(St. Exs. 1 – 16)

36. Dr. Parran reviewed Dr. Karel's medical records for the following patients named in the Notice: Patients 3, 4, 5, 7, 8, 9, 12, 13, 14, 15, and 16. With respect to Patient 13, Dr. Parran rendered no opinion, and thus found no violation with respect to Dr. Karel's care and treatment of that patient. (St. Exs. 17, 41A)

In addition, Dr. Parran's report addressed two patients not identified in the Notice. Neither of those patients is relevant to this matter. (St. Ex. 17)

37. It does not appear from Dr. Parran's report that he had reviewed the Medical Office records for Patients 9, 14, and 15. His patient reviews begin with treatment rendered by Dr. Karel in or subsequent to July 2009, after Dr. Karel had opened Tri-State Primary Care. Further, Dr. Parran did not offer any opinion concerning Dr. Karel's treatment of the patients prior to July 2009. (St. Ex. 17)

The Controlled Substances Act; OxyContin and Oxycodone

38. Dr. Parran testified that the Controlled Substances Act is a federal classification system that differentiates between different drugs with abuse potential. Schedule I includes drugs that

have no legitimate medical purpose, such as heroin and LSD. Schedules II through V include medications that have a legitimate medical purpose in descending order of abuse potential. Dr. Parran testified that Schedule II includes medications that have the highest level of abuse potential and carry the highest risk of causing accidental overdose. Further, a prescription for Schedule II medications cannot include refills, whereas a prescription for a Schedule III through V medication can. (Tr. at 477-478)

39. All patients except one (Patient 11⁶) received from Dr. Karel prescriptions for OxyContin, oxycodone, or both. Dr. Parran testified that both OxyContin and oxycodone are opioid pain relievers and are Schedule II controlled substances. Dr. Parran testified that both OxyContin and oxycodone contain the same active ingredient, which is oxycodone. The difference between the two is that oxycodone is immediate release and OxyContin uses a slow-release formulation that releases oxycodone into the bloodstream slowly over a 12-hour period. (Tr. at 494-496, 546-547)
40. Dr. Parran testified that OxyContin and oxycodone are sought after by drug abusers: “OxyContin is typically abused by crushing it in order to break up that matrix that provides the slow release, and then snorting it or chewing it in order to break up that matrix and [absorb] it very rapidly.” He noted that abusers will sometimes try to dissolve OxyContin to use it intravenously, but that that is not very effective. However, Dr. Parran testified that plain oxycodone tablets “very often are heavily sought after on the street because they can be crushed, dissolved, and shot IV.” (Tr. at 547-548)

Common Elements in Dr. Karel’s Medical Records for Patients 3, 4, 5, 7, 8, 9, 12, 14, 15, and 16

41. Several common elements appear in many or all of the medical records presented. These include the following:

Malpractice Insurance Notices

42. Patients 3, 5, 7, 9, 12, and 14 each signed a form that states: “I have read and understood the following: Douglas B Karel, M.D. is no longer covered by malpractice insurance.” (St. Ex. 3 at 16; St. Ex. 5 at 9; St. Ex. 7 at 11; St. Ex. 9 at 9; St. Ex. 12 at 10; St. Ex. 14 at 9) (Punctuation as in original)
43. Dr. Karel testified that he would like to have had malpractice insurance. However, he testified that, after entering into a consent agreement with the Board, he has been unable to obtain malpractice insurance. (Tr. at 49)

⁶ Patient 11 received hydrocodone with acetaminophen. Hydrocodone is a Schedule III controlled substance. (St. Ex. 11; Drug Information Online <<http://www.drugs.com/hydrocodone.html>>, accessed June 11, 2011.)

Statement Signed by Patients

44. Each of Dr. Karel's patient records include the following pre-printed statement signed and dated by the patient:

I am seeking healthcare services for the treatment of my painful condition from Douglas B. Karel, MD.. I understand that my accuracy, completeness and truthfulness in reporting my history and symptoms will directly contribute to the development of my treatment plan and the improvement in my painful condition. I acknowledge that I intend to provide all necessary releases for healthcare information so that Douglas B. Karel, M.D. may receive my previous healthcare records from other clinicians. I know that if I am not accurate, complete and truthful in providing my history and symptoms Douglas B. Karel, M.D. cannot safely treat me for my painful condition.

I intend to disclose the names of all prior treating practitioners and to inform Douglas B. Karel, M.D.. of all current prescribers of controlled substances. I do not intend to seek medications for any other purposes than my personal medical needs. I will not deliberately misrepresent my history, prevent Douglas B. Karel, M.D. from obtaining my previous medical records, fail to inform Douglas B. Karel, M.D.. about the existence of other sources of prescription medication, or allow anyone other than myself to take medication prescribed to me. I understand that obtaining controlled substances through false representations is a crime and that I will be reported to law enforcement officials for attempting to fraudulently obtain these medications for non-therapeutic purposes.

I am seeking treatment for the purpose of reducing or relieving my pain. I am not seeking care from Douglas B. Karel, M.D. as part of an ongoing investigation. I am a legitimate patient voluntarily seeking healthcare services for a painful condition. (Emphasis added)

(St. Ex. 3 at 8; St. Ex. 4 at 9; St. Ex. 5 at 11; St. Ex. 7 at 14; St. Ex. 8 at 9; St. Ex. 9 at 12; St. Ex. 12 at 13; St. Ex. 13 at 10; St. Ex. 14 at 12; St. Ex. 15 at 13; St. Ex. 16 at 9)

(Punctuation as in originals)

45. With respect to requiring patients to sign a statement that they are not part of an ongoing investigation, Dr. Parran stated that he has "never seen anything like that written in a medical record ever in my life." (Tr. at 505) When asked what his impression had been when he first read that statement, Dr. Parran replied:

I was absolutely astonished. Asking a patient to—to verify in writing that they are not—basically, at least my understanding of this, is the patient's verifying in writing that they're not functioning in an undercover capacity for an—on an investigation of the doctor is—is—is incomprehensible.

(Tr. at 505-506)

46. Dr. Karel testified that he had simply used the same form that was used by his previous employer, the Medical Office. Dr. Karel further testified:

This is what they had done. I assumed it was correct. And when—“as part of an ongoing investigation,” I must point out that I have had people, not too many, but two or three people tell me that they were stopped and they were found with this medication, would I kindly write them a prescription to show that they were positive for that medication—to show that they were prescribed their medications.

* * *

So I—This can be interpreted two ways. As part of an investigation on either me or the patient, that they’re not seeking care from me as part of an investigation.

(Tr. at 142-143) Moreover, Dr. Karel testified that he copied the form and “didn’t bother reading it.” He also testified that he “figured there was some reason it was there” and left it in. Furthermore, Dr. Karel testified: “When I fill out a mortgage application, there’s many * * * things. I don’t know what they mean. That’s required for whatever reason. I just copied the form.” (Tr. at 144)

47. In his report, Dr. Ross expressed the following opinion with respect to the patient statement:

Dr. Karel has an unusual statement in some of his intake forms. So what? The State Medical Board has the responsibility to ask where he obtained that statement, its meaning and purpose. The State Medical Board has absolutely no ethical justification by which it should engage in unbridled supposition or innuendo when assessing a person’s rights to continue his profession.

(Resp. Ex. B at 19-20)

Patients Paid in Cash

48. Dr. Karel acknowledged that the only method of payment he accepted was cash. He did not accept credit cards or checks. He further testified that he did not accept Medicare or Medicaid as payment. Moreover, Dr. Karel testified that he did not take private insurance either, although he said that was more a matter of the insurance companies not accepting him, not the other way around. In addition, Dr. Karel testified that his previous employer, the Medical Office, also accepted only cash. Finally, ledgers from Tri-State Primary Care indicate that the vast majority of Dr. Karel’s patients paid \$200 per visit. (Tr. at 62-64; St. Exs. 24A through 24C)

Patients Previously Seen by Dr. Karel at the Medical Office

49. Dr. Karel testified he had previously seen and treated Patients 1 through 16 at the Medical Office.⁷ Dr. Karel further testified to the effect that their first visits to Tri-State Primary Care were therefore more in the nature of follow-up visits rather than true initial visits. (Tr. at 1344, 1362)
50. The initial office visit notes for Patients 5, 7, 8, 9, 14, 15, and 16 all include a notation indicating “old patient.” (Tr. at 207-210; St. Ex. 5 at 40; St. Ex. 7 at 57; St. Ex. 8 at 57; St. Ex. 9 at 58; St. Ex. 9A; St. Ex. 14 at 23; St. Ex. 14A; St. Ex. 15 at 24; St. Ex. 15A; St. Ex. 16 at 82)

The initial visit notes for Patients 3 and 4 lack the “old patient” notation; however, a KASPER report indicates that Dr. Karel had prescribed medication to these patients since sometime in 2008, when he worked for the Medical Office. (St. Ex. 3 at 101-102; St. Ex. 4 at 31-32; Resp. Ex. K at 17-18, 387-388)

The sole exception is Patient 12. The initial office note for Patient 12 lacks the “old patient” notation, and OARRS and KASPER reports indicate that Dr. Karel had first prescribed controlled substance medication to her on June 24, 2009. This casts some doubt on whether she had been an old patient of Dr. Karel’s at the Medical Office. (Resp. Ex. J at 71; Resp. Ex. K at 276-277)

Evidence Concerning Individual Patients:

Patient 3

51. Patient 3 is a female born in 1968. Her first visit to Tri-State Primary Care was July 22, 2009. Dr. Karel testified that he had previously treated Patient 3 for an extended period of time at the Medical Office. Patient 3’s chart from the Medical Office is not included in the hearing record. She is employed by Dr. Karel. (Tr. at 56, 107; St. Ex. 3 at 2, 101-102)
52. Dr. Karel identified his handwriting on the progress note for Patient 3’s July 22, 2009, visit. It appears on the first page in the sections labeled Notes, Impression, Plan/Discussion, and on the second page. The other handwriting, at the top of the first page (and the highlighted portion under Plan/Discussion), belongs to another one of his employees, probably Patient 10. (Tr. at 105-106; St. Ex. 3 at 101-102)
53. Records in Patient 3’s chart indicate that she had been seen in 2008 by a physical therapist after referral by Dr. Karel. (St. Ex. 3 at 115-129)

⁷ Only Patients 3, 4, 5, 7, 8, 9, 12, 14, 15, and 16 are relevant to the patient care issues addressed by Dr. Parran in his report and testimony.

54. Information written in an employee's handwriting indicates that Patient 3's current medications as of July 22, 2009, had been:

oxycodone 30 mg #150 **3x per day**
OxyContin 20 mg #150 **3x per day**
Xanax 2 mg #15 as prescribed

However, assuming Patient 3 had been prescribed a 30-day supply of oxycodone and OxyContin, 150 pills meant the patient was taking five pills per day, not three. (St. Ex. 3 at 101; emphasis added)

55. Dr. Karel described what he had written on the July 22, 2009, progress note. He checked boxes indicating that Patient 3's heart had "regular rate and rhythm" and that her lungs were "clear to auscultation and palpation." Further, under Notes, he wrote that Patient 3 was alert and oriented times three ("A&Ox3"), neck supple with full range of motion ("Neck Supple \bar{c} FROM"), motor and sensory intact ("M&S intact"), and "Gait intact." Dr. Karel defined the note "motor and sensory intact": "I am a neurologist and to say motor and sensory are intact means quite a bit. They can move their arms and legs very well and there's no apparent sensory deficits." Moreover, Dr. Karel explained that "Gait intact" means that the patient is "able to walk correctly with no limp, with not favoring one side, no apparent quote dizziness, unquote." (Tr. at 108-110; St. Ex. 3 at 101)
56. Dr. Karel testified that the July 22, 2009, progress note documents diagnoses of lower back pain ("LBP") and history of lumbar degenerative disk disease (" \bar{p} lumbar DJD"). (Tr. at 117; St. Ex. 3 at 101)
57. Dr. Karel acknowledged that he had not documented a complete history for Patient 3 at her July 22, 2009, visit. However, he testified that he was familiar with this patient having treated her before at the Medical Office. (Tr. at 117-118)
58. On July 22, 2009, Dr. Karel prescribed the following medications to Patient 3: oxycodone 30 mg #180 with no refills, OxyContin 20 mg #150 with no refills, and Xanax 2 mg #15 with no refills. (St. Ex. 1 at 95-101)
59. When asked where in the chart he documented the reason for prescribing OxyContin, oxycodone, and Xanax to Patient 3, Dr. Karel replied:

The patient had complaints of lower back pain. The patient had had these complaints for many years and seen several physicians for this in the past and been given medication which helped relieve the pain.

* * *

The medication was given. The patient had no side effects or significant compromise. The pain the patient had was relieved with the pain medication.

I thought the patient has pain, it's relieved with medication, no side effects, I would continue prescribing the medications which would allow her to function.

(Tr. at 120)

When asked about the prescription for Xanax, Dr. Karel testified that the calming effects of Xanax “allows the oxycodone—the other agents to work and help relieve the pain considerably.” (Tr. at 120-121)

60. The progress note for July 22, 2009, indicates that Dr. Karel had increased the quantity of oxycodone 30 mg from 150 to 180 pills. When asked if he had documented a reason for the increase, Dr. Karel could not find it documented, but assumed that the patient had complained. (St. Ex. 3 at 101; Tr. at 124-125)

61. Patient 3's chart indicates that Dr. Karel issued her the following prescriptions:

Date of Prescription	Medication	Quantity	Refills	Daily Dose (30-day supply) ⁸
7/22/09	OxyContin 20 mg	150	0	100 mg
7/22/09	oxycodone 30 mg	180	0	180 mg
7/22/09	Xanax 2 mg	15	0	1 mg
8/18/09	OxyContin 20 mg	150	0	100 mg
8/18/09	oxycodone 30 mg	180	0	180 mg
8/18/09	Ativan 1 mg	30	0	1 mg (med change)
9/18/09	OxyContin 20 mg	150	0	100 mg
9/18/09	oxycodone 30 mg	180	0	180 mg
10/12/09	OxyContin 20 mg	150	0	100 mg
10/12/09	oxycodone 30 mg	180	0	180 mg
10/12/09	Ativan 1 mg	30	0	1 mg
11/6/09	OxyContin 80 mg	60	0	160 mg (↑) ⁹
11/6/09	oxycodone 30 mg	180	0	180 mg
11/6/09	Xanax 1 mg	30	0	1 mg (med change)
12/3/09	OxyContin 40 mg	120	0	160 mg
12/3/09	oxycodone 30 mg	180	0	180 mg
12/3/09	Xanax 1 mg	30	0	1 mg
12/30/09	OxyContin 40 mg	120	0	160 mg
12/30/09	oxycodone 30 mg	180	0	180 mg
12/30/09	Xanax XR 1 mg	30	0	1 mg

⁸ Dr. Karel testified that he sees his patients on a monthly basis. (Tr. at 1363)

⁹ An up-arrow indicates that the daily dose of that medication increased over the previous visit. A down-arrow means the daily dose decreased.

Date of Prescription	Medication	Quantity	Refills	Daily Dose (30-day supply) ⁸
1/26/10	OxyContin 40 mg	120	0	160 mg
1/26/10	oxycodone 30 mg	180	0	180 mg
1/26/10	Xanax 1 mg	30	0	1 mg
1/26/10	Zanaflex 4 mg	90	5	12 mg
2/22/10	OxyContin 40 mg	120	0	160 mg
2/22/10	oxycodone 30 mg	180	0	180 mg
2/22/10	Xanax 1 mg	60	0	2 mg (↑)
3/22/10	OxyContin 40 mg	120	0	160 mg
3/22/10	oxycodone 15 mg	180	0	90 mg (↓)
3/22/10	Ativan 2 mg	60	0	4 mg (med change)
3/22/10	Zanaflex 4 mg	90	0	12 mg
4/15/10	OxyContin 40 mg	120	0	160 mg
4/15/10	oxycodone 15 mg	180	0	90 mg
4/15/10	Ativan 2 mg	60	0	4 mg
5/21/10	OxyContin 40 mg	120	0	160 mg
5/21/10	oxycodone 15 mg	180	0	90 mg
5/21/10	Klonopin 1 mg	60	0	2 mg (med change)

(St. Ex. 3 at 19-101)

Testimony of Dr. Parran

62. Dr. Parran testified that Patient 3 presented on July 22, 2009, with a complaint of “longitudinal low-back pain.” He noted that an October 2006 MRI report indicated degenerative disc disease in the lumbosacral spine, “but the radiologist called it very minimal.” Patient 3 reported her then-current medications as OxyContin 20 mg, oxycodone 30 mg, and Xanax 2 mg. There were some prior medical records in the chart, as well as pharmacy profiles and physical therapy progress notes from 2008. (Tr. at 538-539; St. Ex. 3 at 110)
63. Dr. Parran testified that it was good that Dr. Karel had previously referred Patient 3 to physical therapy. Dr. Parran further testified that he would have expected that a patient with an MRI scan such as Patient 3’s would have responded well to physical therapy and that her back pain would have resolved; however, “that apparently didn’t happen.” He acknowledged, however, that not all of the medical charts are available from 2008 onward. (Tr. at 540-541)
64. Dr. Parran acknowledged that, over the course of treating Patient 3, Dr. Karel had reduced Patient 3’s daily oxycodone intake. However, Dr. Parran testified that the benzodiazepine dose had essentially doubled or quadrupled. (Tr. at 672-673)

65. Dr. Parran testified:

[M]y opinion was that the prescribing was done in a way that was inconsistent with the standards of care in the community, and inconsistent with a—with the use—legitimate medical purpose, and inconsistent with using appropriate care and scientific method in the selection of controlled drugs.

(Tr. at 541)

Dr. Ross's Report

66. In his report, Dr. Ross opined as follows concerning Dr. Parran's analysis of Patient 3's chart:

I * * * found that Dr. Parran's analysis of the material was egregiously flawed and biased. * * * I will simply use Dr. Parran's extractions and will not refer to the charts themselves unless otherwise indicated. My analyses of his extractions are underlined for clarity.

* * *

[Patient 3] Patient seen in July 2009 with chronic low back pain. Already on Oxycontin 80mg bid, Oxycodone 30mg five times a day and Xanax. Sent for PT referral. On last office visit of May 2010, the patient is on Oxycontin 40mg tid, and Oxycodone 15mg q3 hours. Patient off Xanax and on Klonopin. **Dr. Parran ignores the fact that the patient's Oxycodone daily regimen has been reduced from 310mg per day to 210 mg per day. The records reflects a reduction of 30 percent in 10 months; this again contradicts the actions of a pill-mill doctor whose vested financial imperative is to increase opioid medications that the facility is dispensing at high profit margins.**

(Resp. Ex. B at 12) (Underline in original, bold added)

67. Both of Dr. Ross's calculations of the amount of oxycodone that Patient 3 received are incorrect:

- At Patient 3's initial visit on July 22, 2009, Dr. Karel prescribed OxyContin 20 mg #150 and oxycodone 30 mg #180 (plus Xanax). Accordingly, Patient 3's daily dose of oxycodone at the outset was $(20 \text{ mg} * 150) / 30 + (30 \text{ mg} * 180) / 30 = 280 \text{ mg}$, *not* 310 mg.
- At Patient 3's last visit on May 21, 2010, Dr. Karel prescribed OxyContin 40 mg #120 and oxycodone 15 mg # 180 (plus Klonopin). Accordingly, Patient 3's daily dose of oxycodone as of May 21, 2010, was $(40 \text{ mg} * 120) / 30 + (15 \text{ mg} * 180) / 30 = 250 \text{ mg}$, *not* 210 mg.

Therefore, from July 2009 through May 2010, Patient 3's daily dose of oxycodone was reduced from 280 mg to 250 mg, roughly an 11 percent reduction, which is a far less dramatic decrease than Dr. Ross's report indicates. Moreover, Dr. Ross failed to address the benzodiazepines that Dr. Karel had prescribed to Patient 3. (St. Ex. 3 at 19, 21, 95, 97)

Testimony of Patient 3

68. Patient 3 testified that she is an employee of Dr. Karel's and that she works for Tri-State Primary Care. She testified that she has worked there for the past two years. Prior to that, Patient 3 had worked for the Medical Office for a very short time. When she started working at the Medical Office, Dr. Karel had already left for his medical leave and Dr. Celec (a *locum tenens* physician) was seeing patients. She had been Dr. Karel's patient at the Medical Office for about one year by that time. (Tr. at 732-733, 738-739, 749-750)
69. Patient 3 testified that, in 1993, her ex-husband beat her severely: "He broke my nose in two places, kicked me in the ribs and sent me down a flight of steps." Patient 3 further testified that she sustained low back injuries as a result. She has seen several physicians over the years. The physician prior to Dr. Karel treated her from 2006 to 2008. Patient 3 testified that that physician put her on oxycodone and Xanax, the Xanax to treat her "[n]erves." Patient 3 testified that she also suffers from panic attacks, and "[a] lot of that stems from my mother's death back in 2006." Patient 3 testified that when she stopped seeing that doctor she had been on OxyContin 80 mg, either 60 or 90 tablets per month, and oxycodone 30 mg, 120 tablets per month. (Tr. at 740-744)
70. Patient 3 testified that, around June 2008, for her first visit to Dr. Karel, she had been asked to bring with her a prescription history and a copy of her MRI. She further testified that, at her first visit, Dr. Karel asked her questions and had her walk across the room, had her bend over as far as she could, and checked her reflexes. She also testified that Dr. Karel spent 20 or 25 minutes examining her and reviewing her history. When asked if that was all that had happened, Patient 3 replied: "I didn't see what else there was to do. * * * I've never had any kind of exam before that was anything other than listening to my heart and [taking my] blood pressure." (Tr. at 745-748, 809)

Moreover, she testified that Dr. Karel told her that she was on an "[e]xtremely" high dosage of medication and "reduced [her] medications constantly" to oxycodone 30 mg #70. (Tr. at 746-747)

When asked if that had helped her, Patient 3 replied that it was hard at first but that she found that the higher amount of medication masked her pain and allowed her to hurt herself more, while the lower dose kept the pain down but left her able to still feel it "to where [she] would not re-injure [her]self." (Tr. at 747)

71. Patient 3 testified that, during her course of treatment with Dr. Karel, he had recommended other modalities of treatment beside controlled substance medication. Patient 3 testified

that he sent her to a physical therapy consult, and orthopedic consult, and she had to have “CBCs” and “CNPs” done. She further testified that she could not have an MRI because of her financial situation, and that she would have had to put “\$800 down just for the MRI.” Patient 3 noted that she did not have health insurance. (Tr. at 762-763)

72. Patient 3 testified that she has not had health insurance since 2003 except during a very brief time, which occurred after she had begun working for Dr. Karel. Patient 3 further testified that she had only had it for two or three months. Patient 3 further testified that she has paid Dr. Karel \$200 for every one of her visits without exception. (Tr. at 801)
73. Patient 3 testified that OxyContin is expensive. She acknowledged that, in October 2007, she had filled a prescription for OxyContin 80 mg #120 prescribed by another physician and paid \$1,371.00 in cash. She further acknowledged that the previous month, September 2007, she had filled another prescription for OxyContin 80 mg #120 and paid \$1,332.11 in cash. Moreover, Patient 3 acknowledged that she had spent around \$18,000.00 per year for OxyContin. When asked if she had been working in 2007 as a waitress and an office worker, Patient 3 added that she had also refinished houses, and worked as a housekeeper and a nanny. (Tr. at 811-813)

Patient 4

74. Patient 4 is a male born in 1973. Patient 4’s first visit to Tri-State Primary Care was on September 21, 2009. His current medications were documented as OxyContin 20 mg twice per day, oxycodone 15 mg twice per day, Motrin 800 mg three times per day, and Zanaflex 4 mg three times per day. In his notes, in addition to vital signs and heart and lung exam, Dr. Karel documented findings that Patient 4 was alert and oriented times three, neck supple with full range of motion, motor and sensory intact, full range of motion, and gait intact. Dr. Karel testified that he had documented impressions of “low back pain, status post L4 and L5 fracture, and history of L-spine DJD.” He ordered bloodwork and prescribed oxycodone 15 mg #60, OxyContin 20 mg #60, and Motrin 800 mg #90. (Tr. at 126-127; St. Ex. 4 at 2, 31)
75. Dr. Karel testified that he had previously seen Patient 4 when he practiced at the Medical Office. Dr. Karel further testified that he had initially assumed that the Medical Office, which by then had changed its name to Greater Medical Advance, would forward him his patients’ charts. However, Dr. Karel testified that, despite repeated requests, those records were never sent to him by the Medical Office/Greater Medical Advance, including Patient 4’s prior medical records. (Tr. at 204, 207-210, 217, 1344, 1362, 1367-1368)
76. Dr. Karel issued the following prescriptions to Patient 4:

Date of Prescription	Medication	Quantity	Refills	Daily Dose (30-day supply)
9/21/09	OxyContin 20 mg	60	0	40 mg
9/21/09	oxycodone 15 mg	60	0	30 mg

Date of Prescription	Medication	Quantity	Refills	Daily Dose (30-day supply)
9/21/09	Motrin 800 mg	90	5	2400 mg
10/21/09	OxyContin 20 mg	60	0	40 mg
10/21/09	oxycodone 15 mg	60	0	30 mg

(St. Ex. 4 at 18-31)

77. A note dated November 2, 2009, and initialed by Patient 10 (Dr. Karel's employee) states: "Pt. was called in for med. count & (UDS) drug screen. He was unable to be reached & was dismissed for not updating personal info, such as ph. #s." (St. Ex. 4 at 17; St. Ex. 35)
78. Patient 4's chart includes a urine drug screen report dated September 21, 2009, that indicates that his urine tested positive for oxycodone and opiates and negative for other substances tested. (St. Ex. 4 at 82) Dr. Karel testified that he uses drug test kits. If there are any questions about the results, the sample can be sent to a lab for further testing. (Tr. at 129-131)
79. Dr. Karel testified that this patient had been discharged from Tri-State Primary Care following two visits. Dr. Karel further testified that he discharges many patients and that that "certainly goes at odds against the basic tenet and concept of a pill mill, that I'm discharging so many patients." (Tr. at 132-133)
80. Patient 4's chart includes a photocopy of his State of Ohio non-driver ID card. When asked if that had raised any concern, Dr. Karel replied that he had not even been aware of that fact. When asked what a non-driver ID card might indicate, Dr. Karel testified that "[m]ost probably the patient is unable to drive for some reason." (St. Ex. 4 at 16; Tr. at 133-134) When asked if he would be concerned about prescribing pain medication to someone who lost their license "for a potential abuse situation," Dr. Karel replied:

Well, if he had lost his license for an abuse, that could be one thing. If he has another medical condition which is preventing him from driving, that would be a reason. I don't know—I had not even noted there was an ID card, not a driver's license, until you pointed that out to me.

* * *

If he—If he lost it for an abuse situation, perhaps. If he was never issued a license for another medical problem or the patient may have—I'm a neurologist. I've had a number of people—I have seen many people who have had seizures who are not allowed to drive, who could not get them. It occurred very often. Someone can't drive, I don't think that they had it revoked because of an abuse. I think it could be medical reasons.

(Tr. at 134-135)

81. When advised that several of the medical records in this matter indicate that patients possessed non-driver ID cards, and asked whether that would surprise or concern him, Dr. Karel replied: “Certainly. I—I was informed of this two seconds ago. I hadn’t even noticed.” (Tr. at 135)

Testimony of Dr. Parran

82. Dr. Parran noted that Patient 4 was a 36-year-old male who presented with back pain complaints, and reported that he had been taking OxyContin 20 mg and oxycodone 15 mg. Patient 4 signed a Consent to Release/Receive Confidential Information which Dr. Parran believes was for the purpose of obtaining records; however, the form was not addressed to any office. (Tr. at 485-486; St. Ex. 4 at 4-8, 31)
83. Dr. Parran testified that Dr. Karel’s documentation of an initial history and physical examination had been insufficient and inconsistent with the standard of care. Dr. Parran further testified that it lacked “the detail and the care necessary to be considered using appropriate caution and appropriate scientific method to try to establish a diagnosis.” Moreover, Dr. Parran testified that he would not change his opinion even if Patient 4 had previously been treated by Dr. Karel when Dr. Karel was practicing in another office. Even if the patients had been seen previously by Dr. Karel at a different practice, Dr. Parran testified he would expect more to be documented with respect to an initial visit. He would not necessarily expect it to be as thorough as a first-ever history and physical examination; nevertheless, since it is the first documentation in the patient’s chart for the new office, he would expect it to be “substantially more rigorous than just a regular follow-up note.” (Tr. at 490-492, 582)

Furthermore, Dr. Parran testified that he did not “see anything that looked like individualized physical exams in the charts,” except for one patient.¹⁰ Moreover, Dr. Parran testified that, with the exception of one chart, those findings have “exactly the same words written in exactly the same place in the physical exam as every single visit” that Dr. Parran reviewed. Finally, Dr. Parran testified that, “typically, the treatment plan was strikingly similar, if not actually identical.” (Tr. at 495-496; St. Ex. 4 at 31)

84. When asked if less documentation for a first visit to a new office would be acceptable if the physician expected to obtain the records from the prior practice, Dr. Parran answered “no.” He explained that, in order to safely treat the patient, the physician must require at least the last two or three progress notes, the original history and physical examination, x-ray studies, and some toxicology screens. Moreover, he testified that, especially with patients who are being prescribed high doses of opiates, “if a doctor makes a mistake and we confuse one patient for another and these doses of opiates were prescribed to a person who didn’t have a lot of tolerance to opiates, it could easily be fatal.” (Tr. at 583-584)

¹⁰ Dr. Parran is probably referring to Patient 16. Dr. Karel’s exam findings for Patient 16 contain more detailed information than, for example, his chart for Patient 4. (St. Ex. 16 at 81)

Dr. Parran further testified that, although he can give some “credence and credit” to Dr. Karel’s having anticipated that his old practice would forward medical records to him:

The issue that I have is that in the records themselves, there aren’t the release of information forms to go to that previous practice to bring the records. What—Actually, several.

At least three or four of the cases at the end of that first progress note it says, “Patient told to go get old records.”¹¹ That—That’s not the way to get old records in the usual course of medical practice. Patients can launder their records, they can throw out the bad stuff and just bring you the good stuff.

The way to get records is to have people fill out a release of information form, fax it over, call over, and then follow up with—with the office.

Now, as I looked through the charts, I didn’t see a lot of those release of information forms to a previous practice.

(Tr. at 586-587)

Moreover, Dr. Parran testified that, if a physician is having difficulty with a former practice that is uncooperative in providing prior records of his care of patients, the physician “better go do the physical and history and get it in the chart * * * because it’s not going to show up from before.” (Tr. at 589-590) He further testified:

[I]f a doctor wants to, you know, put an asterisk in the initial office visit and say, “Please see visit six months from now for more of a thorough H&P since I couldn’t get the old medical records,” then that’s up to the doctor. But the need is to do a thorough H&P, and a thorough H&P takes time and it takes, you know, rigorous clinical thinking, rigorous clinical data gathering and time. But it just has to be done for patient safety.

(Tr. at 590-591)

Finally, Dr. Parran testified that this is not merely a recordkeeping issue, but a “clinical practice issue of taking the time and energy to thoroughly and—and rigorously obtain the clinical database from a patient and to document it in the medical record.” (Tr. at 591)

85. Dr. Parran explained why he believes it is significant when a patient presents with a non-driver ID card:

¹¹ This statement in Patient 4’s chart appears to contradict Dr. Karel’s assertion that he only accepts records directly from the provider. (Tr. at 66-67)

Well, 36-year-old Ohioans who, you know, are ambulatory and not wheelchair bound, and who aren't blind or obviously disabled from something that would preclude them from being able to be a driver, are drivers. And if they're not, it's generally for a fairly important legal and fairly important clinical reason.

And so when faced with non-driver state ID cards, and a person who anyone walking down the street would assume—assume was a driver, that's sort of a critical piece of clinical information which should be addressed in the usual course of medical practice by a clinician. Especially if that clinician is considering prescribing controlled drugs to that patient.

(Tr. at 486)

86. Patient 4's chart includes urine drug screen results obtained during Patient 4's initial visit. With respect to that screen as well as the drug screen results included in each of the patient charts, Dr. Parran testified that the results were positive for opiates and oxycodone. (Tr. at 487-488; St. Ex. 4 at 82) Dr. Parran testified that he had been concerned about the positive opiate results on the urine drug screens because, in the past, and with some drug tests today, oxycodone will not trigger a positive result for opiates. Dr. Parran testified:

I did have some concern, when I saw opiate and oxy on all of these tox screens, that—that that tox screen might pick up oxy as an opiate, in which case it would be completely consistent, but it didn't look like it was checked to see if morphine, heroin, or codeine were there.

(Tr. at 636-637)

87. Dr. Parran testified that Dr. Karel failed to follow proper procedures in his discharging of this patient. (Tr. at 498-499)
88. Dr. Parran testified that, in his opinion, Dr. Karel violated the minimal standard applicable to the selection and administration of drugs to Patient 4. Dr. Parran further testified that, in his opinion, Dr. Karel had prescribed drugs for other than legitimate therapeutic purposes. (Tr. at 500-501)

Dr. Ross's Testimony and Report

89. Dr. Ross opined as follows concerning Dr. Parran's analysis of Dr. Karel's chart for Patient 4:

[Patient 4] The facts are that [Patient 4] was first seen in September 2009 and was released from the practice approximately one month later when he failed to return for a urine drug screen and pill count despite multiple documented attempts to reach him. Thus, the patient was discharged according to national

standards for violating office policy about the safe and appropriate monitoring.

(Resp. Ex. B at 11) (Emphasis in original)

90. With respect to Dr. Karel having previously seen these patients at the Medical Office, Dr. Ross was asked if a more detailed note would be required for the first visit to a new practice than would be required for an ordinary follow-up visit. First, Dr. Ross testified that he finds Dr. Parran's opinion that more documentation is required to be "extremely objectionable" and "contemptible." He further testified:

The bottom line of it is you're not—keeping these medical records to defend it against some witch hunt that he's going to put on his standards. You're trying to take care of patients. If you had good-faith knowledge of that patient, and you couldn't get the records, and you tried, there is no logic by which then you should go back and make up or repeat stuff that you already knew.

* * * [I]f you're living in a small environment, okay, and know these patients for a year, year-and-a-half, what is the practical application of that?

I mean, I find that extremely objectionable in this scenario to try to imply somehow that is malfeasance or below a standard. I really am aghast.

(Tr. at 867-869)

Testimony of Dr. Karel

Dr. Karel further testified:

I could not do an extensive history on the many patients that I saw every day. Every—Normally during the day I will have two or three new patients and the rest are follow-ups. In July of '09, every patient I saw was a new patient. I'd do the medical history and physical on every patient as a new patient, taking considerably more time. And there was—it would have been impossible to spend a half an hour, 40 minutes on every single patient.

(Tr. at 118; see, also, Tr. at 224)

Patient 5

91. Patient 5 is a male born in 1976. He first visited Tri-State Primary Care on July 16, 2009. The progress note for that visit indicates that Patient 5 had previously been a patient of Dr. Karel's at the Medical Office. It is also documented (in Dr. Karel's employee's

handwriting) that, at Patient 5's last visit to the Medical Office, he had been seen by another physician, Dr. Celec, who had lowered his dosage of medication.¹² (St. Ex. 5 at 16, 39-40)

Dr. Karel testified that the second page of his progress notes states:

Called about complaints of hip, neck and upper back pain with post fall from ladder—falling from ladder seven years ago and complaints of lower back pain.

Past medical history: Patient has hypertension. Past surgical history: Without. Allergies to penicillin and tramadol. Patient lives with his wife. He is the father of two and is currently employed as a building supervisor.

(Tr. at 137-138; St. Ex. 5 at 40)

Dr. Karel further testified that he had diagnosed cervicalgia (neck pain), lumbosacral herniation, and stenosis at L3-L4. (Tr. at 138-139; St. Ex. 5 at 39)

Dr. Karel prescribed oxycodone 5 mg with APAP¹³ #240 and methadone 10 mg #240. (St. Ex. 5 at 35, 37)

92. Patient 5's chart includes a photocopy of his Ohio non-driver ID card. (St. Ex. 5 at 16)
93. Dr. Karel issued the following prescriptions to Patient 5:

Date of Prescription	Medication	Quantity	Refills	Daily Dose (30-day supply)
7/17/09 ¹⁴	methadone 10 mg	240	0	80 mg
7/17/09	oxycodone 5 mg/APAP	240	0	40 mg
9/2/09	methadone 10 mg	300	0	100 mg (↑)
9/2/09	Percocet ¹⁵ 5/325	240	0	40 mg (oxycodone)
9/30/09	methadone 10 mg	300	0	100 mg
9/30/09	Percocet 5/325	240	0	40 mg (oxycodone)
10/28/09	methadone 10 mg	300	0	100 mg
10/28/09	Percocet 5/325	240	0	40 mg (oxycodone)

¹² The Tri-State Primary Care progress note indicates that Patient 5 had been taking oxycodone 5 mg, 2 every six hours, and methadone 10 mg, 2 every five hours. Dr. Celec lowered the dose to OxyContin 5 mg, 1 or 2 every eight hours. (St. Ex. 5 at 39)

¹³ APAP is an abbreviation for acetaminophen. (MedlinePlus online medical dictionary <<http://www.merriam-webster.com/medlineplus/APAP>>, accessed May 20, 2011)

¹⁴ The prescription dates differ from the date recorded on the progress note, July 17 versus July 16. (St. Ex. 5 at 35-39)

¹⁵ Percocet is a combination drug that contains oxycodone and acetaminophen. (MedlinePlus online medical dictionary <<http://www.merriam-webster.com/medlineplus/percocet>>, accessed May 20, 2011)

(St. Ex. 5 at 18-39)

94. Dr. Karel testified that on September 2, 2009, he had increased Patient 5's methadone back to the level he was on before Dr. Celec decreased it. (Tr. at 147-149; St. Ex. 5 at 34, 39)
95. Dr. Karel testified that he had treated Patient 5 for a total of about two years, including at the Medical Office, but that Patient 5 was discharged about two months after Dr. Karel began seeing him at Tri-State Primary Care. (Tr. at 145-146)
96. A November 12, 2009, note written by Patient 10 states that Patient 5 had been called in for a pill count and drug screen that day, failed to appear, and was dismissed from the practice. (St. Ex. 5 at 17)

Testimony of Dr. Parran

97. Dr. Parran noted that Dr. Karel had prescribed methadone 10 mg #240 and oxycodone 5mg/APAP at Patient 5's July 17, 2009, visit. Dr. Parran characterized that as a "large amount of methadone" and, with generic Percocet on top of that, "it's a large amount of Scheduled II opiate." Dr. Parran further testified that he had reviewed the MRI reports, EMG study, and toxicology testing, along with "the rest of the clinical information that was available" in the chart, and could find no justification for prescribing that amount of methadone. (Tr. at 502-504)
98. In addition, Dr. Parran expressed concern that, when Patient 5 came in for his September 2, 2009, visit, he had been a little over two weeks late. To Dr. Parran, that meant that either "the patient should have been out of medicine for two weeks, or didn't need the medicine" he was receiving if it had lasted for six weeks.¹⁶ Dr. Parran further testified:

[T]hat's a basic inconsistency in medical care and must be addressed in the medical record because either the patient has other sources, or they're not taking what's been prescribed and that's why they're not in withdrawal, or they spent the last two weeks in fairly severe opiate withdrawal.

I have seen patients come off of this amount of methadone overnight because I work in a methadone maintenance program, and these patients get sick as can be if they abruptly stop this kind of a dose of oxycodone and methadone. And—And so either they've been in withdrawal for a couple weeks and are in the third—entering the third week of three weeks of methadone withdrawal.

Something is wrong here and there is not only not a mention of it being wrong, but there's an increased prescribing of the methadone to the patient,

¹⁶ OARRS and KASPER reports indicate that Patient 5 did not fill any prescriptions for methadone or Percocet, or any other controlled substance, between July 17 and September 2, 2009. (Resp. Ex. J at 11-12; Resp. Ex. K at 42)

and there's no at least evidence in the record of the doctor trying to figure out where the patient's been * * * for these two weeks that they hadn't been there.

(Tr. at 506-507)

99. On September 2, 2009, Dr. Karel increased Patient 5's methadone from 240 tablets to 300 tablets per month. Dr. Parran testified that Dr. Karel documented no medical reason for that increase. Rather, Dr. Parran noted that the pain chart for Patient 5's September 2, 2009, visit had been the same as for his previous visit. Dr. Parran further testified that documentation of medical reasoning is "absolutely essential." (Tr. at 508-510; St. Ex. 5 at 32-34)

Moreover, Dr. Parran testified:

When a physician is changing a medical regimen involving dangerous drugs, meaning prescription drugs, the expectation is that there's an assessment noted for what the clinical thinking is and clinical reasoning based on what data the change is being made; and then the plan, which is how I'm going to change it and then how I'll follow up and monitor it. That's expected. It's especially expected if it's controlled drugs that are involved, and even more especially expected if it's Schedule II controlled drugs involved.

(Tr. at 508-509)

100. As set forth elsewhere in this report, Dr. Karel testified that the *only* reason that he had ever increased a patient's medication had been because the patient asked for an increase because he or she was in pain. When asked if it is acceptable to increase a patient's medication because the patient asked for an increase, Dr. Parran replied that it probably is not okay based on the patient's request alone. However, he further testified:

If the patient says that their function is impaired and that their—and that their pain is increased, and that for whatever reason they have an increased need for an increased pain medicine, then to do an evaluation of that, to provide a discussion of that in the note, and then—and then provide the increase, that certainly would be—would be consistent with * * * usual medical care.

(Tr. at 509)

However, Dr. Parran noted that the pain chart for Patient 5's September 2, 2009, visit had been the same as for his previous visit. (Tr. at 509-510; St. Ex. 5 at 34)

101. When asked why it is "absolutely essential" for a physician to document the reason for an increase in medication, Dr. Parran replied:

The medical record is the doctor's single most useful tool in tracking, monitoring, and—and coordinating the care of a patient. It's the single most useful tool.

Doctors see lots of patients every day. Doctors can't remember everything there is about patients. But if it gets noted in the medical record, then when the doctor goes back later to look at things, it's there and available to—to jog their memory.

So that's why appropriate documentation in the medical record, honestly, it's an issue of patient safety. Clinical practices or clinical offices that are committed to patient safety have appropriate documentation. And it takes some time, but it's—it's essential, and it's essential in terms of the usual course of medical practice.

(Tr. at 510)

102. Dr. Parran testified with respect to Patient 5 presenting with a non-driver ID card:

And, again, no mention, no workup, no evaluation of why this person who apparently had a normal gait—so he was walking and able to come into the office—would not have a driver's license in the State of Ohio. And that is—you know, I can't—can't overstate how important it is to—to rigorously evaluate those kinds of clinical inconsistencies in the medical record before prescribing very large amounts of Schedule II medications.

(Tr. at 504-505)

103. With respect to Dr. Karel's selection and administration of drugs in his treatment of Patient 5, Dr. Parran testified “[t]hat it was done in a manner that was inconsistent with the acceptable standard of care in Ohio and the usual course of medical practice, and that it was done in a way that was unsafe, and, therefore, for other than legitimate medical purpose.” (Tr. at 511)

Dr. Ross's Report

104. Dr. Ross opined as follows concerning Dr. Parran's analysis of Dr. Karel's chart for Patient 5:

[Patient 5] This patient was seen initially in June 2009. He was last seen in October 2009 and discharged in November due to a pill count and urinary drug screen, and an office no show. In summary, the patient was discharged according to national standards for violating office policy about safe and appropriate monitoring.

(Resp. Ex. B at 11) (Emphasis in original)

Patient 7

105. Patient 7 is a male born in 1963. His first visit to Tri-State Primary Care was on July 23, 2009. His then-current medications were recorded as OxyContin 20 mg three times per

day, oxycodone 30 mg three times per day, and Flexeril 4 mg (no dosing recorded).
(St. Ex. 7 at 3, 56)

106. Patient 7 documented his substance use history as follows:

Substance Use History

	No	Yes/Past or Yes/Now	Reason	How Much	How Often	Date/Time of Last Use	Quantity Last Used
Alcohol		yes past		Occasional	week ends	10 years	lot
Caffeine (pills or beverages)	✓						
Cocaine	✓	yes past		occasions	2 times month	10 years	very little
Crystal Meth- Amphetamine	✓						
Heroin	✓						
Inhalants	✓						
LSD or Hallucinogens	✓						
Marijuana		yes past		daily	a lot	10 years	lot
Medication		yes past		Rehab w/long abstinence		daily	120 mgs
Pain Killers		yes					
PCP	✓						
Stimulants (pills)	✓						
Tranquilizers/ Sleeping Pills		yes past		constant sheep	not enough sheep to work	10 years	not much
Ecstasy	✓						
Other							

(St. Ex. 7 at 6)

107. In addition, Patient 7 listed a myriad of medical problems, including hepatitis B and C, "Factor 5 blood clots," heart attack, stroke, hypertension, chronic arthritis, slipped disks in neck and back, COPD, emphysema, blood in stool, chronic fatigue, gallstones, loss of muscle control, chronic migraine headaches, chronic nausea, and severe arteriosclerosis "terminal." Evidently, one and one-half years earlier, "OSU" had given him 6 months to live. Finally, Patient 7 indicated that he needed to be out of pain to take care of his 70-year-old mother. (St. Ex. 7 at 7)

108. On his progress note for Patient 7's July 23, 2009, visit, Dr. Karel listed a medical history of hepatitis C, pleurisy, COPD, emphysema, pancreatitis, cholecystitis, and hernia repair

surgery. He documented that Patient 7's heart had regular rate and rhythm, lungs clear to auscultation and palpation, alert and oriented times three, neck supple with full range of motion, motor and sensory intact, full range of motion, and gait intact. Dr. Karel's impressions were lower back pain with bulging disk, lumbar spine DJD, COPD, and emphysema. (St. Ex. 76 at 26, 40, 56; Tr. at 155)

109. Dr. Karel testified that hepatitis B and C are caused by viruses that cause liver inflammation. He further testified that they are transmitted primarily by body fluids. Moreover, he testified that hepatitis C can be contracted by intravenous drug users, although he testified that that is not the most common route of transmission. (Tr. at 153-154)
110. When asked if Patient 7 had actually attended rehabilitation for methadone, Dr. Karel replied that he did not recall asking Patient 7. Moreover, Dr. Karel testified that he was not too concerned about former drug or alcohol abuse because it had occurred ten years earlier. (Tr. at 151-152)
111. Dr. Karel opined that Patient 7 was an appropriate candidate for oxycodone and OxyContin, "[a]nd after the patient spoke with his cardiologist and his gastroenterologist taking care of his liver, * * * that provided even more reason." (Tr. at 155-156)
112. Dr. Karel issued the following prescriptions to Patient 7:

Date of Prescription	Medication	Quantity	Refills	Daily Dose (30-day supply)
7/23/09	OxyContin 20 mg	90	0	60 mg
7/23/09	oxycodone 30 mg	90	0	90 mg
8/21/09	OxyContin 40 mg	90	0	120 mg (↑) ¹⁷
8/21/09	oxycodone 30 mg	90	0	90 mg
9/18/09	OxyContin 40 mg	90	0	120 mg
9/18/09	oxycodone 30 mg	90	0	90 mg
9/18/09	Flexeril 10 mg	90	5	30 mg
10/16/09	OxyContin 40 mg	90	0	120 mg
10/16/09	oxycodone 30 mg	90	0	90 mg
11/13/09	OxyContin 40 mg	90	0	120 mg
11/13/09	oxycodone 30 mg	90	0	90 mg
12/10/09	OxyContin 40 mg	90	0	120 mg
12/10/09	oxycodone 30 mg	90	0	90 mg

¹⁷ The progress note for Patient 7's August 21, 2009, visit indicates that his current medications included OxyContin 40 mg three times per day, which is incorrect: Patient 7 had been prescribed OxyContin 20 mg three times per day at his previous visit. On his August 21, 2009 progress note, under Plan/Discussion, Dr. Karel noted, "Refill meds as above." For that visit, and all following visits, Patient 7 received prescriptions for OxyContin 40 mg #90. No reason was documented for the increase. (St. Ex. 7 at 21-49, 52, 56)

Date of Prescription	Medication	Quantity	Refills	Daily Dose (30-day supply)
1/7/10	OxyContin 40 mg	90	0	120 mg
1/7/10	oxycodone 30 mg	90	0	90 mg
2/4/10	OxyContin 40 mg	90	0	120 mg
2/4/10	oxycodone 30 mg	90	0	90 mg
3/4/10	OxyContin 40 mg	90	0	120 mg
3/4/10	oxycodone 30 mg	90	0	90 mg
4/1/10	OxyContin 40 mg	90	0	120 mg
4/1/10	oxycodone 30 mg	90	0	90 mg
4/29/10	OxyContin 40 mg	90	0	120 mg
4/29/10	oxycodone 30 mg	90	0	90 mg
4/29/10	Zanaflex 4 mg	90	5	12 mg

(St. Ex. 7 at 21-56)

113. When asked why he had increased Patient 7's dosage of OxyContin in August 2009, Dr. Karel replied that he had indicated in his progress note for Patient 7's previous visit that Patient 7 had requested an increase in his medication (in a circled note in the center-right of the page that says, "Req. an ↑"). (Tr. at 159-160; St. Ex. 7 at 56) When asked if a patient request for more medication justifies an increase, Dr. Karel replied:

That's not reason in itself. However, if there is no abuse and the patient is having pain, taking pain medications and the patient has increased pain, which is—which will not occur sometimes, which will occur in 100 percent of people who are taking any opiate, they—they will become tolerant to it.

They—They are given the medication for pain management. If they're requesting an increase, they're having more pain, they're not having side effects, they're cooperative with the medications, everything else has gone well, they should get the relief they needed.

(Tr. at 160) However, Dr. Karel acknowledged that he had not documented his own reason for the medication increase. (Tr. at 161)

Testimony of Dr. Parran

114. Dr. Parran noted that Patient 7 had presented with a lengthy medical history that included hepatitis B and C. He testified that hepatitis B can be spread through blood products or through unprotected sexual intercourse; hepatitis C is spread "either through blood transfusions that took place before 1985 or because of a history of IV drug use." (Tr. at 515-516)

Dr. Parran testified that Dr. Karel's prescribing OxyContin 20 mg #90 and oxycodone 30 mg #90 to Patient 7 on July 23, 2009, had been dangerous:

[T]he patient indicates they were referred by an OSU physician. There are some prior medical records in this chart, but no release of information form to a named OSU physician to try to figure that out.

The patient volunteered a history of a drinking problem, a marijuana problem, a cocaine problem, and having been on a methadone treatment program in the past, and a history of hepatitis C, which—all of which indicates a person with a substantial past history of addictive disease.

And the—the patient did have some MRI—CT scans and an M- —and several MRI scans showing some degenerative joint disease and degenerative disk disease in his spine area, but not in a way that was consistent with the kind of pain complaints that he had.

There was an insufficient physical exam with no evidence of a neurologic exam, no evidence of a careful extremity exam, no evidence of the kind of initial history and physical exam one would expect with a—with a new patient.

* * * And a prescription for enough Schedule II opiates that in a patient with COPD, meaning bad lung disease, and in a patient with an extensive prior history of addiction, in my opinion, is clinically dangerous and demonstrates sort of clinical disregard for the health and safety of the patient.

(Tr. at 516-517)

115. Dr. Parran testified that the remoteness of a substance abuse history does not diminish its significance: "Once a person has an addictive brain and has activated addiction, the risk of sort of rekindling that addictive disease is honestly a lifelong risk." (Tr. at 665-666)
116. Dr. Parran testified that Dr. Karel had failed to maintain minimal standards applicable to the selection and/or administration of drugs, and that Dr. Karel's prescribing "was dangerous and that's inconsistent with any legitimate medical purpose." Finally, Dr. Parran testified that "there is certainly a lack of clinical evidence supporting the prescribing of Schedule II controlled drugs to this patient." (Tr. at 517-518)

Dr. Ross's Report

117. Dr. Ross opined as follows concerning Dr. Parran's analysis of Dr. Karel's chart for Patient 7:

[Patient 7] Patient was initially seen in July 2009. The patient had a previous history of chronic low back pain, pancreatitis, liver disease, COPD, alcoholism, drug abuse, and opioid addiction. The initial drug screen is positive for opiates

and Oxycodone. Dr. Karel continues the medications that the patient had been on [possibly prescribed at Ohio State University facility]. There is one drug adjustment that increases the Oxycontin from 20mg **bid** to 40mg **bid**. The patient was last seen in April 2010. There is no evidence from Dr. Parran that the patient misused, abused or diverted medications; the drug adjustment is not extreme and without many precedents. In conclusion, there is no basis to state that the actual care fell below the prevailing national standard of care.

(Resp. Ex. B at 11) (Underline in original, bold added)

118. Dr. Ross's description of the adjustment in dosing frequency is incorrect. According to the patient chart the new dosing frequency is *three times* per day (tid) for both OxyContin and oxycodone throughout Dr. Karel's treatment of Patient 7, and not twice per day (bid). (St. Ex. 7 at 21-56) Moreover, Dr. Parran's report identifies the quantities prescribed as 90 tablets, or three times per day for a 30-day supply. (St. Ex. 17 at 3)

Patient 7 Criminal Convictions

119. Patient 7 has a criminal record that includes 1993 misdemeanor convictions for conspiracy and possession of drug paraphernalia; a 1999 conviction for the misdemeanor of altering a prescription label; and a 2010 conviction for "OVI/Urine." (St. Ex. 28)

Patient 8

120. Patient 8, a female born in 1962, first visited Tri-State Primary Care on July 29, 2009. Her current medications were listed as OxyContin 40 mg twice per day, oxycodone 30 mg twice per day, Motrin 800 mg three times per day, and Zanaflex 4 mg three times per day. (St. Ex. 8 at 2, 56)
121. Dr. Karel documented diagnoses of lower back pain, L-spine degenerative disk disease, and L3-L4 spondylosis. (St. Ex. 8 at 56; Tr. at 163)
122. Dr. Karel prescribed the following medications to Patient 8:

Date of Prescription	Medication	Quantity	Refills	Daily Dose (30-day supply)
7/29/09	OxyContin 40 mg	60	0	80 mg
7/29/09	oxycodone 30 mg	60	0	60 mg
8/26/09	OxyContin 40 mg	60	0	80 mg
8/26/09	oxycodone 30 mg	60	0	60 mg
9/24/09	OxyContin 40 mg	60	0	80 mg
9/24/09	oxycodone 30 mg	60	0	60 mg
10/22/09	OxyContin 40 mg	60	0	80 mg
10/22/09	oxycodone 30 mg	60	0	60 mg

Date of Prescription	Medication	Quantity	Refills	Daily Dose (30-day supply)
11/30/09	OxyContin 40 mg	60	0	80 mg
11/30/09	oxycodone 30 mg	90	0	90 mg (↑)
11/30/09	Flexeril 10 mg	90	5	30 mg
11/30/09	Ibuprofen 800 mg	90	5	2400 mg
12/30/09	OxyContin 40 mg	60	0	80 mg
12/30/09	oxycodone 30 mg	90	0	90 mg
2/1/01	OxyContin 40 mg	60	0	80 mg
2/1/10	oxycodone 30 mg	90	0	90 mg
3/15/10	OxyContin 40 mg	90	0	120 mg (↑)
3/15/10	oxycodone 30 mg	90	0	90 mg
4/15/10	OxyContin 40 mg	90	0	120 mg
4/15/10	oxycodone 30 mg	90	0	90 mg
5/13/10	OxyContin 40 mg	90	0	120 mg
5/13/10	oxycodone 30 mg	90	0	90 mg

(St. Ex. 8 at 21-56)

Testimony of Dr. Parran

123. Dr. Karel testified that the physical examination findings at Patient 8's initial visit used exactly the same words and notations as the other charts he reviewed. (Tr. at 520)
124. A lumbar spine MRI report dated July 14, 2006, includes the impression, "Mild degenerative spondylosis at the L3/L4 disc without impingement, otherwise negative MRI examination of lumbar sacral spine." Further, Dr. Parran testified that a report of a July 2006 hip joint MRI indicated that the joint was normal. (Tr. at 520-521; St. Ex. 8 at 65-66)
125. Dr. Parran testified that he was unable to find documentation in Patient 8's chart that established a clinical, scientific basis for prescribing high doses of Schedule II medications. Dr. Parran further testified that, in his opinion, Dr. Karel's treatment of Patient 8 fell below the minimal standards applicable to the selection and administration of medication, and that drugs were prescribed for other than legal and legitimate therapeutic purposes. (Tr. at 522)

Dr. Ross's Report

126. Dr. Ross opined as follows concerning Dr. Parran's analysis of Dr. Karel's chart for Patient 8:

[Patient 8] Patient seen in July 2009 and was given opiates. The patient is complaining of chronic low back pain; MRI's show "minimal DJD: hip MRI

normal. The patient came on Oxycontin and Oxycodone. **Apparently there was only one visit.** Dr. Parran denounces Dr. Karel's recording keeping. On the other hand, there evidence presented is that Dr. Karel simply maintained the patient on her prior medications; he is obligated to do so until such time as records and/or analyses are available. To do otherwise is to punish a probably legitimate chronic pain patient [based on national policy] and to risk withdrawal.

(Resp. Ex. B at 11) (Underline in original, bold added)

127. Although Dr. Parran discussed only one visit in his "extraction," a brief glance at the patient chart reveals that Patient 8 saw Dr. Karel monthly from July 2009 through May 2010, a total of 10 visits. (St. Ex. 8 at 21-56; St. Ex. 17 at 3)

Patient 8 Criminal Record

128. Patient 8 has a criminal record that includes a 2009 felony indictment for receiving stolen property that was dismissed in exchange for guilty pleas to two other cases. No further information concerning the two other cases is included in the record. (St. Ex. 29)

Patient 9

129. Patient 9 is a female born in 1979. She is employed by Dr. Karel. Her first patient visit to Tri-State Primary Care was on July 17, 2009. Her then-current medications were recorded as methadone 10 mg two tablets twice daily, oxycodone 15 mg twice per day, and ibuprofen 800 mg as needed. Dr. Karel's exam findings were: alert and oriented times three, neck supple, motor and sensory intact, full range of motion, and gait intact. He diagnosed lower back pain and lumbar spine degenerative joint disease, and prescribed methadone 10 mg #240 and oxycodone 15 mg #60. (St. Ex. 9 at 2, 55-58; Tr. at 168-169)
130. In addition to the Tri-State Primary Care chart for Patient 9, her chart from the Medical Office is also in evidence. (St. Ex. 9A)
131. An MRI report from December 2007 indicates that Patient 9 had "[m]ild degenerative disc bulging at L1/L2 and L5/S1 without evidence of focal disc herniation or nerve impingement identified." (St. Ex. 9 at 61)
132. Patient 9's next patient visit was on August 14, 2009. At this visit and her previous visit, Patient 9 had rated her pain as a "4" on a scale of 1 to 10. Dr. Karel increased Patient 9's oxycodone from 15 mg twice per day to 30 mg twice per day. When asked if he had documented the reason for the increase, Dr. Karel replied:

[T]his time and virtually every other time I have not written down why I increased it. When there is uniquely one reason why it would be increased, I

have prescribed an increase for no reason other than the unique reason this is. I don't bother writing down every time exactly what that was.

* * *

If the patient reports the pain is the same now as it was last month, maybe it doesn't bother them anymore now. However, the patient had requested an increase because they're having more pain.

* * *

[Although the reason is not documented, it is an absolute certainty that increased pain] is the only reason the patient would have asked me and that is the only reason that I have to increase the medication. It would be because of having more pain. I increased it. I don't have to document why I increased it. I know the only reason I would do it would be the only reason there is.

(Tr. at 171-173)

133. According to Patient 9's chart, Dr. Karel issued the following prescriptions to Patient 9:

Date of Prescription	Medication	Quantity	Refills	Daily Dose (30-day supply)
7/17/09	methadone 10 mg	240	0	80 mg
7/17/09	oxycodone 15 mg	60	0	30 mg
8/14/09	methadone 10 mg	240	0	80 mg
8/14/09	oxycodone 30 mg	60	0	60 mg (↑)
8/14/09	Flexeril 10 mg	90	5	30 mg
9/11/09	methadone 10 mg	240	0	80 mg
9/11/09	oxycodone 30 mg	60	0	60 mg
9/22/09	Xanax 2 mg ¹⁸	15 ¹⁹	0	?
10/15/09	methadone 10 mg	240	0	80 mg
10/15/09	oxycodone 30 mg	60	0	60 mg
10/19/09	Xanax 2 mg ²⁰	16	0	?
11/16/09	methadone 10 mg	240	0	80 mg
11/16/09	oxycodone 30 mg	60	0	60 mg

¹⁸ A notation in the progress note for September 11, 2009, states: "Xanax 2 mg #15 9-22-09 at Kroger Pharmacy, Wheelersburg." No copy of the prescription is included in the chart, which is unusual. (St. Ex. 9 at 51)

¹⁹ A March 19, 2010 OARRS report included in Patient 9's chart indicates that the number of pills had been 16. (St. Ex. 9 at 63)

²⁰ A notation in the progress note for October 15, 2009, progress note states: "On 10/19 prescribed Xanax 2 mg #16." No copy of the prescription is included in the chart. (St. Ex. 9 at 48)

Date of Prescription	Medication	Quantity	Refills	Daily Dose (30-day supply)
11/16/09	Motrin 800 mg	90	5	2400 mg
11/16/09	Flexeril 10 mg	90	5	30 mg
12/15/09	methadone 10 mg	240	0	80 mg
12/15/09	oxycodone 30 mg	60	0	60 mg
1/19/10	methadone 10 mg	240	0	80 mg
1/19/10	oxycodone 30 mg	60	0	60 mg
1/19/10	Motrin 800 mg	90	5	2400 mg
1/19/10	Flexeril 10 mg	90	5	30 mg
2/24/10	OxyContin 40 mg	60	0	80 mg (med change)
2/24/10	oxycodone 30 mg	60	0	60 mg
3/9/10	Xanax 2 mg ²¹	30	3	?
3/24/10	OxyContin 40 mg	60	0	80 mg
3/24/10	oxycodone 30 mg	60	0	60 mg
4/22/10	OxyContin 40 mg	60	0	80 mg
4/22/10	oxycodone 30 mg	60	0	60 mg
5/20/10	OxyContin 40 mg	60	0	80 mg
5/20/10	oxycodone 30 mg	60	0	60 mg

(St. Ex. 9 at 19-58)

134. In addition, Dr. Karel's medical record for Patient 9 includes an OARRS report dated March 19, 2010. The OARRS report indicates that Dr. Karel had issued the following prescriptions to Patient 9 that were **not** documented in the records for the Medical Office or Tri-State Primary Care:

Fill Date	Medication	Quantity	Refills
6/11/09	alprazolam 2 ²² mg	9	0
7/9/09	alprazolam 2 mg	20	0
8/3/09	alprazolam 2 mg	30	0
12/30/09	alprazolam 2 mg	30	0

(St. Ex. 9 at 63; St. Ex. 9A)

²¹ A notation on the February 24, 2010, progress note states: "3/9/10 Prescribed Xanax 2 mg #30 c̄ 3 refills." No copy of that prescription is included in the chart. (St. Ex. 9 at 32)

²² Alprazolam is a generic name for Xanax. (MedLine Plus Online Medical Dictionary <<http://www.merriam-webster.com/medlineplus/xanax>>, accessed June 12, 2011)

135. Moreover, Patient 9 submitted to seven urine drug screens on the following dates: July 17, August 14, September 11, and November 10, 2009; and January 24, March 24, and April 22, 2010. **None** of those screens yielded a positive result for benzodiazepines. (St. Ex. 9 at 79-85)
136. A pharmacy profile from a pharmacy in Columbus, Ohio, indicates that Patient 9 had filled prescriptions for methadone and oxycodone at that pharmacy in April, May, and July, 2009. The medical records state that Patient 9 resides in Portsmouth, Ohio. (St. Ex. 9 at 2, 70)

Testimony of Dr. Parran

137. Dr. Parran noted that “Xanax is the most commonly abused benzodiazepine in the United States.” (Tr. at 527) He testified:

[W]riting a prescription for a controlled drug to a patient without documenting it in the chart is inconsistent with the—the standard of care in the community, and it’s—and especially when adding a benzodiazepine like Xanax which markedly increases the risk of accidental overdose.

(Tr. at 526)

When asked why Xanax increases the risk of accidental overdose, Dr. Parran replied, “Benzodiazepines are sedative-hypnotic. They sedate the brain. Opiates also sedate the brain. The combination of benzodiazepines and opiates is dangerous.” (Tr. at 526)

138. Dr. Parran testified that Xanax should have registered a positive result as a benzodiazepine on Patient 9’s urine drug screens. (Tr. at 527-528; St. Ex. 9 at 79-85)
139. Dr. Parran testified that the examination findings that were documented for Patient 9’s initial visit again used the exact same words seen in other charts. (Tr. at 523)
140. On August 14, 2009, Dr. Karel doubled Patient 9’s dose of oxycodone from 15 mg twice per day to 30 mg twice per day. Dr. Parran testified that there was “no symptomatically clinical information available in the progress note” to support such an increase. (Tr. at 525; St. Ex. 54-55)
141. When asked his opinion of Dr. Karel’s treatment of Patient 9, Dr. Parran testified:

My opinion was that the controlled drug prescribing to this patient of both the opiates, Schedule II opiates, and benzodiazepines were done in a manner which was not supported by sound clinical and scientific data. It was done in a way that was inconsistent with the standard of care in the usual course of practice and [was] for other than legitimate medical purpose.

(Tr. at 527-528)

Dr. Ross's Report

142. Dr. Ross opined as follows concerning Dr. Parran's analysis of Patient 9's chart:

[Patient 9] Patient initially seen in July 2009. **The patient is on Methadone.** MRI's done. Patient was apparently an old patient of the facility when Dr. Karel initiates care. **Continued on Methadone initially.** Over the course of the next year, there are multiple dosage adjustments. To quote, Dr. Parran "Last OV 5/20/10 – Rx Oxy 30mg #60 – down from 40mg #60 in May 2010." Thus, Dr. Parran's extraction attests to Dr. Karel's reduction of [Patient 9]'s opioid usage and contradicts the actions of a pill-mill doctor whose vested financial imperative is to increase opioid medications that the facility is dispensing at high profit margins.

(Resp. Ex. B at 11-12) (Underline in original; bold added)

143. Dr. Ross correctly states that Dr. Karel prescribed methadone to Patient 9 at her initial visit and several visits thereafter, but failed to mention that he had also prescribed oxycodone 15 mg twice per day at the initial visit, and, on ten subsequent occasions, prescribed oxycodone 30 mg twice per day. In addition, Dr. Ross failed to mention the prescriptions for Xanax. Dr. Parran mentioned both the oxycodone and Xanax prescriptions in his report. (St. Ex. 9 at 33-58; St. Ex. 17 at 4)

Testimony of Dr. Karel

144. When questioned about the alprazolam prescriptions filled by Patient 9, Dr. Karel testified that it is possible that he had prescribed alprazolam to Patient 9 without recording it in her chart, but that it was "highly unlikely." Dr. Karel testified, "[T]his is improper, it was incorrect, and I am ultimately responsible, I understand." (Tr. at 178-181)
145. With respect to Patient 9 having been prescribed benzodiazepines without having urine screens that showed a positive result for those drugs, Dr. Karel testified:

I have thought about that and I—I could make a guess. I am totally unsure. I attempted to contact the one person who performed it and I have been unable to in the month's time, amazingly. *The person who had the benzodiazepines prescribed*²³ did not have the prescribed—in the normal course of the—it did not appear in the progress notes as it normally does. However, it was on the bottom of the page.

(Tr. at 1292-1293) (Emphasis added)

²³ There is no evidence that anyone who worked at Tri-State Primary Care other than Dr. Karel was authorized to prescribe medication.

Dr. Karel further testified that he had not been advised of the negative result for benzodiazepines by whoever had performed the urine screens. (Tr. at 1294-1295)

Patient 12

146. Patient 12 is a female born in 1976. She first visited Tri-State Primary Care on July 10, 2009. The chart indicates that she had health insurance with Anthem Blue Cross through her husband's employer. Her then-current medications at that time were oxycodone 30 mg three times per day and Valium 10 mg one-half tablet per day. (St. Ex. 12 at 7, 96)
147. Among his exam findings documented in his July 10, 2009, progress note, Dr. Karel noted that Patient 12's heart had regular rate and rhythm, lungs clear to auscultation and palpation, alert and oriented times three, neck supple with full range of motion, motor and sensory intact, full range of motion, and gait intact. Dr. Karel documented diagnoses of "[c]ervicalgia, bulging cervical vertebrae, C-spine DJD, with a questionable or [sic] Crohn's disease, and insomnia." (Tr. at 190; St. Ex. 12 at 96)

When asked how Patient 12 could have suffered from the conditions that he diagnosed while at the same time her neck was supple with full range of motion, Dr. Karel replied:

Patient's neck pain has not progressed to a significant enough level that will interfere with the patient's motion. However, it is supple. The patient has full range of motion, but it hurts.

(Tr. at 191)

148. An OARRS report indicates that Dr. Karel prescribed medication to Patient 12 on one previous occasion: June 24, 2009, presumably at his first office after leaving the Medical Office. There is no record in OARRS or KASPER that Dr. Karel had prescribed controlled substances to Patient 12 prior to June 24, 2009. (Resp. Ex. J at 71; Resp. Ex. K at 276-277)
149. An OARRS report indicates that, although Patient 12 lives in Wurtland, Kentucky, she filled Dr. Karel's prescriptions at a pharmacy in Columbus, Ohio, on the following four dates: June 24, August 7, September 4, and October 26, 2009. (St. Ex. 12 at 7; Resp. Ex. J at 71, 105)
150. Dr. Karel testified that the number of tablets recorded in the current medications section of his July 10, 2009, progress note were for a two-week supply. Dr. Karel further testified:

And the patient had been seen the month previously at Greater Medical Advance or whatever it was called then, and over there where the—**that is a true pill mill**, they require patients on the initial visit to come back at the—after two weeks. However, in my office, the patients only come back after a month.

(Tr. at 188) (Emphasis added)

When asked about his statement that Greater Medical Advance “is a true pill mill,” Dr. Karel replied: “Contrary to—I’m not sure how I phrased it. Could you—I’m not sure how I phrased it. But what I’ve heard, they have become since I left; it sounds like it would fit.” (Tr. at 189)

151. On September 3, 2009, Dr. Karel referred Patient 12 to physical therapy. (St. Ex. 12 at 82) There is no further information concerning physical therapy in the chart, including whether Patient 12 had gone to see a physical therapist. (St. Ex. 12)
152. According to Patient 12’s chart, Dr. Karel issued the following prescriptions to Patient 12:

Date of Prescription	Medication	Quantity	Refills	Daily Dose (30-day supply)
7/10/09	oxycodone 30 mg	90	0	90 mg
7/10/09	Valium 10 mg	15	0	5 mg
8/7/09	OxyContin 10 mg	60	0	20 mg (added)
8/7/09	oxycodone 30 mg	90	0	90 mg
8/7/09	Valium 10 mg	15	0	5 mg
9/3/09	OxyContin 10 mg	60	0	20 mg
9/3/09	oxycodone 30 mg	90	0	90 mg
9/3/09	Valium 10 mg	15	0	5 mg
9/29/09	OxyContin 10 mg	60	0	20 mg
9/29/09	oxycodone 30 mg	120	0	120 mg (↑)
9/29/09	Valium 10 mg	15	0	5 mg
10/26/09	OxyContin 10 mg	60	0	20 mg
10/26/09	oxycodone 30 mg	120	0	120 mg
10/26/09	Valium 10 mg	16	0	5.3 mg (↑)
11/23/09	OxyContin 10 mg	60	0	20 mg
11/23/09	oxycodone 30 mg	120	0	120 mg
11/23/09	Valium 10 mg	16	0	5.3 mg
11/23/09	ibuprofen 800 mg	90	5	2400 mg
11/23/09	Flexeril 10 mg	90	5	30 mg
12/21/09	OxyContin 10 mg	60	0	20 mg
12/21/09	oxycodone 30 mg	120	0	120 mg
12/21/09	Valium 10 mg	16	0	5.3 mg
12/21/09	ibuprofen 800 mg	90	5	2400 mg
12/21/09	Flexeril 10 mg	90	5	30 mg
1/25/10	OxyContin 10 mg	60	0	20 mg
1/25/10	oxycodone 30 mg	120	0	120 mg
1/25/10	Valium 10 mg	30	0	10 mg (↑)

Date of Prescription	Medication	Quantity	Refills	Daily Dose (30-day supply)
1/25/10	ibuprofen 800 mg	90	5	2400 mg
1/25/10	Flexeril 10 mg	90	5	30 mg ²⁴
2/25/10	OxyContin 10 mg	60	0	20 mg
2/25/10	oxycodone 30 mg	120	0	120 mg
2/25/10	Valium 10 mg	30	0	10 mg

(St. Ex. 12 at 18-96)

153. On September 29, 2009, Dr. Karel increased Patient 12's dose of oxycodone 30 mg from three times per day to four times per day. However, the pain rating scales indicate that Patient 12 rated her pain a "6" out of ten at her September 29, 2009, visit, and a "7" out of ten at her previous visit, indicating that her pain level had decreased. Nevertheless, when asked whether he had documented any indication why Patient 12's oxycodone was increased, Dr. Karel replied: "No indication. I increased them because the patient had complained of increased pain not relieved with medication." When asked if he was relying on memory, Dr. Karel replied: "Not from my memory. That is the unique reason that I will increase medications. I don't have to even remember it. But if I increase it, that was the only reason I could." (Tr. at 194-195; St. Ex. 12 at 71)

Similarly, on January 25, 2010, Dr. Karel increased Patient 12's dose of Valium 10 mg from one tablet every other day to one tablet every day. When asked whether he had documented a reason for increasing Patient 12's Valium that day, he responded that he had documented "pain over [nociceptive²⁵] site (naval)," that Patient 12 had had significant pain over her naval, and that the area was "very tender, tense, and she had a bulging of the naval * * *." Dr. Karel further testified that Patient 12 had been seeing a gastroenterologist concerning that issue. Moreover, Dr. Karel testified that Valium "helps increase the pain medications' effectiveness in many patients" and that the pain had been disturbing her sleep. (Tr. at 195-198; St. Ex. 12 at 35)

Testimony of Dr. Parran

154. Dr. Parran testified concerning Dr. Karel's documentation of Patient 12's July 10, 2009, visit:

My impressions of this visit was that the patient was a relatively young woman, 32-year-old woman from Kentucky with third-party insurance and a—and a primary care doctor listed in the chart; no release of information form filled out for the primary care doctor; with some studies, an MRI of the

²⁴ This is the third time in as many months that Dr. Karel prescribed ibuprofen and Flexeril to Patient 12 with five refills. (St. Ex. 12 at 25, 29, 36, 40, 53, 55)

²⁵ Dr. Karel testified that "nociceptive" means painful. (Tr. at 198)

neck, cervical spine, and—that indicated some degenerative disk disease in the—in the cervical spine area.

There are some prior medical records from—from a hospital, but the prior medical records don't document medications that the patient had previously been on, and there are no prior medical records or a request for records from the patient's primary care physician.

And the history and physical exam documented on Page 96, again, has a clinical history which is insufficient to base prescribing decisions documented in the record, and a physical exam which is insufficient. A physical exam that was, again, almost identical, if not identical, to each of the previous physical exam notations in the previous patients' medical records.

(Tr. at 529-530)

155. Dr. Parran noted that the physical examination documented is insufficient to justify Dr. Karel's prescribing. Furthermore, what *is* documented with respect to her neck is normal. (Tr. at 531-532)

156. Dr. Parran testified that there was no justification in Patient 12's chart for the September 29, 2009, increase in her oxycodone 30 mg from 90 pills per month to 120 pills per month. (Tr. at 534; St. Ex. 12 at 71)

Dr. Parran further testified that there was no justification in Patient 12's chart for Dr. Karel nearly doubling her dose of Valium 10 mg to 30 tablets on January 25, 2010. (Tr. at 533-534; St. Ex. 12 at 35)

157. Dr. Parran noted that a September 29, 2009, urine drug screen yielded a negative result for benzodiazepines, although Patient 12 had been prescribed Valium 10 mg at her previous visit on September 3, 2009, and had been instructed to take one tablet every other day. Dr. Parran testified that that meant that Patient 12 had not taken Valium within a three- to five-day time period prior to the drug screen. Dr. Parran further testified that Dr. Karel did not address this issue in the progress notes or factor it into the patient's care after that point. (Tr. at 532-533, 667-668; St. Ex. 12 at 64-84, 149) When asked if that should have been documented, Dr. Parran replied: "Well, absolutely. When prescribing dangerous drugs, especially * * * when it's potent Schedule II opiates plus the benzodiazepines, which we've already established are potentially dangerous in combination with opiates, when there is an inconsistency in the medical record, it's something that needs to be squared." (Tr. at 533)

158. Dr. Parran testified that Dr. Karel's selection and administration of drugs to Patient 12 "was done in a way that was inconsistent with the usual course of medical practice, inconsistent with the acceptable standards, and done in a way that was for other than legitimate medical purpose." (Tr. at 535)

Dr. Ross's Report

159. Dr. Ross opined as follows concerning Dr. Parran's analysis of Dr. Karel's chart for Patient 12:

[Patient 12] Patient seen in July 2009. Urinary drug screens done. Sent for physical therapy and EMG. **Treatment modified based on non-response to therapy.** Last office visit of February 2/25/2010 shows patient is on Oxycontin 10mg bid; Oxycodone 30mg qid, and Valium qd. The records demonstrated that Dr. Karel sent the patient for alternative non-medical therapy and orders testing; this again contradicts the actions of a pill-mill doctor whose vested financial imperative is to increase opioid medications that the facility is dispensing at high profit margins.

(Resp. Ex. B at 12) (Underline in original, bold added)

160. There is nothing in the record to support Dr. Ross's statement that Patient 12's treatment was modified based on the patient's "non-response to therapy." Further, there did not appear to be any modification of Patient 12's treatment aside from an occasional increase in medication. Moreover, there is no mention in the chart concerning Patient 12's response or non-response to physical therapy, nor are there any records that Patient 12 was even seen by a physical therapist. Furthermore, Dr. Ross could not reasonably have based his statement on anything Dr. Parran said in his report because Dr. Parran had stated only "9/3/09 referred to PT and EMG." Dr. Parran's report concerning Patient 12 says nothing else with respect to physical therapy. (St. Ex. 12; St. Ex. 17 at 4)

Patient 14

161. Patient 14 is a male born in 1978. His first and only visit to Tri-State Primary Care took place on July 15, 2009. (St. Ex. 14 at 2, 22) Copies of Patient 14's medical records from the Medical Office/Greater Medical Advance indicate that Patient 14 had been treated by Dr. Karel at that location from September 24, 2007, until May 11, 2009. (St. Ex. 14A at 96-172) In fact, those records also state that Patient 14 continued to be treated by another physician at the Medical Office/Greater Medical Advance, and received prescriptions for OxyContin 30 mg #60 and oxycodone 30 mg #60 on July 7, 2009, one week before his visit to Tri-State Primary Care. (St. Ex. 14A at 89-91)
162. At Patient 14's July 15, 2009, visit to Dr. Karel's new office, his then-current medications were documented as OxyContin 20 mg twice per day,²⁶ oxycodone 30 mg three times per day, and ibuprofen 800 mg as needed. For his exam findings, Dr. Karel documented that Patient 14's heart had regular rate and rhythm, lungs clear to auscultation and palpation,

²⁶ Patient 14 had actually been prescribed OxyContin 30 mg at the Medical Office/Greater Medical Advance about one week earlier. (St. Ex. 14A at 89)

alert and oriented times three, neck supple with full range of motion, motor and sensory intact, full range of motion, and gait intact. (St. Ex. 14 at 22)

163. Patient 14's chart contains one MRI study and one electromyography [EMG] study. The impressions noted on the MRI report, which is dated July 27, 2007, state:

1. Multilevel mild degenerative disc disease without central canal or neural foraminal stenosis.
2. Posterior right lateral osteophytes are noted off of C2 and C3 with some asymmetrical decreased patency of the neural foramina (greatest at C3-4) but without foraminal stenosis.

(St. Ex. 14 at 31-32)

The EMG report, which is dated June 22, 2007, indicates that it had been ordered because of "[l]ow back pain, with radiation into the legs. Reports tingling, paresthesia, and shaky weakness when standing from the waist down." The findings reported were: "No abnormal spontaneous or insertional activity. Motor units appeared normal in character. Nerve conduction studies were normal except for relatively low-amplitude right peroneal motor evoked response, of questionable significance." Finally, the report documented the following interpretation:

Essentially normal EMG and nerve conduction study of the low back and legs.

There are currently no electromyographic findings to suggest significant ongoing radiculopathy, neuropathy, myopathy, or peripheral impingement syndrome.

(St. Ex. 14 at 26)

164. Dr. Karel documented diagnoses of cervicalgia, C2-C3 osteophytes, and foraminal encroachment at C3-4. He prescribed OxyContin 20 mg #60 and oxycodone 30 mg #90. (St. Ex. 14 at 18-22)

165. Dr. Karel testified that Patients 14 and 15 are brothers. (Tr. at 214)

Testimony of Dr. Parran

166. Dr. Parran testified:

My conclusion regarding the prescribing of Schedule II substances to this patient is that the prescribing of controlled drugs to this patient was done in a manner which was inconsistent with the usual standard of care in the community, the usual course of medical practice, and it was done in a way

that was dangerous to the health and safety of the patient, and, therefore, for certainly no legitimate medical purpose.

(Tr. at 544-545)

Dr. Ross's Report

167. Dr. Ross opined as follows concerning Dr. Parran's analysis of Patient 14's chart:

[Patient 14] **The patient is seen in August 2009 and given Suboxone 8 mg per day down from Suboxone 20mg per day. This patient is treated for addiction/overuse with a reduction of medications; this again contradicts the actions of a pill-mill doctor whose vested financial imperative is to increase opioid medications that the facility is dispensing at high profit margins.**

(Resp. Ex. B at 12) (Underline in original; bold added)

168. Dr. Ross's report erroneously states that Dr. Karel had prescribed Suboxone to Patient 14. There is nothing in Patient 14's chart, or Dr. Parran's report, that supports that assertion. (St. Ex. 14; St. Ex. 17 at 5)

Patient 14's Criminal Conviction

169. In 2005, Patient 14 was convicted of a misdemeanor firearm violation. He was fined \$25 and ordered to return the firearm to its owner. (St. Ex. 32)

Patient 15

170. Patient 15 is a male born in 1971. His first visit to Tri-State Primary Care was July 16, 2009. (St. Ex. 15 at 3, 23) Copies of Patient 15's medical records from the Medical Office/Greater Medical Advance indicate that Patient 14 had been treated by Dr. Karel at that location from September 24, 2007, until April 22, 2009. (St. Ex. 15A at 44-110) In fact, Patient 15 continued to be treated by another physician at the Medical Office (which by then was renamed Greater Medical Advance) on July 20, 2009, and received prescriptions for OxyContin 80 mg #52 and oxycodone 30 mg #45 that day, four days after his first visit to Tri-State Primary Care. Moreover, Patient 15 received prescriptions from Greater Medical Advance for OxyContin 80 mg and oxycodone 30 mg on August 20, September 22, and October 20, 2009, which overlap his visits to and prescriptions from Tri-State Primary Care. (St. Ex. 15A at 18-35, 211-226; Resp. Ex. F at 38-40)

171. Patient 15 presented with an Ohio non-driver ID card. (St. Ex. 15 at 18)

172. Dr. Karel's progress note for Patient 15's July 16, 2009, visit indicates that his then-current medications were OxyContin 80 mg twice daily, oxycodone 30 mg as needed, and ibuprofen 800 mg as needed. Dr. Karel further noted that Patient 15 had requested an

increase in his medication. Dr. Karel’s examination findings were that Patient 15’s heart had regular rate and rhythm, lungs clear to auscultation and palpation, alert and oriented times three, neck supple with full range of motion, motor and sensory intact, full range of motion, and gait intact. Dr. Karel’s diagnoses were low back pain and lumbar spine degenerative joint disease. He prescribed OxyContin 80 mg #60 and oxycodone 30 mg #45 at that visit. (St. Ex. 15 at 19-23)

173. According to Patient 15’s chart, Dr. Karel issued the following prescriptions to Patient 15:

Date of Prescription	Medication	Quantity	Refills	Daily Dose (30-day supply)
7/16/09	OxyContin 80 mg	60	0	160 mg
7/16/09	oxycodone 30 mg	45	0	45 mg
8/13/09	OxyContin 80 mg	60	0	160 mg
8/13/09	oxycodone 30 mg	60	0	60 mg (↑)
9/11/09	OxyContin 80 mg	60	0	160 mg
9/11/09	oxycodone 30 mg	60	0	60 mg
10/9/09	OxyContin 80 mg	60	0	160 mg
10/9/09	oxycodone 30 mg	60	0	60 mg
10/9/09	Motrin 800 mg	90	5	2400 mg
11/6/09	OxyContin 80 mg	60	0	160 mg
11/6/09	oxycodone 30 mg	60	0	60 mg

(St. Ex. 15 at 19-46)

174. Dr. Karel testified that he had increased Patient 15’s dose of oxycodone 30 mg in August 2009 because the patient had complained of continued pain, which he testified would be the only reason he would increase the dose. (Tr. at 221-222) In this particular instance, Dr. Karel documented that Patient 15’s pain rating had increased to “6” from a “5” at his previous visit. (St. Ex. 15 at 29, 34) This is, of course, dubious because Patient 15 was receiving additional controlled substances from another physician in addition to Dr. Karel. (St. Ex. 15A at 28-35, 211-226)

Testimony of Dr. Parran

175. Dr. Parran noted that, at Patient 15’s second visit on August 13, 2009, Dr. Karel increased his dose of oxycodone from 45 tablets per month to 60 tablets per month. Dr. Parran further testified that he could find no medical reason for that increase documented in the chart. (Tr. at 549)

176. On August 13, 2009, and afterward, Dr. Karel had prescribed 220 milligrams per day of oxycodone to Patient 15. Dr. Parran testified that he could find no evidence of a legitimate

medical purpose for such prescribing to this patient. Dr. Parran further testified that Dr. Karel's treatment of Patient 15 fell below the minimal standard applicable to the selection and administration of drugs to this patient. (St. Ex. 15 at 25-46; Tr. at 550)

Dr. Ross's Report

177. Dr. Ross opined as follows concerning Dr. Parran's analysis of Patient 15's chart:

[Patient 15] Patient seen in 7/16/2009. Chief complaint is of chronic low back pain; ER records show visits. **Patient initially treated by Dr. Karel with NSAIDs and steroids.** LS MRI performed. Prior records ordered. Last office visit shows Oxycontin 80mg bid and Oxycodone 30mg bid. This patient again proves that Dr. Karel is not running a pill mill; it refutes the contentions that all Dr. Karel's patients receive opioids. This chart proves irrefutably that Dr. Karel starts some patients on other medications and then adjusts medications based on the response to care and his assessment of their medical needs. This follows sound medical practice and anathema to the practice habits of a pill mill operation.

(Resp. Ex. B at 12)

178. There is nothing in Patient 15's charts from the Medical Office or Tri-State Primary Care to support Dr. Ross's assertion that Dr. Karel initially treated Patient 15 with NSAIDs and steroids. At Patient 15's first visit to Tri-State Primary Care, Dr. Karel prescribed OxyContin 80 mg #60 and oxycodone 30 mg #45, then increased Patient 15's supply of oxycodone 30 to #60 the following visit. (St. Exs. 15, 15A) At Patient 15's first visit with Dr. Karel at the Medical Office (it was still called Southern Pain Management at that time), which occurred on September 24, 2007,²⁷ Dr. Karel prescribed OxyContin 40 mg #60 and oxycodone 30 mg #45. (St. Ex. 15A at 108-110) With respect to any prescribing of NSAIDs and steroids to Patient 15, Dr. Parran's report states, in part, "old records of ER visits reporting CLBP and no medications with tox screen positive for opiates – treated with NSAIDs and steroids[.]" (St. Ex. 17 at 5; emphasis added) A review of Dr. Karel's chart for Patient 15 reveals that the old ER visits referenced by Dr. Parran occurred in **2001**, several years before Patient 15 was seen by Dr. Karel. (St. Ex. 15 at 57-65)

Patient 15's Criminal Conviction

179. In 1996, Patient 15 was convicted of misdemeanor sexual imposition. He was fined \$250 and confined to house arrest for 60 days. (St. Ex. 33)

²⁷ Patient 15 had been seen by another physician prior to this date. (St. Ex. 15A at 111-141)

Patient 16

180. Patient 16 is a male born in 1969. His initial visit to Tri-State Primary Care was July 28, 2009. He presented with a Kentucky non-driver ID card. (St. Ex. 16 at 2, 15, 81)

181. On July 28, 2009, Patient 16's then-current medications were documented as methadone 10 mg three tablets every four hours, and OxyContin 30 mg twice daily. (St. Ex. 16 at 81)

Dr. Karel documented examination findings that included Patient 16's heart with regular rate and rhythm, lungs clear to auscultation and palpation, alert and oriented times three, neck supple with full range of motion, "M&S intact—̄ ↓[illegible – "Pinprick?"] of both LEs," full range of motion, "Gait intact—limps 2° to [right] [illegible – "LBL?"]."

Dr. Karel diagnosed low back pain and status post L3-L4 fusion in 2004. He ordered an MRI of the lumbosacral spine and prescribed methadone 10 mg #360 and oxycodone 30 mg #60. (St. Ex. 16 at 75-81)

182. A July 31, 2009, pharmacy profile in Patient 16's chart indicates that he had filled three prescriptions from Dr. Karel on July 28, 2009: one prescription for methadone 10 mg #360, and two prescriptions for oxycodone 30 mg #60.²⁸ The two oxycodone prescriptions have different prescription numbers. Further, the pharmacy where Patient 16 filled the prescriptions is in Columbus, Ohio. Dr. Karel's office is in Wheelersburg, and Patient 16's chart indicates that he lives in Clay City, Kentucky. (St. Ex. 16 at 4, 104)

183. Dr. Karel's medical records indicate that he had issued the following prescriptions to Patient 16:

Date of Prescription	Medication	Quantity	Refills	Daily Dose (30-day supply)
7/28/09	methadone 10 mg	360	0	120 mg
7/28/09	oxycodone 30 mg	60	0	60 mg
8/26/09	methadone 10 mg	360	0	120 mg
8/26/09	oxycodone 30 mg	60	0	60 mg
9/23/09	methadone 10 mg	360	0	120 mg
9/23/09	oxycodone 30 mg	60	0	60 mg
10/27/09	methadone 10 mg	360	0	120 mg
10/27/09	oxycodone 30 mg	60	0	60 mg
11/24/09	methadone 10 mg	360	0	120 mg
11/24/09	oxycodone 30 mg	60	0	60 mg
12/22/09	methadone 10 mg	360	0	120 mg

²⁸ Only one July 28, 2009, prescription for oxycodone 30 mg #60 is documented in the chart (except for the pharmacy profile). (St. Ex. 16)

Date of Prescription	Medication	Quantity	Refills	Daily Dose (30-day supply)
12/22/09	oxycodone 30 mg	60	0	60 mg
12/22/09	Zanaflex 4 mg	90	5	12 mg
12/22/09	Motrin 800 mg	90	5	2400 mg
1/20/10	methadone 10 mg	360	0	120 mg
1/20/10	oxycodone 30 mg	90	0	90 mg (↑)
2/18/10	methadone 10 mg	360	0	120 mg
2/18/10	oxycodone 30 mg	90	0	90 mg
3/17/10	methadone 10 mg	360	0	120 mg
3/17/10	oxycodone 30 mg	90	0	90 mg
4/15/10	methadone 10 mg	360	0	120 mg
4/15/10	oxycodone 30 mg	90	0	90 mg
5/13/10	methadone 10 mg	360	0	120 mg
5/13/10	oxycodone 30 mg	90	0	90 mg

(St. Ex. 16 at 17-81)

Testimony of Dr. Parran

184. Dr. Parran noted that, at Patient 16's July 28, 2009, visit, Dr. Karel had prescribed methadone 10 mg #360 and oxycodone 30 mg #60. Dr. Parran further testified that that amounts to 120 milligrams of methadone per day which he characterized as "a very large amount of methadone." Moreover, Dr. Parran testified:

I've seen patients in methadone maintenance programs on this amount of methadone. I've seen patients in hospice care on this amount of methadone. I've seen a rare chronic pain patient on this amount of methadone, but with—but—but not with this kind of a medical record.

(Tr. at 551-552)

185. Addressing the issue of the second, undocumented July 28, 2009, prescription for oxycodone 30 mg #60, Dr. Parran testified:

My concern is that the—when prescribing Schedule II opiates, arguably the most dangerous medicines a physician is licensed to prescribe in the practice of medicine, to—to not document what prescriptions are being given to a patient is absolutely inconsistent with the standard of care in our community.

(Tr. at 554)

186. With respect to the January 20, 2010, increase in Patient 16's dose of oxycodone 30 mg from 60 to 90 tablets per month, Dr. Parran testified that there is nothing documented except that the patient requested an increase. Dr. Parran further testified that there is "no clinical information whatsoever in the progress note to justify that change." (Tr. at 555)
187. When asked for his opinion concerning Dr. Karel's treatment of Patient 16, Dr. Parran replied:

My opinion was that the prescribing was done in a way which was inconsistent with the usual standard of care in the community, inconsistent with the usual course of medical practice, and—and was dangerous, and, therefore, inconsistent with a legitimate medical purpose.

(Tr. at 556)

Dr. Ross's Report

188. Dr. Ross opined as follows concerning Dr. Parran's analysis of Dr. Karel's chart for Patient 16:

[Patient 16] Patient seen in July 2009. Patient on Methadone 120mg per day and Oxycodone 30mg bid. The patient has failed low back syndrome. The last office visit shows patient on same dose of Methadone and Oxycodone 30mg tid. Pain secondary to "failed low back syndrome" is one of the most complex and difficult to manage chronic pain problems. Many patients ultimately are managed on significant dosages of opioids; a combination use of Methadone and Oxycodone is not uncommon. The use of Methadone is again anathema to the modus operandi of a pill mill. Methadone is inexpensive; it has little "street value," and is not as easily abused as more popular prescribed medications such as Oxycontin. There is no reason to believe that this patient was specifically abusing his medications.

(Resp. Ex. B at 12) (Emphasis in original)

189. Dr. Ross opined that Patient 16 suffered from "failed low back syndrome." However, Dr. Karel did not document Patient 16's condition as such. (St. Ex. 16)

Testimony of Dr. Karel

190. With respect to the second, undocumented July 28, 2009, prescription for oxycodone 30 mg #60, Dr. Karel testified that he believes that the pharmacy records are incorrect because they also attribute two additional prescriptions to Dr. Karel that he supposedly issued to Patient 16 on June 23, 2009. Dr. Karel testified:

[T]he mild unreliability of the pharmacy charts and records [should be noted]. This is approximately the 30th or 40th I've seen indicating that I prescribed

him the medication in June of '09. That's when I was on sick leave and had not been able to return. It should be noted that an incorrect attribution is made very often.

I see here on 6-23-09 he had been prescribed medication. My name was attributed to it, as well. I obviously was not the prescriber.

(Tr. at 225-226)

Despite Dr. Karel's testimony, it is clear that Dr. Karel *had* prescribed medications in June 2009. Pharmacy records for a different patient, Patient 15, indicate that Dr. Karel had issued two prescriptions to Patient 15 on June 18, 2009: one for OxyContin 80 mg #60 and another for oxycodone 30 mg #45. Those prescriptions were written on a pad labeled "Primary Health Care, Douglas Karel, M.D., 8308 B Ohio River Rd., Wheelersburg, Ohio 45694." Based on Dr. Karel's testimony, this was the location of his first office after leaving the Medical Office. (St. Ex. 15B at 11; Tr. at 43-44)

191. With respect to the location of the pharmacy where Patient 16 filled his prescriptions, Dr. Karel testified that, "[a]t that point," it had not been unusual for one of his patients to fill prescriptions in Columbus. When it was pointed out to Dr. Karel that Patient 16 lived in Kentucky and was asked whether it was unusual for a patient who lived in Kentucky to fill scripts in Columbus, Dr. Karel replied, "That happened occasionally." (Tr. at 227-228)
192. When asked if he had documented the reason for the January 20, 2010, increase in Patient 16's oxycodone dose from twice per day to three times per day, Dr. Karel testified:

You see circled [on the progress note] "Requests an increase." To me, that means the patient wanted an increase for the only reason that people could ask for an increase of the opiate medications, because they're in pain. That's the only reason I prescribe opiates.

(Tr. at 229)

Conclusions of Dr. Parran

193. In his report, Dr. Parran addressed his overall conclusions with respect to Dr. Karel's care and treatment of Patients 3, 4, 5, 7, 8, 9, 12, 14, 15, and 16, which included the following:

There are several characteristics of [Dr. Karel's] medical office that are exceedingly concerning to me:

- 1) The routine prescribing of controlled drugs at the first office visit after collecting \$200 cash.
- 2) The lack of a strong effort to independently obtain patients' prior records.

- 3) The lack of a multi-faceted management strategy for chronic pain patients.
- 4) The prescribing of opioid analgesics to most (perhaps nearly all) pain patients.
- 5) The lack of a large variety of non-controlled drugs, with some use of controlled drugs for pain management.
- 6) The lack of a thorough H&P including routinely requiring patients to undress and be examined in an exam gown and sheet,
- 7) The lack of a reasonable diagnostic work-up of patient reports of pain.
- 8) The lack of individualized treatment planning in response to the broad diversity of pain syndromes and patient pain experiences.
- 9) The lack of consultation, referral for therapy, second opinion, expert review by a physician specializing in the region of the body or organ system involved with the pain.
- 10) The hesitancy of local and regional pharmacies to fill the controlled drug prescriptions from this office, and refusal by some to fill any of the doctor's prescriptions.
- 11) The cash only nature of the office – reportedly \$200 for the IOV and all subsequent OV – that attracted many patients (purportedly up to 45%) from over State lines despite there being physicians available in the area who accepted insurance.
- 12) Having an office with a security guard armed with a Taser gun!
- 13) Notifying patients that the doctor carried no malpractice insurance!
- 14) Requiring patients to sign a statement that they are not seeking office appointments as part of an on-going investigation!

In my experience these are characteristics of an office that indicate a high likelihood of prescribing controlled drugs for profit over patient care, that tend to attract problematic patients with addictive disease or intent to divert controlled drug prescriptions to the office, and that begin to resemble a “pill mill” sort of office rather than a legitimate medical practice. Based on the information that I have been provided thus far, these are omissions of basic physician clinical behaviors and are marked deviations from the usual standard of care. To within a reasonable degree of medical certainty, prescribing controlled drugs in the absence of these behaviors is outside of the course of usual medical practice, and indicates prescribing without the establishment of a legitimate medical purpose.

(St. Ex. 17 at 1-2)

194. With respect to the MRI reports included in the patient records, Dr. Parran testified that he has seen patients with similar MRI results who are prescribed opiate medications, but he has “never seen an MRI report in and of itself as a reason for opiates. * * * And especially these kinds of MRI reports.” (Tr. at 595-596)

195. Dr. Parran testified that an increase in medication based upon a patient telling the physician that they are experiencing increased pain would be acceptable as long as it was corroborated in the medical record that the patient's pain scores went up and the function scores went down, or with at least some summary of the patient's subjective data. (Tr. at 665)

196. Dr. Parran defined the term, "opiate naïve":

An opiate naïve patient is a patient who has not been exposed to substantial doses of opiates recently, within the last couple of weeks to maybe a month to a month-and-a-half, but usually preferably within the last couple of weeks.

So a patient who hasn't been exposed to opiates within the last couple of weeks is ostensibly opiate naïve, meaning they may well have lost a fair amount of tolerance to the sedative and respiratory depressant effect of an opiate.

(Tr. at 655)

Further, Dr. Parran testified that there is danger in starting patients out on the medications and dosages seen with some of these patients: "It certainly could result in an accidental overdose, over-sedation, not being able to be woken up by friends or family, often a trip to the emergency room. Worst case scenario, anoxic brain damage or a fatal overdose." (Tr. at 655)

197. Dr. Parran testified, "I think it's important to ask patients if they have a criminal history if one is considering prescribing controlled substances and especially if the patient doesn't have a driver's license. * * * Because presumptively they do have a criminal history if they don't have a driver's license." When asked about patients who might have a seizure disorder, Dr. Parran testified that that should also be included in the medical history. (Tr. at 662-663)

198. When asked whether he has seen benzodiazepines prescribed in conjunction with opiates for pain relief, Dr. Parran testified:

I have seen benzodiazepines prescribed with opiates by pain management physicians in the management of the patient's pain, but the benzos weren't for pain relief. Benzos don't relieve pain.

* * *

But using the benzodiazepines to treat an anxiety disorder that's been identified or to treat insomnia that's been identified, I have seen them prescribed. It is dangerous.

* * *

When one looks at the fatal accidental overdoses in this state in the last couple of years with prescription opiates, a substantial proportion also involved benzodiazepines. So it's dangerous. But I have seen it done.

By definition, prescribing the two together, in my opinion, is not outside the usual standards of care.

(Tr. at 673-674)

Conclusions of Dr. Ross

199. Dr. Ross responded to Dr. Parran's general conclusions as stated in Dr. Parran's report:

- Dr. Ross stated that it does not concern him that Dr. Karel accepted payment only in cash. (Tr. at 886; Resp. Ex. B at 6)
- Dr. Ross stated that he does not know what Dr. Parran meant when he said there was lack of a "strong" effort to obtain prior medical records. The records indicate that an effort was made. (Tr. at 886-887; Resp. Ex. B at 7)
- Dr. Ross stated that Dr. Karel *did* offer a "multifaceted" pain management strategy. Dr. Ross testified that Dr. Karel offered physical therapy and did tests. Dr. Ross also stated that Dr. Karel practices in an impoverished area where the patients lack access and the ability to afford more expensive care. (Tr. at 887; Resp. Ex. B at 7)
- One of Dr. Parran's criticisms of Dr. Karel's practice was that most or nearly all of Dr. Karel's pain patients received opioid analgesics. (St. Ex. 17 at 1) In Dr. Ross's report, he criticized Dr. Parran for basing his opinion on 13 charts that were not randomly selected, and that Dr. Parran did not take into account patients to whom Dr. Karel may have refused to prescribe, and patients who had their prescriptions reduced. (Resp. Ex. B at 7) When apprised at hearing that the evidence established that Dr. Karel had prescribed opioid analgesics to most if not all of his patients, Dr. Ross testified that that would not change his opinion. (Tr. at 65, 887-888)
- Dr. Ross took exception to Dr. Parran's opinion that Dr. Karel had failed to perform a thorough history and physical examination, including being required to undress and be examined in a gown. Dr. Ross testified that there is no standard that requires patients to disrobe for the physical examinations that neurologists perform. (Tr. at 888-889; Resp. Ex. B at 7)
- Dr. Ross testified that it does not concern him that Dr. Karel used the same words or phrases in documenting his physical examinations. Dr. Ross testified that physicians repeat what works for them, and that this is becoming even more prevalent as electronic medical records are adopted by more and more physicians. (Tr. at 889)

- Dr. Ross disagreed with Dr. Parran’s opinion that there had been a lack of a reasonable diagnostic work-up of the patients’ pain complaints. Dr. Ross said that he cannot discern what that means. Further, “He’s being very ambiguous, you know, that’s just ambiguous. You can’t make heads or tails of what—Whose definition? What are the specific needs? Et cetera.” (Tr. at 890; Resp. Ex. B at 8)
- Dr. Ross disagreed with Dr. Parran’s opinion that Dr. Karel had failed to refer patients for consultations, therapy, or second opinions. Dr. Ross testified that, as a neurologist, Dr. Karel is an expert and that “[n]eurologists are the leading experts in sensation.”
- Dr. Ross testified concerning the statement signed by Dr. Karel’s patients that they are not part of an “ongoing investigation,” and that that had no impact on his evaluation of Dr. Karel’s case. (Tr. at 894)

Dr. Ross further opined as follows concerning Dr. Parran’s preliminary statements:

In summary, Dr. Parran’s preliminary analysis is grievously and irretrievably irrational. He ignores pertinent geographic and demographic details that were readily available to him on the internet. He ignores national guidelines. He ignores pertinent, known facts directly pertinent to the present case. He relies almost exclusively on conjecture and inappropriate application of inductive reasoning in his preliminary state[ments].

(Resp. Ex. B at 11)

200. As alluded to already, Dr. Ross focused the bulk of his testimony and report criticizing Dr. Parran and the Board’s proposed action against Dr. Karel. With respect to Dr. Parran, Dr. Ross criticized Dr. Parran’s qualifications as an expert in this matter because Dr. Parran’s professional focus is addiction. Dr. Ross further testified that “most of the decision-making for chronic pain is usually not made at the level of an internist. It’s usually made at the level of somebody who is seeing a lot of these patients” and who deals with the acute issue and then often sends the patient back to the primary care physician. Moreover, Dr. Ross testified that Dr. Parran has “much, much less” experience managing pain patients that Dr. Ross does. (Tr. at 828-830)

201. In his report, Dr. Ross quoted the following guidelines issued by the American Academy of Pain Medicine and the American Pain Society²⁹ [AAPM/APM guidelines]:

The Use of Opioids for the Treatment of Chronic Pain

A consensus statement from American Academy of Pain Medicine and American Pain Society

I. The management of pain is becoming a higher priority in the United States.

In the last several years, health-policymakers, health professionals, regulators, and the public have become increasingly interested in the provision of better pain therapies. This is evidenced, in part, by the U.S. Department of Health and Human Services' dissemination of Clinical Practice Guidelines for the management of acute pain and cancer pain.

These publications, which have been endorsed by AAPM and APS, state that opioids, sometimes called "narcotic analgesics," are an essential part of a pain management plan. There is currently no nationally accepted consensus for the treatment of chronic pain not due to cancer, yet the economic and social costs of chronic pain are substantial, with estimates ranging in the tens of billions of dollars annually * * *.

VII. Principles of good medical practice should guide the prescribing of opioids.

AAPM and APS believe that guidelines for prescribing opioids should be an extension of the basic principles of good professional practice.

Evaluation of the patient: Evaluation should initially include a pain history and assessment of the impact of pain on the patient, a directed physical examination, a review of previous diagnostic studies, a review of previous interventions, a drug history, and an assessment of coexisting diseases or conditions.

Treatment plan: Treatment planning should be tailored to both the individual and the presenting problem. Consideration should be given to different treatment modalities, such as a formal pain rehabilitation program, the use of behavioral strategies, the use of noninvasive techniques, or the use of medications, depending upon the physical and psychosocial impairment related to the pain. If a trial of opioids is selected, the physician should ensure that the patient or the patient's guardian is informed of the risks and benefits of opioid use and the conditions under which opioids will be prescribed. Some practitioners find a written agreement specifying these conditions to be useful.

²⁹ In his report, Dr. Ross stated: "These two organizations are the United States' largest and leading multi-disciplinary medical/scientific groups dealing with this topic. They are two of the largest such organizations in the world." (Resp. Ex. B at 3)

An opioid trial should not be done in the absence of a complete assessment of the pain complaint.

Consultation as needed: Consultation with a specialist in pain medicine or with a psychologist may be warranted, depending on the expertise of the practitioner and the complexity of the presenting problem. The management of pain in patients with a history of addiction or a comorbid psychiatric disorder requires special consideration, but does not necessarily contraindicate the use of opioids.

Periodic review of treatment efficacy: Review of treatment efficacy should occur periodically to assess the functional status of the patient, continued analgesia, opioid side effects, quality of life, and indications of medication misuse. Periodic reexamination is warranted to assess the nature of the pain complaint and to ensure that opioid therapy is still indicated. Attention should be given to the possibility of a decrease in global function or quality of life as a result of opioid use.

Documentation: Documentation is essential for supporting the evaluation, the reason for opioid prescribing, the overall pain management treatment plan, any consultations received, and periodic review of the status of the patient.

(Resp. Ex. B at 3-4)

202. Dr. Ross related the AAPM/APM guidelines to Dr. Karel's practice:

Going back to minimal, meets the criteria. There were diagnoses, there was a sufficient amount of examination. There were periodic reviews. There were actions taken when people were noncompliant. There were attempts at physical therapy. Within the issues of what I see in a pill mill, he did not exhibit any of those issues.

And even though I would have liked for optimum documentation, he certainly would have met the minimal standards and I could understand what he was doing and by and large extrapolate what his rationale was, and there was nothing overtly objectionable from a national standard.

(Tr. at 851-852)

203. Dr. Ross was asked what the following phrase means to him, as set forth in Section 4731.22(B)(2), Ohio Revised Code: "minimal standards applicable to the selection or administration of drugs." He replied:

By definition, the word standard means that people have come together, discussed what is appropriate, and what are the means by which one makes that decision. Specific to pain, one should go to the international definition of pain, and then thereafter apply standards that are acceptable by major organizations dealing with this.

For example, the American Pain Society, which is a branch of the International Association for the Study of Pain, and the American Academy of Pain Management, that creates a standard, a consensus that guides physicians in decision-making.

(Tr. at 844-845)

204. Further, Dr. Ross was asked about the following phrase, as set forth in Section 4731.22(B)(3), Ohio Revised Code, “[s]elling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes[.]” Dr. Ross testified that, with respect to Dr. Karel, “There is absolutely no evidence that I saw that he falls below a standard or that he did not, in good faith, prescribe medicines for what he thought were therapeutic means. I have no evidence of that.” (Tr. at 847) Moreover, Dr. Ross testified:

By and large, by what is known about the standards and the current views on pain management, he followed national standards and his prescribing was within the scope and limitations of those standards. I found no evidence that he fell outside of it.

(Tr. at 848)

205. Dr. Ross criticized the Board’s methodology in issuing its Notice, and called it inappropriate. When asked why, Dr. Ross testified that, first, “innuendo and profiling have no ultimate role in probative thinking.” Dr. Ross stated that innuendo is not science. Second, Dr. Ross testified:

[I]f you’re going to compare something to a standard, highly—whatever, you’ve got to define the standard. There is nothing in what Ohio has done that defines the standards, they are completely capricious. Let Ohio set a standard that is identifiable that people can recognize and then judge and assess, okay, appropriately. That was not done in this situation.

When you apply national standards, Ohio is not using those national standards and has nothing of its own. That is improper.

(Tr. at 929-930)

206. Dr. Ross testified that he had based his opinions on a national standard rather than a local standard. Dr. Ross further testified, “As far as I can tell, there is no Ohio state standard, there is nothing specific.” (Tr. at 962)

207. When Dr. Ross was asked whether medical standards exist that are not written down, he replied that there are, but “[t]he question becomes how to determine them.”³⁰ However, he testified that you do not rely on an “individual or a person who actually is not even specifically germane to the topic,” particularly if published standards exist. (Tr. at 965)

208. When asked what would be considered a reasonable physical examination of a new pain patient, Dr. Ross testified:

Formulate something, and then gradually over time explore other issues. The issue of a physical examination and of MRIs and EMGs, controversial, there is no complete minimal standard.

The fact of the matter is that the clinical exam is not very helpful for the establishment of chronic pain, use of MRI has been refuted.

MRI does not correlate with the absence, presence or severity of pain, the same thing is true of the EMG, nerve conduction studies. These all then fit together, and one then makes a good-faith effort how much documentation should be.

Since it’s all very vague, **there is no true minimal standard.** * * *

(Tr. at 858) (Emphasis added)

209. Dr. Ross testified that Dr. Karel’s refusal to treat a large number of patients who are screened out, and his dismissal of patients for violating the rules of his practice, is “[a]bsolutely not” consistent with a pill mill. (Tr. at 896)

210. Dr. Ross testified that Dr. Karel’s documentation was “suboptimal” but still within the minimal standard of care. (Tr. at 957-958)

211. Dr. Ross testified that it is inappropriate to prescribe narcotics to patients whom the physician knows are not using them properly. Dr. Ross further testified, “Proving that is problematic, which is why there is a huge problem in the United States.” Moreover, he testified:

The problem becomes how to [identify such patients], and the bottom line is that’s why my invention was put in, and that’s why people are interested in it, and the bottom line is I finally figured out how to do it.

(Tr. at 941)

³⁰ This question was asked toward the end of Dr. Ross’s testimony. The Hearing Examiner observed that Dr. Ross’s voice seemed to take on a more nervous, “shaky” quality responding to this question and the questions that followed.

Additionally, Dr. Ross testified that his invention “separates the sensory physical part from the emotional and social parts of a pain complaint.” Dr. Ross testified:

So what I can do in my office is I put a suspicious patient on my test and then I then confront them and say, “You don’t have a lot of tissue-damage associated sensation. It’s inappropriate for me to then give you a narcotic, we’re going to have to”—and most of these people I inherit, “and I’m going to reduce your narcotic and we’re going to have to go in a different direction.”

I have that ability. I invented that ability. The fact of the matter is, okay, at this point, there are machines in about four other places in the world. I’m trying.

(Tr. at 943-944)

When asked, “So your invention would determine who it would be inappropriate to prescribe narcotics to?” Dr. Ross replied, “Yes, it does.” (Tr. at 941)

212. Dr. Ross acknowledged that Dr. Karel does not have one of his machines. (Tr. at 944)

Testimony of Dr. Karel

213. Dr. Karel testified that he is qualified to treat pain patients because of his training as a neurologist. Dr. Karel testified:

[N]eurology is the only specialty, really, that deals with sensation. Pain being the exaggeration of—or, poor interpretation—or an interpretation of one of the sensory modalities, pain is really best assessed by a neurologist who can then differentiate between other types of pain which may be present.

Additionally, the—being familiar with the—the mechanism of transmission and the various parts of the brain where pain is interpreted and the pathways leading to it are essentially unknown by any other specialty, and probably half the neurologists may after having this [*sic*], but that’s virtually exclusively in the realm of a neurology practice.

(Tr. at 1343-1344)

214. When asked about Dr. Parran’s criticism that he should have either obtained the patients’ old medical records or completed a more thorough history and physical examination before prescribing controlled substances, Dr. Karel replied:

You have to recall that in dealing in the chronic pain, patients are seen on a monthly basis. They’re not seen every three months [as] in some offices or twice a year as in other offices. We’re talking about people I follow month after month after month.

I got to know most of them very well, or pretty well, and I was familiar with them. OARRS and KASPER results were—were obtained on these patients, as well. * * *

* * *

I was already very familiar with the patients and they were all previously seen by me. That combined with the follow-up with the laboratory—the pharmacy reports, there was no problem prescribing the medication.

(Tr. at 1363-1364) Dr. Karel further testified that he had never based his prescribing simply on what a patient told him, and “none of the prescriptions were written without proof in some way or the other.” (Tr. at 1365)

215. Dr. Karel testified that he “understands [Dr. Parran’s] concerns with people who are addicts obtaining state IDs rather than state driver’s licenses.” However, Dr. Karel testified that Dr. Parran’s focus is dealing with people with addictions. Moreover, Dr. Karel testified:

My experience, 11, 12, 13 years as a neurologist, I may have come across somebody who was addicted once. To the best of my knowledge, I—I’ll say that never happened once even. I saw many people with state IDs, not state driver’s licenses. That didn’t even—That wouldn’t occur to me initially that it’s for a problem with addiction rather than a medical problem or a neurologic problem, be it seizure, being a status post stroke, being some developmental disturbance.

(Tr. at 1365-1366)

216. Dr. Karel testified that he does not believe that a physician is able to obtain criminal background checks on his patients. With respect to just asking the patients about their criminal history, Dr. Karel expressed doubt that he would get honest responses from the type of patients that he would be worried about. Moreover, Dr. Karel testified that he believes that it would inhibit the physician/patient relationship to confront patients with questions like that. (Tr. at 1373-1375)
217. Dr. Karel commented on the allegation that he did not offer modalities of treatment other than pain medication. First, Dr. Karel testified that all of the patients relevant to this matter had been his patients at the Medical Office, and that they “already had most of the ancillary examinations performed.” Further, Dr. Karel testified that most of the patients had seen other physicians who had treated them with pain medication which effectively alleviated their pain. Dr. Karel testified, “To me, that’s—explains right then and there that they should be continued on the medication.” (Tr. at 1344-1345) Moreover, Dr. Karel testified:

The opioid medications are—Going along with what I had said to everybody here beforehand, that you may find it paradoxical, but I am generally against medication. And I think people do very well with the least amount of medications possible as every medication has side effects. Sometimes the beneficial effects outweigh the side effects; therefore, you should give it in—the opioid medications are essentially—not essentially—are the only analgesic medications which do not affect other organ systems. They're essentially the safest in the world if taken at the prescribed dosages.

And the side effects that you could see with the opioids, which I discussed already, the main one of concern, the respiratory depression, is essentially only seen in opioid naive patients. Therefore, you can—one can continue prescribing the opiates with no true concern over that.

And as a last note[,] * * * because there are virtually no true side effects, other than a—oh, a paresis of the bowel, can have a slower time passing your waste products, there's virtually no—there is no limit, no upper limit for the opioid medications.

Generally, when you prescribe a medication, you increase the dose until you get either an effect or a side effect. And if you don't—there are no side effects, you can just continue to increase it until you get the desired effect.

(Tr. at 1344-1346)

218. Dr. Karel testified that he knows that a patient has reached the desired effect when he or she is able to function well and resume the activities of daily living. (Tr. at 1346-1347)
219. Dr. Karel testified that he has never prescribed opioid medication that was not medically necessary, or for reasons other than a legitimate therapeutic purpose. (Tr. at 1349-1350)

However, Dr. Karel testified that he has discovered that certain patients to whom he had prescribed controlled substances were not using them appropriately, and he stopped treating them. Dr. Karel acknowledged that he is not immune from being duped by some patients. He testified, “[I]t's unfortunate, but there's no way that you can be a hundred percent right.” (Tr. at 1350-1351)

220. Dr. Karel testified that he does not believe that most patients receive significant benefit from trigger point injections. He testified that patients rarely obtain relief for more than a few days with that modality. (Tr. at 1347)
221. With respect to Dr. Parran's testimony concerning urine screens, and that positive results for opiates should be subjected to further testing, Dr. Karel testified that he believes it

would be inappropriate to subject uninsured patients who already have to pay for visits and medication to the additional expense of sending urine samples to a lab. Dr. Karel further testified:

I'm not overly concerned with treating a patient who's an addict. The people I am treating are—I am treating for pain. I am not treating for addiction. I want to make sure they're taking their medications. And certainly 99 percent of them or maybe only 98 percent are taking the medication exclusively for their pain, for their chronic pains.

If these people have to spend the \$175 a month when they're already short of cash, making them go through the winter without heat, without food on the table, without clothing, without being able to feed their kids, which I have noticed a number of times, charging an extra \$175 for a test to satisfy Dr. Parran does not appear appropriate to me.

(Tr. at 1357-1358)

When asked to clarify his statement that he is not concerned about treating addicts, Dr. Karel replied:

My concern at this point is to treat the patients for their chronic pain. I'm not—I'm not—I'm not dealing with the treatment of people for who are addicted to medication. That is not my primary goal. That's—Dr. Parran is treating people who have problems with addiction. I am not concern—My concern here is not to treat somebody with an addiction. My concern is to treat somebody with chronic pain. Not I'm not concerned; not worried about it.

(Tr. at 1358-1359)

Dr. Karel testified that, when he discovers that a patient has become addicted to the medication he is prescribing, he "sit[s] down with the patient, [has] them take [their] medication appropriately, only the prescribed dosage, and offer[s] them counseling eventually." (Tr. at 1360)

222. When asked what steps he takes when he notices the signs and symptoms of addiction in one of his patients, Dr. Karel replied:

Signs and symptoms not that—I have a very tough time differentiating signs and symptoms of addiction rather than signs and symptoms that they are taking too much or too little of the medication which has been prescribed. It's really tough to tell.

Signs of addiction, maybe if they're craving it, maybe if they're asking for more pills very often. If I think there's any diversion, I'll take the necessary

steps. I'll ask for the pill count, I will ask for the urine drug screen, and observe them more closely.

(Tr. at 1361)

Patients 1, 2, 6, 10, 11, and 13

Patient 1

223. State's Exhibit 1 consists of copies of prescriptions issued to Patient 1 by Dr. Karel. Dr. Karel's medical record for Patient 1 was not included in the exhibit. (St. Ex. 1)
224. Dr. Karel testified that Patient 1 served as a security guard in addition to other duties. When asked why he had hired a security guard, Dr. Karel testified that a number of businesses in Scioto County, Ohio, have security guards. Dr. Karel testified that he had hired a security guard for his office because of concerns expressed to him by two of his employees, and that "the girls were concerned that some of the patients may become unruly[.]" When asked why they would have such a concern, Dr. Karel replied that he is "unsure of what their specific reasons are." When pressed further why *he* had hired a security guard, Dr. Karel replied that he had needed someone else in the office, and that Patient 1 performed duties other than acting as a security guard. Dr. Karel further testified that he had known Patient 1 very well, and that they socialized and had gone on trips together. (Tr. at 52-53, 56, 1317-1318) Moreover, Dr. Karel testified:

He had lost his job; he needed employment. I could use somebody else there and another person to help with the files, to help with running the office. Somebody who was, oh, I don't know, six-three, 250, 260 pounds, a bit imposing. He needed a job, I needed somebody; it was a good match.

(Tr. at 54)

Dr. Karel added that Patient 1 was the husband of Patient 9, whom he also employed in his office. (Tr. at 56)

225. Dr. Karel acknowledged that he had issued the following prescriptions to Patient 1:

Date of Prescription	Medication	Quantity	Refills
12/8/10	OxyContin 80 mg	90	0
12/8/10	Xanax 2 mg	30	0
1/6/11	OxyContin 80 mg	90	0
1/6/11	Oxycodone 30 mg	120	0
1/6/11	Xanax 2 mg	30	0

(Tr. at 84; St. Ex. 1)

226. Court records indicate that Patient 1 has a criminal record that includes the following convictions:
- a. On November 16, 1990, in the Scioto County Common Pleas Court, Patient 1 was found guilty of Burglary, an aggravated felony of the second degree, in violation of Section 2911.12(A), Ohio Revised Code, and was sentenced to five to fifteen years of incarceration, which was stayed, and Patient 1 was placed on five years probation. On June 23, 1993, after finding that Patient 1 had violated the conditions of his probation, the court revoked Patient 1's probation and sentenced him to five to fifteen years of incarceration. (St. Ex. 26 at 1-10)
 - b. On March 28, 1991, in the Portsmouth Municipal Court, Patient 1 was found guilty of two misdemeanor counts of Assault, in violation of Section 537.03, Codified Ordinances of Portsmouth, Ohio. (St. Ex. 26 at 11-14)
 - c. On December 21, 1993, Patient 1 was found guilty in the Scioto County Common Pleas Court, Ohio, of felony Escape, in violation of Sections 2921.34(A) and (C)(2)(b), Ohio Revised Code, and was sentenced to, among other things, two to ten years of incarceration. (St. Ex. 26 at 15-22)
 - d. On February 24, 2005, in the Scioto County Common Pleas Court, Patient 1 was found guilty of felony Aggravated Trafficking in Drugs, to wit: OxyContin, in violation of Section 2925.03(C)(1)(a), Ohio Revised Code, and was sentenced to five years of community control. Subsequently, on December 17, 2009, the court found that Patient 1 had violated community control after testing positive for opiates, including Oxycodone and Methadone, and after being untruthful to police and probation officers regarding his prescriptions. (St. Ex. 26 at 23-23)
227. Dr. Karel did not perform a background check on Patient 1 prior to hiring him because he knew Patient 1 personally. Dr. Karel testified that he did not discover that Patient 1 had a criminal record until after he had hired Patient 1. Dr. Karel testified that he had hired Patient 1 sometime around mid-2010. (Tr. at 78-83)
228. Dr. Karel asked to correct a statement that he had made concerning Patient 1 during a February 15, 2011, interview with Board investigators. He told the investigators that Patient 1 carried a TASER. Dr. Karel testified that Patient 1 does not, in fact carry a TASER, "it is more of a pepper spray that he has." (Tr. at 53, 800; St. Ex. 20, track 2, at 7:55 – 8:20)

Patient 2

229. State's Exhibit 2 consists of copies of prescriptions issued to Patient 2 by Dr. Karel. Dr. Karel's medical record for Patient 2 was not included in the exhibit. Dr. Karel testified that Patient 2 is a friend of one of Dr. Karel's employees, Patient 9. (Tr. at 85; St. Ex. 2)

230. Dr. Karel issued the following prescriptions to Patient 2:

Date of Prescription	Medication	Quantity	Refills
11/24/10	Oxycodone 15 mg	90	0
11/24/10	Oxycodone 30 mg	120	0
11/24/10	Motrin 800 mg	90	5
11/24/10	Flexeril 10 mg	90	5
11/24/10	Xanax 2 mg	30	0
11/24/10	OxyContin 80 mg	90	0
12/23/10	Xanax 2 mg	30	0
12/23/10	Oxycodone 30 mg	120	0
12/24/10 ³¹	Oxycodone 20 mg	70	0
12/24/10	OxyContin 40 mg	180	0
1/20/11	Xanax 2 mg	30	0
1/20/11	Oxycodone 30 mg	120	0
1/20/11	OxyContin 80 mg	90	0
1/27/11	Oxycodone 15 mg	100	0

(St. Ex. 2)

231. Court records indicate that Patient 2 has a criminal record that includes the following conviction:

- On January 6, 2009, in the Portsmouth Municipal Court, Patient 2 was found guilty of misdemeanor Possessing Drug Abuse Instruments, in violation of Section 2925.12, Ohio Revised Code. (St. Ex. 27 at 13-14)

In addition, court records indicate that, on October 20, 2009, in the Scioto County Common Pleas Court, Patient 2 was charged with felony Aggravated Possession of Controlled Substances, to wit: OxyContin, in violation of Sections 2925.11(A) and (C)(1)(a), Ohio Revised Code. After failing to appear for a scheduled proceeding on that matter, a bench warrant was issued for Patient 2, and, on December 22, 2009, Patient 2 was charged with felony Failure to Appear, in violation of Sections 2937.29 and 2937.99, Ohio Revised Code. (Tr. at 25-30)

232. Dr. Karel testified that, until he received the March 9, 2011, Notice of Summary Suspension and Opportunity for hearing, he had been unaware of Patient 2's criminal conviction and charges. When asked if he would acknowledge that Patient 2 has some sort

³¹ Dr. Karel believes that he had incorrectly written December 24 on two of the prescriptions and that the date should have been December 23. (Tr. at 90-94)

of a drug problem, Dr. Karel testified, "I will acknowledge the patient reportedly had a drug problem at one point." (Tr. at 86-87)

233. Dr. Karel believes that it is inappropriate for the Board to review only prescriptions without reviewing or even requesting the patient's chart. (Tr. at 1356)

Patient 6

234. Patient 6, a male born in 1975, first visited Dr. Karel at the Medical Office on December 22, 2008. He lives in Olive Hill, Kentucky. His last visit with Dr. Karel was May 5, 2009, although he was seen again at the Medical Office by Dr. Celec on June 4, 2009. Patient 6's chart indicates that he had medical insurance through his employer. (St. Ex. 6)
235. Patient 6 testified that Olive Hill is approximately one hour from Wheelersburg but that his work location is only about a 10-minute drive from Wheelersburg. (Tr. at 1177)
236. Patient 6 testified that he suffered from back and knee pain caused by injuries he sustained around 2007. He said that he experienced intense pain in his lower back that disturbed his sleep and interfered with his work. Patient 6 further stated that, although back surgery had been recommended to him, he is not interested in having back surgery because of the risk that it could leave him a paraplegic. (Tr. at 1167-1169)
237. Patient 6 testified that he had been referred to Dr. Karel by a co-worker. He testified that, when he first presented to the Medical Office, he had had to see a physical therapist before he could even see Dr. Karel. Patient 6 further testified that, when he first saw Dr. Karel, Dr. Karel had performed an examination and had had Patient 6 go through a series of movements "to see where the pain was at, how intense the pain was" in his knee and back. Patient 6 estimated that the first appointment took at least 20 minutes. Moreover, Patient 6 testified that Dr. Karel prescribed medication at that first visit that helped him a great deal. (Tr. at 1168, 1170-1173)
238. Patient 6 testified that he continued seeing Dr. Karel for approximately four or five months. He indicated that he had discontinued seeing Dr. Karel because the staff at the Medical Office was rude. Moreover, Patient 6 testified that he did not remain on medication long after he discontinued seeing Dr. Karel. Dr. Karel had given him some exercises to help strengthen his back which were effective, and he discontinued taking medication. (Tr. at 1173-1175)
239. On cross-examination, Patient 6 acknowledged that he had filled many of his prescriptions at a Kroger Pharmacy on Glenway Avenue in Cincinnati, Ohio. Patient 6 noted that Cincinnati is a two- to two-and-one-half hour drive from Wheelersburg and from where he was working. (Tr. at 1177-1178) Whereupon the following exchange took place:

Q. [By Mr. Wilcox] Why would you fill your prescriptions all the way in Cincinnati, Ohio?

- A. [By Patient 6] Because that's where I asked the staff would be the best place for me to get them filled and that's where they told me to take them to.
- Q. The staff at Dr. Karel's practice told you to take your prescriptions all the way to Cincinnati to get them filled?
- A. They—Yeah. There was a—there was some different—I can't remember what—the list, how many places there was, but Cincinnati, I did have family down there in Cincinnati, so I would stop in and visit my family while I was down there. So that just made it okay for me to go down there to see them while I was there.
- Q. So you got a list of pharmacies you could go to and that was the closest one for you?
- A. That was the closest one for me to go to that would take my insurance, yes. There was other places closer, but they didn't accept my insurance. They did not take my insurance. And I had insurance for my prescriptions. That was the closest one that took my insurance.
- Q. Are there Kroger locations in Kentucky; do you know?
- A. I don't know. I mean, there is Krogers, but like I said, that was the one that I knew that would take my insurance, so that's the one I went to.
- Q. So there are Krogers closer to your home in Olive Hill, Kentucky?
- A. Yes, there is, but it being an Ohio prescription, I thought I had to have it filled in Ohio[.]³²

(Tr. at 1178-1179)

240. Patient 6 acknowledged that Dr. Karel did not accept his health insurance, and that he had paid cash for each visit. When asked why he did not find a physician who took his insurance, Patient 6 replied: "I just—I was going to where I thought was the best place to go. I mean, it wasn't a problem with me." (Tr. at 1179-1180)

³² This assertion is contradicted by a KASPER report, which indicates that Patient 6 had filled Dr. Karel's prescriptions in Ashland, Kentucky, on December 23, 2008, and January 9, 2009. (Resp. Ex. K at 213)

241. KASPER and OARRS reports, along with Dr. Karel's medical records for Patient 6, indicate that Patient 6 had filled the following prescriptions issued to him by Dr. Karel:

Rx Date	Medication	#	Refills	Daily Dose (30-day Supply)	Pharmacy Location³³
12/23/08	OxyContin 80 mg	56	0	320 mg (14 day supply)	Ashland, KY
12/22/08	oxycodone 15 mg	56	0	60 mg (14 day supply)	Ashland
1/6/09	OxyContin 80 mg	90	0	240 mg	Cincinnati, OH
1/6/09	oxycodone 15 mg	120	0	60 mg	Ashland
2/9/09	OxyContin 80 mg	90	0	240 mg	Cincinnati
2/9/09	oxycodone 15 mg	120	0	60 mg	Cincinnati
3/10/09	OxyContin 80 mg	90	0	240 mg	Cincinnati
3/10/09	oxycodone 15 mg	120	0	60 mg	Cincinnati
5/6/09	OxyContin 80 mg	90	0	240 mg	Cincinnati
5/6/09	oxycodone 30 mg	60	0	60 mg	Cincinnati

(St. Ex. 6 at 17-44)

In addition, Dr. Karel wrote the following prescriptions to Patient 6, but they do not appear on OARRS or KASPER. Either Patient 6 did not fill them, or he did not fill them in either Ohio or Kentucky:

Rx Date	Medication	#	Refills	Daily Dose (30-day Supply)
4/7/09	OxyContin 80 mg	90	0	240 mg
4/7/09	oxycodone 15 mg	120	0	60 mg

(St. Ex. 6 at 24-26; Resp. Ex. J at 52; Resp. Ex. K at 213)

Finally, Dr. *Celec* wrote the following prescriptions to Patient 6. The prescriptions do not appear on either OARRS or KASPER:

Rx Date	Medication	#	Refills	Daily Dose (30-day Supply)
6/4/09	OxyContin 80 mg	90	0	240 mg
6/4/09	oxycodone 15 mg	120	0	60 mg

(St. Ex. 6 at 17-20; Resp. Ex. J at 52; Resp. Ex. K at 213)

³³ All of the prescriptions were filled either at the Broadway Clinic Pharmacy in Ashland, Kentucky, or the Kroger Pharmacy on Glenway Avenue in Cincinnati, Ohio. (Resp. Ex. J at 52, 105; Resp. Ex. K at 213)

242. Each of the progress notes from January 6, 2009, through April 7, 2009, documents that Patient 6 had filled his prescriptions at the Medicine Cabinet Pharmacy in Russell, Kentucky. Moreover, two of those progress notes, dated February 9 and March 10, 2009, document pill counts, strongly indicating that Patient 6 had presented pill bottles at those visits, yet also reference the Medicine Cabinet Pharmacy as having filled the prescriptions. As set forth above, this information is false. (St. Ex. 6 at 23, 26, 29, 33, 36) Only one progress note, dated June 4, 2009, when Dr. Celec was there, correctly reflects that Patient 6 had filled his prescriptions at a Kroger Pharmacy in Cincinnati. (St. Ex. 6 at 20)

Patient 10

243. State's Exhibit 10 consists of copies of prescriptions issued to Patient 10 by Dr. Karel. Dr. Karel's medical record for Patient 10 was not included in the exhibit. Patient 10 was an employee of Dr. Karel's. Dr. Karel testified that Patient 10's chart had not been subpoenaed by the Board. (St. Ex. 10 at 181; Tr. at 182-183)

244. Copies of prescriptions issued by Dr. Karel to Patient 10 indicate that he had prescribed methadone 10 mg #300, oxycodone 30 mg #60, and Ativan 1 mg #30 to Patient 10 on August 16, September 13, October 11, November 8, and December 6, 2010; and on January 3 and 31, 2011, with one exception. On January 3, 2011, Dr. Karel prescribed 90 tablets of oxycodone 30 mg instead of 60. (St. Ex. 10; Tr. at 181)

Patient 11

245. The records for Patient 11 consist of three prescriptions including only one prescription for a controlled substance: a May 4, 2009, prescription for hydrocodone/APAP 5/500 #90. No medical record for Patient 11 is included in the exhibit. (St. Ex. 11)

246. Patient 11 has a criminal record that includes a 2003 misdemeanor conviction for passing bad checks, and 2003 felony criminal complaints for robbery and complicity to burglary that were "waived to grand jury." No further information concerning the felony complaints are included in the record, however. (St. Ex. 30)

Patient 13

247. Dr. Parran had indicated in his report that he had had "no opinion" concerning Dr. Karel's treatment of this patient. (St. Ex. 17)

248. Dr. Karel's medical record for Patient 13 indicates that he had prescribed controlled substances to Patient 13. (St. Ex. 13)

249. In 1990, Patient 13 was convicted of misdemeanor carrying a concealed weapon. He was fined \$100 and the weapon was confiscated. (St. Ex. 31)

Patients Not Accepted into Dr. Karel's Practice or Dismissed from his Practice

Testimony of Dr. Karel

250. Dr. Karel testified that his patients are required to apply for admission to his practice. Dr. Karel presented Respondent's Exhibit H, which he testified is a list of approximately 175 individuals who had applied to be seen by Dr. Karel at Tri-State Primary Care, but whom Dr. Karel had refused to accept as patients. He acknowledged that he may have seen some of them at the office where he previously worked, but not at his own practice "[s]ince I have a say—the say." (Tr. at 1282, 1286-1288; Resp. Ex. H)

Dr. Karel testified that Respondent's Exhibit H does not include individuals whom he would refuse to even consider as patients. Such individuals are turned away immediately and do not even fill out applications to become his patients. Dr. Karel testified that he refuses to see and treat individuals who are under 25 years old, come from Florida, or who have a "very poor presentation," such as the appearance of being intoxicated. (Tr. at 1221, 1282-1284)

251. Dr. Karel also presented Respondent's Exhibit I, which he testified is a list of patients who he is no longer treating. Dr. Karel further testified that the primary reason is that they violated the pain agreement in some way, for example, by seeing other physicians for drugs, missing pill counts, or having inappropriate urine screen results. He testified that it also includes patients who were not happy that Dr. Karel would not increase their medication or prescribe early refills. Dr. Karel added, however, that dismissing a patient from his practice is discretionary, and he does not always discharge a patient for a first violation. (Tr. at 1288-1291; Resp. Ex. I)

252. With respect to Respondent's Exhibits H and I, Dr. Karel testified that he wants to convey that he is very concerned about treating patients appropriately for their pain, and that he makes a significant effort to avoid treating patients who are seeking medication for inappropriate reasons. (Tr. at 1296-1297)

Testimony of Dr. Parran

253. On cross-examination, Dr. Parran was asked to assume that Dr. Karel dismisses approximately 33 percent of his patients because of drug-seeking behaviors, and asked what significance would that have on Dr. Parran's overall opinion of Dr. Karel's practice and perhaps saying that it fit the criteria for a pill mill. Dr. Parran responded:

Well, my opinion—my impression and as my impression would relate to my opinion regarding that goes something like this: If a physician does not bother screening for addiction up front, then the initial prescribing by a physician to that patient is dangerous.

The fact that that physician will attract a lot of addicts to their practice, because addicts will talk with each other and they'll flock to a practice that prescribes substantial amounts of opiates and an occasional benzodiazepine, but substantial amounts of opiates at the first office visit with relatively little evaluation, they'll flock to that practice, I would consider it predictable that that practice down the road would either become completely unmanageable from the addictive behavior or have to start running a fair amount of patients out.

The—The fact that the patients are dismissed, I think, is very positive. The fact that the practice would err on the side of not screening enough up front so that they begin to attract those kind of patients to their practice means that that practice, before they dismissed the patient, actually put the health and safety and maybe even life of those patients in danger. And that's—that's just a real problem.

(Tr. at 675-676)

When asked to assume that, in addition to the 33 percent of Dr. Karel's patients who are dismissed for drug-seeking behavior, another one-third are screened out and never prescribed controlled substance medications, Dr. Parran testified:

Boy, again, if you do the math. So if one out of three people who show up you don't even see because they've got problematic issues, and then one out of three that you start prescribing to you eventually get rid of because of problematic issues, that means this office was attracting—50 percent of the people who were showing up were addicts. And that's absolutely astonishing.

(Tr. at 678-679) Dr. Parran further testified:

A practice where, in retrospect, 50 percent of the people that are showing up either obviously upfront have addictive disease or down the road are identified with out-of-control behavior and are dismissed, is—is an office that's being run in a way that—that honestly that attracts problematic patients. And so there's something that's going on in that office that's attracting huge numbers of problematic patients.

(Tr. at 680)

254. Dr. Parran testified that he has not read the final report of the Ohio Prescription Drug Abuse Task Force. (Tr. at 677)

Testimony of Dr. Ross

255. When asked if Dr. Karel's rejecting or dismissing significant numbers of patients from his practice was indicative of a pill mill, Dr. Ross replied: "Absolutely not. It's directly contradictory, and it is a refutation of a pill mill." (Tr. at 896)

Further Testimony of Dr. Karel

256. With respect to Dr. Parran's criticism that, with so many people on Dr. Karel's denied and dismissed lists, there must be a problem with the practice, Dr. Karel testified: "That appears to be totally irrational thinking. That would seem to me as if someone is looking for any reason whatsoever to find that I am—to find mistakes, regardless of what the facts are."³⁴ (Tr. at 1297)

Testimony of Debra Celec, D.O.

257. Debra J. Celec, D.O., testified that she had obtained her osteopathic medical degree in 1989 from the Ohio University College of Osteopathic Medicine. She then completed one year of rotating internship at Doctors Hospital in Columbus, followed by one year of general surgery residency at Mt. Carmel Hospital. Afterward, Dr. Celec returned to Doctors Hospital and completed a residency in otolaryngology [ENT]. She is currently employed by Avita Health Care in Galion and Bucyrus, Ohio, and has hospital privileges with the Avita Health System. (Tr. at 354-356)

258. Dr. Celec testified that she has practiced as a *locum tenens* physician intermittently for about 15 years. Dr. Celec further testified that a "*locum tenens*" physician "is hired to cover for another physician for a specific period of time." She testified that she has filled in for ENT physicians in a nonsurgical capacity, as well as at urgent care centers and family practices. (Tr. at 356-357)

259. Dr. Celec testified that, around mid-march 2009, after she received a *locum tenens* assignment to work at the Medical Office, she met with the owner of the practice, Mr. Hamilton, and Dr. Karel. Dr. Celec testified that she had reviewed around five charts that were chosen by someone at that office, and she found that nothing was amiss with those charts in terms of documentation. She further testified that copies of prescriptions had been stapled to each progress note, so she was aware of the prescriptions issued. She further testified that it is "fair to say" that she did not have any concerns based on the charts that she had reviewed that day. (Tr. at 359, 395-397)

260. Dr. Celec testified that, shortly after she had met with Mr. Hamilton, he was murdered. She learned about it two weeks later and was very concerned: "My concern was, whomever killed this man, is it connected with this office, and is there a lot of—is there stuff going on there that could be harmful to me, that I would not want to be a part of?" She contacted Dr. Karel with her concerns and he reassured her that the murder was not connected with the medical practice. After speaking with Dr. Karel, she decided to go forward with the assignment. (Tr. at 360-362)

³⁴ It may seem that way at first blush, but Dr. Parran said that it is good that Dr. Karel refuses to treat and/or dismisses problematic patients, but that it is nonetheless bad that he attracts so many problematic patients.

261. Her first day was May 11, 2009, and she worked at the Medical Office through June 11, 2009, Monday through Thursday. (Tr. at 357-358, 363)
262. Dr. Celec testified that she shadowed Dr. Karel her first two days and observed him as he saw patients, and she examined one or two patients herself. Dr. Celec further testified that she had asked Dr. Karel questions throughout the process and that he had answered her questions. When asked if there had been anything unusual about her experience shadowing Dr. Karel, she replied: "From the first two days, it's normal. What I saw appeared normal from the first two days." (Tr. at 363-364, 402-403, 405)
263. On the third day, Dr. Karel left for his medical leave and Dr. Celec took over as the physician. She testified that, after Dr. Karel left, she became "uncomfortable with the whole setting," including the patient population and the type and amount of narcotics that the patients were being prescribed. She further testified that she had prescribed narcotics previously in her practice, but not in the numbers that were requested. She testified: "I've never been in a situation where a patient could take that many pills in a month's time and still be standing." By her fourth day there, Dr. Celec began contacting the *locum tenens* recruiter to let him know she wanted out of the contract. (Tr. at 354-365, 373-375)
264. Dr. Celec testified that she had considered the staff at the Medical Office to be "very unprofessional," meaning: "Loud, overly loud communication. Cussing. Sloppy work." Further, Dr. Celec had numerous conflicts with Ms. Neuman, who by that time had taken over the practice from her father. (Tr. at 367, 379, 429, 451)

Dr. Celec testified that, around the third week she was there, Ms. Neuman's uncle, Marshall Adkins, started coming to the Medical Office every day. Dr. Celec further testified that Mr. Adkins carried a handgun in a holster in plain view. Moreover, Dr. Celec testified that she had the impression that Mr. Adkins was going to take over as the owner of the practice. (Tr. at 382-383)

265. On February 15, 2011, Dr. Celec was interviewed by a Board investigator. The interview was recorded. During the interview, Dr. Celec stated that she had worked as a *locum tenens* physician at the Medical Office from sometime in May 2009 through June 2009, during Dr. Karel's medical absence. Dr. Celec stated that she initiated a transfer request within three days of working at the Medical Office practice because it was "a drug mill," and expressed fear for her personal safety due to retaliation from the patients. Dr. Celec reported that all patients, including some who showed up from as far away as Florida, came to the practice with the expectation of receiving a prescription for narcotics. Further, after Dr. Celec began to discharge patients in response to inappropriate urine screen results, including the presence of illicit drugs, she was admonished by Ms. Neuman, who is not a physician, for "ruining her business." Thereafter, Dr. Celec reported that Dr. Karel contacted her and informed her that he did not believe that marijuana in a patient's urine was significant and that she should probably not terminate patients from the pain practice because they tested positive for marijuana. (St. Ex. 21; see, also, Tr. at 377, 379-380)

Dr. Karel's March 31, 2010, and February 15, 2011, Interviews with Board Investigators

266. Curtis Fortner testified that he is employed as an Enforcement Investigator for the Board, and that he has held that position since June 2006. Prior to joining the Board's staff, Investigator Fortner worked for six years as a deputy sheriff in Pickaway County, Ohio, and, prior to that, he had worked for 12 years as a deputy sheriff in Hocking County, Ohio. Investigator Fortner testified that his primary responsibility as an enforcement investigator is to investigate complaints, interview complainants, licensees, and potential witnesses. Investigator Fortner testified that he is assigned to the southeast region of Ohio. (Tr. at 234-236)

March 31, 2010, Interview with Dr. Karel

267. Investigator Fortner testified that he had interviewed Dr. Karel on March 31, 2010. Investigator Fortner further testified that the interview took place at Dr. Karel's office, then located at 7997 Ohio River Road.³⁵ He testified that he had attempted to record the March 31, 2010, interview; however, the recorder malfunctioned and he was unable to record it. (Tr. at 236-237, 277)
268. Investigator Fortner testified that, during the interview, he had seen the file for Patient 3. He further testified that Dr. Karel had reviewed the file and that Investigator Fortner did not read or view the contents of the file. Nevertheless, Investigator Fortner testified that he had had an opportunity to observe the file and estimated that it contained approximately six to eight pages. However, he testified that Dr. Karel had said something that gave Investigator Fortner the impression that Patient 3's chart was incomplete. Dr. Karel called to Patient 9 and handed her the folder, telling her that that something was missing from the file. Patient 9 left with the file and Investigator Fortner and Dr. Karel continued the interview. Investigator Fortner further testified that Patient 9 later returned with Patient 3's chart and gave it back to Dr. Karel who placed it on a pile of records. They never returned to the topic of Patient 3. Investigator Fortner did not view the contents of the file after it was returned. (Tr. at 248-249, 273-276)
269. The parties entered into a stipulation that the true number of pages of the medical record from which State's Exhibit 3 was copied totaled 77 pages. The additional pages of State's Exhibit 3 resulted from the copying process, whereby the front and back of each prescription was copied. (Tr. at 199-202)
270. Dr. Karel testified that it is "impossible" that Patient 3's chart had contained only six to eight pages. However, he acknowledged that, after having received the Board's subpoena for patient records, including Patient 3's records, he had added pharmacy profiles to the Patient 3's chart that were clearly dated May 10, 2010, and testified that he had added "[d]ated laboratory information." (Tr. at 72-75, 1335-1336)

³⁵ This was the location of Dr. Karel's office after having been locked out of 8308B Ohio River Road, and prior to moving back to 8308B Ohio River Road.

271. Investigator Fortner was asked if he can recall a discussion regarding whether Dr. Karel obtains vital signs and listens to the heart and lungs. Investigator Fortner replied that he remembers Dr. Karel made a comment that, “if the patient had a problem with the neck or the shoulder, that there wasn’t any sense to listen to the heart or lungs because that wasn’t the problem. I don’t require—I don’t recall exactly verbatim.” (Tr. at 250)
272. Dr. Karel denied that he had ever told a Board investigator that he never took patients’ vital signs during follow-up visits. Dr. Karel testified that he took and documented vital signs at every visit for all patients. Dr. Karel acknowledged that he had not done heart and lung examinations during follow-up visits before December 2009. (Tr. at 76-78)

February 15, 2011, Interview with Dr. Karel

273. Investigator Fortner testified that he and Chief Enforcement Investigator Douglas Edwards interviewed Dr. Karel again on February 15, 2011. Investigator Fortner further testified that this interview had taken place at Dr. Karel’s current office at 8308B Ohio River Road. Moreover, Investigator Fortner testified that he had recorded the interview. The recording of that interview was admitted to the hearing record as State’s Exhibit 20. (Tr. at 253-254)

Investigator Fortner testified that, partway through the interview, Dr. Karel stated that he needed to speak with an attorney. He left the room and made a telephone call. After speaking with his attorney, Dr. Karel returned and indicated that, on the advice of counsel, he would not answer any more questions. Investigator Fortner testified that he read the rest of the questions to Dr. Karel that they were going to ask him in order that Dr. Karel could advise his attorney what they were looking for. (Tr. at 254-255; St. Ex. 20, track 2 beginning at around 28:30; St. Ex. 20, track 5)

274. During the February 15, 2011, interview when asked by board investigators what percentage of his patients receive a prescription for controlled substances, Dr. Karel replied, “They all do.” (St. Ex. 20, track 2, at 25:30 – 25:46)
275. Dr. Karel testified that, during his February 11, 2011, interview with Investigator Fortner, Dr. Karel did report to Investigator Fortner that he takes vital signs on follow-up visits, and that that is audible on the recording. (Tr. at 1332-1334)
276. The recording of the February 11, 2011, interview contains a statement from Dr. Karel that typical office visits include taking the patient’s vital signs. (St. Ex. 21, track 2, at 13:30 – 13:53)

Pharmacies Honoring or Not Honoring Dr. Karel’s Controlled Substance Prescriptions

277. In the Notice, the Board alleged that “many, if not most area pharmacies will not honor prescriptions [issued by Dr. Karel] for controlled substances.” (St. Ex. 41A at 5)

278. Dr. Karel agreed that the Board's allegation is "probably true" that many or most of the pharmacies in his area do not accept his prescriptions for controlled substances. Dr. Karel further testified that "it occurs considerably less for me than for other pain clinics in the area." Moreover, Dr. Karel testified that that is more reflective of other pain clinics in the area than his own practice. (Tr. at 71, 1340-1341)
279. Dr. Karel presented the testimony of six pharmacists from six different pharmacies in southern Ohio and northern Kentucky, all of whom testified that they fill Dr. Karel's prescriptions for controlled substances. (Tr. at 979-1100)
280. Patient 3 testified that she is aware of 19 pharmacies that would accept Dr. Karel's prescriptions in the tri-state area. In identifying the locations of these pharmacies, Patient 3 listed several, including Groveport, Ohio, a suburb of Columbus. (Tr. at 782-783)
- Noting that Groveport is some distance from Wheelersburg, Patient 3 testified, "It wasn't the radius of the doctor's office, it was the radius of the patient and where they lived."³⁶ Patient 3 further testified that she and the pharmacy in Groveport [Groveport pharmacy] "came up with what we called a criteria for [patients] to meet to even be able to fill" their prescriptions at the Groveport pharmacy. (Tr. at 782-784)
281. Patient 3 testified that there are some area pharmacies whose general policy is to refuse controlled substance prescriptions from physicians in Wheelersburg, but who will accept such prescriptions from Dr. Karel: Medicine Cabinet in Russell, Kentucky, and Medi-Mart in Portsmouth. (Tr. at 787-788)

October 1, 2010, Final Report of the Ohio Prescription Drug Abuse Task Force

282. The Notice also included allegations concerning an October 1, 2010, Final Report of the Ohio Prescription Drug Abuse Task Force. (St. Ex. 41A)
283. On April 2, 2010, Governor Strickland signed an executive order establishing the Ohio Prescription Drug Abuse Task Force [Task Force] to "develop a coordinated and comprehensive approach to Ohio's prescription drug abuse epidemic." On October 1, 2010, the Task Force completed its work and submitted a final report [Task Force Report] to the Governor. (St. Ex. 18 at 2, 5)

The Task Force Report is a 90-page document, including appendices, and contains an analysis of the issue and recommendations for law enforcement agencies, regulatory bodies, and other entities. Among the information included in the analysis, the Task Force Report identified a set of criteria that characterize "pill mill" operations:

³⁶ However, as referenced above, both Patient 9, a resident of Portsmouth, and Patient 16, a resident of Clay City, Kentucky, filled Dr. Karel's prescriptions at pharmacies in Columbus. (St. Ex. 16 at 4, 104)

A growing problem for law enforcement throughout the state, particularly in southern Ohio, is diversion through clinics that prescribe and/or dispense powerful narcotics inappropriately or for nonmedical reasons. These clinics are often referred to as “pill mills.” Pill mills are sometimes disguised as independent pain-management centers. They often exhibit certain characteristics, such as:

- Not accepting insurance and operating as a cash-only business;
- Not requiring a physical exam, medical records, or x-rays;
- Treating pain with prescription medication only;
- Avoiding scrutiny by pharmacists by dispensing medication within the clinic;
- Irregular hours of operation;
- Presence of security guards; and
- Long lines of people waiting outside of the building.

These facilities usually open and shut down quickly in order to evade law enforcement. Authorities believe that as many as eight pill mills could be operating in Scioto County alone, which has a population of 76,000 residents

(St. Ex. 18 at 20)

Further, the Task Force Report states that, between 2006 and 2008, the highest average annual death rates due to unintentional drug overdose in Ohio occurred primarily in Ohio’s southern region, which includes Scioto County. This, along with a rise in crime and an increase in the number of individuals seeking treatment for opioid addiction, led the city and county health commissioners in Scioto County to declare a public health emergency in January 2010. (St. Ex. 18 at 12, 22)

Testimony of Patient M.P. in Support of Dr. Karel

284. Patient M.P. testified that he resides in Catlettsburg, Kentucky. He is 60 years old. Patient M.P. testified that he used to work on heating and air conditioning, and has also held jobs at a steel foundry and doing concrete work. However, Patient M.P. testified that he has been on disability and unable to work since 2000. He testified that he has a tumor on his spinal cord that presses on a nerve that is painful and is causing the muscles in his left leg to deteriorate. He further testified that he cannot have surgery to correct the problem because of a heart condition; he has had “five bypasses.” His cardiologist told him that he cannot undergo anesthesia for the length of time required for the surgery.³⁷ He testified that, because surgery is not an option he must rely on pain medication.
(Tr. at 1130-1132)

³⁷ The transcript indicates that Patient M.P. said the surgery would last 46 hours; however, it is likely that he said “four to six hours.” (Tr. at 1132)

Patient M.P. testified that his condition was diagnosed in 2004, and he had been receiving pain medication since 2005. (Tr. at 1132-1133)

285. Patient M.P. testified that he first began seeing Dr. Karel in 2007 or 2008. Prior to that, Patient M.P. had been seeing a physician in Ashland, Kentucky, who passed away in 2007 or 2008. Subsequently, Patient M.P. saw a physician who gave him some injections in his back. Patient M.P. testified that the injections did not help. Patient M.P. also tried chiropractors, who did not help. Finally, Patient M.P. got a referral to Dr. Karel. (Tr. at 1133-1136)

286. Patient M.P. testified concerning his first visit with Dr. Karel:

Well, the first encounter, he examined me, naturally, had me do different movements, I guess checking my spine, and my pinching my legs and all of that. He ordered a blood test, physical therapy, CT Scan, I'm thinking, I can't promise you, but I was thinking that I got all of my medical records to him from Dr. Powell,³⁸ and all of that that was doctoring me at the time.

(Tr. at 1136-1137)

287. Patient M.P. testified that he does not wish to be treated at a pill mill: "I don't want that, I want help. I've got five girls and seven grandbabies that I like to enjoy time with, and I don't want to—I've never been addicted to drugs or alcohol or anything of that nature. I don't want something I'm addicted to." (Tr. at 1138-1139)

288. Patient M.P. testified that he had found the staff at the Medical Office to be unprofessional and had used foul language. Patient M.P. further testified that the staff had charged him for urine screens that were never performed. However, Tri-State Primary Care has a "totally different atmosphere." Patient M.P. stated that the office was cleaner and more professional. (Tr. at 1137-1140, 1152)

289. Patient M.P. testified that his quality of life has improved under Dr. Karel's care:

Well, I'm able to enjoy life a little better because I've had to do that without pain medication, and I know what it is to be in constant pain.

I'm able to spend quality time with my grandchildren, where before I couldn't, I couldn't—I was kind of bedridden really because of it, I couldn't go out and do the things I'm doing today. And if I would have done what the other doctors told me, to live with the pain and try to live with it, there is no way, I don't—I can't do it.

* * *

³⁸ Patient M.P. testified that Dr. Powell was the physician who diagnosed his condition. (Tr. at 1133)

My family is the whole thing. It's my life and to have your grandchildren come up and say, "Pappa, can you go outside and play with me?" "Can you play ball with me?", and have to say, "Pappa is hurting too bad, I can't."

I want them to remember me as someone they can spend quality time with and have a life with, but if I didn't have the pain medication, like I say, I would be an invalid.

(Tr. at 1141-1142)

290. The Hearing Examiner observed that Patient M.P. walks with a pronounced limp.

291. Patient M.P. wrote a letter of support for Dr. Karel. (Resp. Ex. E at 52)

Patient Letters of Support

292. Dr. Karel submitted numerous letters of support written by his patients. These letters praise his medical abilities. Many describe in detail the exams that he performs, how his treatment has improved their lives, and the serious injuries or conditions that they have suffered. (Resp. Ex. E)

293. With respect to the letters of support, Dr. Karel testified that he has had patients continue to come into his office for the first two or three weeks following the summary suspension of his license, and that he had asked them to write a letter concerning his practice. Dr. Karel testified that he never instructed the patients concerning what to write. Dr. Karel further testified:

I would like the Board, the Board members, and gentlemen and reporter * * * [to understand that] a high percentage or the majority of the letters here, specifically stat[e] that I do not run a pill mill, that I am extremely interested and dedicated to the proper administration of drugs to the careful selection of patients, to the prudent prescribing of medications to all of my patients.

Additionally, the patients are—patients remark, virtually unanimously, to the fact that I care significantly for their other medical problems, and I care for the patients' wellbeing as a whole.

(Tr. at 1189-1190)

Moreover, Dr. Karel testified:

Most of these letters here are extremely important. I believe the—at least two of the letters here are rather indicative; and they should give the—the reviewers of the case, the examiners, some further insight into the type of

practice that is run, how I help the patients, and what can be—why the patients insist upon coming to my practice, why they would like to. Why I have patients calling me up, telling me they have still not seen another physician, they're waiting for me to come back. Why my employees are seen by me. Why I cannot comfortably suggest that they see other physicians, but that they should continue seeing me.

(Tr. at 1299)

Additional Information

294. Dr. Karel acknowledged that his patients at Tri-State Primary Care were not seeing him for neurology consultations. (Tr. at 49)
295. Dr. Karel agreed that all or nearly all of the patients who came to see him at the Medical Office and at his own practice received prescription narcotics. (Tr. at 65)
296. Dr. Karel testified that he would estimate that approximately 50 percent of his patients complain of lower back pain. (Tr. at 65; 1368-1369)
297. Dr. Karel acknowledged that a significant proportion of his patients—approximately 45 percent—came to him from outside of Ohio, mainly Kentucky and West Virginia. Dr. Karel testified that that this is unsurprising because his office is located near Ohio's borders with those states. (Tr. at 64, 1314-1315)
298. Dr. Karel acknowledged that he would not necessarily discharge a patient whose urine tested positive for marijuana. (Tr. at 70-71)
299. Dr. Karel denied that he had ever changed office locations for the purpose of evading law enforcement. He testified that he had to move to leave the Medical Office and start his own practice. After he was locked out of his first location, he had to move to a different location, which was approximately one-half mile away. Because of that building's poor condition, he moved back to his previous location when he had the opportunity. Dr. Karel testified that all of these locations are within the same small community of 7,000 residents. (Tr. at 205-207, 1309-1312)
300. When Dr. Karel was asked why he treats all of his employees, he stated that most of them had worked for the Medical Office and wanted to follow him when he left. With respect to Patient 1, who had not worked for the Medical Office, Dr. Karel testified that he had known him well personally. Finally, Dr. Karel testified that he had told his employees that, as patients, they would be "under more scrutiny than anybody else" and that the patient/physician relationship was totally separate from the employer/employee relationship. (Tr. at 1315-1317)

301. When asked if his practice is a pill mill, Dr. Karel replied:

My practice is far from a pill mill. The—All the criteria generally associated with pill mills are not applicable to my practice.

We are not there solely to bring in patients to make money regardless of how the patients are being treated. We do not give out medications like that and have people come in. We have a strict policy to screen the patients on one, two, three steps. We do accurate correct measurements of the patients. We care for the general condition, general way they're treated. We ask for the ancillary examinations on all or virtually all of the patients.

And there are some criteria which are found in pill mills that would seemingly apply to my practice; however, they are all readily explained, and that—we made no effort to try and dupe anybody in any way, shape, or form. We're just trying to perform our best to help us and to help the community.

(Tr. at 1376-1377) Dr. Karel further testified that he has never knowingly prescribed to people who are diverting drugs. (Tr. at 1377)

302. Dr. Karel testified that he prescribes Suboxone to patients to treat their addiction to opiates, which he testified is “diametrically opposed to the concept of a pill mill.”
(Tr. at 1206-1211)

303. Dr. Karel offered the following concluding statement:

I guess I would like to leave you all with the impression that I am a hardworking, concerned physician for the patients, and I—I do my best. I cannot say that I have not—I have made a slightest mistake, there are small mistakes, I cannot—I make every effort never to make a big mistake.

I do my best for the patients and I try to assure the best follow-up patient care. After seeing the care that was done elsewhere, where I've worked before, I made every effort to make—do everything, make everything better, since the other clinics. I said I'll be one or two rungs up the ladder from anybody else who was doing pain management. And I felt that that would be—that would be good, that would be more than sufficient. Trying to help both the patient as well as myself.

I've never—I've never done anything other than what's in the interests of the patient for medical reasons, medical purposes. And reading the charges against me, I believe that I have explained them all, excellent reasons for all of them.

One patient had negative and false-negative benzodiazepines in the urine. Besides that, I don't believe there's a single mistake there. Thank you.

(Tr. at 1375-1376)

LEGAL ISSUE

In its Notice, the Board alleged in paragraph 1 that, “[f]rom in or about November 2007 to in or about March 2011, [Dr. Karel] undertook the care of Patients 1 – 16 [as identified on a confidential Patient Key], to whom [he] prescribed controlled substances and/or drugs of abuse, in the course of [his] medical practice[.]” No specific patient-care allegations were made in that paragraph. However, the rest of Notice includes references and allegations comparing Dr. Karel’s practice to a “pill mill” or “drug mill.” Accordingly, the Notice was sufficient to apprise Dr. Karel that his prescribing practices were an issue in this case and, in fact, Dr. Karel did defend against that issue at hearing presenting, among other things, the report and testimony of an expert witness.

CREDIBILITY OF EXPERT WITNESSES

Dr. Parran

Based upon Dr. Parran’s education and experience, and his presentation and demeanor at hearing, he is deemed to be a credible expert witness. The Hearing Examiner is satisfied that Dr. Parran rendered his opinions following a reasonable review of Dr. Karel’s patient charts from Tri-State Primary Care with respect to Patients 3, 4, 5, 7, 8, 9, 12, 13, 14, 15, and 16.³⁹ He offered patient-specific testimony at hearing with respect to each of those patients.

At hearing, the Respondent asserted that Dr. Parran’s testimony should be accorded little weight on the bases that Dr. Parran is not a neurologist, and he does not specialize in, or see a sufficient number of patients requiring, pain management. The evidence establishes that both Dr. Karel and his expert, Dr. Ross, completed residencies in neurology, and that Dr. Ross is board-certified in neurology. Dr. Karel specializes in pain management, and Dr. Ross specializes in post-traumatic neurocognitive deficits and pain.

The fact that Dr. Parran was not trained in neurology, whereas Dr. Karel and Dr. Ross were, is a fair issue. However, Dr. Parran did not offer an opinion on the practice of neurology. For example, he did not opine on the methodology of electrodiagnostic testing or interventional pain management techniques. His opinions were limited to the appropriate prescribing of controlled substances in the management of pain, which the evidence establishes was the only treatment offered by Dr. Karel to the aforementioned patients. Dr. Karel did not offer neurological testing or interventional techniques that

³⁹ For one of those patients, Patient 13, Dr. Parran found no violation, although that patient was named elsewhere in the Notice as having had a criminal conviction.

might arguably go beyond the scope of Dr. Parran's training in internal medicine. In addition, although some neurologists practice and specialize in pain management, pain management is not the exclusive province of neurology. Many non-neurologists, including Dr. Parran, practice pain management. Moreover, the evidence establishes that Dr. Karel was not practicing neurology. In fact, Dr. Karel himself testified that his patients were not seeing him for neurology consultations. Accordingly, Dr. Parran's testimony was not accorded lesser weight based upon his training.

Moreover, the evidence indicates that, although Dr. Parran does not specialize in pain management, he does treat pain patients, including pain patients with addiction issues who would seem to be very difficult patients, and he treats them using controlled substances. He also serves as a consultant to pain specialists and other physicians concerning the evaluation and management of their pain patients. Further, he teaches courses in the area of chronic pain management in Ohio and other states. Moreover, he has been invited by the Department of Neurology at the Cleveland Clinic Foundation to give grand rounds to its residents, fellows, and attendings on the subject of prescribing opiates for chronic pain. Accordingly, he is clearly qualified to opine on the subject of pain management.

Therefore, for the reasons set forth above, Dr. Parran is deemed to be a credible expert witness in this matter.

Dr. Ross

The evidence indicates that Dr. Ross has solid training in the field of neurology, and has practiced in the area of pain management for some time. However, for the reasons set forth below, the Hearing Examiner cannot find that Dr. Ross is a credible expert witness.

Many of Dr. Ross's opinions concerning the patient charts, or, as he put it, Dr. Parran's "extractions" from the patient charts, contain misstatements of fact:

- Dr. Ross accused Dr. Parran of ignoring the "fact" that Dr. Karel had lowered Patient 3's daily regimen of oxycodone from 310 mg to 210 mg, or 30 percent. In fact, Dr. Karel lowered Patient 3's daily regimen of oxycodone from 280 mg to 250 mg.
- Dr. Ross misstated the dosing frequency of Patient 7's OxyContin as twice per day rather than three times per day.
- Dr. Ross stated that Patient 8 had "apparently" visited Dr. Karel only once, when in fact she had visited him 10 times. It thus appears that Dr. Ross had not even looked at the patient chart.
- With respect to Patient 9, Dr. Ross failed to mention that, in addition to methadone, Dr. Karel also prescribed oxycodone 30 mg at every visit, as well as Xanax 2 mg on occasion.

- Dr. Ross falsely stated that Dr. Karel modified his treatment of Patient 12 “based on non-response to therapy.” There is no evidence whatsoever to support that assertion. Even the assertion that Dr. Karel modified Patient 12’s treatment is unsupported.
- Dr. Ross stated that Patient 14 had been seen by Dr. Karel in August 2009, which is incorrect. Patient 14’s one and only visit to Tri-State Primary Care occurred on July 15, 2009. Worse, Dr. Ross falsely stated that Dr. Karel treated Patient 14 with Suboxone. Dr. Karel did not treat Patient 14 with Suboxone.
- Dr. Ross stated that Patient 15 was “initially treated by Dr. Karel with NSAIDs and steroids.” This is false. The chart clearly shows that Dr. Karel started Patient 15 on OxyContin 80 mg and oxycodone 30 mg and continued prescribing those medications at every visit.

No one is perfect. An occasional, relatively small factual error in an expert’s report or testimony may not significantly diminish that expert’s credibility as a witness. This is not the case with Dr. Ross. He made a small error with respect to Patient 7, and his miscalculation of Patient 3’s dosages could be overlooked in the absence of other significant mistakes. However, his gross factual errors with respect to Patients 8, 9, 12, 14, and 15 are, in the Hearing Examiner’s experience, unique. Making his error-fraught report even more unusual, Dr. Ross chose to refer to Dr. Parran’s opinions in such strident and disparaging terms as “egregiously flawed and biased,” “irrational,” and “contemptible.” This is simply astonishing.

Given the numerous factual errors in Dr. Ross’s report, all of which favor Dr. Karel, it is reasonable to conclude that, at best, Dr. Ross did not review, or give careful review to, the patient charts, and based his opinions on self-induced misinformation. At worst, he was intentionally trying to mislead the finder of fact. Accordingly, Dr. Ross is deemed to be a non-credible and unreliable witness, and his report and testimony are accorded no weight.

FINDINGS OF FACT

- 1(a) From 1996 through 2005 or 2006, Douglas B. Karel, M.D., practiced neurology in Lima, Ohio. In 2005 or 2006, after a job opportunity in another state fell through, Dr. Karel found himself without a position. As a result, he worked as a *locum tenens* physician and practiced one day per week at a pain management practice in Waverly, Ohio. In 2007, he left the practice in Waverly and began working full-time at a pain management practice in South Point, Ohio. Shortly thereafter, the practice moved to Wheelersburg, Ohio, which is located in Scioto County. Dr. Karel continued to practice pain management in Wheelersburg until his license was summarily suspended by the Board on March 9, 2011.
- 1(b) From about November 2007 until March 2011, Dr. Karel undertook the care of Patients 1 through 16, identified on a Confidential Patient Key, to whom he prescribed controlled substances and/or drugs of abuse in the course of his medical practice.

- 1(c) The State presented convincing evidence that Dr. Karel inappropriately prescribed large amounts of controlled substances to Patients 3, 4, 5, 7, 8, 9, 12, 14, 15, and 16 in a manner that was below the minimal standard of care applicable to the selection of drugs and/or without a legitimate medical purpose. Examples of such conduct include the following: failure to perform or document performing adequate diagnostic work-ups with respect to patients' pain complaints, a lack of individualized treatment planning to treat patients suffering from various pain complaints, and failure to perform or document performing adequate patient histories and physical examinations to the extent that patients' safety was put at risk. Moreover, in the cases of Patient 9, an employee, and Patient 16, Dr. Karel issued prescriptions for controlled substances without documenting those prescriptions in the patients' charts. Furthermore, Dr. Karel admitted during his testimony that a former practice where he worked from 2007 through May 2009 "is a true pill mill." His efforts to backtrack from that comment were unconvincing. Finally, Dr. Karel prescribed large amounts of narcotics to one patient, Patient 5, who was two weeks late for his visit, and documented nothing concerning withdrawal symptoms or possible lack of need for such medication.

Dr. Karel noted that he performs frequent pill counts and urine drug screens on his patients. However, the evidence showed, with respect to urine drug screens, that when the screens failed to match the medications being prescribed in the cases of Patient 9 and Patient 12, nothing was done. Moreover, with respect to pill counts, in the case of Patient 6, which concerns only Dr. Karel's former practice at the Medical Office, misinformation was included on the progress notes concerning the pharmacy where Patient 6 filled his prescriptions.

Dr. Karel also offered evidence that he refuses to accept about one-third of the patients who come to him due to problems with those patients, and dismisses about one-third of the patients he sees once he discovers they are problematic. It is good that Dr. Karel does that, but Dr. Parran offered persuasive testimony that there is also a downside to that situation. The numbers mean that about 50 percent of the patients who come to Dr. Karel's practice are addicts. Dr. Parran testified that addicts talk with each other and "flock" to a practice that prescribes large amounts of controlled substances with relatively little evaluation.

2. On October 1, 2010, the Ohio Prescription Drug Abuse Task Force, which was established to address Ohio's prescription drug abuse epidemic, issued its Final Report to the Governor. The Taskforce Report identified a set of criteria that characterize "pill mill" facilities, often disguised as independent pain-management centers, some of which apply to Dr. Karel's practice:
- (a) The Task Force Report states that the highest annual average death rates due to unintentional drug overdose occurred primarily in the state's southern region, which includes Scioto County, causing the city and county health commissioners in Scioto County to declare a public health emergency in January 2010. Dr. Karel's practice is located in Scioto County.
 - (b) The Task Force Report states that "pill mills" open and shut down quickly in order to evade law enforcement. Dr. Karel has had three different practice locations since

commencing practice in Scioto County 2007. He moved June 2009 when he left one practice, moved from another practice in June or July 2009 after being locked out of the building, and moved again approximately ten months later when better office space became available. All of these moves took place in Wheelersburg, a small community of 7,000 residents. Accordingly, the evidence is insufficient to support a finding that Dr. Karel had moved “in order to evade law enforcement.” Dr. Karel provided explanations for each move that rebut this allegation.

- (c) The Task Force Report states that “pill mills” do not accept insurance and operate as cash-only businesses. Dr. Karel does not accept private insurance, Medicaid or Medicare, and only accepts cash at his practice, usually charging \$200 per visit.
- (d) The Task Force Report states that “pill mills” treat pain with prescription medications only. Dr. Karel treats his patients with controlled substance medication, and he does not offer other treatment modalities such as trigger point injections. In fact, during a February 15, 2011, interview with Board investigators, when asked what percentage of his patients receive a prescription for controlled substances, Dr. Karel answered, “They all do.”

Additionally, Dr. Karel has four employees at his practice, and he prescribes controlled substances to all of them.

- (e) The Task Force Report states that “Pill mills” have the presence of security guards. Dr. Karel has a male employee, identified as Patient 1, whose job includes working as a security guard. Dr. Karel told board investigators that this employee carries a TASER [stun gun] in the office, but later testified that that was not correct, that the employee carries pepper spray.
- (f) Further, Dr. Karel prescribes controlled substances to Patient 1, including OxyContin, Oxycodone, and Alprazolam. Notably, Patient 1 has the following criminal history:
 - (i) On November 16, 1990, in the Scioto County Common Pleas Court, Patient 1 was found guilty of Burglary, an aggravated felony of the second degree, in violation of Section 2911.12(A), Ohio Revised Code, and was sentenced to five to fifteen years of incarceration, which was stayed, and Patient 1 was placed on five years probation. On June 23, 1993, after finding that Patient 1 had violated the conditions of his probation, the court revoked Patient 1’s probation and sentenced him to five to fifteen years of incarceration.
 - (ii) On March 28, 1991, in the Portsmouth Municipal Court, Patient 1 was found guilty of two misdemeanor counts of Assault, in violation of Section 537.03, Codified Ordinances of Portsmouth, Ohio.
 - (iii) On December 21, 1993, Patient 1 was found guilty in the Scioto County Common Pleas Court, Ohio, of felony Escape, in violation of Sections

2921.34(A) and (C)(2)(b), Ohio Revised Code, and was sentenced to, among other things, two to ten years of incarceration.

- (iv) On February 24, 2005, in the Scioto County Common Pleas Court, Patient 1 was found guilty of felony Aggravated Trafficking in Drugs, to wit: OxyContin, in violation of Section 2925.03(C)(1)(a), Ohio Revised Code, and was sentenced to five years of community control. Subsequently, on December 17, 2009, the court found that Patient 1 had violated community control after testing positive for opiates, including Oxycodone and Methadone, and after being untruthful to police and probation officers regarding his prescriptions.
- (g) Although not specifically identified as a criterion in the Task Force Report, approximately 40 to 45 percent of Dr. Karel's patients come from out-of-state, primarily with complaints of lower back and neck pain. Because Wheelersburg is on the Ohio River close to the border with Kentucky, and is not far from West Virginia, it does not seem that unusual that he would have a number of patients who reside in those states.
3. In addition to Patient 1, other patients identified on the Confidential Patient Key who have received prescriptions for controlled substances (Patients 2, 7, 8, 11, 13, 14, and 15) have criminal arrests and/or convictions for illicit drug use, abuse and/or possession, or other criminal behavior; for example:
- On January 6, 2009, in the Portsmouth Municipal Court, Patient 2 was found guilty of misdemeanor Possessing Drug Abuse Instruments, in violation of Section 2925.12, Ohio Revised Code.
 - On October 20, 2009, in the Scioto County Common Pleas Court, Patient 2 was charged with felony Aggravated Possession of Controlled Substances, to wit: OxyContin, in violation of Sections 2925.11(A) and (C)(1)(a), Ohio Revised Code. After failing to appear for a scheduled proceeding on that matter, a bench warrant was issued for Patient 2, and, on December 22, 2009, Patient 2 was charged with felony Failure to Appear, in violation of Sections 2937.29 and 2937.99, Ohio Revised Code.
 - Further, prescription records show that Dr. Karel has recently authorized the following prescriptions for controlled substances to Patient 2:

Date of Prescription	Medication	Quantity
11/24/10	Oxycodone 15 mg	90
11/24/10	Oxycodone 30 mg	120
11/24/10	Xanax 2 mg	30
11/24/10	OxyContin 80 mg	90
12/23/10	Xanax 2 mg	30

Date of Prescription	Medication	Quantity
12/23/10	Oxycodone 30 mg	120
12/24/10	Oxycodone 20 mg	70
12/24/10	OxyContin 40 mg	180
1/20/11	Xanax 2 mg	30
1/20/11	Oxycodone 30 mg	120
1/20/11	OxyContin 80 mg	90
1/27/11	Oxycodone 15 mg	100

4. A *locum tenens* physician covered Dr. Karel's practice at the Medical Office from May 11, 2009, through June 11, 2009, during Dr. Karel's medical absence. This physician was interviewed by Board investigators on February 15, 2011. This physician stated that she initiated a transfer request within three days of working at the Medical Office because it was "a drug mill," and expressed fear for her personal safety due to retaliation from the patients. This physician reported that all patients, including some who showed up from as far away as Florida, came to the practice with the expectation of receiving a prescription for narcotics. Further, after this physician began to discharge patients in response to inappropriate urine screen results, including the presence of illicit drugs, she was admonished by the owner of the clinic, who is not a physician, for "ruining her business." Thereafter, this physician reported that Dr. Karel contacted her and informed her that he did not believe that marijuana in a patient's urine was significant and that she should probably not terminate patients from the pain practice because they tested positive for marijuana.
5. On February 15, 2011, Dr. Karel was interviewed by Board investigators. Dr. Karel answered the investigators' questions at first. Partway through the interview, Dr. Karel stated that he needed to speak with an attorney. He left the room and made a telephone call. After speaking with his attorney, Dr. Karel returned and indicated that, on the advice of counsel, he would not answer any more questions. A Board investigator read to Dr. Karel the remainder of the questions that they were going to ask him so that Dr. Karel could advise his attorney what they were looking for.
- 6(a) The evidence is insufficient to support a finding that, on or about March 31, 2010, during a previous interview with a Board investigator, Dr. Karel informed the investigator that he did not obtain vital signs or listen to the heart/lungs of patients returning for follow-up visits for back pain because it was unnecessary, and that medical charts subsequently subpoenaed from Dr. Karel by the Board contained this information. It seems very unlikely that Dr. Karel would have attempted to fool a Board investigator into thinking that Dr. Karel did **not** obtain vital signs or listen to the heart and lungs when, in fact, he really did, as evidenced by the patient charts. The Hearing Examiner believes that this must have been a miscommunication.
- 6(b) During the March 31, 2010 interview, the medical chart for one of Dr. Karel's employees, Patient 3, was reviewed by Dr. Karel in the presence of a Board investigator, and appeared

to the investigator to contain only about six or eight pages; nonetheless, when the chart was produced to the Board in response to a subpoena *duces tecum*, it consisted of approximately 77 pages, around 65 pages of which pre-date the March 31, 2010 interview. However, evidence was presented during hearing that Dr. Karel had said something during the interview that gave the investigator the impression that the chart was incomplete, and that Dr. Karel gave the chart to an employee to find the missing information. Subsequently, after the file was returned to Dr. Karel, it was not reviewed again by either Dr. Karel or the investigator. Furthermore, State's Exhibit 3, which is a copy of Patient 3's chart, does not appear to have been a slim chart with numerous pages hastily created at the same time and added to it; rather, its contents appear to be legitimate.

- 6(c) Additionally, in between the time when Dr. Karel was served with a subpoena *duces tecum* on or about May 5, 2010, and the time he provided the patient record for Patient 3 on or about May 26, 2010, approximately seven pages of pharmacy prescription profiles for Patient 3, all dated May 10, 2010, were added to Patient 3's medical chart.
7. The Board alleged that additional facts concerning Dr. Karel's practice situation are atypical from standard medical practice. The evidence is sufficient to find the following:
- (a) Although Dr. Karel works in southern Ohio, he continues to reside in northern Ohio, and maintains a second address in Wheelersburg close to his office.
 - (b) Dr. Karel has no clinical privileges at any hospital.
 - (c) Dr. Karel does not have malpractice insurance, and his patients sign a form stating that they have been informed of that fact.
 - (d) Each of the patient charts presented at hearing for Patients 3, 4, 5, 7, 8, 9, 12, 14, 15, and 16 contains a prepared written statement, signed by the patient, stating, among other things, "I am not seeking care from Douglas B. Karel, M.D. as part of an ongoing investigation."
 - (e) Dr. Karel acknowledged at hearing that many, if not most, pharmacies in his area will not honor prescriptions he issues for controlled substances.

CONCLUSIONS OF LAW

1. The acts, conduct, and/or omissions of Douglas B. Karel, M.D., as described in Findings of Fact 1(b), 1(c), 7(d), and 7(e), collectively constitute "[f]ailure to maintain minimal standards applicable to the selection or administration of drugs, or failure to employ acceptable scientific methods in the selection of drugs or other modalities for treatment of disease," as those clauses are used in Section 4731.22(B)(2), Ohio Revised Code.

2. Dr. Karel's acts, conduct, and/or omissions as described in Findings of Fact 1(b), 1(c), 7(d), and 7(e), collectively constitute "[s]elling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes * * *," as that clause is used in Section 4731.22(B)(3), Ohio Revised Code.
3. For the reasons set forth below, the evidence is insufficient to support a conclusion that Dr. Karel's acts, conduct, and/or omissions as described in Findings of Fact 2 and 2(a) through 2(g), individually and/or collectively, constitute "[f]ailure to maintain minimal standards applicable to the selection or administration of drugs, or failure to employ acceptable scientific methods in the selection of drugs or other modalities for treatment of disease," as those clauses are used in Section 4731.22(B)(2), Ohio Revised Code; and/or "[s]elling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes * * *," as that clause is used in Section 4731.22(B)(3), Ohio Revised Code.

Findings of Fact 2 and its subparagraphs outline criteria that the Ohio Prescription Drug Abuse Task Force reported are commonly found in connection with "pill mills." However, there is no evidence whether such criteria, individually or in combination, could apply to a legitimate medical practice. Moreover, some of the criteria, such as being located in Scioto County, are far too inclusive. It is as though all physicians who practice in Scioto County already have one strike against them. Accordingly, Findings of Fact 2 and its subparagraphs do not constitute violations of Sections 4731.22(B)(2) and/or (B)(3), Ohio Revised Code.

4. For the reasons set forth below, the evidence is insufficient to support a conclusion that Dr. Karel's acts, conduct, and/or omissions as described in Findings of Fact 2(f), 2(f)(i) through 2(f)(iv), and 3, individually and/or collectively, constitute "[f]ailure to maintain minimal standards applicable to the selection or administration of drugs, or failure to employ acceptable scientific methods in the selection of drugs or other modalities for treatment of disease," as those clauses are used in Section 4731.22(B)(2), Ohio Revised Code; and/or "[s]elling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes * * *," as that clause is used in Section 4731.22(B)(3), Ohio Revised Code.

These Findings of Fact concern Dr. Karel's prescribing of controlled substances to patients with criminal records. Some of the patients named in Finding of Fact 3 had committed very minor offenses. To conclude that these findings violate the Ohio Medical Practices Act as alleged would place a burden on all Ohio physicians to perform criminal background checks on patients who receive controlled substances. Moreover, it would potentially deprive citizens with minor criminal records from receiving necessary medical treatment. As a matter of public policy, this should not occur. Such a change to the regulatory landscape should be reserved for the Board's rule-making process where such changes can be narrowly tailored to address a problem. Accordingly, Findings of Fact 2(f), 2(f)(i) through 2(f)(iv), and 3 do not constitute violations of Sections 4731.22(B)(2) and/or (B)(3), Ohio Revised Code.

5. For the reasons set forth below, the evidence is insufficient to support a conclusion that Dr. Karel's acts, conduct, and/or omissions as described in Finding of Fact 4, individually and/or collectively, constitute "[f]ailure to maintain minimal standards applicable to the selection or administration of drugs, or failure to employ acceptable scientific methods in the selection of drugs or other modalities for treatment of disease," as those clauses are used in Section 4731.22(B)(2), Ohio Revised Code; and/or "[s]elling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes * * *," as that clause is used in Section 4731.22(B)(3), Ohio Revised Code.

Finding of Fact 4 details the observations of a *locum tenens* physician who filled in for Dr. Karel at Dr. Karel's former practice. These observations do not support the violations alleged because all of the observations referenced in the finding took place in Dr. Karel's absence. In fact, the physician testified that she had not seen anything amiss during the two days that she shadowed Dr. Karel. Accordingly, Finding of Fact 4 does not constitute violations of Sections 4731.22(B)(2) and/or (B)(3), Ohio Revised Code.

6. For the reasons set forth below, the evidence is insufficient to support a conclusion that Dr. Karel's acts, conduct, and/or omissions as described in Finding of Fact 5, individually and/or collectively, constitute "[f]ailure to maintain minimal standards applicable to the selection or administration of drugs, or failure to employ acceptable scientific methods in the selection of drugs or other modalities for treatment of disease," as those clauses are used in Section 4731.22(B)(2), Ohio Revised Code; and/or "[s]elling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes * * *," as that clause is used in Section 4731.22(B)(3), Ohio Revised Code.

Finding of Fact 5 concerns Dr. Karel speaking with his attorney partway through an interview with Board investigators and then, upon the advice of counsel, refusing to answer any more questions. Dr. Karel simply exercised his right to speak to counsel and to refuse to answer questions. This potentially could have violated Section 4731.22(B)(34), Ohio Revised Code, which requires licensees to cooperate in Board investigations, but that offense was not charged. It does not violate Sections 4731.22(B)(2) and/or (B)(3), Ohio Revised Code.

7. The evidence is insufficient to support a conclusion that Dr. Karel's acts, conduct, and/or omissions as described in Findings of Fact 6(a) and 6(b), individually and/or collectively, constitute "[f]ailure to maintain minimal standards applicable to the selection or administration of drugs, or failure to employ acceptable scientific methods in the selection of drugs or other modalities for treatment of disease," as those clauses are used in Section 4731.22(B)(2), Ohio Revised Code; "[s]elling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes * * *," as that clause is used in Section 4731.22(B)(3), Ohio Revised Code; and/or "[c]ommission of an act that constitutes a felony in this state, regardless of the jurisdiction

in which the act was committed,” as that clause is used in Section 4731.22(B)(10), Ohio Revised Code, to wit: Section 2921.12, Ohio Revised Code, Tampering with Evidence.

8. For the reasons set forth below, the evidence is insufficient to support a conclusion that Dr. Karel’s acts, conduct, and/or omissions as described in Finding of Fact 6(c), individually and/or collectively, constitute “[f]ailure to maintain minimal standards applicable to the selection or administration of drugs, or failure to employ acceptable scientific methods in the selection of drugs or other modalities for treatment of disease,” as those clauses are used in Section 4731.22(B)(2), Ohio Revised Code; and/or “[s]elling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes * * *,” as that clause is used in Section 4731.22(B)(3), Ohio Revised Code.

The evidence establishes that Dr. Karel added a pharmacy profile to his chart for Patient 3 after the Board had subpoenaed that chart. However, the pages of that document are each dated appropriately, and there does not appear to have been any attempt to alter the pre-existing documents in the chart. Accordingly, Finding of Fact 6(c) does not constitute violations of Sections 4731.22(B)(2) and/or (B)(3), Ohio Revised Code.

9. For the reasons set forth below, the evidence is insufficient to support a conclusion that Dr. Karel’s acts, conduct, and/or omissions as described in Finding of Fact 6(c), individually and/or collectively, constitute “[c]ommission of an act that constitutes a felony in this state, regardless of the jurisdiction in which the act was committed,” as that clause is used in Section 4731.22(B)(10), Ohio Revised Code, to wit: Section 2921.12, Ohio Revised Code, Tampering with Evidence.

The evidence establishes that Dr. Karel added a pharmacy profile to his chart for Patient 3 after the Board had subpoenaed that chart. However, the pages of that document are each dated appropriately, and there does not appear to have been any attempt to alter the pre-existing documents in the chart. Adding those pages to the chart after it had been subpoenaed was not a good idea, but it does not rise to the level of Tampering with Evidence. Accordingly, Finding of Fact 6(c) does not constitute violation of Section 4731.22(B)(10), Ohio Revised Code.

10. Maintaining a residence in Lima, Ohio, while maintaining a second residence close to a practice in Wheelersburg, Ohio, does not violate the Medical Practices Act. Neither does a lack of hospital privileges. Moreover, not having malpractice insurance and having patients sign a form stating that they are aware of that fact actually follows the requirements of Section 4731.143(A), Ohio Revised Code. Accordingly, the evidence is insufficient to support a conclusion that Dr. Karel’s acts, conduct, and/or omissions as described in Findings of Fact 7(a) through 7(c), individually and/or collectively, constitute “[f]ailure to maintain minimal standards applicable to the selection or administration of drugs, or failure to employ acceptable scientific methods in the selection of drugs or other modalities for treatment of disease,” as those clauses are used in Section 4731.22(B)(2), Ohio Revised Code; and/or “[s]elling, giving away, personally furnishing, prescribing, or

administering drugs for other than legal and legitimate therapeutic purposes * * *," as that clause is used in Section 4731.22(B)(3), Ohio Revised Code.

RATIONALE FOR THE PROPOSED ORDER

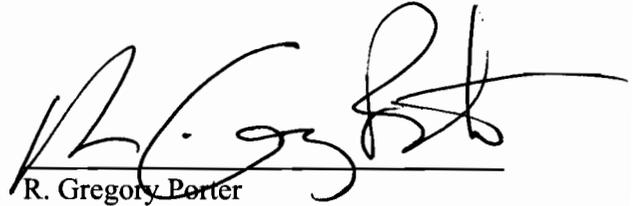
Dr. Karel's conduct in repeatedly making large amounts of narcotics and other controlled substances available to patients with relatively little examination or scrutiny deserves the severest sanction.

PROPOSED ORDER

It is hereby ORDERED that:

The certificate of Douglas B. Karel, M.D., to practice medicine and surgery in the State of Ohio shall be PERMANENTLY REVOKED.

This Order shall become effective immediately upon the mailing of the notification of approval by the Board.



R. Gregory Porter
Hearing Examiner

State Medical Board of Ohio

30 E. Broad Street, 3rd Floor, Columbus, OH 43215-6127

Richard A. Whitehouse, Esq.
Executive Director

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EXCERPT FROM THE DRAFT MINUTES OF JULY 13, 2011

REPORTS AND RECOMMENDATIONS AND PROPOSED FINDINGS AND PROPOSED ORDERS

Dr. Suppan announced that the Board would now consider the Reports and Recommendations, and the Proposed Findings and Proposed Order appearing on its agenda.

Dr. Suppan asked whether each member of the Board had received, read and considered the hearing records; the Findings of Fact, Conclusions of Law, Proposed Orders, and any objections filed in the matters of: Douglas B. Karel, M.D.; Rula Nadim Al-Aouar, M.D.; Steven Francis Brezny, M.D.; Allan William Clark, M.D.; Janice Electa Green Douglas, M.D.; Martin Escobar, M.D.; Philip M. Hutchison, D.O.; Melissa J. Marker, D.O.; and Larry Lee Smith, D.O. A roll call was taken:

ROLL CALL:	Dr. Strafford	- aye
	Mr. Hairston	- aye
	Dr. Stephens	- aye
	Dr. Mahajan	- aye
	Dr. Steinbergh	- aye
	Dr. Suppan	- aye
	Dr. Madia	- aye
	Dr. Talmage	- aye
	Ms. Elsass	- aye
	Dr. Ramprasad	- aye

Dr. Suppan asked whether each member of the Board understands that the disciplinary guidelines do not limit any sanction to be imposed, and that the range of sanctions available in each matter runs from dismissal to permanent revocation. A roll call was taken:

ROLL CALL:	Dr. Strafford	- aye
	Mr. Hairston	- aye
	Dr. Stephens	- aye
	Dr. Mahajan	- aye
	Dr. Steinbergh	- aye
	Dr. Suppan	- aye
	Dr. Madia	- aye
	Dr. Talmage	- aye
	Ms. Elsass	- aye
	Dr. Ramprasad	- aye

Dr. Suppan noted that, in accordance with the provision in section 4731.22(F)(2), Ohio Revised Code, specifying that no member of the Board who supervises the investigation of a case shall participate in further adjudication of the case, the Secretary and Supervising Member must abstain from further

participation in the adjudication of these matters. In the matters before the Board today, Dr. Talmage served as Secretary and Mr. Albert and Dr. Amato served as Supervising Member. In addition, Dr. Steinbergh served as Acting Secretary in the case of Steven Francis Brezny, M.D., and therefore she cannot vote in that matter.

Dr. Suppan reminded all parties that no oral motions may be made during these proceedings.

The original Reports and Recommendations shall be maintained in the exhibits section of this Journal.

.....

DOUGLAS B. KAREL, M.D., Case No. 11-CRF-023

.....

Dr. Steinbergh moved to approve and confirm Mr. Porter’s Findings of Fact, Conclusions of Law, and Proposed Order in the matter of Douglas B. Karel, M.D. Dr. Madia seconded the motion.

.....

A vote was taken on Dr. Steinbergh’s motion to approve:

ROLL CALL:	Dr. Strafford	- aye
	Mr. Hairston	- aye
	Dr. Stephens	- aye
	Dr. Mahajan	- aye
	Dr. Steinbergh	- aye
	Dr. Suppan	- aye
	Dr. Madia	- aye
	Dr. Talmage	- abstain
	Ms. Elsass	- aye
	Dr. Ramprasad	- aye

The motion carried.

State Medical Board of Ohio

30 E. Broad Street, 3rd Floor, Columbus, OH 43215-6127

Richard A. Whitehouse, Esq.
Executive Director

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March 9, 2011

Case number: 11-CRF-023

Douglas B. Karel, M.D.
101 Timberfield Drive
Lima, Ohio 45807

Dear Doctor Karel:

Enclosed please find certified copies of the Entry of Order, the Notice of Summary Suspension and Opportunity for Hearing, and an excerpt of the Minutes of the State Medical Board, meeting in regular session on March 9, 2011, including a Motion adopting the Order of Summary Suspension and issuing the Notice of Summary Suspension and Opportunity for Hearing.

You are advised that continued practice after receipt of this Order shall be considered practicing without a certificate, in violation of Section 4731.41, Ohio Revised Code.

Pursuant to Chapter 119, Ohio Revised Code, you are hereby advised that you are entitled to a hearing on the matters set forth in the Notice of Summary Suspension and Opportunity for Hearing. If you wish to request such hearing, that request must be made in writing and be received in the offices of the State Medical Board within thirty days of the time of mailing of this notice. Further information concerning such hearing is contained within the Notice of Summary Suspension and Opportunity for Hearing.

THE STATE MEDICAL BOARD OF OHIO



Lance A. Talmage, M.D., Secretary

LAT/dsz-rjm/flb
Enclosures

Mailed 3-10-11

CERTIFICATION

I hereby certify that the attached copies of the Entry of Order of the State Medical Board of Ohio and the Motion by the State Medical Board, meeting in regular session on March 9, 2011, to Adopt the Order of Summary Suspension and to Issue the Notice of Summary Suspension and Opportunity for Hearing, constitute true and complete copies of the Motion and Order in the Matter of Douglas B. Karel, M.D., Case Number: 11-CRF- 023 as they appear in the Journal of the State Medical Board of Ohio.

This certification is made under the authority of the State Medical Board of Ohio and in its behalf.


Lance A. Talmage, M.D., Secretary

(SEAL)

March 9, 2011
Date

BEFORE THE STATE MEDICAL BOARD OF OHIO

IN THE MATTER OF :
 :
DOUGLAS B. KAREL, M.D. :
 :
CASE NUMBER: 11-CRF- *023* :

ENTRY OF ORDER

This matter came on for consideration before the State Medical Board of Ohio the 9th day of March, 2011.

Pursuant to Section 4731.22(G), Ohio Revised Code, and upon recommendation of Lance A. Talmage, M.D., Secretary, and Raymond J. Albert, Supervising Member; and

Pursuant to their determination, based upon their review of the information supporting the allegations as set forth in the Notice of Summary Suspension and Opportunity for Hearing, that there is clear and convincing evidence that Douglas B. Karel, M.D., has violated Sections 4731.22(B)(2), (B)(3), and (B)(10), Ohio Revised Code, as alleged in the Notice of Summary Suspension and Opportunity for Hearing that is enclosed herewith and fully incorporated herein; and,

Pursuant to their further determination, based upon their review of the information supporting the allegations as set forth in the Notice of Summary Suspension and Opportunity for Hearing, that Dr. Karel's continued practice presents a danger of immediate and serious harm to the public;

The following Order is hereby entered on the Journal of the State Medical Board of Ohio for the 9th day of March, 2011:

It is hereby ORDERED that the certificate of Douglas B. Karel, M.D., to practice medicine and surgery in the State of Ohio be summarily suspended.

It is hereby ORDERED that Douglas B. Karel, M.D., shall immediately cease the practice of medicine and surgery in Ohio and immediately refer all active patients to other appropriate physicians.

This Order shall become effective immediately.

(SEAL)


Lance A. Talmage, M.D., Secretary

March 9, 2011
Date

State Medical Board of Ohio

30 E. Broad Street, 3rd Floor, Columbus, OH 43215-6127

Richard A. Whitehouse, Esq.
Executive Director

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EXCEPT FROM THE DRAFT MINUTES OF MARCH 9, 2011

CITATIONS, PROPOSED DENIALS, ORDERS OF SUMMARY SUSPENSION & NOTICES OF IMMEDIATE SUSPENSION

DOUGLAS B. KAREL, M.D. – ORDER OF SUMMARY SUSPENSION AND NOTICE OF OPPORTUNITY FOR HEARING

Dr. Stephens and Dr. Strafford exited the meeting prior to this discussion.

At this time the Board read and considered the proposed Order of Summary Suspension and Notice of Opportunity for Hearing in the above matter, a copy of which shall be maintained in the exhibits section of this Journal.

Dr. Madia moved to enter an Order of Summary Suspension in the matter of Douglas B. Karel, M.D., in accordance with Section 4731.22(G), Ohio Revised Code, and to issue the Notice of Summary Suspension and Opportunity for Hearing. Mr. Hairston seconded the motion. A vote was taken:

ROLL CALL:	Mr. Hairston	- aye
	Dr. Mahajan	- aye
	Dr. Steinbergh	- aye
	Dr. Suppan	- aye
	Mr. Albert	- abstain
	Dr. Madia	- aye
	Dr. Talmage	- abstain
	Dr. Amato	- abstain
	Dr. Ramprasad	- aye

The motion carried.

State Medical Board of Ohio

30 E. Broad Street, 3rd Floor, Columbus, OH 43215-6127

Richard A. Whitehouse, Esq.
Executive Director

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NOTICE OF SUMMARY SUSPENSION AND OPPORTUNITY FOR HEARING

March 9, 2011

Case number: 11-CRF-023

Douglas B. Karel, M.D.
101 Timberfield Drive
Lima, Ohio 45807

Dear Doctor Karel:

The Secretary and the Supervising Member of the State Medical Board of Ohio [Board] have determined that there is clear and convincing evidence that you have violated Sections 4731.22(B)(2), (B)(3), and (B)(10), Ohio Revised Code, and have further determined that your continued practice presents a danger of immediate and serious harm to the public, as set forth in paragraphs (1) through (7), below.

Therefore, pursuant to Section 4731.22(G), Ohio Revised Code, and upon recommendation of Lance A. Talmage, M.D., Secretary, and Raymond J. Albert, Supervising Member, you are hereby notified that, as set forth in the attached Entry of Order, your certificate to practice medicine and surgery in the State of Ohio is summarily suspended. Accordingly, at this time, you are no longer authorized to practice medicine and surgery in Ohio.

Furthermore, in accordance with Chapter 119., Ohio Revised Code, you are hereby notified that the Board intends to determine whether or not to limit, revoke, permanently revoke, suspend, refuse to register or reinstate your certificate to practice medicine and surgery, or to reprimand you or place you on probation for one or more of the following reasons:

- (1) During or about November 2007, you ceased practicing neurology in Lima, Ohio, located in northern Ohio, and commenced practicing pain management in Wheelersburg, Ohio, located in Scioto County in southern Ohio, where you continue to practice to date. From in or about November 2007 to in or about March 2011, you undertook the care of Patients 1 – 16, to whom you prescribed controlled substances and/or drugs of abuse, in the course of your medical practice, as

identified on the attached Patient Key (Patient Key confidential and to be withheld from public disclosure).

- (2) On October 1, 2010, the Ohio Prescription Drug Abuse Task Force, which was established to address Ohio's prescription drug abuse epidemic, issued its "Final Report" [Taskforce Report] to the Governor and the Ohio General Assembly. The Taskforce Report identified a constellation of certain criteria and conduct that characterized "pill mill" facilities, often disguised as independent pain-management centers, many of which apply to your practice:
- (a) The highest annual average death rates due to unintentional drug overdose occurred primarily in the state's southern region, which includes Scioto County, causing the city and county health commissioners in Scioto County to declare a public health emergency in January 2010. Your practice is located in Scioto County.
 - (b) "Pill mills" open and shut down quickly in order to evade law enforcement. You have had three different practice locations since commencing practice in Scioto County in or about November 2007, moving in or about August 2009, and again in or about June 2010.
 - (c) "Pill mills" do not accept insurance and operate as a cash-only business. You do not accept private insurance, Medicaid or Medicare, and only accept cash at your practice, generally charging \$200.00 per visit.
 - (d) "Pill mills" treat pain with prescription medications only. Approximately 40-45% of your patients come from out-of-state, primarily with complaints of lower back and neck pain. Moreover, you do not offer treatment modalities other than prescribing, such as trigger point injections, and characterized your practice as "primarily a pain clinic." In fact, on or about February 15, 2011, when asked by board investigators what percentage of your patients receive a prescription for controlled substances, you answered, "They all do."

Additionally, you identified to the Board staff that you have four employees at your practice, and furthermore, you prescribe controlled substances and/or drugs of abuse to each and every one of these employees.

- (e) "Pill mills" have the presence of security guards. You have a male employee whose job you identified as "Security." You also told board investigators that this employee carries a taser [stun gun] in the office. Further, you prescribe controlled substances to your security guard, herein referred to as Patient 1, including OxyContin, Oxycodone, and Alprazolam. Notably, Patient 1 has the following criminal history:

- (i) On or about November 26, 1990, Patient 1 was found guilty in the Scioto County Common Pleas Court, Ohio, of Burglary, an aggravated felony, in violation of Section 2911.12(A), Ohio Revised Code, and was sentenced, *inter alia*, to five to fifteen years of incarceration, which was stayed, and Patient 1 was placed on five years probation. After subsequent parole violations, on or about December 23, 1993, Patient 1's stay regarding the incarceration was revoked by the Scioto County Common Pleas Court, Ohio.
 - (ii) Further, on or about March 28, 1991, Patient 1 was found guilty in the Portsmouth Municipal Court, Scioto County, Ohio, of two misdemeanor counts of Assault, in violation of Section 537.03, Codified Ordinances of Portsmouth, Ohio.
 - (iii) Further, on or about December 23, 1993, Patient 1 was found guilty in the Scioto County Common Pleas Court, Ohio, of felony Escape, in violation of Section 2921.34(A), Ohio Revised Code, and was sentenced, *inter alia*, to two to ten years of incarceration.
 - (iv) Further, on or about January 12, 2005, Patient 1 was found guilty in the Scioto County Common Pleas Court, Ohio, of felony Aggravated Trafficking in Drugs, *to wit*: OxyContin, in violation of Section 2925.03(C)(1)(a), Ohio Revised Code, and was sentenced, *inter alia*, to five years of community control. Moreover, on or about December 21, 2009, Patient 1 was found to have violated his community control by the Scioto County Common Pleas Court, Ohio, after Patient 1 tested positive for opiates, including Oxycodone and Methadone, and for being untruthful to police and probation officers regarding his prescriptions.
- (3) In addition to Patient 1, many of your other patients identified on the attached Confidential Patient Key, and who have received and/or are receiving prescriptions for controlled substances (including at least Patients 2, 7, 8, 11, 13, 14, and 15), in fact, have criminal arrests and/or convictions for illicit drug use, abuse and/or possession, or other criminal behavior; for example:

On or about January 6, 2009, Patient 2 was found guilty in the Portsmouth Municipal Court, Scioto County, Ohio, of misdemeanor Possessing Drug Abuse Instruments, in violation of Section 2925.12, Ohio Revised Code.

Further, on or about October 20, 2009, Patient 2 was charged in the Scioto County Common Pleas Court, Ohio, with felony Aggravated Possession of Controlled Substances, *to wit*: OxyContin, in violation of Sections 2925.11(A) and (C)(1)(a), Ohio Revised Code. After failing to appear for a scheduled proceeding in this matter, a bench warrant was issued by the Court for Patient 2,

and on or about December 22, 2009, Patient 2 was also charged with felony Failure to Appear, in violation of Sections 2937.29 and 2937.99, Ohio Revised Code.

Further, records received by the Board show that you have recently authorized the following prescriptions for controlled substances to Patient 2:

Name	Medication	Quantity	Date Written
Patient 2	Oxycodone 15 mg	90	11/24/2010
Patient 2	Oxycodone 30 mg	120	11/24/2010
Patient 2	Xanax 2 mg	30	11/24/2010
Patient 2	OxyContin 80 mg	90	11/24/2010
Patient 2	Xanax 2 mg	30	12/23/2010
Patient 2	Oxycodone 30 mg	120	12/23/2010
Patient 2	Oxycodone 20 mg	70	12/24/2010
Patient 2	OxyContin 40 mg	180	12/24/2010
Patient 2	Xanax 2 mg	30	1/20/2011
Patient 2	Oxycodone 30 mg	120	1/20/2011
Patient 2	OxyContin 80 mg	90	1/20/2011
Patient 2	Oxycodone 15 mg	100	1/27/2011

- (4) A *locum tenens* physician who covered your practice at one of your prior locations during your medical absence in or about May 2009 through June 2009 was interviewed by board investigators on or about February 15, 2011. This physician stated that she initiated a transfer request within three days of working at your practice because it was “a drug mill,” and expressed fear for her personal safety due to retaliation from you and/or the group of people with whom you are associated. This physician reported that all patients, including some who showed up from as far away as Florida, came to the practice with the expectation of receiving a prescription for narcotics. Further, after this physician began to discharge patients in response to inappropriate urine screen results, including the presence of illicit drugs, she was admonished by the owner of the clinic, who is not a physician, for being “bad for business.” Thereafter, this physician reported that you contacted her and specifically informed her that patients should not be terminated from the pain practice even though they tested positive for marijuana.
- (5) On or about February 15, 2011, you were interviewed by board investigators. Although you initially cooperated in answering questions about your practice, as the questioning continued, you declined to provide any further responses, including questions regarding what you do to combat drug-seeking behavior; whether you knowingly prescribed to persons with drug-related criminal convictions; and why you think many local pharmacies refuse to fill your prescriptions.

- (6) During a prior interview on or about March 31, 2010, you informed a board investigator that you did not obtain vital signs or listen to the heart/lungs of patients retuning for follow-up visits for back pain because it was unnecessary; nevertheless, medical charts subsequently subpoenaed from you by the Board contained this information.

Further, the medical chart for your office supervisor, herein referred to as Patient 3, was reviewed by you and the board investigator at the March 31, 2010 interview, and only contained approximately eight pages; nonetheless, when said medical chart for Patient 3 was produced to the Board in response to a subpoena duces tecum, it consisted of approximately seventy-seven pages, around sixty-five pages of which pre-date the March 31, 2010 interview.

Additionally, in between the time in which you were served with the subpoena duces tecum by a board investigator on or about May 5, 2010, and the time you provided the patient record for Patient 3 on or about May 26, 2010, approximately seven pages of pharmacy prescription profiles for Patient 3, all dated May 10, 2010, were added to Patient 3's medical chart.

- (7) Additional facts about your practice situation are atypical from standard medical practice. Although you work in southern Ohio, you continue to reside in northern Ohio, staying in southern Ohio on the days you work at your pain clinic practice. You have no clinical privileges at any hospital. You do not have malpractice insurance. Further, some of the patient charts you provided to the Board contain a prepared written statement, signed by the patient, stating, "I am not seeking care from Douglas B. Karel, MD as part of an ongoing investigation." Finally, when board investigators contacted area pharmacies about your prescriptions, the investigators learned that many, if not most, area pharmacies will not honor prescriptions you issue for controlled substances.

Your acts, conduct, and/or omissions as alleged in paragraphs (1) through (7) above, individually and/or collectively, constitute "[f]ailure to maintain minimal standards applicable to the selection or administration of drugs, or failure to employ acceptable scientific methods in the selection of drugs or other modalities for treatment of disease," as those clauses are used in Section 4731.22(B)(2), Ohio Revised Code.

Further, your acts, conduct, and/or omissions as alleged in paragraphs (1) through (7) above, individually and/or collectively, constitute "[s]elling, giving away, personally furnishing, prescribing, or administering drugs for other than legal and legitimate therapeutic purposes or a plea of guilty to, a judicial finding of guilt of, or a judicial finding of eligibility for intervention in lieu of conviction of, a violation of any federal or state law regulating the possession, distribution, or use of any drug," as those clauses are used in Section 4731.22(B)(3), Ohio Revised Code.

Notice of Summary Suspension
& Opportunity for Hearing
Douglas B. Karel, M.D.
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Further, your acts, conduct, and/or omissions as alleged in paragraph (6) above, individually and/or collectively, constitute “[c]ommission of an act that constitutes a felony in this state, regardless of the jurisdiction in which the act was committed,” as that clause is used in Section 4731.22(B)(10), Ohio Revised Code, to wit: Section 2921.12, Ohio Revised Code, Tampering with Evidence.

Pursuant to Chapter 119., Ohio Revised Code, and Chapter 4731., Ohio Revised Code, you are hereby advised that you are entitled to a hearing concerning these matters. If you wish to request such hearing, the request must be made in writing and must be received in the offices of the State Medical Board within thirty days of the time of mailing of this notice.

You are further advised that, if you timely request a hearing, you are entitled to appear at such hearing in person, or by your attorney, or by such other representative as is permitted to practice before this agency, or you may present your position, arguments, or contentions in writing, and that at the hearing you may present evidence and examine witnesses appearing for or against you.

In the event that there is no request for such hearing received within thirty days of the time of mailing of this notice, the State Medical Board may, in your absence and upon consideration of this matter, determine whether or not to limit, revoke, permanently revoke, suspend, refuse to register or reinstate your certificate to practice medicine and surgery or to reprimand you or place you on probation.

Please note that, whether or not you request a hearing, Section 4731.22(L), Ohio Revised Code, provides that “[w]hen the board refuses to grant a certificate to an applicant, revokes an individual’s certificate to practice, refuses to register an applicant, or refuses to reinstate an individual’s certificate to practice, the board may specify that its action is permanent. An individual subject to a permanent action taken by the board is forever thereafter ineligible to hold a certificate to practice and the board shall not accept an application for reinstatement of the certificate or for issuance of a new certificate.”

Copies of the applicable sections are enclosed for your information.

Very truly yours,



Lance A. Talmage, M.D.
Secretary

LAT/DSZ-RJM/flb
Enclosures

CERTIFIED MAIL #91 7108 2133 3938 3022 3309
RETURN RECEIPT REQUESTED

Notice of Summary Suspension
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cc: BY PERSONAL SERVICE

cc: Judith Galeano, Esq., Chelsea Long, Esq.
Mowery Youell & Galeano Ltd.
425 Metro Place North, Suite 420
Dublin, Ohio 43017

CERTIFIED MAIL #91 7108 2133 3938 3022 3293
RETURN RECEIPT REQUESTED

**IN THE MATTER OF
DOUGLAS B. KAREL, M.D.**

11-CRF-023

**MARCH 9, 2011, NOTICE OF
SUMMARY SUSPENSION AND
OPPORTUNITY FOR HEARING
PATIENT KEY**

**SEALED TO
PROTECT PATIENT
CONFIDENTIALITY AND
MAINTAINED IN CASE
RECORD FILE.**

**PROBATIONARY
CONSENT AGREEMENT
BETWEEN
DOUGLAS B. KAREL, M.D.
AND
THE STATE MEDICAL BOARD OF OHIO**

OHIO STATE MEDICAL BOARD

FEB 10 2004

This Consent Agreement is entered into by and between Douglas B. Karel, M.D. [Dr. Karel], and the State Medical Board of Ohio [Board], a state agency charged with enforcing Chapter 4731., Ohio Revised Code.

Dr. Karel enters into this Consent Agreement being fully informed of his rights under Chapter 119., Ohio Revised Code, including the right to representation by counsel and the right to a formal adjudicative hearing on the issues considered herein.

BASIS FOR ACTION

This Consent Agreement is entered into on the basis of the following stipulations, admissions and understandings:

- A. The Board is empowered by Section 4731.22(B)(18), Ohio Revised Code, to limit, revoke, suspend a certificate, refuse to register or reinstate an applicant, or reprimand or place on probation the holder of a certificate for “[v]iolation of any provision of a code of ethics of the American medical association . . .”
- B. The Board enters into this Consent Agreement in lieu of formal proceedings based upon the violation of Section 4731.22(B)(18), Ohio Revised Code, to wit: Principle II of the American Medical Association’s Principles of Medical Ethics, “A physician shall uphold the standards of professionalism . . .” and Principle IV of the American Medical Association’s Principles of Medical Ethics, “A physician shall respect the rights of patients, colleagues, and other health professionals . . .” as such violation is set forth in Paragraph E below, and expressly reserves the right to institute formal proceedings based upon any other violations of Chapter 4731. of the Revised Code, whether occurring before or after the effective date of this Consent Agreement.
- C. Dr. Karel is licensed to practice medicine and surgery in the State of Ohio, License number 35-071689.
- D. Dr. Karel states that at this time he is also licensed to practice medicine and surgery in the State of Connecticut, and admits that he currently has pending an application to practice medicine and surgery in the State of Florida, where he has accepted an employment position beginning shortly after the start of 2004.

- E. Dr. Karel admits that during the time period beginning in or about the year 2000 and ending during or about September 2003, he engaged in behaviors involving several hospital coworkers that constituted inappropriate boundary crossings or otherwise unethical conduct in violation of the American Medical Association's Principles of Medical Ethics. Dr. Karel further admits that such behavior included, but was not limited to, his acts of repeatedly inviting female coworkers to meet him for coffee, questioning a male nurse regarding his sexual orientation, and repeatedly making inappropriate social comments and offensive humorous remarks to patients and hospital staff. Dr. Karel further states that although one female patient alleged that Dr. Karel briefly made inappropriate personal physical contact with her during a medical house call, Dr. Karel specifically denies that any such physical contact occurred.

Dr. Karel further admits that at the request of Lima Memorial Hospital, based upon complaints related to his poor bedside manner, excessive joking, and inappropriate remarks, he submitted to a psychiatric evaluation on June 8, 2002. Dr. Karel further admits that such evaluation determined that Dr. Karel does not demonstrate any mental illness, that a significant head injury he sustained in 1976 may contribute to his persistent inappropriate remarks, and that cognitive behavioral therapy might increase his awareness of his behavior. Dr. Karel further admits that he initiated such therapy with a psychologist on or about August 28, 2002, and acknowledges that his treating psychologist has opined that Dr. Karel has shown steady improvement in understanding that his quick sense of humor is often not well received and is modifying his behavior with his patients in an attempt to be less abrupt or offensive. Dr. Karel further admits that at the request of St. Rita's Medical Center, based upon staff complaints alleging sexual harassment by Dr. Karel, he submitted to a psychiatric evaluation on or about April 3, 2003, which determined that Dr. Karel does not suffer from any mental disorder. Dr. Karel further admits that commencing on or about April 6, 2003, his medical staff privileges at St. Rita's Medical Center were suspended for a period of three days based upon the hospital's finding that the conduct complained of constituted inappropriate behavior under the Medical Staff Credentials Manual.

AGREED CONDITIONS

Wherefore, in consideration of the foregoing and mutual promises hereinafter set forth, and in lieu of any formal proceedings at this time, Dr. Karel knowingly and voluntarily agrees with the Board to the following terms, conditions and limitations:

Douglas B. Karel, M.D., is hereby REPRIMANDED.

Further, Dr. Karel knowingly and voluntarily agrees with the Board to the following PROBATIONARY terms, conditions and limitations:

1. Dr. Karel shall obey all federal, state, and local laws, and all rules governing the practice of medicine in Ohio.
2. Dr. Karel shall submit quarterly declarations under penalty of Board disciplinary action or criminal prosecution, stating whether there has been compliance with all the conditions of this Consent Agreement. The first quarterly declaration must be received in the Board's offices on the first day of the third month following the month in which this Consent Agreement becomes effective. Subsequent quarterly declarations must be received in the Board's offices on or before the first day of every third month.
3. Dr. Karel shall appear in person for an interview before the full Board or its designated representative during the third month following the effective date of this Consent Agreement. Subsequent personal appearances must occur every six months thereafter, and/or as otherwise requested by the Board. If an appearance is missed or is rescheduled for any reason, ensuing appearances shall be scheduled based on the appearance date as originally scheduled.
4. In the event Dr. Karel is found by the Secretary of the Board to have failed to comply with any provision of this Consent Agreement, and is so notified of that deficiency in writing, such period(s) of noncompliance will not apply to the reduction of the probationary period under this Consent Agreement.

Releases

5. Dr. Karel shall provide continuing authorization, through appropriate written consent forms, for disclosure to the Board by his treating physicians and others who may have information related to the pertinent issues of this Consent Agreement and/or necessary to the respective duties and obligations herein.

Required Reporting by Licensee

6. Within thirty days of the effective date of this Consent Agreement, Dr. Karel shall provide a copy of this Consent Agreement to all employers or entities with which he is under contract to provide health care services or is receiving training; and the Chief of Staff at each hospital where he has privileges or appointments. Further, Dr. Karel shall provide a copy of this Consent Agreement to all employers or entities with which he contracts to provide health care services, or applies for or receives training, and the Chief of Staff at each hospital where he applies for or obtains privileges or appointments.
7. Within thirty days of the effective date of this Consent Agreement, Dr. Karel shall provide a copy of this Consent Agreement by certified mail, return receipt requested, to the proper licensing authority of any state or jurisdiction in which he currently

holds any professional license or currently has any professional license application pending. Dr. Karel further agrees to provide a copy of this Consent Agreement by certified mail, return receipt requested, at time of application to the proper licensing authority of any state in which he applies for any professional license or for reinstatement of any professional license. Further, Dr. Karel shall provide this Board with a copy of the return receipt as proof of notification within thirty days of receiving that return receipt.

Annual Continuing Medical Education Course(s) in Personal and Professional Ethics

8. Before the end of the first year of probation, or as otherwise approved by the Board, Dr. Karel shall provide documentation acceptable to the Board verifying his successful completion of a professional ethics course dealing specifically with the ethical standards of conduct that Dr. Karel violated in this matter. The exact number of hours and the specific content of the course(s) shall be subject to the prior approval of the Board or its designee but in no event shall be less than thirty hours. Any course(s) taken in compliance with this provision shall be in addition to the Continuing Medical Education requirements for licensure renewal for the Continuing Medical Education acquisition period(s) in which they are completed.

Before the end of each subsequent year of probation, Dr. Karel shall provide documentation acceptable to the Board verifying his successful completion during the prior twelve-month period of at least five hours of Continuing Medical Education credit in personal and/or professional ethics. Any course(s) taken in compliance with this provision shall be approved in advance by the Board or its designee and shall be in addition to the Continuing Medical Education requirements for licensure renewal for the Continuing Medical Education acquisition period(s) in which they are completed.

Notification to Board

9. In the event that Dr. Karel becomes aware that he is the subject of a complaint and/or investigation concerning conduct generally similar to that set forth in Paragraph E herein, Dr. Karel shall notify the Board in writing within seven days, specifying the investigating or charging entity and the offense for which he is being investigated or charged.

Cognitive Behavioral Therapy Treatment

10. Within thirty days of the effective date of this Consent Agreement, Dr. Karel shall submit to the Board for its prior approval the name and qualifications of a psychologist of his choice experienced in providing cognitive behavioral therapy. Upon approval by the Board, Dr. Karel shall undergo and continue cognitive behavioral therapy treatment no less than once every four weeks, or as otherwise directed by the Board. Dr. Karel shall comply with his cognitive behavioral therapy

treatment plan. Within thirty days of the effective date of this Consent Agreement, Dr. Karel shall provide his approved treating psychologist with a copy of this Consent Agreement.

Dr. Karel shall ensure that reports are forwarded by his treating psychologist to the Board on a quarterly basis, or as otherwise directed by the Board. These reports shall contain information describing Dr. Karel's current cognitive behavioral therapy treatment plan and any changes that have been made to the treatment plan since the prior report; Dr. Karel's compliance with his treatment plan; Dr. Karel's mental status; Dr. Karel's progress in treatment; and results of any laboratory studies that have been conducted since the prior report. Dr. Karel shall ensure that his treating psychologist immediately notifies the Board of his failure to comply with his treatment plan and/or counseling and/or any determination that Dr. Karel is unable to practice due to any condition. It is Dr. Karel's responsibility to ensure that quarterly reports are received in the Board's offices no later than the due date for Dr. Karel's quarterly declaration.

FAILURE TO COMPLY

If, in the discretion of the Secretary and Supervising Member of the Board, Dr. Karel appears to have violated or breached any term or condition of this Consent Agreement, the Board reserves the right to institute formal disciplinary proceedings for any and all possible violations or breaches, including, but not limited to, alleged violations of the laws of Ohio occurring before the effective date of this Consent Agreement.

DURATION/MODIFICATION OF TERMS

Dr. Karel shall not request termination and/or modification of the probationary terms, conditions and limitations contained in this Consent Agreement for a minimum of one year. Further, any request by Dr. Karel for such termination and/or modification shall be accompanied by documentation from Dr. Karel's treating psychologist referenced in Paragraph 10 above, or another psychologist approved in advance by the Board, indicating that such psychologist supports Dr. Karel's request for modification and/or termination. Otherwise, the above-described probationary terms, limitations and conditions may be amended or terminated in writing at any time upon the agreement of both parties.

ACKNOWLEDGMENTS/LIABILITY RELEASE

Dr. Karel acknowledges that he has had an opportunity to ask questions concerning the terms of this Consent Agreement and that all questions asked have been answered in a satisfactory manner.

Any action initiated by the Board based on alleged violations of this Consent Agreement shall comply with the Administrative Procedure Act, Chapter 119., Ohio Revised Code.

Dr. Karel hereby releases the Board, its members, employees, agents, officers and representatives jointly and severally from any and all liability arising from the within matter.

This Consent Agreement shall be considered a public record as that term is used in Section 149.43, Ohio Revised Code, and may be reported to appropriate organizations, data banks, and governmental bodies. Dr. Karel agrees to provide his social security number to the Board and hereby authorizes the Board to utilize that number in conjunction with that reporting.

EFFECTIVE DATE

It is expressly understood that this Consent Agreement is subject to ratification by the Board prior to signature by the Secretary and Supervising Member and shall become effective upon the last date of signature below.



DOUGLAS B. KAREL, M.D.

7 Feb 04

DATE



JERRY JOHNSON, ESQ.
Attorney for Dr. Karel

2/9/04

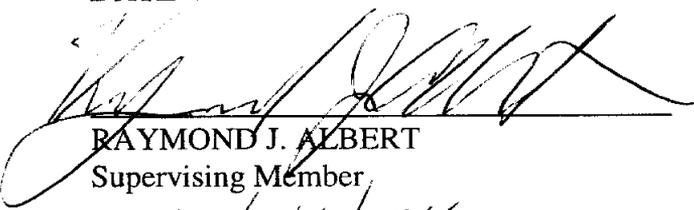
DATE



LANCE A. TALMAGE, M.D.
Secretary

2-11-04

DATE



RAYMOND J. ALBERT
Supervising Member

2/11/04

DATE



REBECCA J. MARSHALL, ESQ.
Enforcement Attorney

02/10/04

DATE