

The Supreme Court of Ohio

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SUPREME COURT OF OHIO

W. David Leak, M.D.

Case No. 2011-1113

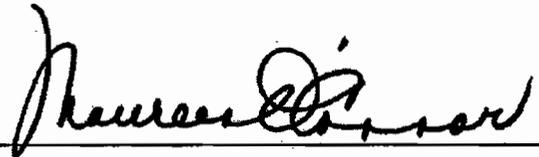
v.

ENTRY

State Medical Board of Ohio

Upon consideration of the jurisdictional memoranda filed in this case, the Court declines jurisdiction to hear the case and dismisses the appeal as not involving any substantial constitutional question.

(Franklin County Court of Appeals; No. 09AP1215)



Maureen O'Connor
Chief Justice

FILED

The Supreme Court of Ohio

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CLERK OF COURT
SUPREME COURT OF OHIO

W. David Leak, M.D.

Case No. 2011-1113

v.

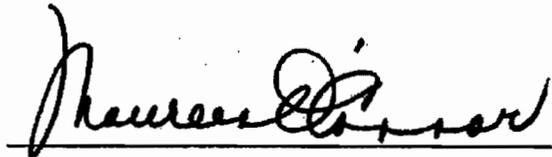
ENTRY

State Medical Board of Ohio

This cause is pending before the Court as a discretionary appeal and claimed appeal of right.

Upon consideration of appellant's motion for stay of the judgment entry of the court of appeals during appeal and request for oral argument, it is ordered by the Court that the motion for stay and request for oral argument are denied.

(Franklin County Court of Appeals; No. 09AP1215)



Maureen O'Connor
Chief Justice

ORIGINAL

IN THE SUPREME COURT OF OHIO

W. DAVID LEAK, M.D.,	:	
	:	
Appellant,	:	On Appeal from the Court
	:	of Appeals Ohio, Tenth
	:	
v.	:	Appellate District
	:	
STATE MEDICAL BOARD,	:	Court of Appeals
	:	Case No. 09-AP-001215
Appellee.	:	

11-1113

NOTICE OF APPEAL OF APPELLANT W. DAVID LEAK, M.D.

Douglas E. Graff (0013222) (Counsel of Record)
 James M. McGovern (0061709)
 Levi. J. Tkach (0066025)
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COUNSELS FOR APPELLANT W. DAVID LEAK, M.D.

Mike DeWine (0009181)
 Ohio Attorney General
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CLERK OF COURT SUPREME COURT OF OHIO

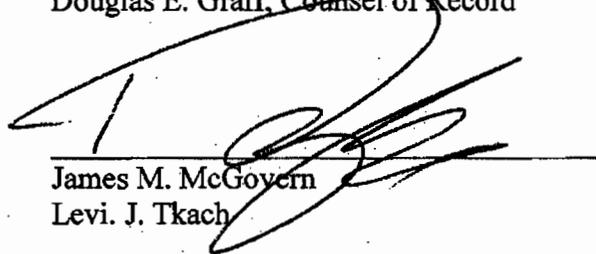
COUNSELS FOR APPELLEE STATE MEDICAL BOARD OF OHIO

Notice of Appeal of Appellant W. David Leak, M.D.

Appellant W. David Leak, M.D. hereby gives notice of appeal to the Supreme Court of Ohio from the judgment of the Court of Appeals Ohio, Tenth Appellate District, entered in Court of Appeals case No. 09-AP-001215 on May 25, 2011.

This case raises a substantial constitutional question and is one of public or great general interest.

Respectfully submitted,
Douglas E. Graff, Counsel of Record



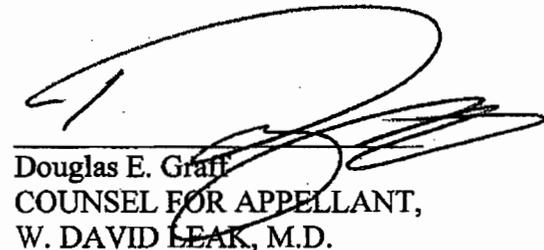
James M. McGovern
Levi J. Tkach

COUNSELS FOR APPELLANT,
W. DAVID LEAK, M.D.

CERTIFICATE OF SERVICE

I hereby certified that a copy of the foregoing Notice of Appeal was served via regular U.S. Mail; postage prepaid this 29 day of June 2011, upon counsel for Appellee, State Medical Board of Ohio to:

Kyle C. Wilcox
Assistant Attorney General
Health & Human Services Section
Ohio Attorney General
30 East Broad Street, 26th Floor
Columbus, Ohio 43215-3400



Douglas E. Graff
COUNSEL FOR APPELLANT,
W. DAVID LEAK, M.D.

IN THE COURT OF APPEALS OF OHIO
TENTH APPELLATE DISTRICT

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TENTH APPELLATE DISTRICT
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CLERK OF COURTS

W. David Leak, M.D., :
Appellant-Appellant, :
v. : No. 09AP-1215
State Medical Board of Ohio, : (REGULAR CALENDAR)
Appellee-Appellee. :

JOURNAL ENTRY

Appellant's June 6, 2011 motion to expedite ruling on motion for stay is granted. Appellants' June 6, 2011 request for oral argument on the motion for stay is denied, this court able to determine the motion without argument. Appellant's June 6, 2011 motion for a stay of execution of the Ohio State Medical Board's order pending appeal to the Ohio Supreme Court is denied, appellant not demonstrating entitlement to a stay pursuant to R.C. 119.12.



Judge Susan Brown



Judge Lisa L. Sadler



Judge G. Gary Tyack



IN THE COURT OF APPEALS OF OHIO
TENTH APPELLATE DISTRICT

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OHIO
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CLERK OF COURTS

W. David Leak, M.D.,	:	
Appellant-Appellant,	:	
v.	:	No. 09AP-1215 (C P C No 08CVF 8 12288)
State Medical Board of Ohio,	:	(REGULAR CALENDAR)
Appellee-Appellee.	:	

JUDGMENT ENTRY

For the reasons stated in the decision of this court rendered herein on May 24, 2011, appellant's four assignments of error are overruled, and it is the judgment and order of this court that the judgment of the Franklin County Court of Common Pleas is affirmed. Costs are assessed against appellant.

BROWN, SADLER, & TYACK, JJ.



Judge Susan Brown

IN THE COURT OF APPEALS OF OHIO
TENTH APPELLATE DISTRICT

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CLERK OF COURTS

W. David Leak, M.D.,
Appellant-Appellant,

v.

State Medical Board of Ohio,
Appellee-Appellee.

No. 09AP-1215
(C.P.C. No. 08CVF 8 12288)
(REGULAR CALENDAR)

D E C I S I O N

Rendered on May 24, 2011

Graff & Associates, LPA, Douglas E. Graff, and James McGovern, for appellant.

Michael DeWine, Attorney General, and Kyle C. Wilcox, for appellee.

APPEAL from the Franklin County Court of Common Pleas.

BROWN, J.

{¶1} Appellant, W. David Leak, M.D., appeals from a decision of the Franklin County Court of Common Pleas, upholding an order of the State Medical Board of Ohio ("board") permanently revoking Dr. Leak's license to practice medicine and surgery.

{¶2} Dr. Leak is a board certified anesthesiologist and a diplomate of the American Board of Pain Medicine. He directed a practice in Columbus, Ohio, known as Pain Control Consultants, Inc. ("PCC"), practicing interventional pain medicine. Beginning in 1998, appellant offered a fellowship program in pain management through

PCC, giving medical practitioners practical experience and, later, progress toward board certification in this field.

{¶3} In August 2006, the board notified Dr. Leak of proposed disciplinary action based on three grounds: allegations of a violation of minimum standard of care for patients; Dr. Leak's failure to notify his patients and receive signed acknowledgements of his lack of malpractice insurance, and an allegation that Dr. Leak had aided and abetted a podiatrist, Dr. Hoogendoorn, to unlawfully practice medicine and surgery in Ohio. This last allegation was based upon Dr. Hoogendoorn's participation in Dr. Leak's pain management fellowship at PCC, and did not ultimately give rise to any adverse action against Dr. Leak.

{¶4} A medical board hearing examiner conducted a 17-day evidentiary hearing on the charges against Dr. Leak as well as consolidated charges against Dr. Hoogendoorn and another participant in the fellowship program, Dr. Griffin. The state's expert medical witnesses presented testimony that Dr. Leak had performed unnecessary and invasive tests on patients, had failed to adapt his treatment methods and recommendations based on the results of these tests, and that Dr. Leak had generally engaged in pain management treatment that maximized fees rather than providing critical individualized treatment to patients. Dr. Leak presented expert witnesses to rebut this testimony.

{¶5} At the conclusion of the proceedings, the hearing examiner issued a lengthy report and recommendation detailing the evidence and finding that, from November 1998 to November 2001, with reference to 24 confidentially protected patients, Dr. Leak had "inappropriately utilized testing and/or failed to provide treatment in accordance with the minimal standards of care." July 7, 2008 report at 131. The hearing examiner further

concluded that Dr. Leak's malpractice insurance lapsed from August 2003 to March 2004, and, during this period, Dr. Leak had failed to provide written notice of his lack of malpractice insurance to each patient and obtain from each patient a signature acknowledging receipt of the malpractice insurance notice; these two deficiencies together constituting a violation of R.C. 4731.143. Based upon these conclusions of fact and law, the examiner recommended permanent revocation of Dr. Leak's medical license. Both the state and Dr. Leak filed objections to the hearing examiner's report and recommendation. The board eventually voted 7-2 to adopt the hearing examiner's report and recommendation and permanently revoked Dr. Leak's certification to practice medicine and surgery in Ohio, effective September 14, 2008.

{¶6} Dr. Leak appealed the board's order to the Franklin County Court of Common Pleas, also moving the court to admit additional evidence pursuant to R.C. 119.12. The court of common pleas denied Dr. Leak's motion to admit additional evidence and upheld the board's order, finding that it was supported by reliable, probative, and substantial evidence and in accordance with law. The court of common pleas further noted in its decision that, even if it were "inclined to impose a more lenient sanction than permanent revocation, the Board's action is well within its statutory authority, and the Court has no authority to reverse or modify it."

{¶7} Dr. Leak has timely appealed and brings the following four assignments of error:

[I.] THE LOWER COURT ERRED AND ABUSED ITS DISCRETION IN FINDING THAT THE SANCTION IMPOSED BY THE BOARD WAS NOT A VIOLATION OF APPELLANT'S CONSTITUTIONAL RIGHT TO DUE PROCESS AND EQUAL PROTECTION WHEN SIMILARLY SITUATED WHITE PHYSICIANS WHO ADMINISTER THE TESTING AND TREATMENT AT QUESTION WERE

SANCTIONED SIGNIFICANTLY LESS HARSHLY, ONE WITH A DISMISSAL AND ONE WITH A PROBATION AND EDUCATIONAL REQUIREMENT. THE LOWER COURT ERRED AND ABUSED ITS DISCRETION IN NOT FINDING THE ACTIONS OF THE BOARD WERE IMPROPER, PREJUDICIAL AND ABUSE OF DISCRETION. APPELLANT'S FOURTEENTH AMENDMENT RIGHTS WERE VIOLATED.

[II.] THE TRIAL COURT ERRED AND ABUSED ITS DISCRETION IN FINDING THAT THE ORDER WAS SUPPORTED BY RELIABLE, PROBATIVE, AND SUBSTANTIAL EVIDENCE BECAUSE THE EXPERTS RELIED UPON BY THE BOARD WERE INHERENTLY UNRELIABLE.

[III.] THE TRIAL COURT ERRED AND ABUSED ITS DISCRETION [WHEN] IT FAILED TO PERMIT THE INTRODUCTION OF ADDITIONAL EVIDENCE.

[IV.] THE ORDER SHOULD BE VACATED BASED UPON THE BOARD'S FAILURE TO FILE A COMPLETE ADMINISTRATIVE RECORD, AS REQUIRED BY R.C. §119.12

{¶8} We begin by stating our standard of review upon appeal. In an appeal pursuant to R.C. 119.12 from an order of the state medical board, the court of common pleas is bound to uphold the order if it is supported by reliable, probative, and substantial evidence and is in accordance with law. *Pons v. Ohio State Med. Bd.*, 66 Ohio St.3d 619, 621, 1993-Ohio-122. Reliable, probative, and substantial evidence has been defined as follows:

(1) "Reliable" evidence is dependable; that is, it can be confidently trusted. In order to be reliable, there must be a reasonable probability that the evidence is true. (2) "Probative" evidence is evidence that tends to prove the issue in question; it must be relevant in determining the issue. (3) "Substantial" evidence is evidence with some weight; it must have importance and value.

Our Place, Inc. v. Ohio Liquor Control Comm. (1992), 63 Ohio St.3d 570, 571. Upon further appeal to this court, however, our review is more limited than that of the court of common pleas. *Pons* at 621. While it is incumbent on the court of common pleas to examine the evidence, the court of appeals must determine only if the lower court abused its discretion in finding that the board's order was supported by reliable, probative, and substantial evidence and in accordance with law. *Id.* Moreover, 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. *Pons* at 621-22. "The purpose of the General Assembly in providing for administrative hearings in particular fields was to facilitate such matters by placing the decision on facts with boards or commissions composed of [people] equipped with the necessary knowledge and experience pertaining to a particular field." *Farrand v. State Med. Bd.* (1949), 151 Ohio St. 222, 224. On questions of law, however, our review is plenary. *Univ. Hosp., Univ. of Cincinnati College of Medicine v. State Emp. Relations Bd.* (1992), 63 Ohio St.3d 339, paragraph one of the syllabus.

{¶9} In Dr. Leak's first assignment of error, he asserts that the board's order violates his constitutional rights to due process and equal protection under the law. These asserted violations are based upon the fact that similarly situated white physicians, i.e., Drs. Griffin and Hoogendoorn, received little or no discipline from the board, while Dr. Leak, who is African American, saw his license permanently suspended. Dr. Leak's argument of constitutional violations based upon racial discrimination was not raised before the board or the court of common pleas in his initial appeal. Only now upon appeal to this court does Dr. Leak argue that the action taken by the board was based upon race and that he received a harsher sanction than similarly situated white

physicians. It is a fundamental tenet of appellate review that a reviewing court will not consider in the first instance any alleged error known to a party but not brought to the lower tribunal's attention. *Schade v. Carnegie Body Co.* (1982), 70 Ohio St.2d 207, 210. Sometimes deemed a forfeiture, and more commonly termed a waiver, this forecloses the right to contest an issue on appeal if the issue was in existence at the time the matter was heard before the trial court or initial administrative tribunal, and the party did not raise it at the appropriate time for consideration by the lower tribunals. *Varisco v. Varisco* (1993), 91 Ohio App.3d 542, 545; *Little Forest Med. Ctr. of Akron v. Ohio Civ. Rights Comm.* (1993), 91 Ohio App.3d 76, 80. In proceedings emanating from the board, we have applied this rule in the form of waiver to preclude initial consideration on appeal of issues not raised before the board. *Ansar v. State Med. Bd. of Ohio*, 10th Dist No. 08AP-17, 2008-Ohio-3102: "the * * * argument was not raised before the court of common pleas, and therefore cannot be raised for the first time in this appeal." *Id.* at ¶41. Because Dr. Leak did not raise his constitutional arguments alleging racial discrimination before either the medical board or the court of common pleas, we decline to address them for the first time in his appeal to this court. Dr. Leak's first assignment of error is accordingly overruled.

{¶10} Dr. Leak's second assignment of error asserts that the court of common pleas abused its discretion in finding that the board's order was supported by reliable, probative, and substantial evidence. Dr. Leak argues that the experts principally relied upon by the board were inherently unreliable because these experts were unfamiliar with the standard of care in the practice of pain medicine. Specifically, Dr. Leak argues that the experts presented before the board, Drs. Chelimsky and Katirji, while well-qualified neurologists, are insufficiently versed in the practice of interventional pain medicine.

{¶11} Both board experts testified regarding their assessment of Dr. Leak's practice, particularly Dr. Leak's use of Selective Tissue Conductance Tests ("STC") and Somatosensory Evoked Potentials ("SSEP") to substantiate or corroborate a patient's claims of pain before administering palliative medication. Both Drs. Katirji and Chelimsky testified that these tests were ineffective or worthless from a diagnostic standpoint, and that each of Dr. Leak's patients was referred for the same array of tests regardless of pain symptoms or otherwise accessible factors and circumstances underlying the complaints of pain. The experts also testified that the testing ordered and conducted by Dr. Leak lacked sufficient documentation in the patients' medical records establishing the fundamental reasoning or medical judgment underlying the need for the tests, and little follow up or invocation of the test results when proceeding to prescribe pain treatment medication and treatment for those patients.

{¶12} This assignment of error essentially questions whether there was reliable, probative, and substantial evidence in the form of testimony supporting the board's disciplinary order against Dr. Leak. Although such evidence need not be heard by the board in the form of expert testimony, when the board does hear expert testimony, the expert must be capable of expressing an opinion grounded in the particular standard of care applicable to the area of practice for the physician facing discipline. *Lawrence v. State Med. Bd. of Ohio* (Mar. 11, 1993), 10th Dist. No. 92AP-1018. "The court shall not permit an expert in one medical specialty to testify against a health care provider in another medical specialty unless the expert shows both that the standards of care and practice in the two specialties are similar and that the expert has substantial familiarity [with them]." *Griffin v. State Med. Bd. of Ohio*, 10th Dist. No. 09AP-276, 2009-Ohio-4849, ¶13. This rule is codified at R.C. 2743.43(A)(3). This rule acknowledges that a

medical expert well-versed and well-credentialed in one field may not be an expert in other medical fields. Id.

{¶13} Drs. Chelimsky and Katirji, Dr. Leak alleges, are perhaps eminently qualified neurologists, but not qualified as experts in pain medicine, Dr. Leak's area of practice. The board, to the contrary, argues on appeal that Dr. Leak's practice in the diagnosis and alleviation of pain eventually involved the use of nerve blocks and STC and SSEP studies, which in fact represented an attempt by Dr. Leak to practice in the area of neurology. A neurological standard of care, the board argues, is necessary to understand the board's critical assessment of Dr. Leak's diagnostic testing practices.

{¶14} Dr. Chelimsky was board certified in neurology and neurophysiology by the American Board of Psychiatry and Neurology ("ABPN") in 1994, and in pain management by that body in 2000. Dr. Katirji was board certified in neurology and neurophysiology by the ABPN in 1985 and 1992 respectively, certified by the American Board of Electroencephalography in 1985, by the American Association of Electrodiagnosis and Electromyography in 1986, and by the American Board of Electrodiagnostic Medicine in 1990. He is not certified in any area of pain management. Dr. Katirji however, did, present himself as an expert in SSEP testing such as that ordered by Dr. Leak.

{¶15} Dr. Katirji described SSEPs as studies involving stimulating nerves in the limbs and recording the resulting nerve activity from spine to brain. This nerve activity is recorded by electrodes placed at the base of the neck and the fingers which detect the nerve response when electric current is introduced to the nervous system. With respect to Dr. Leak's practice, Dr. Katirji testified specifically that, although SSEPs may indicate an abnormality along the nerve route, they do not permit a treating physician to pinpoint the nerve damage or other condition causing pain. His professional opinion was that

SSEPs have not been productively utilized in the localization and diagnosis of pain, although there were many attempts toward using these tests for that purpose when the tests became available in the mid-1980s. Eventually the profession concluded that SSEPs were ineffective in the diagnosis of radiating pain, giving too many false positives and some false negatives. Finally, Dr. Katirji opined that SSEPs had become obsolete, both because of a diminishing professional regard for the accuracy of the test and the introduction of more accurate MRI scans that produced more conclusive results.

{¶16} With respect to the nerve conduction studies ("NCS") ordered by Dr. Leak, Dr. Katirji testified that these studies also cannot reliably diagnose radiating pain because in many instances the root lesion will be near the spine, and the NCS studies do not test that area.

{¶17} After reviewing the patient records in the matter, Dr. Katirji opined that the SSEP and NCS studies ordered by Dr. Leak appeared to be ordered for all patients without regard to the patients' actual condition, and without any assessment of whether the tests were medically necessary. Dr. Katirji also opined that the test results were never integrated into a comprehensive clinical analysis as part of a treatment program. Dr. Katirji opined that Dr. Leak's notes did not reflect any thoughtful attempt to tailor the testing process to the condition of the patient, but simply ordered a battery of tests for all patients regardless of their condition. These included, Dr. Katirji stated, patients who did not suffer from spinal-type radiating pain, who would have been even less indicative for NCS tests yet nonetheless received them by reference of Dr. Leak.

{¶18} Turning to the testimony of the states other expert, in addition to his other credentials, Dr. Chelimsky directed the pain center at University Hospitals in Cleveland from 1994 to 2004. In this position he treated many patients using interventional pain

therapy treatment methods, including sympathetic blocks or epidurals. After reviewing the confidentially identified patients' charts from Dr. Leak's practice, Dr. Chelimsky opined that the overarching observation was that the charts lacked any coherent, systematic analytical approach to patient needs and proposed treatment plans. Dr. Chelimsky opined that this fell below one of the threshold requirements of the standard of care of any practice. Opining further on the diagnostic evaluations performed on the selected patients, Dr. Chelimsky specifically opined that the NCS studies ordered by Dr. Leak, when performed without a complementary procedure known as a needle examination, were "meaningless." (Tr. Vol. 6, 1587.)

{¶19} Dr. Chelimsky also opined that the STC tests ordered by Dr. Leak were not reproducible in their results and therefore not useful. Dr. Chelimsky described these tests as measuring the galvanic skin response of the patient, or the electrical conductivity of the patient's skin. Dr. Chelimsky felt that the theory upon which such tests were based, that the electrical conductivity of the skin would reflect corresponding levels of nervous activity, was an unproved diagnostic tool at best and that performance of such tests in pain medicine was, of itself, below a minimum standard of care because such tests were purely experimental; rather than clinically oriented.

{¶20} Giving due deference to the board's expertise, we cannot find that the court of common pleas abused its discretion in finding that the board properly held that Drs. Chelimsky and Katirji were qualified to establish the minimum standard of care in Dr. Leak's area of practice and to assess whether Dr. Leak had conformed to that standard of care. Both doctors undertook extensive and knowledgeable critical analyses of the testing battery ordered by Dr. Leak, and the board was within its discretion to accept both experts as "similar" practitioners to Dr. Leak. Likewise, the board could within its

discretion accept the expert opinions provided and base its final conclusions upon them. As we noted in *Griffin*, neither the board nor the court of common pleas was required to reconcile any philosophical conflicts between two different schools of pain management that was predicated on anesthesiology and those predicated on neurology because "[t]he decision as to which medical philosophy is more appropriate for pain management is best left to the medical professionals, not appellate judges or trial court judges sitting in an appellate role on an administrative appeal." *Griffin* at ¶25, citing *Pons*.

{¶21} We accordingly find that the court of common pleas did not abuse its discretion in finding that the medical board's decision was based upon reliable, probative, and substantial evidence and in accordance with law, and Dr. Leak's second assignment of error is overruled.

{¶22} Dr. Leak's third assignment of error asserts that the court of common pleas abused its discretion when it refused to allow the introduction of additional evidence. This evidence included minutes and audiotapes of board proceedings and deliberations in related cases, a request for testimony before the court of common pleas by the board's president addressing the board's procedural handling of several motions brought by Dr. Leak, the board's final orders in its disciplinary cases involving Drs. Griffin and Hoogendoorn, and production of written decisions by the board addressing Dr. Leak's motions before the board for additional time, motion to strike the testimony of an expert witness, and motion to strike the state's objections to the hearing examiner's report and recommendation.

{¶23} R.C. 119.12 provides that "[u]nless otherwise provided by law, in the hearing of the [administrative] appeal, the court is confined to the record as certified to it by the agency. Unless otherwise provided by law, the court may grant a request for the

admission of additional evidence when satisfied that the additional evidence is newly discovered and could not with reasonable diligence have been ascertained prior to the hearing before the agency."

{¶24} The court of common pleas in the present case concluded, pursuant to *Gordon Lending Corp. v. Ohio Dept. of Commerce, Div. of Financial Insts.*, 10th Dist. No. 08AP-84, 2008-Ohio-3952, ¶11, that "newly discovered" evidence under the statute is evidence that was in existence at the time of the administrative hearing but that could not have been discovered with the exercise of due diligence prior to the hearing. Under this definition, newly discovered evidence does not refer to *newly created* evidence. See also *Steckler v. Ohio State Bd. of Psychology* (1992), 83 Ohio App.3d 33, 38.

{¶25} We find that the trial court correctly denied Dr. Leak's motion for additional submissions. First, we note that the "evidence" proposed by Dr. Leak constitutes, in large part, not evidence at all but reproduction of the record in various forms from the proceeding at which evidence was heard, i.e., the hearings before the board hearing officer and subsequent proceedings before the board itself. An administrative appeal under R.C. 119.12 is a review of the record as transmitted by the administrative agency, not a collateral attack upon those proceedings involving outside evidence to establish corruption, bias, or other irregularities based upon the conduct of the medical board and its hearing officers. To the extent that Dr. Leak believed that the record transmitted by the agency was incomplete, his remedy was a motion to supplement the record with required items, not a motion to submit additional evidence. Even if some of the cited items were taken as proper evidence, none by their nature could be in existence at the time of the board hearing, since they reflect the board's subsequent proceedings in large part. They cannot fit the definition of newly discovered evidence under R.C. 119.12 and

Gordon Lending. The trial court therefore did not err in denying Dr. Leak's motion to submit additional evidence. Dr. Leak's third assignment of error is overruled.

{¶26} Dr. Leak's fourth assignment of error asserts that the trial court should have vacated the board's order based upon the board's failure to file a complete administrative record. Under this assignment of error, Dr. Leak points in particular to the board's failure to provide written rulings on three of his motions before the board: (1) a motion for additional time to address the board; (2) a motion to strike the testimony of the state's expert witness; and (3) a motion to strike the state's objections to the hearing examiner's report. Failure to include written decisions on these motions, Dr. Leak asserts, constitutes a failure to provide a complete and certified record for the appeal to the court of common pleas under R.C. 119.12. Dr. Leak argues that the failure to file a complete record deprives the court of common pleas of jurisdiction, by which we understand him to mean that the court of common pleas is deprived of the jurisdiction to uphold the board's order, citing our decision in *Sinha v. Ohio Dept. of Agriculture* (Mar. 5, 1996), 10th Dist. No. 95APE-1239. In *Sinha*, we held that "when the agency has failed to certify any record whatsoever within the thirty-day period [required by R.C. 119.12], the court of common pleas must enter judgment for the appellant."

{¶27} The state responds that the record of proceedings before the board reflects that the board in fact ruled orally upon all motions, and denied them. The state points out that Dr. Leak can demonstrate no prejudice from the board's failure to provide a written ruling on these motions, since Dr. Leak was fully aware of the denial of his motions before the board at the time the denial took effect, and denial of those motions was not a point at issue at anytime in the proceedings before the court of common pleas. While *Sinha* certainly stands for the proposition that a complete failure by the agency to file a record

within the required time on appeal might require a reviewing court to vacate the agency order, *Sinha* certainly does not expressly stand for the proposition that partial, and especially trivially partial, omissions from the agency record on appeal would require such a result.

{¶28} In order to demonstrate a denial of due process warranting relief, Dr. Leak must establish both a constitutional deprivation and prejudice flowing therefrom. *Estes v. Texas* (1965), 381 U.S. 532, 85 S.Ct. 1628. Assuming, arguendo, that failure to render a written ruling on Dr. Leak's motions constituted a deprivation, there is simply no prejudice in the present case that would warrant tailoring a constitutional remedy to correct the procedural flaws in the proceedings. Dr. Leak's fourth assignment of error is accordingly overruled.

{¶29} Based upon the foregoing, Dr. Leak's four assignments of error are overruled, and the judgment of the Franklin County Court of Common Pleas is affirmed.

Judgment affirmed.

SADLER and TYACK, JJ., concur.

IN THE COURT OF COMMON PLEAS OF FRANKLIN COUNTY, OHIO
GENERAL DIVISION

W. DAVID LEAK, M.D.,

Appellant,

v.

STATE MEDICAL BOARD OF OHIO,

Appellee.

:

:

:

:

:

Case No. 08 CVF-08-12288

Judge: Guy L. Reece, II

DECISION AND ENTRY
GRANTING APPELLANT'S DECEMBER 31, 2009
MOTION FOR STAY OF ENFORCEMENT DURING APPEAL

RENDERED THIS 13th DAY OF JANUARY 2010.

REECE, J.

On December 31, 2009, Appellant W. David Leak, M.D. ("Appellant") filed a Motion for Stay of Enforcement During Appeal, asking the Court to stay enforcement of its December 15, 2009 "Decision and Entry on Merits of Revised Code §119.12 Administrative Appeal, Affirming Order Issued by State Medical Board of Ohio on August 15, 2008, Permanently Revoking Appellant's Certificate to Practice Medicine and Surgery in Ohio." Appellant informs the Court that he is appealing the Court's decision with the Tenth District Court of Appeals and is requesting that the Court's decision be stayed pending the appeal.

Appellee State Medical Board of Ohio ("Appellee") filed its Memorandum Contra on January 4, 2010, opposing Appellant's request for a stay. Appellee maintains that: 1.) Appellant has failed to establish that an unusual hardship will result if the Board's order is not stayed, as required by R.C. §119.12; 2.) the safety and welfare of the public will not be protected if the

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Board's order is stayed; and 3.) the Board's order has been stayed for a period longer than that allowed by R.C. §119.12. Appellee argues that the loss of one's license to practice does not qualify as an unusual hardship and, given the testimony before the Board that led to its decision to permanently revoke Appellant's license, Appellant's continued practice would threaten the safety and welfare of the public. Finally, Appellee notes the Board's decision was already stayed on September 9, 2008, and the stay was extended on November 23, 2009. Although the stay exceeded the 15-month stay allowed by R.C. §119.12, Appellee notes the stay expired because of the Court's ruling on the merits of this case and the Board's decision cannot be extended beyond the 15-month period at this time.

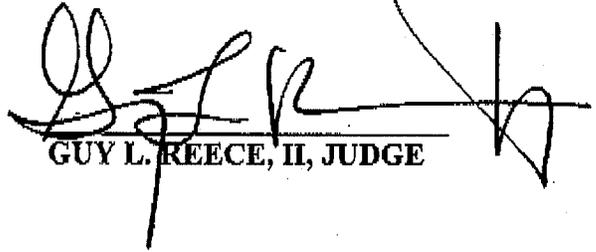
Appellant filed his Reply Memorandum in Support of Motion for Stay of Enforcement During Appeal on January 6, 2010. He maintains his appeal is an appeal of right pursuant to App.R. 4 and his request for a stay is pursuant to App.R. 7. Appellant notes that the Board's order was stayed once on September 9, 2008, at which time the Court found that he would suffer unusual harm unless the stay was granted. Appellant notes the Court also, in that same order, found that "the health, safety and welfare of the public will not be threatened by suspension of the order during this appeal." Thus, the argument continues, unusual harm, having once been found to exist and warrant the original stay, will continue to exist. Likewise, Appellant argues that once the Court found that a stay of the Board's order would not harm the health, safety and welfare of the public, that finding remains the law of the case and continues to be true at this time, citing to *Hopkins v. Dyer*, 104 Ohio St.3d 461, 2004-Ohio-6769, at ¶15, in support thereof. Appellant further maintains Appellee's argument that the Court's authority to grant a stay of enforcement of its own order arises from R.C. §119.12 is misplaced. Instead, Appellant argues the request that the Court stay enforcement of its order is pursuant to App.R. 7, which makes a

request for a stay to the common pleas court a condition precedent to requesting a stay at the appellate court level. Thus, Appellant argues the Court's authority to stay enforcement of its order pending the appeal arises pursuant to App.R. 7, not R.C. §119.12, even though this case was filed here as an administrative appeal pursuant to R.C. §119.12.

Having reviewed the parties' respective arguments, the Court finds Appellant's request for a stay to be well-taken. Accordingly, the Court hereby **GRANTS** Appellant's December 31, 2009 Motion for Stay of Enforcement During Appeal.

Enforcement of the Court's December 15, 2009 "Decision and Entry on Merits of Revised Code §119.12 Administrative Appeal, Affirming Order Issued by State Medical Board of Ohio on August 15, 2008, Permanently Revoking Appellant's Certificate to Practice Medicine and Surgery in Ohio" will be **STAYED** during the appeal of this matter to the Tenth District Court of Appeals or further order by that court.

IT IS SO ORDERED.


GUY L. REECE, II, JUDGE

Copies To:

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Counsel for Defendant

IN THE COMMON PLEAS COURT OF FRANKLIN COUNTY, OHIO

W. DAVID LEAK, M.D.)
99 North Brice Road,)
Columbus, Ohio 432)
Appellant,)
vs.)

CASE NO. _____

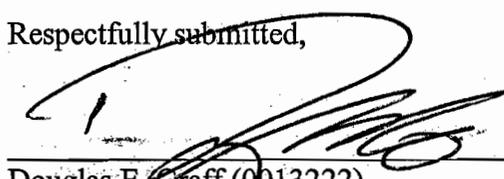
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FRANKLIN CO. OHIO
2009 DEC 31 AM 10:03
CLERK OF COURTS

NOTICE OF APPEAL

STATE OF OHIO, OHIO STATE)
MEDICAL BOARD,)
30 East Broad Street, 3rd Floor)
Columbus, Ohio 43215)
Appellee.)

Notice is hereby given that W. David Leak, M.D., hereby appeals to the Court of Appeals of Franklin County, Ohio, Tenth Appellate District from the final judgment order of Franklin Court Common Pleas Court Judge G. Reese, II, entitled *Decision And Entry On Merits Of Revised Code §119.12 Administrative Appeal, Affirming Order Issued By State Medical Board Of Ohio On August 15, 2008, Permanently Revoking Appellant's Certificate To Practice Medicine And Surgery In Ohio* entered in this action on the 15th day of December 2009.

Respectfully submitted,



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FILED
COMMON PLEAS COURT
FRANKLIN CO. OHIO
2009 DEC 31 AM 9:50
CLERK OF COURTS

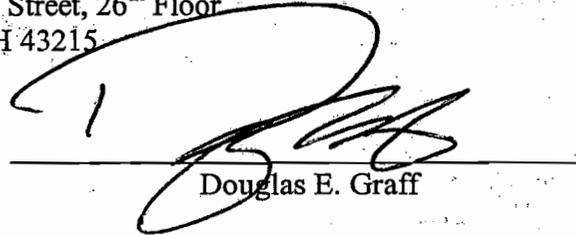
STATE MEDICAL BOARD
OHIO
2010 JAN -6 PM 2:35

09APE12 1215

CERTIFICATE OF SERVICE

I hereby certify that a copy of this NOTICE OF APPEAL was delivered to the Ohio State Medical Board, 30 East Broad Street, Third Floor, Columbus, OH 43215 on the 31 day of Dec, 2009. I further certify that a true and accurate copy of the foregoing NOTICE OF APPEAL was sent by regular U.S. mail, postage prepaid, on the on the 31 day of Dec, 2009, to:

Kyle Wilcox, Esq.
Assistant Attorney General
Office of the Attorney General
30 East Board Street, 26th Floor
Columbus, OH 43215



Douglas E. Graff

2010 JAN -6 PM 2:35

STATE MEDICAL BOARD

IN THE COURT OF COMMON PLEAS OF FRANKLIN COUNTY, OHIO
GENERAL DIVISION

W. DAVID LEAK, M.D.,		CASE NO. 08CVF08-12288
Appellant,		JUDGE REECE
vs.		FINAL APPEALABLE ORDER
STATE MEDICAL BOARD OF OHIO,		<i>10</i> <i>cdl 12-15-09</i>
Appellee.		

DECISION AND ENTRY DENYING "APPELLANT, WILLIAM DAVID LEAK, M.D.'S, MOTION TO INTRODUCE ADDITIONAL EVIDENCE," FILED DECEMBER 2, 2008

DECISION AND ENTRY ON MERITS OF REVISED CODE 119.12 ADMINISTRATIVE APPEAL, AFFIRMING ORDER ISSUED BY STATE MEDICAL BOARD OF OHIO ON AUGUST 15, 2008, PERMANENTLY REVOKING APPELLANT'S CERTIFICATE TO PRACTICE MEDICINE AND SURGERY IN OHIO

Issued this 15th day of December 2009.

REECE, J.

This case is a Revised Code 119.12 administrative appeal, by W. David Leak, M.D. (Appellant), from an Order that the State Medical Board of Ohio issued on August 15, 2008, permanently revoking Appellant's certificate to practice medicine and surgery in Ohio. Having reviewed the certified record of the Board's proceedings, the Court hereby renders the following decision denying Appellant's December 2, 2008 motion to admit additional evidence, and affirming the Board's August 15, 2008 Order.

FILED
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FRANKLIN CO. OHIO
2009 DEC 15 PM 3:03
CLERK OF COURTS

Factual and Procedural History

Appellant obtained his medical degree in 1979 from the Bowman-Gray School of Medicine at the Wake Forest University, in Winston-Salem, North Carolina. From 1979 through

1980, he participated in a rotating internship in the Department of Anesthesia at the Ohio State University Hospitals, in Columbus, Ohio. From 1981 through 1983, Appellant participated in a residency in anesthesiology at the Hospital of the University of Pennsylvania, in Philadelphia, Pennsylvania. From 1983 through 1984, he participated in a clinical and research fellowship in cardiovascular and regional anesthesia and pain management, at that same institution. From April through June 1984, Appellant completed his fellowship at the Pain Control Center at the University of Cincinnati in Cincinnati, Ohio.

In 1984, Appellant was certified in anesthesiology by the American Board of Anesthesiology. In 1992, he became a diplomate of the American Board of Pain Medicine. In 1993, Appellant was awarded a certificate of added qualifications in pain medicine by the American Board of Anesthesiology. In 1995, he became a fellow of the American Academy of Pain Management. Appellant's certificate of added qualifications in pain medicine, from the American Board of Anesthesiology, expired in 2003 when he did not recertify his added qualifications in pain medicine.

Appellant has published articles and book chapters on the subject of pain management, and he has given many presentations and lectures on that subject throughout his career.

From 1984 through the time of the administrative hearing below (May and June 2007), Appellant was the Medical Director of Pain Control Consultants, Inc. (PCC), in Columbus, Ohio, where he practiced interventional pain medicine. Beginning in approximately 1998, Appellant offered a fellowship in pain management, through PCC. From 1999 to 2001, Brian Frederic Griffin, M.D. (Dr. Griffin), participated in the fellowship at PCC, and he then continued as an employee of PCC until 2003. From August 2000 through February 2003, Kyle Elliot Hoogendoorn, D.P.M. (Dr. Hoogendoorn), participated in the fellowship at PCC.

At the time of the administrative hearing below, Appellant had staff privileges at Morrow County Hospital, which is located approximately 30 minutes north of the Polaris development in southern Delaware County, Ohio. Appellant did not have staff privileges at any Columbus hospitals.

By a notice of opportunity mailed to Appellant on August 10, 2006, the State Medical Board of Ohio notified Appellant that the Board proposed to take disciplinary action against Appellant's certificate to practice medicine and surgery in Ohio. The Board based its proposed action on (1) allegations arising out of Appellant's treatment of 24 patients identified on a confidential patient key, and (2) Appellant's alleged failure to notify his patients of his lack of malpractice insurance coverage. (The Board also based its proposed action on Appellant's allegedly aiding and abetting Dr. Hoogendoorn, a podiatrist, to unlawfully practice medicine and surgery in Ohio. However, inasmuch as the Board ultimately determined that the evidence was insufficient to support a conclusion that Appellant engaged in such conduct, the Court will not address that allegation.) The Board alleged that Appellant's conduct constituted:

- o "[a] departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used R.C. 4731.22(B)(6); and

- o "failure to provide notice to, and receive acknowledgment of the notice from, a patient when required by section 4731.143 of the Revised Code prior to providing nonemergency professional services, or failure to maintain that notice in the patient's file," as that clause is used in R.C. 4731.22(B)(30).

The Board advised Appellant of his right to a hearing on the alleged violations, and received his written request for a hearing on September 5, 2006.

The Board notified Appellant's former colleagues, Dr. Griffin and Dr. Hoogendoorn, that the Board proposed to take disciplinary action against their professional licenses as well. By agreement of all parties, all three disciplinary matters were consolidated for purposes of the administrative hearing below.

Over the course of seventeen days in May and June 2007, Medical Board Hearing Examiner R. Gregory Porter (Hearing Examiner) conducted an evidentiary hearing on the charges against all three doctors. The hearing generated a 3,100-page transcript. The State presented the testimony of Mark V. Boswell, M.D., David Shawn McCafferty, Murray Kopelow, M.D., Bashar Katirji, M.D., Thomas C. Chelimsky, M.D., Dr. Griffin, Dr. Hoogendoorn, and Appellant, the latter three witnesses as if upon cross-examination. Appellant and his former colleagues, Dr. Griffin and Dr. Hoogendoorn, testified and presented the testimony of David R. Longmire, M.D., Richard Weiner, D.P.M., James P. Bressi, D.O., Todd C. Loftus, D.P.M., Andrew Thomas, M.D., David S. Bastawros, D.P.M., and Gary W. Jay, M.D. Numerous exhibits were admitted into evidence.

Thomas C. Chelimsky, M.D. (Dr. Chelimsky), and Bashar Katirji, M.D. (Dr. Katirji), the State's expert medical witnesses, opined, among other things, that Appellant had performed unnecessary and invasive tests on his patients, including somatosensory evoked potentials (SSEPs), nerve conduction studies, and selective tissue conductance (STC) studies, that Appellant had failed to change the treatment of his patients based on abnormal results of such tests, that Appellant had inappropriately threatened to withhold prescriptions from patients unless they gave consent to perform such invasive tests, and that Appellant had engaged in a "cook book" approach to pain management treatment rather than provide critical individualization of treatment to his patients. Dr. Chelimsky and Dr. Katirji opined that Appellant's conduct

constituted a departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances.

Appellant and his expert medical witnesses, in particular James P. Bressi, D.O. (Dr. Bressi), disagreed with the opinions expressed by Dr. Chelimsky and Dr. Katirji, and opined that Appellant's conduct had not constituted a departure from, or failure to conform to, the minimal standards of care.

On July 7, 2008, the Hearing Examiner issued a 140-page Report and Recommendation in Appellant's case, containing a meticulous examination of the evidence, detailed findings of fact, and conclusions of law. The Hearing Examiner issued separate Reports and Recommendations in the cases of Dr. Griffin and Dr. Hoogendoorn.

The Hearing Examiner found that, from about November 1998 to about November 2001, in the routine course of his practice, Appellant undertook the treatment of Patients 1 through 24 as identified on a confidential patient key. *Finding of Fact No. 1.* The Hearing Examiner found that, in treating Patients 1 through 24, Appellant "inappropriately utilized testing and/or failed to provide treatment in accordance with the minimal standards of care." *Id.* Examples of such conduct included, but were not limited to, the following:

- Appellant failed to refer or timely refer and/or document the referral or timely referral of Patients 1-4, 9, 11-13, 16-21, and 23 for psychological consultation.
- Appellant should have but failed to refer Patients 20 and 23 to an addiction medicine specialist and/or obtain toxicology screens despite signs of drug abuse and/or diversion.
- Appellant performed unnecessary testing including somatosensory evoked potentials (SSEPs), nerve conduction studies, and/or selective tissue conductance (STC) studies (collectively EDX studies) on Patients 1, 2, 4-6, 15-17, and 23.

- Appellant performed unnecessary testing including SSEPs and/or STC studies (collectively EDX studies) on Patients 7-9, 11-14, 18-20, and 22.
- Appellant improperly performed and/or caused to be improperly performed SSEPs.
- Even if the EDX studies on Patients 1, 2, 4-9, and 11-23 had been necessary, Appellant inappropriately failed to perform, recommend, and/or document the performance or recommendation of needle EMG examinations as was appropriate.
- Appellant failed to identify and/or document an appropriate indication for the use of the EDX studies on Patients 1, 2, 4, 5, 7-9, and 11-23.
- Appellant failed to properly document an appropriate comment on purported abnormal EDX study results for Patients 1, 5-9, 11-14, 17-19, 21, and 22.
- Appellant failed to change and/or document a change in treatment or management of Patients 1, 5-9, 11-14, 17-19, 21, and 22 based on the abnormal results of EDX studies.
- Appellant failed to form and/or document the formation of an individualized clinical impression for Patients 1-10 and 12-24.
- Appellant inappropriately threatened to withhold prescriptions from Patients 5 and 12 unless they gave consent to perform diagnostic and/or invasive procedures.
- Appellant failed to provide critical individualization of treatment, and instead inappropriately engaged in a "cook-book" approach to pain management treatment.
- Appellant engaged in and/or supervised the excessive use of invasive techniques and blocks, including: chemoneurolytic and other injections and/or radiofrequency lesioning; and/or spinal decompression; and/or discography or provocative discography; and/or thoracic decompression; and/or root ganglion injections in Patients 2-5, 7-9, 11, 12, 14, 15, 17, and 20-22.
- Appellant inappropriately used, and/or supervised a podiatrist to engage in the use of destructive modalities of treatment such as chemolytic agents indiscriminately on nerves and muscles on Patients 7 and 17.

- Appellant inappropriately targeted and treated nine roots in a single radio-frequency procedure on Patient 20. *Finding of Fact No. 1(a), (b), (c), (e), (f), (g), (h), (i), (j), (k), (l), (n), and (o).*

The Hearing Examiner found that, despite the lapse of Appellant's malpractice insurance coverage during the period from about August 2003 to about March 2004, he failed to:

- Provide written notice of his lack of malpractice insurance coverage (malpractice notice) to every patient seeing him for nonemergency professional services, which provided a space for the patient to acknowledge receipt of the malpractice notice.
- Obtain from every patient seeing him for nonemergency professional services the patient's signature acknowledging receipt of the malpractice notice.
- Maintain a signed written malpractice notice in the patient chart for every patient who saw him for nonemergency professional services. *Finding of Fact No. 3(a), (b), and (c).*

The Hearing Examiner concluded that Appellant's conduct, as set forth in Finding of Fact No. 1, above, constituted "[a] departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in R.C. 4731.22(B)(6). *Conclusion of Law No. 1.* The Hearing Examiner concluded that Appellant's conduct, as set forth in Finding of Fact No. 3, above, constituted a "failure to provide notice to, and receive acknowledgment of the notice from, a patient when required by Section 4731.143 of the Revised Code¹ prior to providing nonemergency professional services, or failure to maintain that notice in the patient's file," as that clause is used in R.C. 4731.22(B)(30). *Conclusion of Law No. 2.*

Revised Code 4731.22(B)(6) and (30) provides:

§ 4731.22. Grounds for discipline ***

¹ As that statute was in effect from April 10, 2001 through December 29, 2004.

(B) The board, by an affirmative vote of not fewer than six members, shall, to the extent permitted by law, limit, revoke, or suspend an individual's certificate to practice, *** or reprimand or place on probation the holder of a certificate for one or more of the following reasons:

(6) A departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established;

(30) Failure to provide notice to, and receive acknowledgment of the notice from, a patient when required by section 4731.143 of the Revised Code prior to providing nonemergency professional services, or failure to maintain that notice in the patient's file[.]

The Hearing Examiner recommended that the Board permanently revoke Appellant's certificate to practice medicine and surgery in Ohio, and concluded his Report and Recommendation with this assessment:

The evidence clearly shows that Dr. Leak's treatment of Patients 1 through 24 fell below the minimal standard of care. His violations included subjecting his patients to unnecessary tests - - in some cases to an extraordinary number of unnecessary tests - - without documenting the necessity for those tests and seemingly without heed to abnormal results when abnormal results were obtained. Further, Dr. Leak subjected patients to an excessive number of invasive procedures, including chemoneurolytic injections into muscle tissue. Moreover, his practice withheld prescriptions from two patients until they gave consent to have diagnostic or invasive procedures performed, and the procedures were unnecessary. Finally, he failed to follow the statutory requirements for notifying patients of his lapse of medical malpractice insurance. Such conduct, taken together, merits the severest sanction.

On July 16, 2008, the State filed objections to the Hearing Examiner's Report and Recommendation. On August 5, 2008, Appellant filed objections to the Hearing Examiner's Report and Recommendation.

The Board met to consider Appellant's case on August 13, 2008, at which time the Members of the Board engaged in the following discussion:

Dr. Varyani directed the Board's attention to the matter of William David Leak, M.D. He advised that objections were filed by both the State and Dr. Leak to Hearing Examiner Porter's Report and Recommendation and were previously distributed to Board members.

Dr. Stephens stated that she is new to the Board, but she's not new to pain. She stated that she has to say that she thinks that the Board and its attorneys have gotten it all wrong. Dr. Stephens stated that she's a spine surgeon and she deals with pain every single day. She deals with all the pain management people and the providers of pain management all the time. Dr. Stephens stated that it is a still-evolving area. There are so many different specialties involved and no one specialty has the right answer. For a neurologist to come in and say, "I know this and this is the way it is," is ridiculous. Dr. Stephens stated that there is such an incredible overlap in every single specialty in pain.

Dr. Stephens continued that, in terms of the testing that went on, when you have someone in a desperate situation with pain, you keep trying to find a reason for their pain. Dr. Stephens stated that she knows a lot of pain people who do nerve conduction studies, she knows a lot of people who do the temperature things, she knows a lot of people who do the SSEP, and they're kind of just trying to find anything to help these people. Dr. Stephens stated that sometimes, most times, these diagnostic studies don't point to anything, but you're still obligated to help somebody that comes back to you. Dr. Stephens stated that physicians haven't figured out pain. That's why there are so many articles in *Time Magazine*. That's why there's so much controversy.

Dr. Stephens stated that she didn't see anything wrong with what Dr. Leak has done. ***

Dr. Stephens added that, to say that cortisone or steroid injections are worthless, she has patients that come to her every three months for these injections because they do provide some relief. It's a difficult population, there aren't enough physicians in the specialty, and it's a still-evolving specialty. Dr. Stephens stated that she just doesn't get this.

Dr. Mahajan stated that he's a neurologist and he understands what Dr. Stephens is saying, but all the testing - - the SSEP, nerve conduction studies - - are uncomfortable procedures, and ordering them as a routine on everybody, the majority of the people, without rationale is not logical. Many of these studies, soft tissue conduction, and so forth, are best left with institutions that have parameters on what to make out of them. These are not the standard of care in the community practice. Dr. Mahajan stated that in looking at this case, the tests were ordered excessively and they were not rational.

Dr. Stephens stated that in her community they are standard of care. She stated that she knows that all the pain people do all these different things. Every community and even different hospitals have different standards of care. Dr. Stephens again stated that she doesn't see anything wrong with any of this stuff.

Dr. Egner stated that she has moderately lengthy comments on this case, and added that she'll try not to be too long.

Dr. Egner thanked Hearing Examiner Porter, adding that she can't imagine combining three citations into one hearing, with all of the physicians and the podiatrist being represented by their own lawyers, and then the State's lawyers. Dr. Egner stated that, from the way the record read, she would say that it appears that the hearing was held in a very orderly fashion, and she gives Mr. Porter a tremendous amount of credit. She also stated that she is sure that taking one hearing and creating three Reports and Recommendations was just an incredibly difficult task. She again thanked Mr. Porter and said that he did an excellent job and a wonderful representation for the Medical Board.

Dr. Egner stated that this isn't really about pain management being in a gray zone. She stated that she agrees with Dr. Stephens that there are not absolute answers in pain management, nor were there from 1999 to 2001, but it was also not caveman medicine. In 1999 and 2001, it wasn't that long ago, physicians did not know a lot about pain, maybe not as much as they do today, but it wasn't just a hit and miss practice of medicine.

Dr. Egner stated that Dr. Leak was accused of many counts in his citation. She stated that she will not go through all of them, but she will go through some that she feels are the most important. Dr. Egner stated that she also feels that the expert witnesses were reliable and were appropriate. Dr. Chelimsky is a neurologist, an expert in electrodiagnostic medicine, and was director of the Cleveland Hospital pain center. Dr. Egner stated that, even if Dr. Chelimsky doesn't do a lot of interventional medicine, she can't believe that he doesn't know about it.

Dr. Egner stated that Dr. Leak failed to perform, recommend or document EMG. She stated that this seems to be at the heart of much of the issue. She stated that this is a test that was readily available from 1999 to 2001, a test that is considered much of the gold standard by many physicians, whether they be neurologists or anesthesiologists. It wasn't that EMG wasn't used often, but rather it is that, in a practice that used testing on every patient, averaging more than ten tests per patient, he never used an EMG in the 24 patients that were looked at. Dr. Egner stated that there must be a reason for that. Is it that it's too cumbersome? Is it that it had to be done by a specialist that wasn't employed by PCC? Is it the billing of the EMG was not a cost-effective thing to do? Dr. Egner stated that she doesn't know, but she does know that there's a glaring red flag that an EMG was never ordered. One-third of patients suffered from radicular pain. They received

the NCS, but no EMG. The NCS tests limbs, not roots, and without being done with an EMG is meaningless. Dr. Egner commented that experts on both sides spoke to that issue.

Dr. Egner continued that two thirds of the patients suffered from joint and back pain. They received the unnecessary SSEP test. This test was available in the 1980s and at that time was kind of the state of the art. She stated that as medicine improves and advances are made, tests fall by the wayside. That's what should have happened with this test. Dr. Egner stated that she's not saying that it should never be used, but it was the primary test in this practice. It's now outdated and it was then. The false positive rate was high and MRIs, which were available from 1999 to 2001, would give a lot of the information from these tests.

Dr. Egner stated that Dr. Leak gave a lot of testimony, saying that the tests were done to confirm pain. She stated that's very different from doing tests, sometimes painful tests, to find out the cause and treatment for the pain. Saying that you want to see if the patient, when he says he has pain, really does have pain, is a whole different approach to medicine. Dr. Egner stated that she's not saying that it's not appropriate to a point in a pain medicine practice, but it should not be a practice's primary goal to see who's lying and who's not. The test, the McGill Pain Questionnaire and the Visual Analog Scale, was never used, and experts said that that is the test that really helps to confirm a patient's subjective nature of the pain.

Confirming whether the patient really does have pain is not the primary purpose for any of these tests. Dr. Egner stated that in Dr. Griffin's testimony, even he dispels the EMG over the SSEP to establish the existence of pain. Dr. Egner stated that the whole operation of the practice was to prove that the patient's not lying. She stated that the tests don't do that, that's not the purpose of the tests, and so they were unnecessary tests.

Dr. Egner stated that PCC did have the cookbook approach. Every patient got the same battery of tests and got them multiple times. They tested multiple nerve roots when the complaint was confined to only one. She noted that even Dr. Leak's expert, James P. Bressi, D.O., states that they used the tests to validate pain and that is not an appropriate indication.

Dr. Egner stated standing orders were in place for all 24 patients. They failed to form an individual clinical impression. The plan of care was the same for all patients - - extensive diagnostic testing. Dr. Egner stated that the histories and physicals are minimal and often non-detailed, except for the patient questionnaire. There was major lacking in the impression and plan part of the medical record. Dr. Egner stated that there appears to be both a problem with documentation, as well as a problem with routine care plans or even a lack of care plan.

Dr. Egner noted a failure to obtain psychological consultation. She stated that Dr. Chelimsky states that patients should have a psychological evaluation within three months of their initial visit, and this was rarely done. There was no documentation of it and no follow-up. There was no consideration of these factors in many of the plans of care, and Dr. Leak himself states that a person threatening suicide would be in need of psychological help. Dr. Egner stated that this is a basic lack of respect for patients in pain and needing chronic benign pain management. She stated that this would be akin to only suggesting that one get financial help after they've declared bankruptcy. She stated that it makes no sense to have that as the baseline standard. It is practicing below the minimal standards.

Dr. Egner stated referring patients for addition evaluation, treatment or drug screens was not done. If it was done, tests were never in the chart. Dr. Egner stated that partly, PCC had very poor documentation, but it is, again, a lack of respect for the patients that you're taking care of and not looking at their overall treatment of pain in a broader view. It was doing pain management by techniques and prescriptions. This was especially evident when care was denied to patients unless they consented to diagnostic or invasive procedures. She noted that medicines were withheld from patients 5 and 12 until they would consent to the spinal differential block. Dr. Egner stated that this is absolute malpractice and practicing below the minimal standards.

Dr. Egner stated that people practice below minimal standards for the most part for one of three, or a combination of three, reasons:

- 1) greed -- "It is a moneymaking operation, and the more patients I see, the more tests I order, the more procedures that I do, I make more money," and in that, practice below minimal standards.

- 2) the "cowboy syndrome" -- Those physicians practice outside of what you would call "traditional medical practice." They see things a little bit differently. They feel they're always on the cutting edge - "I don't have to follow the rules. I can practice. I don't have to go with what the community says. I know better in pain management." Or "I know better and alternative cares are so much better than what the community usually does." They're willing to try new things -- they think that they're rather innovative and a free thinker. Dr. Egner stated that, on the one hand, everyone in medicine has a little bit of that cowboy syndrome, and it's a good thing. It's how medical advances are made. Dr. Egner stated that when it goes too far your practice is completely outside the community standard, which she believes this one was, and it becomes dangerous and damaging to patients. Rules just don't apply. It is isolating and it can get out of control. Dr. Egner stated that she believes that it is also one of the reasons why Dr. Leak has absolutely no hospital privileges in any hospital in Columbus. She stated that she doesn't know the circumstances of his not having privileges, but it is part of that syndrome of not being part of the medical community.

3) lack of knowledge - - Dr. Egner stated that, in Dr. Leak's case, she doesn't believe that he really suffers from a lack of knowledge. She thinks that he knows his subject matter quite well. He knows what tests do what, he knows how they're reimbursed, how to do them technique-wise, and what the side-effects are.

Dr. Egner stated that greed, thinking he knows better than anyone else and that he can practice in a very untraditional way are Dr. Leak's problems. Unfortunately, those are not amenable to improvement. A lack of knowledge can be. You send someone through training and they acknowledge that what they did wasn't the best practice of medicine. Nowhere in Dr. Leak's testimony at hearing, or even today, at all suggests that perhaps there's a better way to do things. His greed and his untraditional practice are reflected in the number of procedures for the patients, ongoing care without an end-point or functional goal. It is reflected in not using EMGs, relying on the SSEPs and the STCs, and not changing any plan of care based on test results. He justifies every unnecessary diagnostic test. He justifies not changing his plan of care based on test results. He justifies his documentation, noting that "it just takes more time to get through our charts." He justifies being interested only in tests and procedures and not a comprehensive pain medicine approach. Dr. Egner stated that he justifies his plan of care and not adjusting it to individual needs. Dr. Egner stated that, therefore, she is very in favor of permanent revocation in this case.

Dr. Stephens again stated that she is a spine surgeon and she refers at least ten people a day to pain management. She's seen records from the Cleveland Clinic, from University Hospital, from all over, and this is what everyone does in pain. This is not below the standard, it's what everyone's doing. In pain management in her area, one of her two top referrals don't have hospital privileges. She stated that that's not unusual - - they're in competition with the hospital, they don't need hospital privileges and a lot of them don't have hospital privileges.

Dr. Stephens stated that, in terms of the "cookie cutter" approach and everyone having the same forms and things like that, the Board should see the forms from the Cleveland Clinic. They all look the same. You shouldn't even bother to read them because you can't distinguish one patient from another. Dr. Stephens stated that she just doesn't get that criticism.

Referring to the EMG and nerve conduction studies, Dr. Stephens stated that she's a spine surgeon and based on MRI findings of disc herniations and patient complaints, she never relies on EMG and nerve conduction studies. Dr. Stephens added that, in terms of pain management, that's what you try to do - - confirm that the patients are really having pain. Withholding medication and things like that for procedures is oftentimes done. It's not like you're trying to bribe the patient to do a procedure, but it's kind of like you need a reason to do the procedure. Dr. Stephens stated that she has lots of patients who have epidural blocks injections for years, eight to ten years.

Dr. Amato stated that the discussion back and forth on the testing he finds interesting, as an OB/GYN. The problem he has is, if one wants to have a cookbook approach to medicine, and everybody has said that this is still a developing area, it seems to him the place where that belongs is in the university setting, to try to establish a criterion, if it is possible. Dr. Amato stated that it bothers him that in the practice of the art and the science of medicine, every patient seemed to be tested the same. The thing that made no sense to him is that the outcome of the tests made no difference in the treatment. What's the reason for doing a test if it's not going to affect how you're going to treat the patient?

Dr. Amato stated that he was also a little bit concerned that, since he's had a family member injected for trigger points, and having been there when the injections were done, it kind of bothers him when you have 40 trigger points injected in one visit. Dr. Amato stated that a lot of what he saw here seems to smack of a production line to develop CPT codes.

Dr. Varyani stated that he would like to speak on this issue as well, because he trained in pain management between 1979 and 1980 at the Cleveland Clinic. He had a very good relationship with the Cleveland Clinic and he does practice pain therapy, although anesthesiology is his first job. Dr. Varyani stated that he has met and knows Dr. Gabor Racz. He stated that if this discussion was being held in the 1990s, he would agree that pain management was in its infancy. He believes that the conductant spark that is being talked about was proven to be a questionable modality in the late 1990s. When you lose everything else, then you rely on, maybe, the sympathetic or the parasympathetic system as having this, or having this overreaction. But in 2008, pain management is a science. If someone tells him that they're doing ten epidural injections in ten months, it has been proven that if you do three and if the three don't work, it doesn't work.

Dr. Varyani said that he is in Dr. Egner's camp on this. She has outlined what pain therapy is, and he congratulated her on hitting the nail right on the head. He stated that this is not a cowboy issue, this is purely greed. You cannot have conductance done on everybody - - not everybody has either a phantom pain, or you cannot figure out what dermatome it's coming from, or if you have reflex sympathetic changes, or whatever. Dr. Varyani stated that he cannot fathom everybody having a conductance test. That's basically testing your autonomic system, and that's proven to be questionable today.

Dr. Varyani stated that he had read this case, and he's reserved his comments for the end. He stated that all he will say is that he hopes to God that the Cleveland Clinic Pain Management Institute is not just gibberish. Dr. Varyani stated that he was a resident from there and he thinks that they've grown. They're now doing things of which they never dreamed. It has evolved, and he's sure that it will evolve more. Dr. Varyani stated that if a pain patient comes to him, he's not just going to do epidural blocks, or conductant tests or this or that. If he doesn't understand, he'll go straight to an MRI. Dr. Varyani indicated that with an MRI

you can see up to 1 mm inside the body. Why are these totally questionable tests being done? You can do them at certain times when you can't diagnose the pain, but not on everybody. Why would you do conductants on everybody? Dr. Varyani stated that that happens to be the routine at PCC. You need an EMG. If the pain is following another dermatome, and you cannot figure out why its happening, then you would need an EMG to see if there's weakness in that dermatome or not. You don't need an EMG on everybody. You don't need conductants on everybody. Physicians know how things work now.

Dr. Steinbergh stated that she's a primary care physician and not as much of an expert as some other Board members, but she does refer patients frequently or pain consultation. She did thoroughly review this chart, and she feels, quite frankly that she does agree with the Hearing Examiner's findings, except for one. She does agree that Dr. Leak subjected his patients to unnecessary tests and to an extraordinary number of tests as Dr. Egner outlined. She also felt that he did an excessive number of invasive procedures. Dr. Steinbergh stated that she also agrees that Dr. Leak unlawfully aided and abetted the unlicensed practice of medicine in the case of Dr. Hoogendoorn.

Dr. Steinbergh stated that if she, as a primary care physician, saw that this type of thing was going on, she would not refer the patient to this pain physician because she feels that he's very inappropriate.

Dr. Stephens stated that she would just like to say that a lot of the pain management centers that she uses, including the Cleveland Clinic and University Hospital, operate like this. *Board Minutes, Aug. 13, 2008, 17739-17750.*

At the conclusion of this discussion, the Board voted, 7 to 2, to adopt the Hearing Examiner's Report and Recommendation, and to permanently revoke Appellant's certificate to practice medicine and surgery in Ohio. The Order was to become effective 30 days after it was mailed on August 15, 2008, thereby making it effective on September 14, 2008.

On August 25, 2008, pursuant to R.C. 119.12, Appellant appealed the Board's Order to this Court. On September 9, 2008, on Appellant's motion, the Court suspended the Board's Order pending this appeal.

Appellant's Motion to Admit Additional Evidence

Before the Court may address the merits of this appeal, the Court must rule on "Appellant, William David Leak, M.D.'s, Motion to Introduce Additional Evidence," filed on

December 2, 2008. Appellant has moved the Court to admit the following six items into evidence: (1) the minutes from the Board's August 13, 2008 meeting regarding the Board's deliberations leading to the Orders in the matters of Appellant, Dr. Griffin, and Dr. Hoogendoorn; (2) the audiotape of the Board's August 13, 2008 meeting regarding the Board's deliberations leading to the Orders in the matters of Appellant, Dr. Griffin, and Dr. Hoogendoorn; (3) the transcript of the audiotape of the Board's August 13, 2008 meeting regarding the Board's deliberations leading to the Orders in the matters of Appellant, Dr. Griffin, and Dr. Hoogendoorn; (4) written decisions on Appellant's post-hearing motions for additional time to address the Board, to strike the testimony of Dr. Chelimsky, and to strike the State's objections to the Report and Recommendation of the Hearing Examiner; (5) the testimony of Nandlal Varyani, M.D., President of the Medical Board, regarding his/the Board's process for ruling on and advising the parties of the rulings on Appellant's post-hearing motions; and (6) the Board's August 2008 Orders regarding Dr. Griffin and Dr. Hoogendoorn. The State has opposed Appellant's motion.

Revised Code 119.12, which governs Appellant's motion to admit additional evidence, provides as follows:

Unless otherwise provided by law, in the hearing of the appeal, the court is confined to the record as certified to it by the agency. Unless otherwise provided by law, the court may grant a request for the admission of additional evidence **when satisfied that the additional evidence is newly discovered and could not with reasonable diligence have been ascertained prior to the hearing before the agency.** (Emphasis added.)

"Newly discovered" evidence is evidence that was in existence at the time of the administrative hearing. *Gordon Lending Corp. v. Ohio Dept. of Commerce, Div. of Financial Insts.*, Franklin App. No. 08AP-84, 2008-Ohio-3952, at ¶11, citing *Golden Christian Academy v. Zelman* (2001),

144 Ohio App. 3d 513, 517, appeal dismissed, 93 Ohio St. 3d 1473 (2001). “Newly discovered” evidence does not refer to newly created evidence. *Id.*

Applying R.C. 119.12 to the six items that Appellant seeks to have admitted into evidence, the Court concludes that none of those items is “newly discovered” evidence that was in existence at the time of the administrative hearing in May and June 2007. Accordingly, none of those items may be admitted into evidence in this appeal. For this reason, “Appellant, William David Leak, M.D.’s, Motion to Introduce Additional Evidence,” filed December 2, 2008, is hereby **DENIED**.

Standards of Appellate Review

Turning, then, to the merits of this appeal, the Court observes that it must uphold the Board’s August 15, 2008 Order if the Court finds that the Order is supported by reliable, probative, and substantial evidence and is in accordance with law. R.C. 119.12; *Pons v. Ohio State Med. Bd.* (1993), 66 Ohio St. 3d 619, 621. In the absence of such a finding, the Court may reverse, vacate, or modify the Order or make such other ruling as is supported by reliable, probative, and substantial evidence and is in accordance with law. R.C. 119.12.

“Reliable” evidence is dependable; that is, it can be confidently trusted. *Our Place, Inc. v. Ohio Liquor Control Comm.* (1992), 63 Ohio St. 3d 570, 571. In order to be “reliable,” there must be a reasonable probability that the evidence is true. *Id.* “Probative” evidence is evidence that tends to prove the issue in question; it must be relevant in determining the issue. *Id.*

“Substantial” evidence is evidence with some weight; it must have importance and value. *Id.*

The Supreme Court has recognized that the General Assembly granted the Medical Board a significant measure of discretion in its disciplinary proceedings. See *Arlen v. State* (1980), 61

Ohio St. 2d 168, 174. In *Farrand v. State Med. Bd. of Ohio* (1949), 151 Ohio St. 222, 224, the Supreme Court stated the policy reason behind this broad grant of discretion:

*** The purpose of the General Assembly in providing for administrative hearings in particular fields was to facilitate such matters by placing the decision on facts with boards or commissions composed of [persons] equipped with the necessary knowledge and experience pertaining to a particular field. ***

Accordingly, when reviewing a Medical Board order, courts must accord due deference to the Board's interpretation of the technical and ethical requirements of its profession. *Pons, supra*, at the syllabus.

With these standards of appellate review in mind, the Court will address the assigned errors asserted by Appellant in this appeal.

Appellant's Assignments of Error

Appellant has asserted, in this appeal, that the Board's August 15, 2008 Order is not supported by reliable, probative, and substantial evidence and is not in accordance with law. In support of this assertion, Appellant has set forth six assignments of error.

Appellant's First Assignment of Error

Appellant's first assignment of error is that the Board violated his due-process rights by waiting approximately five years after the alleged violations occurred to bring formal disciplinary charges against him. Specifically, Appellant contends, "[t]he delay itself demonstrates that Dr. Leak has been prejudiced."

This identical argument, however, was recently rejected by the Franklin County Court of Appeals in the case of *Griffin v. State Med. Bd. of Ohio*, Franklin App. No. 09AP-276, 2209-Ohio-4849, copy attached. That case was Dr. Griffin's appeal from Judge Charles Schneider's decision in Dr. Griffin's R.C. 119.12 administrative appeal. In that case, the Court of Appeals held that the analysis of such a due-process argument must be "whether the licensee suffered any

material prejudice as a result of the agency's delay. (Emphasis added.)" *Id.*, citing *Smith v. State Med. Bd. of Ohio* (July 19, 2001), Franklin App. No. 00AP-1301.

Appellant asserts that he was prejudiced simply due to the passage of time, but he has demonstrated no actual, identifiable, material prejudice that he may have suffered because of the Board's delay in bringing formal charges against him. Absent such a demonstration, the Court cannot hold that the Board violated his due-process rights. *Griffin, supra*. Appellant's first assignment of error is therefore overruled.

Appellant's Second Assignment of Error

Appellant's second assignment of error is that the Board failed to provide him with sufficient notice of the charges against him, specifically, that the August 10, 2006 notice of opportunity did not set forth the precise dates of the alleged incidents that constituted his violations of R.C. 4731.22(B)(6) and (30). "Without this crucial information," Appellant asserts, "it was impossible for Dr. Leak to prepare an adequate defense to the Board's allegations." Belying this contention, of course, is the massive record that Appellant himself created in the course of presenting his evidence during the hearing in May and June 2007.

Moreover, as to the Board's charge of Appellant's substandard care of his patients, the Board notified Appellant, in the August 10, 2006 notice of opportunity, that the Board intended to take action against Appellant's medical license for his treatment of Patients 1 through 24, who were identified in a confidential patient key provided to Appellant. In addition, a specific timeframe (November 1998 - November 2001) was identified in the notice of opportunity, along with the patient names and the treating records covering that identified timeframe. As to each of the 24 patients, the Board provided Appellant with specific allegations as to how he had violated R.C. 4731.22(B)(6) and (30).

In addition, prior to the hearing in May 2007, Appellant was provided with expert witness reports, identifying precisely how the State alleged that he had violated the standard of care with respect to the 24 patients identified. Appellant was provided with the patient charts for all 24 patients in question, as well as all of the materials reviewed by the State's expert witnesses, months before the hearing began in May 2007. The State's expert medical witnesses, Dr. Chelimsky and Dr. Katirji, wrote detailed reports in which they reviewed all 24 of the patient records and expressed their opinions, based upon those records, that Appellant had violated R.C. 4731.22(B)(6). Those reports not only identified specific instances where the experts offered their opinions that Appellant's conduct fell below the standard of care, the reports also identified specific patients and specific page references in the patient charts where the offending conduct occurred.

Revised Code 119.07 provides:

*** [I]n all cases in which section 119.06 of the Revised Code requires an agency to afford an opportunity for a hearing prior to the issuance of an order, the agency shall give notice to the party informing the party of the party's right to a hearing. **Notice shall be given by registered mail, return receipt requested, and shall include the charges or other reasons for the proposed action, the law or rule directly involved, and a statement informing the party that the party is entitled to a hearing if the party requests it within thirty days of the time of mailing the notice.** *** (Emphasis added.)

The Board complied with R.C. 119.07 and provided Appellant with sufficient notice of the allegations against him, well in advance of the hearing that began in May 2007.

Finally, on this particular issue, Appellant's case is very dissimilar from the case he cites in his brief, *Sohi v. State Dental Bd.* (1998), 130 Ohio App. 3d 414. In that case, the appellant dentist was accused of substandard care but, despite all of his requests for the names of the patients involved in his allegedly substandard care, he was provided with the names of only two patients prior to his hearing before the Ohio State Dental Board. Appellant, to the contrary, was

provided with the names of all 24 of his patients well in advance of his hearing, had the ability to prepare and present evidence to rebut the State's evidence against him, and did, in fact, present a substantive defense at his hearing. Having reviewed the voluminous record in this case, the Court finds that Appellant's second assignment of error is not supported by, and in fact is contradicted by, the certified record. It is therefore overruled.

Appellant's Third Assignment of Error

Appellant's third assignment of error is that the testimony of the State's expert medical witnesses, Dr. Chelimsky and Dr. Katirji, was "inherently unreliable" because, according to Appellant, they were not adequately familiar with the standards of care applicable to Appellant's practice in interventional pain medicine. Put more succinctly, Appellant is an anesthesiologist, while the State's expert witnesses, Dr. Chelimsky and Dr. Katirji, are neurologists. Having reviewed the transcript and the Hearing Examiner's Report and Recommendation, the Court does not agree with Appellant's argument that the testimony of Dr. Chelimsky and Dr. Katirji was "inherently unreliable."

Dr. Chelimsky obtained his medical degree in 1983 from Washington University in St. Louis, Missouri. From 1983 through 1986, he was a resident in internal medicine at Mayo Clinic, in Rochester, Minnesota, and, from 1986 through 1989, he was a resident in neurology at the same institution. From 1986 through 1987, Dr. Chelimsky participated in a fellowship in autonomic research at Mayo Clinic. From 1989 through 1990, he participated in a fellowship in electromyography at Mayo Clinic.

Dr. Chelimsky was certified by the American Board of Internal Medicine in 1986 and by the American Board of Electrodiagnostic Medicine in 1992. He was certified in neurology by the American Board of Psychiatry and Neurology (ABPN) in 1992. In 1994, Dr. Chelimsky

obtained an additional qualification in clinical neurophysiology from the ABPN and, in 2000, he obtained an additional qualification in pain management from the ABPN.

At the time of the Board hearing, Dr. Chelimsky had served in academic capacities at Case Western Reserve University (CWRU) since 1990 and was a Professor of Neurology. Since 1990, Dr. Chelimsky had been a member of the attending staff, a member of the staff at the EMG laboratory, and Director of the Division of Autonomic Disorders at University Hospitals of Cleveland. From 1994 through 2000, and from 2001 through 2004, Dr. Chelimsky was Director of the Pain Center at University Hospitals of Cleveland.

As the Director of the Pain Center at University Hospitals of Cleveland, Dr. Chelimsky supervised an active fellowship program in pain medicine. The fellows were usually neurologists, and they were trained in both interventional and non-interventional techniques. Interventional pain medicine techniques include any kind of injection, such as nerve blocks, as well as radiofrequency lesioning and surgical procedures.

Dr. Chelimsky participated in many presentations and lectures throughout the United States, and he authored numerous articles and book chapters.

At the time of the Board hearing, Dr. Chelimsky had been licensed to practice medicine in Ohio since 1990. Approximately 50 percent of his medical practice consisted of pain management, and the other 50 percent consisted of evaluating patients in the autonomic laboratory and performing research in that area. Dr. Chelimsky performed all of his work as a member of the faculty at CWRU and he did not have a private practice.

Dr. Katirji received his medical degree in 1977 from the University of Aleppo in Aleppo, Syria. From 1977 through 1980, he trained in internal medicine in the Middle East. From 1980 through 1983, Dr. Katirji participated in a neurology residency at the University Health Center of

Pittsburgh in Pittsburgh, Pennsylvania. From 1983 through 1984, he participated in a fellowship in electromyography at The Cleveland Clinic.

In 1985, Dr. Katirji was certified in neurology by the American Board of Psychiatry and Neurology (ABPN) and, in 1992, he obtained added qualifications in clinical neurophysiology from the ABPN. He was certified by the American Board of Electroencephalography in 1985, by the American Association of Electrodiagnosis and Electromyography in 1985, and by the American Board of Electrodiagnostic Medicine in 1990.

Dr. Katirji has held several academic appointments in the United States beginning in 1984. At the time of the Board hearing, he was Professor of Neurology at the Case Western Reserve University School of Medicine (CWRU) in Cleveland, Ohio, and he was a Lecturer in the Department of Medicine at the Ohio College of Podiatric Medicine, also in Cleveland. At the time of the Board hearing, in addition to his academic appointments, Dr. Katirji held several hospital appointments at University Hospitals of Cleveland, where he was the Director of the Electromyography Laboratory, Chief of the Neuromuscular Division, Program Director of Clinical Neurophysiology, and Director of the Muscle Disease Center. At the time of the Board hearing, he was a member of the attending staff in the Department of Neurology.

At the time of the Board hearing, Dr. Katirji held medical licenses in Ohio and Pennsylvania. His work was approximately 80 percent clinical in nature. Dr. Katirji did not administer trigger point injections, joint injections, or nerve block injections. He did not prescribe opioid medication to patients and did not practice in the field of interventional pain management. Dr. Katirji testified, however, that he was an expert in somatosensory evoked potentials (SSEPs), the studies that involve stimulating nerves in the limbs and recording nerve activity from the spine to the brain.

Appellant also presented expert testimony at the hearing below. James P. Bressi, D.O. (Dr. Bressi), was certified in anesthesiology by the American Osteopathic Board of Anesthesiology in 1993, with a qualification in pain management in 1996, and was also certified by the American Academy of Pain Management. At the time of the hearing below, Dr. Bressi was the director of the Falls Pain Management Center in Cuyahoga Falls, Ohio. David R. Longmire, M.D. (Dr. Longmire), a neurologist, was certified by the American Academy of Pain Management in 1982, and by the American Board of Electroencephalography and Neurophysiology in 1989. At the time of the hearing below, Dr. Longmire was a clinical associate professor and in private practice and was affiliated with the Department of Internal Medicine at the University of Alabama at Birmingham-Huntsville Regional Hospital. Gary W. Jay, M.D. (Dr. Jay), graduated from Northwestern University Medical Center in 1976, and at the time of the hearing below, had 25 years in the private practice of pain medicine, and was the Medical Director for Pain at Schwarz Biosciences.

In addition to the expert testimony of Dr. Chelimsky and Dr. Katirji, the State presented a fact witness, Mark V. Boswell, M.D., Ph.D. (Dr. Boswell). Dr. Boswell was certified by the American Board of Anesthesiology in 1993, and by the American Board of Pain Medicine in 1995 and 2004. At the time of the hearing below, Dr. Boswell was Professor and Chair of the Department of Anesthesiology, as well as Director of the Messer Racz Pain Center, at the Texas Tech University Health Sciences Center, in Lubbock, Texas. The pain medicine program at Texas Tech University is considered to be one of the top ten programs of its kind in the country.

Dr. Boswell explained that there is a difference in philosophy between the way that neurologists and anesthesiologists look at pain:

*** The neurology approach is more medication and less intervention.
Anesthesiology has always been more interventional in the sense of doing nerve

blocks and stimulators and pumps, things like that. *** Yeah, there's differences between the two. I think that continues to be the case. There are so many more anesthesiologists doing pain medicine than neurologists ***. *T. 43-44.*

When asked whether it was a qualitative difference in the way anesthesiologists and neurologists treat patients, or just a difference in philosophy, Dr. Boswell responded:

*** Well, I think it's a difference of philosophy. And I think that philosophy may be gradually changing or will change as our knowledge changes, but it's not only - - it's a difference in philosophy. Probably a difference in knowledge base as well. I mean, they're just different specialties. *T. 44.*

When asked whether it would be fair to say that different specialties would see the work of others from their own viewpoints rather than necessarily the viewpoints of those within the same specialties, Dr. Boswell responded:

*** I think that's the case. And that's why - - I mean, I worked with [Dr.] Chelimsky for 15 years and we would have interdisciplinary meetings and we could discuss patients and work together because we had different approaches. And that was the beauty of working with Dr. Chelimsky. I mean, he's a very good neurologist. And I have high respect for him. And we didn't always agree on approaches, but we always had a good collegial relationship and we would formulate a good plan for the patients that we co-managed. *T. 45.*

Dr. Boswell then testified that both he and Dr. Chelimsky were still within the standard of care, although they might see the same patient differently and have differences in opinion about treatment. *T. 45.*

The Court has reviewed all of the testimony given by all of the medical experts who testified before the Hearing Examiner, those called by the State and those called by Appellant and his colleagues, Dr. Griffin and Dr. Hoogendoorn. Without a doubt, all of the expert medical witnesses who spoke on the subject of pain management were highly qualified and well versed in that subject. Clearly, as the testimony of Dr. Boswell underscores, there are two contrasting philosophies in the field of pain management, the philosophy of the anesthesiologists, whose approach is more interventional, and the philosophy of the neurologists, whose approach is less

interventional. Three separate certifying boards offer subspecialty certification in pain medicine: the American Board of Anesthesiology; the American Board of Psychiatry and Neurology; and the American Board of Physical Medicine and Rehabilitation. All three boards use the same certifying examination. The Court concludes that the difference in philosophies between the anesthesiologists and the neurologists does not render the expert opinions of the neurologists, in this case Dr. Chelimsky and Dr. Katirji, "inherently unreliable."

The Court finds persuasive the following language from Judge Charles Schneider's decision in Dr. Griffin's R.C. 119.12 administrative appeal from the Board's revocation of his certificate to practice medicine and surgery in Ohio:

The standards of care that were found to have been breached in this matter are not esoteric in nature. Failure to obtain psychological consultations or addiction specialists, performing tests with limited or no value and excessive prescription of narcotics **are matters that cannot be countenanced in any physician review whether viewed under the point of view of anesthesiology or neurology.** (Emphasis added.)

Griffin v. State Med. Bd. of Ohio, Franklin C.P. No. 08CVF09-13539 (Feb. 4, 2009).

Finally, with respect to Appellant's third assignment of error, the Court also finds persuasive the following language from the Franklin County Court of Appeals' decision in Dr. Griffin's appeal to that Court:

*** The decision as to which medical philosophy is more appropriate for pain management is best left to the medical professionals, not appellate judges or trial court judges sitting in an appellate role on an administrative appeal. This is the clear indication of *Pons, supra*."

Griffin v. State Med. Bd. of Ohio, Franklin App. No. 09AP-276, 2009-Ohio-4849, at ¶25.

Appellant's third assignment of error is overruled.

Appellant's Fourth Assignment of Error

Appellant's fourth assignment of error is that the Board's August 15, 2008 Order, permanently revoking Appellant's certificate to practice medicine and surgery in Ohio, is a disproportionately harsh sanction. However, where the evidence supports an agency's decision, the common pleas court must affirm that decision and has no authority to modify the penalty. *Miller v. Columbus City Pub. Schools*, Franklin App. No. 08AP-1082, 2009-Ohio-2756, at ¶11, citing *Henry's Cafe, Inc. v. Bd. of Liquor Control* (1959), 170 Ohio St. 233. The sanction of permanent revocation is authorized by R.C. 4731.22(B). Accordingly, Appellant's fourth assignment of error is overruled.

Appellant's Fifth Assignment of Error

Appellant's fifth assignment of error is that the State did not have the authority to file objections to the Hearing Examiner's Report and Recommendation, and the Board therefore erred by not granting Appellant's motion to strike those objections.

Revised Code 119.09 provides:

In any adjudication hearing required by sections 119.01 to 119.13 of the Revised Code, the agency may appoint a referee or examiner to conduct the hearing. *** The referee or examiner shall submit to the agency a written report setting forth the referee's or examiner's findings of fact and conclusions of law and a recommendation of the action to be taken by the agency. A copy of such written report and recommendation of the referee or examiner shall within five days of the date of filing thereof, be served upon the party or the party's attorney or other representative of record, by certified mail. The party may, within ten days of receipt of such copy of such written report and recommendation, file with the agency written objections to the report and recommendation, which objections shall be considered by the agency before approving, modifying, or disapproving the recommendation. *** (Emphasis added.)

Appellant contends that the State is not a "party" and it therefore had no authority to file objections to the Hearing Examiner's Report and Recommendation.

However, Ohio Adm. Code 4731-13-15(C) provides:

4731-13-15. Reports and recommendations.

(C) **Either representative of record** may, within ten days of receipt of the hearing examiner's report and recommendation, file written objections to the report and recommendation. Only those objections filed in a timely manner shall be considered by the board before approving, modifying, or disapproving the hearing examiner's recommendation, unless otherwise determined by the board. (Emphasis added.)

Furthermore, in *Brindle v. State Med. Bd. of Ohio*, 168 Ohio App. 3d 485, 2006-Ohio-4364, at ¶31, the Franklin County Court of Appeals held that Ohio Adm. Code 4731-13-15(C) "is reasonable, does not impermissibly add to the legislative enactment, and does not clearly conflict with the statutory intent of the General Assembly in enacting R.C. 119.09."

The Court concludes that the State did, in fact, have the authority to file objections to the Hearing Examiner's Report and Recommendation, and the Board therefore did not err by not granting Appellant's motion to strike the State's objections. Appellant's fifth assignment of error is overruled.

Appellant's Sixth Assignment of Error

Appellant's sixth, and final, assignment of error is that the Board violated Appellant's due-process rights by not providing him, prior to the Board meeting on August 13, 2006, with written rulings on his post-hearing motions for additional time to address the Board, to strike the testimony of Dr. Chelimsky, and to strike the State's objections to the Hearing Examiner's Report and Recommendation. Without such written rulings in advance of the Board's meeting, Appellant asserts, he was "unable to effectively argue his case during the Board's deliberations on August 13, 2008." For the following reasons, Appellant's arguments on this issue are not well taken.

First, at the Board's meeting on August 13, 2006, Board President Varyani granted Appellant 15 minutes, as opposed to the usual five minutes, to address the Board, and the Board approved that ruling. Second, at the Board's meeting on August 13, 2006, Board President Varyani denied Appellant's motion to strike the testimony of Dr. Chelimsky, and the Board approved that ruling. Third, although the Board did not, prior to or at its meeting on August 13, 2006, rule on Appellant's motion to strike the State's objections to the Hearing Examiner's Report and Recommendation, such error, if any, was harmless, inasmuch as the State had the right to file objections to the Hearing Examiner's Report and Recommendation, in accordance with this Court's decision above.

Finally, Appellant has failed to show how, if at all, he was prejudiced by the Board's failure to rule on his post-hearing motions prior to the Board's meeting on August 13, 2006. Appellant's protests to the contrary, the Court concludes that Appellant and his attorney argued Appellant's case most effectively to the Board.

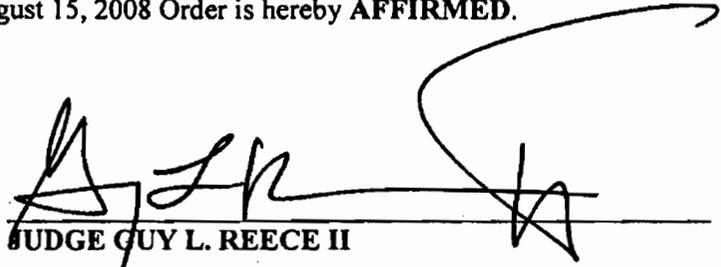
Appellant's sixth assignment of error is overruled.

Conclusion

Having considered the record that the Board has certified to this Court, as well as the parties' arguments as set forth in their briefs, the Court finds that the Board's August 15, 2008 Order, permanently revoking Appellant's certificate to practice medicine and surgery in Ohio, is supported by reliable, probative, and substantial evidence and is in accordance with law. Even if the Court were inclined to impose a more lenient sanction than permanent revocation, the Board's action is well within its statutory authority, and the Court has no authority to reverse or modify it. See *Miller v. Columbus City Pub. Schools*, *supra*, citing *Henry's Cafe, Inc.*, *supra*.

In closing, it is important to note that there is no dispute that Appellant violated R.C. 4731.22(B)(30), due to his "failure to provide notice to, and receive acknowledgment of the notice from, a patient when required by section 4731.143 of the Revised Code prior to providing nonemergency professional services, or failure to maintain that notice in the patient's file," as that clause is used in R.C. 4731.22(B)(30). Appellant's attorney candidly admitted the violation at the Board's meeting on August 13, 2006. That violation, standing alone, was sufficient for the Medical Board to revoke Appellant's license pursuant to R.C. 4731.22(B)(30).

Accordingly, the Board's August 15, 2008 Order is hereby **AFFIRMED**.



JUDGE GUY L. REECE II

Copies (with 12-page attachment) mailed to:

DOUGLAS E. GRAFF, ESQ. (0013222), Counsel for Appellant, 694 E. Rich St., Columbus, OH 43215-5341

KYLE C. WILCOX, AAG (0063219), Counsel for Appellee, 30 E. Broad St., Fl. 26, Columbus, OH 43215-3400

[Cite as *Griffin v. State Med. Bd. of Ohio*, 2009-Ohio-4849.]

IN THE COURT OF APPEALS OF OHIO

TENTH APPELLATE DISTRICT

Brian Frederic Griffin, M.D.,	:	
Appellant-Appellant,	:	
v.	:	No. 09AP-276
State Medical Board of Ohio,	:	(C.P.C. No. 08CVF-13539)
Appellee-Appellee.	:	(REGULAR CALENDAR)

D E C I S I O N

Rendered on September 15, 2009

Dinsmore & Shohl, LLP, Thomas W. Hess and Gregory P. Mathews, for appellant.

Richard Cordray, Attorney General, and Kyle C. Wilcox, for appellee.

APPEAL from the Franklin County Court of Common Pleas.

TYACK, J.

{¶1} This is an administrative appeal from the Ohio State Medical Board ("Board"). On August 13, 2008, the Board permanently revoked Dr. Brian F. Griffin's medical license, staying the revocation in lieu of three years probation. The conduct at issue allegedly occurred between 1999 and 2001 when Dr. Griffin was a student in a fellowship, at a Columbus, Ohio pain management clinic. In addition to his argument that the Board's decision was not supported by reliable, probative, or substantial evidence, Dr. Griffin also argues that the Board violated his due process rights by waiting roughly five

years after learning about the complained-of conduct to bring a formal disciplinary proceeding against him. The trial court affirmed the Board's order, and this appeal ensued.

{¶2} Dr. Griffin assigns three errors for our review:

[I.] THE COURT OF COMMON PLEAS ABUSED ITS DISCRETION BY APPLYING THE INCORRECT LEGAL STANDARD TO DR. GRIFFIN'S DUE-PROCESS ASSIGNMENT OF ERROR.

[II.] THE COURT OF COMMON PLEAS ABUSED ITS DISCRETION BY FINDING THAT THE BOARD DID NOT VIOLATE DR. GRIFFIN'S DUE PROCESS RIGHTS BY WAITING FIVE YEARS TO INSTITUTE THE ADMINISTRATIVE ACTION AGAINST HIM.

[III.] THE COURT OF COMMON PLEAS ABUSED ITS DISCRETION BY FINDING THAT THE ORDER WAS SUPPORTED BY RELIABLE, PROBATIVE, AND SUBSTANTIAL EVIDENCE WHERE THE EXPERTS RELIED UPON BY THE BOARD WERE INHERENTLY UNRELIABLE.

{¶3} The Ohio Revised Code vests the Board with broad authority to regulate the medical profession in this state, and to discipline any physician whose care constitutes "[a] departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established." R.C. 4731.22(B)(6).

{¶4} The common pleas court is the reviewing tribunal for appeals from administrative agencies, such as the Board, and the standard of review is provided by R.C. 119.12. This statute provides that the trial court may affirm the agency's order complained of in the appeal if, after considering the entire record, the court finds that the order is supported by reliable, probative, and substantial evidence, and is in accordance

with law. R.C. 119.12; *Pons v. Ohio State Med. Bd.*, 66 Ohio St.3d 619, 621, 1993-Ohio-122. On appeal, courts must defer to the Board's interpretation of the technical and ethical requirements of that profession. *Id.* at syllabus.

{¶5} Our review is even more limited than that of the trial court because it is the trial court's function to examine the evidence. *Id.* The court of appeals' function is solely to determine whether the trial court abused its discretion—"not merely an error of judgment, but perversity of will, passion, prejudice, partiality, or moral delinquency." *Id.* Furthermore, neither we, nor the trial court may substitute our judgment for that of the Board. See *id.* (citing *Lorain City Sch. Dist. Bd. of Ed. v. State Emp. Relations Bd.* (1988), 40 Ohio St.3d 257, 260–61).

DUE PROCESS

{¶6} The first two assignments of error are procedural, in that they claim that the Board violated Dr. Griffin's due-process rights by waiting so long after the alleged violations to bring formal accusations against him. We will therefore address these assigned errors together.

{¶7} One of the fundamental principles of due process is that it is considered procedurally unfair to allow the state to bring charges against an individual long after the individual committed the alleged wrongful acts. See generally *U.S. v. McDonald* (1982), 456 U.S. 1, 7, 102 S.Ct. 1497 (noting that delays before indictment may give rise to a general due process violation, but do not violate the speedy trial clause of the Sixth Amendment). This is why most crimes have statutes of limitations. In Ohio, excluding murder, the state must prosecute most crimes (felonies) within six years. See R.C. 2901.13; see also *State v. Selvage*, 80 Ohio St.3d 465, 467, 1997-Ohio-287.

{¶8} This case is, of course, *not* a criminal prosecution, but rather a professional disciplinary proceeding by an administrative agency. The Board derives its authority to conduct its disciplinary proceeding from R.C. 4731.22(B)(6), which provides:

The board, by an affirmative vote of not fewer than six members, shall, to the extent permitted by law, limit, revoke, or suspend an individual's certificate to practice * * * for one or more of the following reasons:

* * *

(6) A departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established[.]

{¶9} There is no per se statute of limitations in R.C. 4731.22. We have held that administrative agencies must give licensees a fair hearing and determination as expeditiously as possible under the circumstances, but we have never imposed a per se time limitation upon an agency. See, e.g., *Gourmet Beverage Center, Inc. v. Ohio Liquor Control Comm.*, 10th Dist. No. 01AP-1217, 2002-Ohio-3338, ¶25 ("[I]t is the duty of an administrative agency to hear matters pending before it without unreasonable delay and with due regard to the rights and interests of the litigants."). Agencies are free to set their own parameters regarding time limitations, but this is purely voluntary. One court of appeals opined that when an administrative agency *does not* have a self-imposed time limitation for prosecution, the agency might leave itself vulnerable to due process challenges such as this one. See *Mowery v. Ohio St. Bd. of Pharmacy* (Sept. 30, 1997), 11th Dist. No. 96-G-2005, 1997 WL 663505, at *4, n.1. Thus, when evaluating a due-process argument within the context of an agency's delay in bringing formal accusations against a professional license holder, there is no precise standard. In the absence of a

specified time limit, we focus our analysis on whether the licensee suffered any material prejudice as a result of the agency's delay. See, e.g., *Smith v. State Med. Bd. of Ohio* (July 19, 2001), 10th Dist. No. 00AP-1301, 2001 WL 811839, at *5 ("[W]e find that appellant failed to demonstrate how he has been materially prejudiced by the Board's delay, and that the trial court did not abuse its discretion by rejecting the affirmative defense of laches.").

{¶10} The crux of Dr. Griffin's due-process argument centers not on any prejudice that he may have suffered, but on the Board's "unjustified delay." (Appellant's brief, at 7.) Further, he argues that the common pleas court applied the wrong standard to his due-process argument—that the court instead considered the doctrines of laches and estoppel, which he argues are separate and distinct from due process: "Laches is an equitable doctrine that discourages parties from sitting on their rights. * * * 'The purpose of equitable estoppel is to prevent actual or constructive fraud[,] and to promote the ends of justice.' " (Appellant's brief, at 10, citing *Ohio State Bd. of Pharmacy v. Frantz*, 51 Ohio St.3d 143, 145.) Regardless of the origins of these two principles, they exist to protect the fundamental fairness of our judicial system, much like due process. Moreover, regardless of which standard the common pleas court applied, Dr. Griffin has still failed to demonstrate any material prejudice.

{¶11} Absent demonstrating some material prejudice as a result of the Board's delay in bringing formal accusations against Dr. Griffin, we cannot hold that the Board violated his due process rights, or that the trial court abused its discretion by applying the wrong legal standard to the claimed due-process violation. We, therefore, overrule the first and second assignments of error.

RELIABILITY OF EXPERT TESTIMONY

{¶12} The third assignment of error is substantive, and concerns the merits of whether there was reliable, probative, and substantial evidence supporting the Board's disciplinary order against Dr. Griffin. Dr. Griffin argues that the evidence the Board relied upon was insufficient because the state's expert testimony was inherently unreliable, based on the experts' lack of familiarity with the relevant standard of care in the field of pain management. (See Appellant's brief, at 16.) We will examine the 3100-page transcript of the 17-day hearing before the Board (hereafter "Tr."), and specifically focus on the 136-page report and recommendation issued by Board hearing officer, R. Gregory Porter, filed on July 7, 2008 (hereafter "Report").

{¶13} Although the Board is not required to present expert testimony to support a charge against an accused physician, the charge must somehow be supported by reliable, probative, and substantial evidence. *In re Williams* (1991), 60 Ohio St.3d 85, syllabus. When the Board does present expert testimony, however, the expert must be capable of expressing an opinion in terms of the particular standard of care that applies to the physician whose license is at issue. *Lawrence v. State Med. Bd. of Ohio* (Mar. 11, 1993), 10th Dist. No. 92AP-1018, 1993 WL 69476, at *3. In civil litigation, the legislature has enacted a statutory provision that a person is not competent to testify unless they practice in the "same or a substantially similar specialty as the defendant." R.C. 2743.43(A)(3). "The court shall not permit an expert in one medical specialty to testify against a health care provider in another medical specialty unless the expert shows both that the standards of care and practice in the two specialties are similar and that the expert has substantial familiarity between the[m]." *Id.* The rationale behind this rule is

that just because a medical expert is well-educated and well-credentialed does not necessarily mean that the expert should be qualified as an expert in every medical field. See, e.g., *Valentine v. Conrad*, 110 Ohio St.3d 42, 2006-Ohio-3561, ¶17 ("[E]ven a qualified expert is capable of rendering scientifically unreliable testimony.").

{¶14} The experts at issue in this case are Thomas Chelimsky, M.D., and Bashar Katirji, M.D., who are purportedly world-renowned in the field of neurology. (See Appellee's brief, at 6.) According to the hearing examiner's report, the pain management field has two differing philosophical foundations, one rooted in neurology, the other rooted in anesthesia. This is supported in part by the fact that three separate certifying boards "offer subspecialty certification in pain medicine: the American Board of Anesthesiology, the American Board of Psychiatry and Neurology [ABPN], and the American Board of Physical Medicine and Rehabilitation." (Report, at 23.) Dr. Chelimsky testified that all three boards use the same certifying exam. *Id.*

{¶15} Prior to his training in pain management, Dr. Griffin was board certified in emergency medicine in 1988. He was later certified by the American Academy of Pain Management in 2001, and certified with a subspecialty in pain medicine by the American Board of Anesthesiology in 2004. Since 2003, Dr. Griffin has been the president and owner of Interventional Pain Solutions, in Columbus, Ohio. His practice is solely devoted to interventional pain management. (Report, at 14.)

{¶16} Dr. Chelimsky was board certified in internal medicine in 1986 by the American Board of Electrodiagnostic Medicine in 1992, in neurology and neurophysiology by the ABPN in 1992 and 1994 respectively, and in pain management by the ABPN in 2000. (Report, at 17.)

{¶17} Dr. Katirji was board certified in neurology and neurophysiology by the ABPN in 1985 and 1992 respectively, by the American Board of Electroencephalography in 1985, by the American Association of Electrodiagnosis and Electromyography in 1986, and by the American Board of Electrodiagnostic Medicine in 1990. (Report, at 16.) Dr. Katirji is not certified in any area of pain management, or physical medicine and rehabilitation, and he testified that he does not practice in the field of interventional pain management. (Report, at 17.)

{¶18} Dr. Katirji opined that he is an expert in somatosensory evoked potentials (SSEPs), which are studies that involve stimulating nerves in the limbs and recording nerve activity from the spine to the brain. (Tr. 1016.) SSEPs are performed by placing electrodes on nerves at the base of the neck and on the fingers. (Tr. 1017–18.) Then, the practitioner sends an electric current through the nerves and documents the nerve response. Dr. Katirji stated that although SSEPs may indicate an abnormality along the nerve route, there is no way for the doctor to pinpoint the problem. His conclusion, thus, was that SSEPs have no ability to identify the source of pain, and that there is no medical reason for a physician to conduct these tests.

{¶19} Dr. Katirji specifically reviewed the records of those of Dr. Griffin's patients referenced in the Board's allegations, and his general conclusion was that neither Dr. Griffin nor W. David Leak, M.D., the fellowship's program director, specifically indicated why they performed SSEPs and other similar tests on each patient. (Report, at 27.) Dr. Katirji's belief was that for each new patient presenting radiating pain, Drs. Griffin and Leak simply ordered a standard battery of tests that included SSEPs. See *id.* "In summary, I find that Drs. [Leak and Griffin] practiced below minimal standards of care by

performing unnecessary electrodiagnostic testing for no apparent clinical reason in most of their patients." (Report, at 28.) Despite this generalized conclusion, Dr. Katirji stated that the original test data for the patients was not available, and that he was only able to review tabulated charts of the data. See *id.* at 27–28. The report does not state whether the reason the original test data was unavailable was in any way attributable to the length of time that had passed since the tests were administered.

{¶20} In response to the Board's expert testimony, Dr. Griffin argues that although well qualified in neurology, Drs. Chelimsky and Katirji were not qualified to render reliable expert opinions regarding the diagnosis, management, and treatment of the interventional pain patients at issue. (Appellant's brief, at 17.)

The opinions of Dr. Chelimsky and Dr. Katirji reflected the general consensus of neurologists on the use of * * * pain medications, and various injections to diagnose and treat pain. Using their neurology approach, [they] testified that a needle EMG is always necessary in conjunction with nerve conduction studies in the diagnosis of rad[ating pain], that STCs are not reproducible, reliable, or valid, and that SSEPs are not effective in the diagnosis of rad[ating pain], and have no ability to identify pain.

Id. at 18 (quoting Tr. 1024–25, 1142–43, 1154, 1584–94).

{¶21} Another of the Board's witnesses, Mark V. Boswell, M.D., Ph.D., explained, however, how the viewpoints and philosophies of neurologists and anesthesiologists differ in the field of pain medicine:

The neurology approach is more medication and less intervention. Anesthesiology has always been more interventional in the sense of doing nerve blocks and stimulators and pumps, things like that.

Dr. Boswell went on to explain that he worked with Dr. Chelimsky for 15 years, and would have interdisciplinary meetings so they could discuss patients and work together because they had different approaches. They did not always agree on approaches, but they always had a good plan for the patients that they co-managed. (Tr. 43–45.)

{¶22} Dr. Boswell was also board certified in pain medicine by the American Board of Anesthesiology in 1993, and by the American Board of Pain Medicine in 1995, and 2004. (Report, at 22.) At the time of the hearing, Dr. Boswell was Professor and Chair of the Department of Anesthesiology, and Director of the Messer Racz Pain Center at the Texas Tech University Health Sciences Center in Lubbock, Texas. The pain medicine program at Texas Tech is one of the top ten programs of its kind in the country. Id.

{¶23} Dr. Boswell further stated that regardless of the different approaches taken by him in comparison with Dr. Chelimsky, both physicians' treatments were within the standard of care. Id. Perhaps if Dr. Chelimsky had been practicing alongside Dr. Griffin, they would have co-managed their patients in a similar manner.

{¶24} Dr. Griffin also proffered expert testimony at the Board's hearing. James P. Bressi, D.O., was board certified in anesthesiology by the American Osteopathic Board of Anesthesiology in 1993, with a qualification in pain management in 1996, and was also certified by the American Academy of Pain Management. (Report, at 19.) David R. Longmire, M.D., was certified by the American Academy of Pain Management in 1982, and by the American Board of Electroencephalography and Neurophysiology in 1989, and Gary W. Jay, M.D., who graduated from Northwestern University Medical Center in

1976, and has 25 years experience in the private practice of pain medicine. At the time of the hearing, Dr. Jay was the medical director for pain at Schwarz Biosciences.

{¶25} The trial court found that there was "no dispute as to any of [the] experts' qualifications." (February 4, 2009 Decision, at 12.) The trial court also found that "[a]ll of the experts appeared highly qualified and well-versed in the arena of pain management." *Id.* Although the trial court recognized the two contrasting philosophies in pain medicine, the court did not attempt to explain or reconcile the differences in testimony proffered by the experts from a neurological background versus the experts from an anesthesiology background. Indeed, the trial court did not have to reconcile the two because the trial court's analysis centered on two issues: (1) was the Board's decision in accordance with law?; and (2) was the Board's decision based upon reliable, substantial, and probative evidence? The decision as to which medical philosophy is more appropriate for pain management is best left to the medical professionals, not appellate judges or trial court judges sitting in an appellate role on an administrative appeal. This is the clear indication of *Pons*, *supra*.

{¶26} As noted above, the trial court was supposed to review the record in this case, and determine whether there was reliable, probative, and substantial evidence to support the Board's action. The trial court having found that there was such evidence in the record, our review is limited to whether the trial court abused its discretion in so finding. This is a difficult standard to overcome, and was not overcome here.

{¶27} The evidence clearly demonstrates that there were two types of expert witnesses in this case: Some of the experts were highly trained in neurology. The other

experts were experienced and highly-credentialed pain medicine doctors, with backgrounds in anesthesiology. *Lawrence*, at *3; *Valentine*, at ¶17.

{¶28} The trial court considered the disparity in qualifications among the experts in this case. The trial court then found:

Based upon the evidence presented[,] the Hearing Officer came to the conclusion that the [sic] Dr. Griffin's treatment of 23 patients violated the minimum standard of care * * * includ[ing] subjecting patients to unnecessary tests[,] and in some cases an extraordinary number of tests. The Hearing Officer found that Dr. Griffin had done so without documenting the necessity for those tests and without heed to abnormal results when abnormal results were obtained. * * *

(Decision, at 9.) These findings were clearly supported by the witnesses called by the Board. It is not our place to substitute our judgment for that of the Board (or the trial court).

{¶29} After reviewing the evidence in this case, we conclude that the trial court did not abuse its discretion in finding that there was reliable, probative, and substantial evidence supporting the Board's order. Accordingly, we overrule the third assignment of error.

{¶30} Having overruled all three assignments of error, we affirm the judgment of the Franklin County Court of Common Pleas.

Judgment affirmed.

BRYANT and CONNOR, JJ., concur.

IN THE COMMON PLEAS COURT OF FRANKLIN COUNTY, OHIO

W. DAVID LEAK, M.D.

Appellant,

vs.

STATE OF OHIO, OHIO STATE
MEDICAL BOARD,

Appellee.

CASE NO. 2008-CVF 08-012288

JUDGE G. REECE, II

2009 NOV 23 AM 12:32
CLERK OF COURTS

COMMON PLEAS COURT
FRANKLIN CO. OHIO

DECISION AND ENTRY GRANTING MOTION TO EXTEND STAY OF
OHIO STATE MEDICAL BOARD ORDER OF AUGUST 13, 2008

Rendered this 20th day of November, 2009. Reece, J.

This matter came before the Court on Motion of Appellant. The Appellant seeks for this Court to Extend the current Stay of the Ohio State Medical Board pending the decision on the merits of this administrative appeal.

R.C. §119.12 provides, in pertinent part,

In the case of an appeal from the state medical board or state chiropractic board, the court may grant a suspension and fix its terms if it appears to the court that an unusual hardship to the appellant will result from the execution of the agency's order pending determination of the appeal and the health, safety, and welfare of the public will not be threatened by suspension of the order. This provision shall not be construed to limit the factors the court may consider in determining whether to suspend an order of any other agency pending determination of an appeal.

In this case, the Court finds that Appellant would suffer an unusual harm and the health, safety, and welfare of the public will be threatened without a suspension of the order during this appeal.

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[Handwritten signature]

IN THE COMMON PLEAS COURT OF FRANKLIN COUNTY, OHIO

W. DAVID LEAK, M.D.

CASE NO. 2008-CVF 08-012288

Appellant,

JUDGE G. REECE II

vs.

STATE OF OHIO, OHIO STATE
MEDICAL BOARD,

Appellee.

RECEIVED
BY *wd 9-9-08*

DECISION AND ENTRY GRANTING MOTION FOR STAY OF
OHIO STATE MEDICAL BOARD ORDER OF AUGUST 13, 2008

Rendered this 9th day of September, 2008. Reece, J.

This matter came before the Court on a hearing held September 8, 2008, and the briefs filed by the parties. The Appellants seek for this Court to Stay an order of the Ohio State Medical Board pending this administrative appeal.

R.C. §119.12 provides, in pertinent part,

In the case of an appeal from the state medical board or state chiropractic board, the court may grant a suspension and fix its terms if it appears to the court that an unusual hardship to the appellant will result from the execution of the agency's order pending determination of the appeal and the health, safety, and welfare of the public will not be threatened by suspension of the order. This provision shall not be construed to limit the factors the court may consider in determining whether to suspend an order of any other agency pending determination of an appeal.

In this case, the Court finds that Appellant would suffer an unusual harm and the health, safety, and welfare of the public will not be threatened by suspension of the order during this appeal. Pursuant to O.R.C. 119.12, this Order shall terminate not more than fifteen months after the date of the filing of a notice of appeal in the court of common pleas, or

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CLERK OF COURTS
FRANKLIN COUNTY, OHIO

upon the rendering of a final decision or order in the appeal by the court of common pleas, whichever occurs first.

The motion for Stay of the Medical Board's August 13, 2008 Order in Case No. 2008-CVF 08-012288 is GRANTED.

IT IS SO ORDERED.



Judge Guy Reece II

Copies to:

Douglas Graff
Appellant's Attorney

Kyle Wilcox
Asst. AG for State Medical Board

**IN THE COMMON PLEAS COURT OF FRANKLIN COUNTY, OHIO
AND
BEFORE THE OHIO STATE MEDICAL BOARD**

W. DAVID LEAK, M.D.)	CASE NO. _____
)	
Appellant,)	JUDGE _____
vs.)	
)	
STATE OF OHIO, OHIO STATE MEDICAL BOARD,)	CATEGORY _____
)	
Appellee.)	

STATE MEDICAL BOARD
2008 AUG 25 P 3:50

NOTICE OF APPEAL

William David Leak, M.D. ("Dr. Leak"), Appellant, hereby gives Notice of Appeal on questions of law and fact to the Court of Common Pleas, Franklin County, Ohio, pursuant to Chapter 119 of the Ohio Revised Code from the Decision of the Ohio State Medical Board ("Board") dated August 13, 2008, (mailed August 15, 2008) against Dr. Leak. A copy of the Board Order is attached hereto as Exhibit A.

The grounds for the appeal and the errors complained of, known as of this time, are as follows:

I. The Decision of the Ohio State Medical Board should be reversed on the basis that the Decision is not supported by reliable, probative and substantial evidence and is not otherwise in accordance with law, both factually and on the basis of unqualified witnesses;

II. Appellant was denied substantive due process in violations of the Ohio and United States Constitutions when the State knowingly presented evidence to the Board that included information outside of the charges set forth in the citation issued against the Appellant;

III. The Appellant was denied substantive due process under both the Ohio and the United States Constitutions when the citation of claims against Appellant deliberately included information for which there was no claim of wrongdoing, but was done solely for the purpose of improperly influencing the Board;

IV. Appellant was denied substantive due process rights under Ohio and the United States Constitutions when the Board considered factors beyond the Notice of Opportunity of Hearing sent to Appellant, and outside of the hearing record, during the Board's deliberation of the Report and Recommendation of the Hearing Examiner;

V. Appellant was denied substantive due process rights under the Ohio and Federal Constitutions when the State offered multiple hearsay statements in evidence before the Board, which was considered over objections by Appellant;

VI. Appellant was denied substantive due process rights and equal protection under the Ohio and United States Constitutions when the Board failed to consider the Motions of Appellant, and the Rulings of the Hearing Examiner, as required by Board's own Administrative Rules and the Ohio Revised Code, prior to consideration of the Report and Recommendation of the Hearing Examiner.

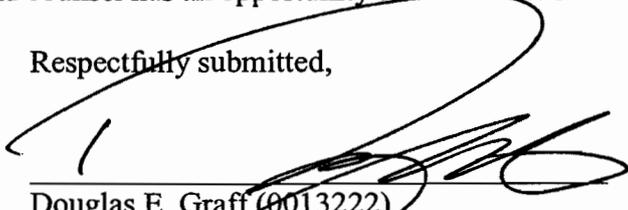
VII. Appellant was denied substantive due process rights and equal protection when the Board reviewed similar conduct as that alleged against Appellant as specified within the Combined hearing with two other Medical Board licensees, and imposed a penalty unwarranted by the evidence, and substantially disproportionate from the Dismissal of the Charge against one practitioner, and the imposition of a Probationary sanction against the other practitioner, based upon the identical factual situation.

VIII. Further, and without limiting the generality of the foregoing, Appellant contends that the Entry of Order and the related investigation and hearing conducted by the Board violated the protections afforded to the Appellant pursuant to the Constitution

of the State of Ohio and the Constitution of the United States including, without limitation, the due process and equal protection rights thereof.

Appellant reserves the right to add additional assignments of error and grounds for appeal, factually and under the Ohio Administrative Code, the Ohio Revised Code, the Ohio Constitution and the United States Constitution, once the transcript of proceedings has been completed and counsel has an opportunity to review the record.

Respectfully submitted,



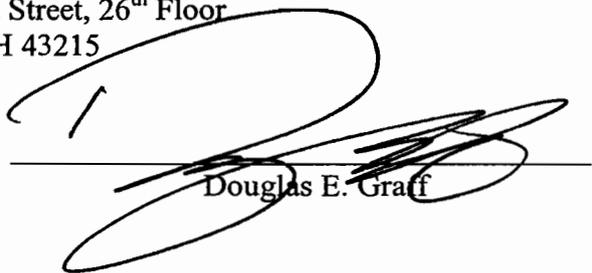
Douglas E. Graff (0013222)
GRAFF & ASSOCIATES, LPA
694 East Rich Street
Columbus, Ohio 43215-5341
(614) 228-5800
(614) 228-8811 (Fax)
Doug@Grafflaw.com
Counsel for Appellant, W. David Leak, M.D.

STATE MEDICAL BOARD
2008 AUG 25 P 3:50

CERTIFICATE OF SERVICE

I hereby certify that the original of this NOTICE OF APPEAL was delivered to the Ohio State Medical Board, 30 East Broad Street, Third Floor, Columbus, OH 43215 on the 25 day of Aug, 2008. I further certify that a true and accurate copy of the foregoing NOTICE OF APPEAL was sent by regular U.S. mail, postage prepaid, on the on the 25th day of Aug, 2008 to:

Kyle Wilcox, Esq.
Assistant Attorney General
Office of the Attorney General
Health and Human Services Div.
30 East Board Street, 26th Floor
Columbus, OH 43215



Douglas E. Graff

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



August 13, 2008

William David Leak, M.D.
99 N. Brice Road, Suite 270
Columbus, OH 43213

Dear Doctor Leak:

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 August 13, 2008, 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 setting forth the Order appealed from and the grounds of the appeal must be commenced by the filing of an original Notice of Appeal with the State Medical Board of Ohio and a copy of the Notice of Appeal with the Franklin County Court of Common Pleas. 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

A handwritten signature in black ink, appearing to read "Lance A. Talmage", with a circled "P" at the end.

Lance A. Talmage, M.D.
Secretary

LAT:jam
Enclosures

CERTIFIED MAIL NO. 91 7108 2133 3934 3690 5951
RETURN RECEIPT REQUESTED

CC: Douglas E. Graff, Esq.
CERTIFIED MAIL NO. 91 7108 2133 3934 3690 5968
RETURN RECEIPT REQUESTED

Mailed 8-15-08

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 Attorney Hearing Examiner; and excerpt of draft Minutes of the State Medical Board, meeting in regular session on August 13, 2008, 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 William David Leak, M.D., 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)

August 13, 2008

Date

BEFORE THE STATE MEDICAL BOARD OF OHIO

IN THE MATTER OF

*

*

WILLIAM DAVID LEAK, M.D.

*

ENTRY OF ORDER

This matter came on for consideration before the State Medical Board of Ohio on August 13, 2008.

Upon the Report and Recommendation of R. Gregory Porter, State Medical Board Attorney 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 William David Leak, M.D., to practice medicine and surgery in the State of Ohio shall be PERMANENTLY REVOKED.

This Order shall become effective thirty days from the date of mailing of notification of approval by the Board. In the thirty day interim, Dr. Leak shall not undertake the care of any patient not already under his care.

(SEAL)



Lance A. Talmage, M.D.
Secretary

August 13, 2008

Date

REPORT AND RECOMMENDATION 2008 JUL -7 A 8: 32
IN THE MATTER OF WILLIAM DAVID LEAK, M.D.

The Matter of William David Leak, M.D., was heard by R. Gregory Porter, Hearing Examiner for the State Medical Board of Ohio, on May 14 through 18, 21, 23 through 25, and June 11, 12, 14, 15, and 18 through 21, 2007.¹

INTRODUCTION

Basis for Hearing

By letter dated August 9, 2006, the State Medical Board of Ohio [Board] notified William David Leak, M.D., that it had proposed to take disciplinary action against his certificate to practice medicine and surgery in Ohio. The Board based its proposed action on allegations pertaining to Dr. Leak's treatment of Patients 1 through 24 as identified on a confidential Patient Key, his alleged aiding and abetting a podiatrist to unlawfully practice medicine and surgery, and/or his alleged failure to notify his patients of his lack of malpractice insurance coverage. The Board alleged that Dr. Leak's conduct constitutes:

- “[a] departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established,’ as that clause is used in Section 4731.22(B)(6), Ohio Revised Code”;
- “[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 2923.03, Ohio Revised Code, Complicity, to wit: Section 4731.41, Ohio Revised Code, Practice of medicine or surgery without certificate. Pursuant to Section 4731.99(A), Ohio Revised Code, violation of Section 4731.41, Ohio Revised Code, constitutes a felony offense”; and/or
- “failure to provide notice to, and receive acknowledgment of the notice from, a patient when required by section 4731.143 of the Revised Code prior to providing nonemergency professional services, or failure to maintain that notice in the patient’s file,’ as that clause is used in Section 4731.22(B)(30), Ohio Revised Code.”

The Board advised Dr. Leak of his right to request a hearing, and received his written request for hearing on September 5, 2006. (State Exhibits 54C, 54G)

¹ The hearing in this matter was presented in conjunction with the matters of Brian Frederic Griffin, M.D., and Kyle Elliott Hoogendoorn, D.P.M. Nevertheless, a separate Report and Recommendation was prepared for each individual.

Appearances

Nancy Hardin Rogers, Attorney General, by Damion M. Clifford and Kyle C. Wilcox, Assistant Attorneys General, for the State.

Douglas E. Graff, Esq., for Dr. Leak.

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EVIDENCE EXAMINED

Testimony Heard

A. Presented by the State

- Mark V. Boswell, M.D.
- Kyle E. Hoogendoorn, D.P.M., as upon cross-examination
- David Shawn McCafferty
- Murray Kopelow, M.D.
- W. David Leak, M.D., as upon cross-examination
- Brian F. Griffin, M.D., as upon cross-examination
- Bashar Katirji, M.D.
- Thomas C. Chelimsky, M.D.

B. Presented by the Respondents

- David R. Longmire, M.D.
- Richard Weiner, D.P.M.
- Kyle E. Hoogendoorn, D.P.M.
- James P. Bressi, D.O.
- Todd C. Loftus, D.P.M.
- Andrew Thomas, M.D.
- David S. Bastawros, D.P.M.
- W. David Leak, M.D.
- Gary W. Jay, M.D.
- Brian F. Griffin, M.D.

Exhibits Examined

(Exhibits marked with an asterisk [*] have been sealed to protect confidentiality.)

A. Presented by the State

* State's Exhibits 1 through 24: Copies of medical records for Patients 1 through 24.

* State's Exhibit 26: Patient Key.

State's Exhibits 27 and 27A: Curriculum vitae of Thomas C. Chelimsky, M.D.

* State's Exhibits 28 and 29: Copies of written reports prepared by Dr. Chelimsky dated January 31, 2005, and May 2, 2006, respectively.

State's Exhibit 30: Curriculum vitae of Bashar Katirji, M.D.

* State's Exhibit 31: Copy of August 8, 2006, report prepared by Dr. Katirji.

State's Exhibit 32: Copy of August 31, 2001, letter to Board enforcement staff from Murray Kopelow, M.D., Chief Executive, Accreditation Council for Continuing Medical Education [ACCME], Chicago, Illinois.

State's Exhibit 33: Copy of document published on the Internet by the Accreditation Council for Graduate Medical Education [ACGME] entitled Section II: Essentials of Accredited Residencies in Graduate Medical Education, printed October 18, 2001, <<http://www.acgme.org/GmeDir/Sect2.asp>>.

State's Exhibit 36: Excerpt from transcript of August 17, 2001, Board investigative deposition of Dr. Leak.

State's Exhibit 41: Copy of Dr. Leak's responses to the Board's Second Set of Interrogatories.

State's Exhibit 42: Copy of Dr. Leak's responses to the Board's Third Set of Interrogatories.

State's Exhibits 44 and 44A: Copies of current and previous versions of Section 4731.51, Ohio Revised Code, Defining Practice of Podiatric Medicine and Surgery.

State's Exhibit 45: Copy of April 7, 2001, letter to Dr. Hoogendoorn from Dr. Leak, and attached materials concerning the fellowship offered by Pain Control Consultants.

State's Exhibit 46: Curriculum vitae of Mark V. Boswell, M.D., Ph.D.

State's Exhibit 47: Section 4731.41, Ohio Revised Code, Practicing Medicine without Certificate

State's Exhibits 48A and 48B: Previous versions of Section 4731.143, Ohio Revised Code, Notice of Lack of Coverage of Medical Malpractice Insurance, as effective April 10, 2001, and December 30, 2004, respectively.

State's Exhibit 49: Section 2923.03, Ohio Revised Code, Complicity.

State's Exhibit 53: Copy of April 27, 2007, letter to Damion M. Clifford, Assistant Attorney General, from Dr. Chelimsky, with portions redacted.

State's Exhibits 54A through 54WWW: Procedural exhibits. [State's Exhibits 54JJ and 54KK have been sealed to protect patient confidentiality.]

State's Exhibit 55: Printed copy of April 2, 2007, email from Mr. Clifford to counsel for Drs. Leak, Griffin, and Hoogendoorn.

State's Exhibit 57: Copy of document published on the Internet by the American Board of Medical Specialties [ABMS] concerning Dr. Griffin's board certification, indicating that he has been certified in Emergency Medicine by the American Board of Emergency Medicine, and that he holds subspecialty certification in Pain Medicine from the American Board of Physical Medicine and Rehabilitation, printed June 4, 2007, <<http://www.abms.org/searchdetail.asp?key=323675>>.

State's Exhibit 58: Copy of document published on the Internet by the ABMS concerning the American Board of Anesthesiology and the specialty and subspecialty certifications it offers, printed June 4, 2007, <http://www.abms.org/Who_We_Help/Consumers/About_Physician_Specialties/anesthesiolo... [remainder of citation not included in original]>.

State's Exhibit 59: Copy of document published on the Internet by the ABMS concerning Dr. Leak's board certification, indicating that he has been certified in Anesthesiology by the American Board of Anesthesiology, printed June 4, 2007, <<http://www.abms.org/searchdetail.asp?key=57133>>.

State's Exhibit 60: State's Closing Argument. [This exhibit was marked by the Hearing Examiner and admitted post-hearing.]

State's Exhibit 61: State's Rebuttal Argument. [This exhibit was marked by the Hearing Examiner and admitted post-hearing.]

B. Presented by the Respondent

Respondents' Exhibit 103H: Curriculum vitae of Kyle E. Hoogendoorn, D.P.M.

Respondents' Exhibit 104H: Curriculum vitae of W. David Leak, M.D.

Respondents' Exhibit 105A-G: Curriculum vitae of Brian F. Griffin, M.D.

Respondents' Exhibit 106G: Curriculum vitae of James Patrick Bressi, D.O.

Respondents' Exhibit 109H: Curriculum vitae of David S. Bastawros, D.P.M.

Respondents' Exhibit 110H: Course Curriculum published by the Ohio College of Podiatric Medicine concerning the four-year curriculum and the five-year extended curriculum, <http://www.ocpm.edu/students/course_curriculum/> (March 19, 2007).

Respondents' Exhibit 111H: Copy of January 1999 *CPME 320: Standards, Requirements, and Guidelines for Approval of Residencies in Podiatric Medicine*, approved by the Council on Podiatric Medical Education [CPME], October 1998.

Respondents' Exhibits 112H and 112aH: Copy and original of October 1999 *CPME 330: Procedures for Approval of Residencies in Podiatric Medicine*, approved by the Council on Podiatric Medical Education [CPME], October 1999.

Respondents' Exhibit 114H: Copy of an April 7, 2001, letter to Dr. Hoogendoorn from Dr. Leak.

Respondents' Exhibit 115H: Copy of Pain Net Inc.'s Fellowship Guidelines for Pain Control Consultants.

Respondents' Exhibits 117H and 118H: Copies of letters to Dr. Hoogendoorn from Vincent J. Hetherington, D.P.M., Vice President and Dean of Academic Affairs, OCPM.

Respondents' Exhibit 119H: Copy of September 19, 2001, Memorandum of Affiliation between The Ohio College of Podiatric Medicine and Pain Control Consultants, Inc.

Respondents' Exhibit 121H: Copy of January 8, 2002, letter to Dr. Leak from Alan Tinkleman, Director, CPME.

Respondents' Exhibit 122H: Copies of various certificates of Dr. Hoogendoorn.

Respondents' Exhibit 156: Copy of March 21, 2007, written report of Gary W. Jay, M.D.

Respondents' Exhibit 157: Copy of the written report of David R. Longmire, M.D.

Respondents' Exhibit 165: Curriculum vitae of Dr. Jay.

Respondents' Exhibit 201: Copies of documents from a seminar entitled "Prescription Paradigm Shift: Kroger Pharmacy and Pain Net," offered by Pain Net, Inc., Pain Control Consultants, Inc., and Kroger Pharmacies on February 13, 2002.

Respondents' Exhibit 202: Copy of document entitled "Building Blocks of Evidence Based Medicine," from Pain Net Technology, LLC.

Respondents' Exhibit 203: Copy of JRRC Application for New Fellowship Program.

Respondents' Exhibit 213L: Longmire D.R.: "An Electrophysiological Approach to the Evaluation of Regional Sympathetic Dysfunction: A Proposed Classification." *Pain Physician* 2006;9:69-82, 2006.

Respondents' Exhibit 214: Ochoa, J.L.: "Chronic Pains Associated with Positive and Negative Sensory, Motor, and Vasomotor Manifestations: CPSMV (RSD;CRPS?). Heterogeneous Somatic Versus Psychopathologic Origins." <<http://mitpress.mit.edu/e-journals/JCN/articles/002/Ochoa.html>> (August 14, 1997).

Respondent's Exhibit 214L: Curriculum Vitae of Dr. Longmire.

Respondents' Exhibits 215 and 215A: Copies of documents from a seminar entitled "Clinical Development for Chronic Pain Therapeutics," offered by Marcus Evans Conferences on March 29 and 30, 2007.

Respondents' Exhibit 216: Luis Garcia-Larrea, *Handbook of Clinical Neurology, Volume 81, 3rd Series, Neurophysiological Examinations in Neuropathic Pain, Chapter 30, Evoked Potentials in the Assessment of Pain.* (Elsevier B.V., 2006)

Respondents' Exhibit 217: Burneo, J.G., Barkley, G.L.: "Somatosensory Evoked Potentials: Clinical Applications." <<http://www.emedicine.com/neuro/topic344.htm>> (May 23, 2007).

Respondents' Exhibit 218: Copies of various certification documents for Dr. Leak.

Respondents' Exhibits 219 through 221: Closing arguments of Drs. Griffin, Hoogendoorn, and Leak, respectively. [Note: These exhibits were marked and admitted by the Hearing Examiner post-hearing.]

C. Presented by the Hearing Examiner

Board Exhibit A: June 27, 2007, Entry establishing schedule for filing written closing arguments.

Board Exhibit B: Copy of the Respondents' joint motion to extend time for filing written closing arguments.

Board Exhibit C: Copy of September 13, 2007, Entry granting the Respondents' motion to extend time for filing written closing arguments.

Board Exhibit D: Copy of the Respondents' second joint motion to extend time for filing written closing arguments.

Board Exhibit E: Copy of September 28, 2007, Entry granting the Respondents' second joint motion to extend time for filing written closing arguments.

Board Exhibit F: Transcript of April 24, 2007, pre-hearing conference.

Board Exhibit G: Copy of the State's October 9, 2007, emailed request to extend time for filing rebuttal closing argument, and responses.

Board Exhibit G1: Copy of October 10, 2007, Entry granting the State's request for an extension of time.

Board Exhibit H: Patient Key conversion chart for the Master Patient Key (Board Exhibit I) and Dr. Katirji's written report.

Board Exhibit I: Master Patient Key which cross references the patient numbers used in Dr. Leak's notice letter (which is identical to the Master Patient Key), Dr. Griffin's notice letter (which differs from the patient numbers used in the Master Patient Key and Dr. Leak's notice letter), and Dr. Hoogendoorn's notice letter (which differs from the patient numbers used in the Master Patient Key, Dr. Leak's notice letter, and Dr. Griffin's notice letter).

PROFFERED EXHIBITS

The following documents were neither admitted to the record nor considered as evidence. However, they have been sealed from public disclosure and will be held as proffered material:

State's Exhibit 25: Copies of Dr. Leak's billing records. (See Hearing Transcript [Tr.] at 2019-2022)

State's Exhibit 43: Copy of the Board's May 13, 1998, Position Paper concerning the Delegation of Medical Tasks. (See Tr. at 2044-2045)

State's Exhibits 50 through 52: Excerpts from the Ohio Administrative Code. (See Tr. at 2051-2055)

State's Exhibit 53: Unredacted April 27, 2007, letter to Mr. Clifford from Dr. Chelimsky. (See Tr. at 2055-2062)

Respondents' Exhibit 113H: Copy of a March 22, 2001, letter to Dr. Hoogendoorn from Dr. Leak. (See Procedural Matters 3.d, below.)

Respondents' Exhibit 120H: Copy of October 29, 2001, letter to the Joint Residency Review Committee [JRRC] from Dr. Leak. (See Procedural Matters 3.e, below.)

PROCEDURAL MATTERS

1. On August 9, 2006, the Board issued notices of opportunity for hearing to Dr. Leak, Dr. Griffin, and Dr. Hoogendoorn. Each requested a hearing. Subsequently, by Entry dated October 12, 2006, and with the agreement of all parties, the matters of Dr. Leak, Dr. Griffin, and Dr. Hoogendoorn were consolidated for purposes of the administrative hearing. (State's Exhibits 54A, 54B, 54C, 54E, 54G, 54L, and 54BB)
2. The record in this matter was held open until October 15, 2007, to give the parties an opportunity to file written closing arguments. These documents were timely filed and admitted to the record as State's Exhibits 60 and 61, and Respondents' Exhibits 219 through 221.
3. At hearing, the final determination regarding the admissibility of the following exhibits was deferred:
 - a. St. Ex. 32: This exhibit was to be admitted on the condition that it had been identified at hearing by Murray Kopelow, M.D. (Hearing Transcript [Tr.] at 2032-2035) The hearing record indicates that Dr. Kopelow identified the document. (Tr. at 359) Accordingly, the document is admitted to the hearing record.
 - b. St. Ex. 33: This document was to be removed from the record if all witnesses agreed that there was no ACGME²-approved fellowship available in pain management until 2002. If any witness testified to the contrary, the document was to be admitted to the hearing record. (Tr. at 2032-2035) The hearing record indicates that Mark V. Boswell, M.D., testified that the pain medicine fellowship at Case Western Reserve University School of Medicine had obtained ACGME accreditation in 1996 through the American Board of Anesthesiology. (Tr. at 18) Accordingly, this document is admitted to the hearing record.
 - c. St. Ex. 36: This exhibit was to be admitted on the condition that it was used by the State for the purpose of impeaching Dr. Leak's testimony. (Tr. at 2035-2041) The hearing record indicates that pages 93 through 106 of this document had been used by the State for that purpose. (Tr. at 416-423, 471-473) Accordingly, pages 1, 2, and 93-106 of this document are admitted to the hearing record. (This ruling concerns the admissibility of the document only and does not reflect the Hearing Examiner's opinion concerning the success or lack of success of the State's effort to impeach.)

² Accreditation Council for Graduate Medical Education.

- d. Respondent's Exhibit 113H: This document was to be admitted on the condition that it had been referenced during hearing. (Tr. at 3120-3121) The Hearing Examiner could find no reference to this exhibit in the hearing record. Accordingly, it will be removed from the record and held as proffered material for the Respondents.
 - e. Respondent's Exhibit 120H: This document was to be admitted on the condition that it had been referenced during hearing. (Tr. at 3123-3124) The Hearing Examiner could find no reference to this exhibit in the hearing record. Accordingly, it will be removed from the record and held as proffered material for the Respondents.
4. Dr. Leak made an objection at hearing, and the ruling was deferred. (See Tr. at 951-952) The objection is overruled. Mr. Clifford's characterization of Dr. Griffin's previous testimony during his questioning of Dr. Longmire was accurate. (See Tr. at 663-665)
 5. Any other objections where rulings were deferred are hereby overruled. Further, any motions to strike where rulings were deferred are hereby denied.

SUMMARY OF THE EVIDENCE

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

Background Information – Respondents

W. David Leak, M.D.

1. W. David Leak, M.D., obtained his medical degree in 1979 from the Wake Forest University, Bowman-Gray School of Medicine, in Winston-Salem, North Carolina. From 1979 through 1980, Dr. Leak participated in a rotating internship in the Department of Anesthesia at the Ohio State University Hospitals in Columbus, Ohio. From 1981 through 1983, Dr. Leak participated in a residency in anesthesiology at the Hospital of the University of Pennsylvania in Philadelphia, Pennsylvania. From 1983 through 1984, Dr. Leak participated in a clinical and research fellowship in cardiovascular and regional anesthesia and pain management at that same institution. Finally, from April through June 1984, Dr. Leak completed his fellowship at the Pain Control Center at the University of Cincinnati in Cincinnati, Ohio. (Respondent's Exhibit [Resp. Ex.] 104H at 1; Hearing Transcript [Tr.] at 380-381, 2680-2683)

Dr. Leak's curriculum vitae states that, in 1984, he was certified in anesthesiology by the American Board of Anesthesiology. In 1992, Dr. Leak became a diplomate of the American Board of Pain Medicine. In 1993, Dr. Leak was awarded a certificate of added

qualifications in pain medicine from the American Board of Anesthesiology.³ In 1995, Dr. Leak became a fellow of the American Academy of Pain Management. (Resp. Ex. 104H; Tr. at 2683-2685)

Dr. Leak testified that he has published articles and book chapters on the subject of pain management, and has made numerous presentations and lectures on that subject throughout his career. (Resp. Ex. 104H; Tr. at 2691)

2. From 1984 through the time of the hearing, Dr. Leak has been the Medical Director of Pain Control Consultants, Inc., [PCC], in Columbus, Ohio, where he practices interventional pain medicine. (Resp. Ex. 104H; Tr. at 2687) From approximately 1998, through Pain Control Consultants, Inc., Dr. Leak ran a fellowship in pain management. Dr. Leak testified that the PCC fellowship is currently inactive and has “not taken a fellow for quite a few years.” (Tr. at 408; Tr. at 2689)

Dr. Leak testified that he currently holds privileges at Morrow County Hospital. Dr. Leak further testified that Morrow County Hospital is located about 30 minutes north of the “Polaris” development in southern Delaware County, north of Columbus, Ohio. Dr. Leak indicated that he does not have privileges at any hospital in Columbus, stating:

Hospitals [in Columbus] usually require physicians who are anesthesiologists to be part of the anesthesia department. They don't have what's known as open staff. And most of the anesthesiologists that do pain end up working either out of their offices or at hospitals where they have open staff. Morrow County has open staff.

(Tr. at 2897-2898)

Brian F. Griffin, M.D.

3. Brian F. Griffin, M.D., obtained his medical degree in 1978 from the University of Cincinnati College of Medicine. From 1978 to 1979 he participated in a one-year internship at Good Samaritan Hospital in Cincinnati, Ohio. Dr. Griffin testified that he did not participate in a residency. He was licensed to practice medicine and surgery in Ohio in 1979. (Resp. Ex. 105a-g at 12; Tr. at 634-635, 2978)

Dr. Griffin testified that, following his internship, he completed a year of training in hospital administration where he “served as a liaison between the medical staff and hospital administration at Providence Hospital in Cincinnati.” Dr. Griffin then became the Director of the Emergency Department at Adams County Hospital where he practiced emergency medicine for two years. He then moved to Portsmouth where he practiced emergency medicine at both Scioto Memorial and Mercy Hospitals for two years. Next, Dr. Griffin moved to Columbus where he practiced emergency medicine at Grant Hospital, Riverside

³ Dr. Leak testified that he has not recertified his added qualifications in pain medicine, and that it expired in 2003. (Tr. at 2684, 3145-3146)

Hospital, Doctors North Hospital, and Doctors West Hospital. In 1994, Dr. Griffin took a position in the emergency department at Columbus Community Hospital [CCH]. Dr. Griffin testified that he had worked in the emergency department at CCH for four years. (Tr. at 634-640)

Dr. Griffin testified that, while he was employed at CCH, Dr. Leak had offered to him a position in an unaccredited pain medicine fellowship at PCC, where Dr. Leak was the owner and medical director. Dr. Griffin testified that he had accepted the offer, entered the fellowship in 1999, and completed two years of fellowship. Dr. Griffin testified that, after his fellowship ended in 2001, he had continued as an employee of PCC until 2003. In December 2003, Dr. Griffin left PCC and opened his own practice of pain medicine in Hilliard, Ohio. (Resp. Ex. 105a-g; Tr. at 640-641, 633, 644, 2978-2979)

4. Dr. Griffin testified that, since late 2003, he has been the president and owner of Interventional Pain Solutions in Columbus. Dr. Griffin testified that Interventional Pain Solutions is “a practice solely devoted to patients in pain, and I do both the clinical side of pain management and the surgical side of pain medicine or management, depending on what phrase you like.” Dr. Griffin testified that his practice employs two registered nurses, a licensed practical nurse, a medical assistant, a front desk clerk, and an office manager. Dr. Griffin further testified that he has over 1,200 patient charts on file, although not all of those patients are active. (Tr. at 2988-2990)

Dr. Griffin testified that he draws patients from all over Ohio, but primarily from Franklin County and nearby counties. However, Dr. Griffin testified that he has patients from other states as well, and has one patient from Florida. When asked why a patient would travel from Florida to see him, Dr. Griffin replied that he has more fellowship training than many other pain physicians. Dr. Griffin further testified that he knows some physicians in Florida who are familiar with his practice and refer patients to him. (Tr. at 2990-2991)

5. Dr. Griffin was certified by the American Board of Emergency Medicine in 1988 and recertified in 1998. In 2001, Dr. Griffin was certified by the American Academy of Pain Management. (Resp. Ex. 1051a-g)

Dr. Griffin’s curriculum vitae states that, in 2004, Dr. Griffin was certified by the American Board of Anesthesiology with subspecialty certification in pain medicine. (Resp. Ex. 105a-g at 1) However, a document presented by the State indicates that Dr. Griffin actually holds subspecialty certification in pain medicine from the American Board of Physical Medicine and Rehabilitation [ABPMR]. (State’s Exhibit [St. Ex.] 57) Dr. Griffin denied that he holds his subspecialty certification through the ABPMR, and that that had just been the board through whom he had taken the certification examination. Nevertheless, Dr. Griffin acknowledged that he does not hold subspecialty certification through the American Board of Anesthesiology. (Tr. at 3088-3090)

Dr. Griffin testified that all of his certifications are current. (Tr. at 2980-2981)

6. Dr. Griffin testified that he writes and publishes extensively. (Resp. Ex. 105a-g; Tr. at 2994-2995)
7. Dr. Griffin testified that, since 2001, he has been the executive director for the medical team at the annual Arnold Schwarzenegger Classic. (Resp. Ex. 105a-g at 2; Tr. at 2985-2986)
8. Dr. Griffin testified that, aside from his medical practice, from 1981 to 2002 he had worked about 20 hours per week as a volunteer deputy for the Adams County Sheriff's Department. Dr. Griffin further testified that, for three of those years, he had worked as a squad leader for the S.W.A.T. team of the Delaware County Sheriff's Office. (Resp. Ex. 105a-g at 10; Tr. at 2979-2980, 2983-2984)

Kyle E. Hoogendoorn, D.P.M.

9. Kyle Elliott Hoogendoorn, D.P.M., obtained his podiatric medical degree in 1997 from the Ohio College of Podiatric Medicine in Cleveland, Ohio. From 1997 through 1998, Dr. Hoogendoorn participated in a primary podiatric medical residency at Richmond Heights Hospital⁴ in Richmond Heights, Ohio. Subsequently, from August 2000 to February 2003, Dr. Hoogendoorn participated in a pain management fellowship through PCC. (Resp. Ex. 103H; Tr. at 81-84, 411, 2181-2182)

Since 1997, Dr. Hoogendoorn has been licensed by the Board to practice podiatric medicine and surgery in Ohio. (Resp. Ex. 103H)

10. Dr. Hoogendoorn has been certified by the American Board of Orthopedic and Primary Podiatric Medicine and the American Academy of Wound Management. (Resp. Ex. 103H)

In addition, Dr. Hoogendoorn testified that he has been certified by the American Academy of Pain Management, and that he sits on the academy's committee for continuing education. Dr. Hoogendoorn noted that M.D.s, D.O.s, D.P.M.s, and dentists who practice pain management are eligible for membership in that organization, and that they all take the same certifying examination. (Tr. at 2215-2216)

11. Dr. Hoogendoorn currently practices at Pro-Active Wound Care Clinics, Inc., in Hilliard, Ohio, and the Foot and Ankle Health Center, Inc., in Grove City, Ohio. (Resp. Ex. 103H)

Background Information – Expert Witnesses

Bashar Katirji, M.D.

12. Bashar Katirji, M.D., testified as an expert on behalf of the State. Dr. Katirji obtained his medical degree in 1977 from the University of Aleppo in Aleppo, Syria. From 1977 through 1980, Dr. Katirji trained in internal medicine in the Middle East. From 1980

⁴ Dr. Hoogendoorn testified that Richmond Heights Hospital is now known as PHC-Mt. Sinai East Hospital. (Tr. at 82-83)

through 1983, Dr. Katirji participated in a neurology residency at the University Health Center of Pittsburgh in Pittsburgh, Pennsylvania. Finally, from 1983 through 1984, Dr. Katirji participated in a fellowship in electromyography at The Cleveland Clinic Foundation in Cleveland, Ohio. (St. Ex. 30 at 1-3; Tr. at 987)

In 1985, Dr. Katirji was certified in neurology by the American Board of Psychiatry and Neurology and, in 1992, he obtained added qualifications in clinical neurophysiology from the same board. In addition, Dr. Katirji was certified by the American Board of Electroencephalography in 1985, by the American Association of Electrodiagnosis and Electromyography in 1986, and by the American Board of Electrodiagnostic Medicine in 1990. (St. Ex. 30 at 3; Tr. at 989-991)

Dr. Katirji has held several academic appointments in the United States beginning in 1984. He is currently Professor of Neurology at the Case Western Reserve University School of Medicine [CWRU] in Cleveland, Ohio, and a Lecturer in the Department of Medicine at the Ohio College of Podiatric Medicine, also located in Cleveland. In addition to his academic appointments, Dr. Katirji currently holds several hospital appointments at University Hospitals of Cleveland: Director of the Electromyography Laboratory, Chief of the Neuromuscular Division, Program Director of Clinical Neurophysiology, and Director of the Muscle Disease Center. In addition, he is a member of the attending staff in the Department of Neurology. (St. Ex. 30 at 1-2; Tr. at 988-989)

13. Dr. Katirji holds medical licenses in Ohio and Pennsylvania. (Tr. at 991)
14. Dr. Katirji testified that his work is about 80 percent clinical in nature. (Tr. at 991-992)
15. Dr. Katirji testified that he does not administer trigger point injections, joint injections, or nerve block injections. Dr. Katirji further testified that he does not prescribe opioid medication to patients. Moreover, Dr. Katirji testified that he does not practice in the field of interventional pain management. (Tr. at 1002-1004)

Thomas C. Chelimsky, M.D.

16. Thomas C. Chelimsky, M.D., testified as an expert on behalf of the State. Dr. Chelimsky obtained his medical degree in 1983 from Washington University in St. Louis, Missouri. From 1983 through 1986, Dr. Chelimsky participated in a residency in internal medicine at the Mayo Clinic in Rochester, Minnesota and, from 1986 through 1989, he participated in a residency in neurology at the same institution. In addition, from 1986 through 1987, Dr. Chelimsky participated in a fellowship in autonomic research at the Mayo Clinic. Finally, from 1989 through 1990, Dr. Chelimsky participated in a six-month fellowship in electromyography at the same institution. (St. Ex. 27A; Tr. at 1487-1491)

Dr. Chelimsky was certified by the American Board of Internal Medicine in 1986 and by the American Board of Electrodiagnostic Medicine in 1992. He was also certified in neurology by the American Board of Psychiatry and Neurology [ABPN] in 1992. Subsequently, in 1994, Dr. Chelimsky obtained an added qualification in clinical neurophysiology from the

ABPN and, in 2000, he obtained an added qualification in pain management from the ABPN. (St. Ex. 27A; Tr. at 1491-1493)

Since 1990, Dr. Chelimsky has served in academic capacities at CWRU and is currently a Professor of Neurology. In addition, since 1990, Dr. Chelimsky has been a member of the attending staff, a member of the staff at the EMG laboratory, and Director of the Division of Autonomic Disorders at University Hospitals of Cleveland. In addition, from 1994 through 2000 and from 2001 through 2004, Dr. Chelimsky was Director of the Pain Center at University Hospitals of Cleveland. (St. Ex. 27A; Tr. at 1499)

17. Dr. Chelimsky testified that, as director of the pain center, he had supervised an active fellowship program in pain medicine. The fellows were usually neurologists, and they were trained in both interventional and non-interventional techniques.⁵ (Tr. at 1508)
18. Dr. Chelimsky has participated in many presentations and lectures throughout the United States and has authored numerous articles and book chapters. (St. Ex. 27A)
19. Dr. Chelimsky has been licensed to practice medicine in Ohio since 1990. (Tr. at 1491)
20. Dr. Chelimsky testified that about 50 percent of his current medical practice consists of pain management and the other 50 percent consists of evaluating patients in the autonomic laboratory and doing research in that area. Dr. Chelimsky noted that he performs all his work as a member of the faculty at CWRU and that he has no private practice. (Tr. at 1493-1494, 1498)
21. Dr. Chelimsky testified that he has taught podiatric students; however he has not worked with podiatric students or residents in a clinical setting. (Tr. at 1557-1560)

Dr. Chelimsky's Pain Medicine Practice

22. Dr. Chelimsky testified that, from 1994 through 2004, with the exception of one year between 2000 and 2001, he had directed the Pain Center at University Hospitals of Cleveland. Dr. Chelimsky further testified:

The Pain Center is no longer in existence. It was an interdisciplinary center that included anesthesiology, neurology, and psychology, as well as P.T. and O.T. And the amount of money being spent on rehabilitating the patients with this—it was a very intense program, five days a week, eight hours a day, for four weeks. And the insurers were no longer paying for that kind of support, so the hospital administration decided to, to use a polite term, axe it.

⁵ Dr. Chelimsky testified that interventional pain medicine techniques include any kind of injection, such as nerve blocks, as well as radiofrequency lesioning and surgical procedures. (Tr. at 1506)

(Tr. at 1499) Dr. Chelimsky testified that Mark V. Boswell, M.D., an anesthesiology-trained pain management physician who also testified during the hearing, had done most of the anesthesiology work for the Pain Center. (Tr. at 1500)

23. Dr. Chelimsky testified that he currently has a grant that allows him “to teach primary care physicians the management of chronic pain and to support them with ancillary services.” Dr. Chelimsky testified that he goes to the physicians’ offices, asks the physicians to choose two of their most difficult chronic pain patients, and teaches them how to manage the chosen patients. Dr. Chelimsky further testified that he has a team that consists of physical therapists, an occupational therapist, and a psychologist that works closely with the physicians. (Tr. at 1496-1497)

Dr. Chelimsky testified that he teaches all aspects of pain management, including interventional pain management. Dr. Chelimsky further testified that the interventional techniques that he performs are trigger point injections, injections into the bursa, and local nerve injections. (Tr. at 1506-1507)

Dr. Chelimsky testified that, in conjunction with his education program, he currently performs approximately two nerve blocks, three trigger point injections, and one joint injection per month. (Tr. at 1548)

24. Dr. Chelimsky testified that, in addition to his education program, he also runs a clinic that includes an anesthesiologist and a psychologist to treat patients who suffer from complex regional pain syndrome (formerly called reflex sympathetic dystrophy). (Tr. at 1498)

James P. Bressi, D.O.

25. James P. Bressi, D.O., testified as an expert on behalf of the Respondents. Dr. Bressi obtained his osteopathic medical degree in 1987 from the Ohio University College of Osteopathic Medicine. From 1987 to 1988, he participated in a rotating internship at Warren General Hospital (St. Joseph Health Center) [Warren General] in Warren, Ohio. From 1988 to 1989, Dr. Bressi worked as an emergency department staff physician at Warren General. From 1989 to 1992, Dr. Bressi participated in an anesthesiology residency at Warren General. In 1992, Dr. Bressi participated in a six month pain medicine fellowship at the University of Rochester Medical Center, Strong Memorial Hospital, in Rochester, New York. Dr. Bressi is currently the Director of the Falls Pain Management Center at Cuyahoga Falls General Hospital in Cuyahoga Falls, Ohio, and has served in that capacity since 1998. (Resp. Ex. 106G)

Dr. Bressi was certified in Anesthesiology by the American Osteopathic Board of Anesthesiology in 1993, and obtained added qualifications in pain management from that board in 1996. Dr. Bressi was also certified by the American Academy of Pain Management. (Resp. Ex. 106G)

26. Dr. Bressi testified that he has lectured, and continues to lecture, on the subject of interventional pain management. Dr. Bressi further testified that he has written on the subject as well. (Resp. Ex. 106G; Tr. at 2259-2260)

Dr. Bressi's Pain Medicine Practice

27. Dr. Bressi testified that his current practice as the director of Falls Pain Management Center is devoted entirely to the treatment of chronic pain, "both interventional and pain medicine." He explained that "[i]nterventional pain medicine requires a specialist trained for more invasive-type procedures" such as placement of spinal cord stimulators or intrathecal or spinal pumps, spinal blocks, and injections such as trigger point injections and peripheral nerve blocks. (Resp. Ex. 106G at 2; Tr. at 2250-2253)

Dr. Bressi testified that, besides himself, his practice consists of a partner who is also an interventionalist, a family doctor, two physician assistants, a nurse practitioner, many nurses and medical assistants, and clerical staff. He further testified that his practice is "blended into the hospital pain clinic[.]" Dr. Bressi testified that a large physical therapy/ occupational therapy facility is across the hall from the pain clinic. (Tr. at 2255-2257)

28. Dr. Bressi testified that the pain center currently serves 6,000 patients, and draws patients from the Akron area and from three counties around Summit County. Dr. Bressi testified that he treats patients ranging from 18 years old to 102, and that all suffer from chronic pain that impacts their lives in a negative way. Dr. Bressi stated that most of his patients are employed and need treatment to allow them to continue working and being productive. (Tr. at 2250, 2255-2256)
29. Dr. Bressi testified that residents and medical students from the area hospitals rotate through his pain center. In addition, Dr. Bressi testified that nurses and pharmacists come to the pain center for lectures and to observe. (Tr. at 2260-2261)
30. Dr. Bressi testified that about 90 percent of his time involves the clinical care of patients. (Tr. at 2262-2264)

David R. Longmire, M.D.

31. David R. Longmire, M.D., testified as an expert on behalf of the Respondents. Dr. Longmire obtained his medical degree in 1980 from the McMaster University School of Medicine and Health Sciences in Hamilton, Ontario. From 1980 through 1981, he participated in an internship at McMaster University Health Sciences Centre; from 1981 through 1982, he participated at the PGY-2 level in a Pediatric/Adult Neurology residency at the University of Toronto/Hospital for Sick Children and Toronto Western Hospital; from 1982 through 1983, he participated at the PGY-3 level in a Pediatric Neurology residency at the University of Toronto/Hospital for Sick Children; and from 1983 through 1984, he participated at the PGY-4 level as an Adult Neurology Clinical Research Fellow at the Clinical Institute of the Addiction Research Foundation, Department of Medicine, University of Toronto. (Resp. Ex. 214L)

Dr. Longmire is a Clinical Associate Professor in the Department of Internal Medicine at the University of Alabama at Birmingham-Huntsville Regional Medical Campus. He is also a Consulting Neurologist at Helen Keller Hospital in Sheffield, Alabama; an Attending Neurologist at Russellville Hospital in Russellville, Alabama; and is engaged in the private practice of neurology, clinical neurophysiology, and pain management. (Resp. Ex. 214L)

Dr. Longmire was certified by the American Academy of Pain Management in 1982, and by the American Board of Electroencephalography and Neurophysiology in 1989. (Resp. Ex. 214L)

32. Dr. Longmire noted that he has published widely, including in peer-reviewed publications, and that he has authored textbook chapters on the subject of selective tissue conductance [STC]. Dr. Longmire noted that his most recent article concerns methods for classifying abnormalities of sympathetic sudomotor dysfunction. The article was published in 2006 in *Pain Physician*. (Resp. Exs. 213L, 214L; Tr. at 859-860)

Dr. Longmire further testified that he had co-authored chapters in Weiner's Textbook of Pain Management, along with Dr. Mark V. Boswell and Dr. Gary W. Jay. (Tr. at 861)

33. Dr. Longmire testified that neither the American Academy of Pain Management or the American Board of Electroencephalography and Neurophysiology is recognized by the American Board of Medical Specialties [ABMS]. (Tr. at 923)

Dr. Longmire testified that he is not board certified in neurology. (Tr. at 923)

Gary W. Jay, M.D.

34. Gary W. Jay, M.D., testified as an expert on behalf of the Respondents. Dr. Jay testified that he had obtained his medical degree in 1976 from Northwestern University Medical Center. Dr. Jay participated in an internship and residency in neurology at that same institution in 1980, and spent the next 25 years in the private practice of pain medicine. (Tr. at 2808)

Dr. Jay testified that he is currently the medical director for pain at Schwarz Biosciences and has been so employed for two and one-half years. Dr. Jay noted that he is no longer engaged in the clinical care of patients. However, Dr. Jay stated that he supervises clinical research. (Tr. at 2807-2809)

Dr. Jay testified that he is currently licensed to practice medicine in Florida, Ohio, Nebraska, and Colorado. (Tr. at 2808)

35. Dr. Jay is a member of several certifying boards, although he testified that none are ABMS-approved. Among these, Dr. Jay became a diplomate of the American Academy of Pain Management in 1992, and became a fellow of the American Academy of Pain Medicine in 1996. (Resp. Ex. 165 at 9; Tr. at 2809-2810)

36. Dr. Jay has published extensively, including authoring three medical textbooks, a large number of book chapters, and articles. Dr. Jay has also spoken at numerous presentations and medical meetings. (Resp. Ex. 165; Tr. at 2810-2812)

Background Information – Fact Witness – Mark V. Boswell, M.D., Ph.D.

37. Mark V. Boswell, M.D., Ph.D., testified as a fact witness on behalf of the State. In 1982, Dr. Boswell obtained a Doctor of Philosophy degree in experimental pathology from CWRU in Cleveland, Ohio. In 1984, he obtained a medical degree from CWRU. From 1984 through 1985, he participated in a general surgery categorical internship at the Oregon Health Sciences University in Portland, Oregon. From 1985 through 1987, he participated in an anesthesiology residency at CWRU. Finally, from 1987 through 1988, Dr. Boswell participated in a fellowship in anesthesiology in “Clinical Scientist Track (Neuroscience)” at CWRU. (St. Ex. 46; Tr. at 12)

Dr. Boswell was certified by the American Board of Anesthesiology in 1988, and he obtained subspecialty certification in pain medicine from the same board in 1993. Further, in 1995, Dr. Boswell was certified by the American Board of Pain Medicine, for which he recertified in 2004. Finally, in 2005, Dr. Boswell became a Fellow in Interventional Pain Practice. (St. Ex. 46)

Dr. Boswell testified that he is licensed to practice medicine in Ohio, Texas, Oregon, and Arizona. (Tr. at 17)

38. Since 1988, Dr. Boswell has held academic appointments. These include academic appointments at CWRU and University Hospitals of Cleveland from 1990 through 2005. In 1990, Dr. Boswell joined the faculty as an Assistant Professor and Chief of the Pain Medicine Service in the Department of Anesthesiology. Further, in 1996, he obtained appointments as Associate Professor in the Department of Anesthesiology and Director of the Pain Medicine Fellowship. In 2005, Dr. Boswell left CWRU and University Hospitals of Cleveland for Texas Tech University Health Sciences Center in Lubbock, Texas. At the time of the hearing, Dr. Boswell was Professor and Chair of the Department of Anesthesiology and Director of the Messer Racz Pain Center at that institution. (St. Ex. 46)
39. Dr. Boswell testified concerning the interventional pain management program at Texas Tech University. Dr. Boswell testified that the founding chairman of the Department of Anesthesiology at Texas Tech had been Gabor Racz, M.D. Dr. Boswell testified that Dr. Racz “was the founding chairman, I believe, in about 1977, and he was a pioneer in pain medicine and anesthesiology.” Dr. Boswell further testified:

[Dr. Racz] was involved in, as far as I could tell, in the same pain medicine community that ultimately founded the American Board of Pain Medicine, was involved with that group and with Dr. Leak as well. * * * [Dr.] Racz developed a well recognized pain medicine program at Texas Tech, lectured widely * * * and developed an international following with the program.

(Tr. at 37)

40. Dr. Boswell testified that the pain medicine program at Texas Tech is one of the top ten pain medicine programs in the country. (Tr. at 38)

Subspecialty Certification in Pain Medicine

41. Three ABMS-member certifying boards offer subspecialty certification in pain medicine: the American Board of Anesthesiology, the American Board of Psychiatry and Neurology, and the American Board of Physical Medicine and Rehabilitation. However, Dr. Chelimsky testified that the same certifying examination is used by each board. (Tr. at 1536-1537)

Dr. Leak's Medical Practice: PCC and Pain Net

Pain Control Consultants

42. From 1984 through the time of the hearing, Dr. Leak was the Medical Director of Pain Control Consultants, Inc. [PCC] (Resp. Ex. 104H at 5)
43. Dr. Leak testified that his practice is limited to "pain medicine and pain management[]." Dr. Leak further testified, "given my background and training, the emphasis is on interventional methodologies, but we do offer a balanced service for our patients." (Tr. at 2688)
44. Dr. Griffin testified that "interventional pain management" refers to the treatment of pain with invasive modalities such as epidural injections, nerve blocks, and partial nerve destruction. (Tr. at 2986-2987)

Testimony of Dr. Leak Regarding the PCC Fellowship Program

45. Dr. Leak testified that during his career he had gained a reputation for his ability to diagnose and treat patients with "otherwise intractable painful conditions." He stated that physicians from all over the country had come to Columbus to observe his work. Dr. Leak further testified that, in the early 1990s, he along with others formed organizations called Pain Net and Pain Net Education, which he described as "a network to communicate with physicians." (Tr. at 2694-2695)

Dr. Leak testified that "[t]he dearth of knowledge about [pain] medicine needed to be filled, so we wanted to have some didactic information. So we first embarked on looking at procedure-based training. We would teach people how to do a procedure and how to do that procedure right * * *." However, Dr. Leak testified that it had been ineffective. Dr. Leak stated that they had physicians come in, do a "weekend warrior course," and then return to their practices and perform procedures "on people that they had no business operating on* * *." Accordingly, Dr. Leak testified that, around 1991 or 1992, he and Dr. Longmire developed an outline for fellowship training in pain medicine. That

eventually became the 75-page Pain Net Fellowship Guidelines for Pain Control Consultants [Fellowship Guidelines]. Finally, Dr. Leak testified that the PCC began a fellowship program in around 1998. (Resp. Ex. 115H; Tr. at 2695-2698)

46. Dr. Leak testified that fellows in the PCC program worked from 10 to 14 hours per day seeing patients, doing paperwork, and doing clinical research. Their duties also included reading a number of relevant journals and writing for publication. Further, their duties included making presentations during grand rounds. (Tr. at 2720, 2729-2730, 2733-2734)

Dr. Leak testified that his fellows worked very hard. Dr. Leak further testified:

It was not uncommon to hear statements such as, to work around there, you needed to be a cyborg. It was demanding and we had a lot of information to cover. The service demands were high. The academic and the didactic demands were high. And we had to make up for everything that had been missed [concerning the treatment of pain] in medical school, residency, and postgraduate experience.

(Tr. at 2721-2722)

47. Dr. Leak testified that the PCC fellowship program took approximately 14 months for a full-time fellow to complete because of the volume of material covered. Dr. Leak further testified that the curriculum was also designed for part-time fellows to complete in 36 months. (Tr. at 2699)
48. Dr. Leak testified that, during the time he offered the fellowship, which lasted through at least 2003, a total of about 12 fellows completed the program, including Dr. Griffin and Dr. Hoogendoorn. Dr. Leak testified that all but two of the fellows who completed the PCC fellowship obtained subspecialty certification in pain medicine from ABMS-approved boards. Dr. Leak noted that one fellow who did not, Dr. Hoogendoorn, did not meet ABMS requirements because he was a podiatrist; however, Dr. Hoogendoorn obtained certification from the American Academy of Pain Management. (Tr. at 2698, 2701-2703)
49. Dr. Leak testified that the PCC fellowship had not been accredited by the Accreditation Council for Graduate Medical Education [ACGME], and that he had not contacted the ACGME prior to establishing the PCC fellowship. However, Dr. Leak further testified that he had applied for and received accreditation from the Accreditation Council for Continuing Medical Education [ACCME] so that his fellows could get CME credit for grand rounds. (Tr. at 413-414, 2702, 2734-2735)

Testimony of Dr. Boswell Concerning Dr. Leak's Fellowship Program

50. Dr. Boswell testified that Pain Net had been a program created by Dr. Leak that included the leaders in pain medicine. Dr. Boswell further testified that he had first spoken at a Pain Net program in Dallas in 1995, and that he had been "honored to be in that program" because he

had been just an assistant professor at the time. Dr. Boswell testified that he has worked with Pain Net almost every year since that time. (Tr. at 41-42)

51. Dr. Boswell further testified that Dr. Leak had had a faculty appointment at CWRU which permitted CWRU's fellows to spend some time at Dr. Leak's facility. Dr. Boswell noted that Dr. Leak had sought to formally affiliate his program with CWRU; however, that never came to fruition. (Tr. at 25-28)

Dr. Boswell testified that he had thought that Dr. Leak had a good program. Moreover, Dr. Boswell testified that Dr. Leak "was doing some of the invasive techniques that are now fairly commonplace, actually. But he was doing them back in '96, so it was a very attractive opportunity for the residents." (Tr. at 29-30)

52. Dr. Boswell testified that Dr. Leak's program was not accredited. Dr. Boswell stated that both accredited and non-accredited pain medicine fellowship programs offer the same clinical training opportunities and level of education, but an accredited program allows the fellow to sit for the pain medicine subspecialty examination. Nevertheless, Dr. Boswell testified that there are "some potential advantages to a non-accredited program." He stated that more emphasis can be placed on interventional techniques and other areas of interest to someone focusing on interventional pain management. Dr. Boswell testified that, by contrast, "[w]e have to teach a lot of things in the accredited program that might be of, say, tangential interest to some residents." (Tr. at 50-52, 75)

Dr. Boswell testified that, other than obtaining board certification, the general purpose for taking a fellowship is to acquire additional knowledge and skills. Dr. Boswell stated that that can happen in both accredited and non-accredited programs. (Tr. at 78-79)

Dr. Griffin's Participation in the PCC Fellowship

53. According to Dr. Griffin, he had entered the PCC fellowship program in August 1999 and completed it two years later in 2001. (Tr. at 800, 3004) Dr. Griffin's participation in the fellowship will be described in greater detail later in this report.
54. Dr. Griffin testified that he did not have any ownership interest in PCC. (Tr. at 642)

Dr. Hoogendoorn's Participation in the PCC Fellowship

55. Dr. Hoogendoorn testified that he had entered the PCC fellowship in August 2000. He remained in the program until around November 2003. (Tr. at 2498, 2528)
Dr. Hoogendoorn's participation in the fellowship will be described in greater detail later in this report.

Allegations (1), (1)(c):

56. In its August 9, 2006, notice of opportunity for hearing, the Board alleged, in part, as follows:

Allegation (1):

From in or about November 1998 to in or about November 2001, in the routine course of [his] practice, [Dr. Leak] undertook the treatment of Patients 1 through 24 as identified on a confidential Patient Key. In treating Patients 1 through 24, [Dr. Leak] inappropriately utilized testing and/or failed to provide treatment in accordance with the minimal standards of care. [Specific allegations of such treatment were numbered (1)(a) through (1)(o).]

Allegation (1)(c):

[Dr. Leak] performed unnecessary testing including somatosensory evoked potentials, nerve conduction studies and/or “selective tissue conductance” studies [collectively, EDX studies] on Patients 1, 2, 4-6, 15-17 and 23. Further, [Dr. Leak] performed unnecessary testing including somatosensory evoked potentials and/or “selective tissue conductance” studies on Patients 7-9, 11-14, 18-20 and 22. Further, [Dr. Leak] improperly performed and/or caused to be improperly performed somatosensory evoked potentials testing. For example, the latencies purportedly observed for Patient 1 differ by far more than could be true clinically.

(St. Ex. 54C)

Electrodiagnostic [EDX] Studies – Background

57. Several of the allegations against Dr. Leak and Dr. Griffin concern the use of electrodiagnostic [EDX] studies; specifically: somatosensory evoked potentials [SSEP], nerve conduction studies [sometimes abbreviated as NCS], and selective tissue conductance [STC] studies. Moreover, Dr. Leak and Dr. Griffin are accused of failing to order, perform, or recommend needle electromyography [EMG] studies in conjunction with the nerve conduction studies performed. (St. Ex. 54C; St. Ex. 54A)
58. In his August 8, 2006, written report, Dr. Katirji stated that he had reviewed the records of 26 patients, which included two patients not referenced in the Board’s allegations against Drs. Leak and Griffin. Dr. Katirji’s review concerned the use by Dr. Leak and Dr. Griffin of SSEP and nerve conduction studies, and the lack of use of needle EMG, in the diagnosis and management of patients. Dr. Katirji stated, in part:

Most patients suffered from a chronic pain, mostly of spine origin, but others had joint pain, mostly knees and ankles. Only in about 1/3 of cases

[Patients 7-9, 11-14, 18-20, and 22]⁶ [do] the charts show that the patients suffered from radicular pain or signs of lumbar canal stenosis. * * * All had NCSs and dermatomal SSEPs on the upper extremities, lower extremities, and/or thoracic dermatomes.⁷ None had (or were referred for) a needle electromyography (EMG). * * *

After reviewing these charts, it was clear to me that the SSEP and NCS were done on all of these patients as part of a routine diagnostic testing. A common statement encountered in these charts is “We will plug him (her) into our very extensive diagnostic process.” Though spinal pain was [a] common complaint[] in many of these patients, only few had symptoms of cervical, thoracic or lumbar radiculopathy. In many patients, EDX tests were performed to evaluate two or three segments of spine (cervical, thoracic or lumbar) despite that the major complaint was to only one of these segments. These EDX tests were clearly performed with a “cookbook” approach as evidenced by identical[] SSEPs and NCSs done on all patients regardless of symptoms. * * * Dr. Leak, who interpreted the EDX tests, did not perform or recommend a needle EMG examination, the most essential EDX testing for the diagnosis of radiculopathy * * *.

* * * [N]one of the physician notes, in all the charts I reviewed, ever discussed the indication for these tests, More importantly, the physicians never commented on the results of these tests in their notes, nor did they act upon these results, even when they were reported to be significantly abnormal. In all the charts I reviewed, I found no indication of any change in the treatment or management of these patients based on the results of these EDX tests. It was clearly below minimal standards of care for these physicians to not reflect any need or indication for the EDX tests.

In a significant number of patients, the physician interpreting the EDX testing (mainly Dr. Leak) found abnormalities on SSEPs (and rarely on NCS, based on H-reflex studies) suggesting one or multiple radiculopathies. [As the raw test data was not available,] I only was able to review the tabulated charts of the results of these EDX tests, and I cannot comment on their accuracy. However, I was amazed to find that many of these patients [Patients 1, 3, 5-9, 11-14, 17-19, 21, and 22] had significantly abnormal dermatomal SSEPs, including those that evaluated the thoracic roots (Thoracic radiculopathies and thoracic disc herniations are extremely rare). This contradicts clinical experience or published studies that points to the fact that dermatomal SSEPs are insensitive for the diagnosis of radiculopathies. Despite these EDX abnormalities that were reported the treating physician failed to comment on these findings in his

⁶ Dr. Katirji’s patient numbers as used in his report differ from the Patient Key used during this hearing. For purposes of this Report and Recommendation, the patient numbers in Dr. Katirji’s report have been replaced by the appropriate patient number as set forth in the Master Patient Key. (St. Ex. 31; Board Exhibit H)

⁷ Dr. Leak testified to the effect that a dermatome is a distribution of peripheral nerves that originate from a single nerve root. (Tr. at 522-526)

notes, or act upon the results such as requesting needle EMG or changing his treatment plan.

In summary, I find that Drs. William David Leak and Brian F. Griffin practiced below minimal standards of care by performing unnecessary electrodiagnostic testing for no apparent clinical reason in most of their patients. In addition, they omitted the most sensitive electrodiagnostic testing (needle electromyography) in patients with clinical symptoms of radiculopathy. Most importantly, these physicians did not acknowledge or act upon the results of these tests, even when they were abnormal. It is clear to me from this review that they did not intend to use nor [did they utilize] the results of the studies to influence the management of their patients.

(St. Ex. 31)

59. Dr. Leak and Dr. Griffin testified that that they had used EDX studies not for diagnostic purposes, but to obtain objective evidence to support their patients' subjective complaints of pain. (Tr. at 563-569, 614-615, 660-661, 683-684, 696, 2794-2795, 2862-2864) For example, Dr. Leak testified why an EDX study that was performed on Patient 1 on July 23, 2001, had been necessary. Dr. Leak explained, "The patient complained subjectively of having pain, and we wished to determine whether there was an objective measure or evidence outside his verbal attestation that there was pathology that would be consistent with his complaint of pain." Dr. Leak added that the tests yielded some abnormal results. (Tr. at 563-565) Dr. Leak further testified:

If clinically we have determined we need to treat a person for pain and we live in a culture where treatment of pain is challenged frequently, the more objective data you have, the more comfortable one is with saying I have this objective information, I've got a positive MRI, I've got positive nerve studies, and I've got a positive physical exam, they all lead me to the same conclusion and I should treat this person.

(Tr. at 568) For another example, with regard to another EDX study performed on Patient 1, Dr. Griffin testified that the test had been performed because "there is no objective test for pain other than the electrophysiologic studies, with SSEP being the best." (Tr. at 659)

Testimony of Dr. Chelimsky

60. Dr. Chelimsky was asked at hearing to comment on testimony that Dr. Leak and Dr. Griffin had ordered or performed EDX studies for the purpose of obtaining objective evidence of pathology to support their patient's subjective pain complaints. Dr. Chelimsky replied that medical evidence shows that there are only two objective and valid measurements for pain: the visual analog scale and the McGill Pain Questionnaire. Dr. Chelimsky testified that both instruments "have been validated and shown to be excellent, reproducible measures of how much pain a person is having." Moreover, Dr. Chelimsky testified that both had been used

by Dr. Leak and Dr. Griffin, and should have been used in the treatment of these patients. (Tr. at 1608-1609)

Dr. Chelimsky testified that pain “is intrinsically a subjective experience. There is no test of any kind, even conceptually. How could one imagine a test that would tell us how much pain a person is having? It’s impossible.” Dr. Chelimsky testified that there are documented cases of patients who suffered from pain where no abnormal condition could be found until MRI came into existence. On the other hand, there are patients who have physical findings of many abnormalities but do not suffer from pain. Dr. Chelimsky testified that “the presence of physical findings doesn’t mean the patient is in physical pain and the absence of physical findings doesn’t mean the absence of pain.” (Tr. at 1609-1610)

EDX Studies – Somatosensory Evoked Potentials [SSEP]

Testimony of Dr. Katirji

61. Dr. Katirji testified that SSEPs are performed by applying electrical stimulation to a patient’s limb and recording the electrical stimulation conducted to the spine and brain. For example, the SSEP electrode would be placed over the patient’s wrist or fingers, and sensors would be placed over three locations: above the clavicle, spine, and brain. If the electrical signal is delayed in reaching the sensors, the physician tries to locate the area of the abnormality. Dr. Katirji testified: “You hope to localize it, but you’re not localizing it very accurately. You’re localizing it to a long segment of the pathway.” (Tr. at 1016-1018)
62. Dr. Katirji testified that SSEP had become available in the 1980s. Studies published in the late 1980s indicated that SSEP tests could be used to diagnose radiculopathy. In addition, prior to MRI becoming widely available, SSEP had been used to diagnose multiple sclerosis. However, by the mid 1990s, newer studies indicated that SSEP is not an effective tool for diagnosing radiculopathy. Dr. Katirji testified that SSEP was shown not to be effective in the diagnosing of radiculopathy due to false negative results. (Tr. at 1016-1019)

Dr. Katirji further testified that “there are several problems” with SSEP as a diagnostic tool. He stated that, for one thing, SSEP “only looks at latencies * * * and doesn’t look at the actual potential size.” Dr. Katirji explained that, even if 50 percent of the nerve bundle is damaged, the remaining 50 percent of the nerve that is still intact allows the electrical signal to travel at a normal speed, yielding a normal SSEP result. (Tr. at 1019)

Moreover, Dr. Katirji testified that, today, SSEP is “not used at all in most centers” to diagnose radiculopathy. He stated that, currently, SSEP is most often “used in the intraoperative monitoring of patients who are undergoing [cervical or thoracic] spinal cord surgery[.]” (Tr. at 1017, 1020)

Furthermore Dr. Katirji testified that SSEP is “never used” today to diagnose radiculopathy in the thoracic region. Dr. Katirji testified that thoracic radiculopathy and/or disc herniation is very rare, occurring in about one out of 50 cases in the general population of spine patients. This is true because the thoracic spine is rigid and not as prone to those maladies

as the cervical or lumbar spine, which are flexible. Finally, Dr. Katirji testified that thoracic disk herniations can be diagnosed only by using MRI. (Tr. at 1020, 1141, 1269-1270)

63. Dr. Katirji disagreed with Dr. Griffin's testimony that SSEP is the best objective test for pain. Dr. Katirji testified that SSEP studies "have no relevance to pain," and that there is "no correlation between the somatosensory and pain levels." Dr. Katirji likened it to comparing apples and oranges. (Tr. at 1025; See also Tr. at 659)
64. On cross-examination, Dr. Katirji acknowledged that some physicians continue to use SSEPs based upon earlier literature. (Tr. at 1181-1184)

Testimony of Dr. Chelimsky

65. Dr. Chelimsky testified that Dr. Leak's and Dr. Griffin's use of SSEPs on nerve roots for which no normal range is established had violated the standard of care. Dr. Chelimsky testified: "Any test without norms is below the standard of care. It's an experimental test by definition." (Tr. at 1921-1922)
66. Based upon the SSEP test forms used by Dr. Leak and Dr. Griffin, which were used for nearly all of the SSEP and nerve conduction studies performed on Patients 1 through 24, no normal ranges have been established for SSEP studies of the following:
 - C4 and C5;
 - T8, T10, and T12; and
 - L2 and L3.

(St. Exs. 1-24)

Testimony of Dr. Bressi

67. Dr. Bressi testified that he is familiar with SSEP testing. Dr. Bressi further testified that the tests can be used to find underlying pathology in the nerves and muscles that could underlie the patient's pain complaint. Dr. Bressi testified that he has not utilized SSEPs very often because, until recently, there was no one in his area who could perform them. (Tr. at 2332-2333, 2373-2375)
68. Dr. Bressi testified that there is literature for and against the use of SSEP testing. Dr. Bressi testified that the literature against it states that the test is not reliable "[b]ecause it's a skin-based diagnostic testing, and they feel that the skin electrodes may not be representative of what's going on in the deeper tissues that you're trying to analyze." (Tr. at 2934-2935)

Testimony of Dr. Leak

69. Dr. Leak testified that, for some nerve distributions for which no normal ranges of values have been established, the data obtained from one side is compared to the data obtained

from the contralateral side. If the difference between those values exceeds a certain amount, then the result is considered abnormal. (Tr. at 531-532)

70. Dr. Leak testified that SSEPs are still being utilized in pain management practice. Dr. Leak presented articles in support of his position. First, Dr. Leak presented an excerpt from the Handbook of Clinical Neurology, Vol. 81 (3rd Series) entitled *Neurophysiological Examinations in Neuropathic Pain, Chapter 30, Evoked Potentials in the Assessment of Pain*, authored by Luis Garcia-Larrea, M.D., Ph.D., and published by Elsevier B.V. in 2006. Dr. Leak testified that that article discusses the use of SSEPs in the practice of pain management. (Resp. Ex. 216; Tr. at 2883-2884)

Dr. Leak also presented an article entitled, *Somatosensory Evoked Potentials: Clinical Applications*, authored by Jorge G. Burneo, M.D., Ph.D., and Gregory L. Barkley, M.D., and published online at <<http://www.emedicine.com/neuro/topic344.htm>> (May 23, 2007). The printed article indicates that it had last been updated on September 28, 2006. Dr. Leak testified that that report indicates that SSEPs were being used in the practice of pain management in 2006. (Resp. Ex. 217; Tr. at 2885-2886)

Although the article does support the use of SSEPs to test the peripheral nervous system, it does not necessarily support Dr. Leak's use of SSEPs on the spinal cord and brain. With regard to the use of SSEPs to test the peripheral nervous system, the article states:

Peripheral nervous system

SEPs may be used in evaluation of the peripheral nervous system when traditional nerve conduction studies (NCSs) are not possible (for any reason) or are not reliable (eg, technical problems, or artifacts).

Peripheral neuropathy: SEPs rarely are used to assess peripheral neuropathy since standard NCSs are the test of choice. The stimulation is applied at 2 or more sites and the responses are recorded over the scalp. In the presence of polyneuropathies and mononeuropathies, SEP waveforms recorded over the scalp may be absent or show delayed latencies with normal central conduction velocities. In this way, SEPs can be used to measure the afferent fiber conduction velocities of proximal segments. Higher stimulation currents typically are required in patients with peripheral neuropathies. Use of SEPs has been reported for the following peripheral nerve disorders:

- Hereditary neuropathies (eg, Charcot-Marie-Tooth disease, Friedreich ataxia)
- Diabetic neuropathy
- Inflammatory polyradiculopathies, such as Guillain-Barré syndrome, particularly early in the course of the disease, when distal conduction and F-wave studies may be normal
- Infectious causes (eg, HIV)
- Toxic neuropathies

Focal neuropathy: The test of choice in focal neuropathy is standard NCSs. Entrapment neuropathies, such as carpal tunnel syndrome, may be found incidentally when SEPs are recorded. The use of SEP for detection of saphenous neuropathy, intercostal neuropathy, and trigeminal neuropathy has been reported. However, standard NCSs are the preferred diagnostic test for these conditions.

Plexopathy: SEPs are useful for evaluation of brachial plexopathy and traumatic plexopathies. In thoracic outlet syndrome, SEPs are of limited value with regard to the neurogenic variety of plexopathy and have no established value in diagnosis of the nonneurogenic (ie, vascular) variety. The value of SEPs in preventing or minimizing intraoperative damage of the peripheral nervous system is unproven.

Ventral rootlets and roots: Recent studies suggest that SEPs may have some utility in the evaluation of rootlet and root dysfunction. However, needle electromyography (EMG) provides superior information in these disorders and remains the test of choice.

Lumbosacral root disease: SEPs may have some utility in the evaluation of acute lumbosacral root disease or in lumbosacral spinal stenosis.

Thoracic root disease: No data are available.

Cervical root disease: EMG is the best neurophysiological tool for evaluation of this condition. SEPs may or may not have a limited role in these conditions.

(Resp. Ex. 217 at 2-3)

Testimony of Dr. Griffin

71. Dr. Griffin testified that, in his current practice, he had not ordered any SSEPs for about six months because the practitioner who had performed those tests for him passed away. When asked if he has since found anyone else to perform the tests for him, Dr. Griffin replied:

We have, but they have their way of doing it and it's not—it would help, but it's just not what I want out of the tests, and I don't—I think it would be a waste of patients' money to do a test that I don't want or I don't need.

(Tr. at 3084-3085)

Testimony of Dr. Boswell

72. Dr. Boswell testified that some clinicians use SSEP to determine if the patient has “a neurologic problem that doesn't involve motor fibers.” (Tr. at 57-58)

EDX – Nerve Conduction Studies

Testimony of Dr. Katirji

73. Dr. Katirji testified that nerve conduction studies involve stimulating a nerve in a limb and recording from another location on the same limb. Dr. Katirji further testified:

For example, you could stimulate the wrist and record from the fingers. You can stimulate the ankle and record from the foot. You can stimulate from the knee and record from the foot, and so on. So there are several stimulation points and you can make a calculation of speed of nerve and also of the potential size, telling us whether there is any loss of nerve.

(Tr. at 1020)

Testimony of Dr. Chelimsky

74. Dr. Chelimsky further defined nerve conduction studies thusly:

[Nerve conduction studies] are examinations of the nerves performed by providing a shock to the nerve and then recording along the nerve, either away from the center of the body or towards the center of the body that shock wave as it propagates. And then you can tell how much of the nerve is working and how fast it's working by looking to see how long it takes for the time between the shock and the recording and the size of the response.

(Tr. at 1570-1571)

Testimony of Dr. Leak

75. Dr. Leak testified that, whereas SSEP testing focuses more on the spinal cord and brain, nerve conduction studies focus on the peripheral nerves. Dr. Leak testified that high frequency stimulation is used in sensory nerve conduction studies and low frequency stimulation is used for motor nerve conduction studies. (Tr. at 547-548)

*Selective Tissue Conductance [STC] Studies – Autonomic Nervous System*⁸Testimony of Dr. Longmire

76. Dr. Longmire testified that he is one of the co-developers of STC testing and a device that is used to perform such testing, called the Epi-Scan. Dr. Longmire further testified that he had begun working on the principles of selective tissue conductance in the 1960s. The other co-designer is William Woodley, a physiologist with a Master's degree in biomedical engineering. (Tr. at 853)

Dr. Longmire testified that, at one time, he and Mr. Woodley had owned the patent to STC technology. However, Dr. Longmire stated that the patent is now held by the EDX Epi-Scan Company in Huntsville, Alabama. Dr. Longmire testified that he is not employed by EDX Epi-Scan and that he receives no remuneration from the company. However, he testified that the company contacts him from time to time with questions concerning the use and development of STC. (Tr. at 854)

77. Dr. Longmire testified that the Epi-Scan employs a target-shaped sensor that consists of a flat, smooth center core and a circular, washer-shaped outer rim. The conductivity of the skin is tested by placing the sensor on the skin and passing a small electrical current through the device and onto the skin. The device measures the electrical current that passes from the center contact to the outer rim. The results are then expressed in nanosiemens per square centimeter. (Tr. at 878-884)

78. Dr. Longmire testified that STC testing measures the activity of the sympathetic nervous system by measuring the part of the sympathetic nervous system that controls the body's sweat glands, the sudomotor nerve fibers. (Tr. at 872-873)

Dr. Longmire further testified that the surface of skin conducts electricity. How well it conducts electricity is determined by the amount of moisture on the skin. As the moisture level of the skin increases via increased activity of the sweat glands, the conductivity of the skin increases. Moreover, Dr. Longmire testified that the extent to which the sudomotor nerve fibers cause the sweat glands to increase or decrease activity is affected by the health of the nerve. Dr. Longmire further testified that, if the nerve is cut or damaged, sweat decreases. Alternatively, if the nerve is irritated by a painful disorder, sweat increases. (Tr. at 873-877)

79. Dr. Longmire testified that multiple locations on the body are measured during an STC test. For example, in Dr. Leak's *Pain Medicine* article, with regard to a patient who suffered from facial pain, 36 measurements were taken on her face: nine (in three rows of three) above the right eyebrow, nine (in three rows of three) below the right eye, and a similar number on the left side of the face. (Resp. Ex. 213L at 78; Tr. at 889-890)

⁸ The term "autonomic nervous system" and the term describing one of its components, the "sympathetic nervous system," were used interchangeably by witnesses in this matter.

Dr. Longmire testified: “The measuring end of the system would go against the surface of the skin in sequence, and the screen on the device tells you where to measure. It tells you what sequence, what measurement you're going to make next.” After finishing one side of the body, the corresponding areas on the other side of the body are measured. The final calculations are then made by the machine. (Tr. at 896-899)

Dr. Longmire testified that, prior to and after testing the area to be measured, measurements are taken from a neutral, unaffected part of the body to measure variability. (Tr. at 897)

Dr. Longmire testified that measurements from the two sides are then compared.

Dr. Longmire further testified:

[W]hat you look for specifically is you must have an asymmetry that is greater—in an unheated person that's greater than 1.5 times the opposite number. And what you try to do is to look for the greatest area of difference, the greatest area of asymmetry. And when you look at that in terms of where it is distributed, it frequently tells you what areas of the nerve roots are more hyperactive in terms of their sympathetic outflow to the skin. And that guides you. That's part of your overall diagnosis.

It's not the only thing. And it certainly does not say—even though there is a high relationship between the number of areas that are high STC regionally and where the patients say their pain is, this device does not measure the intensity of the person's pain. This is not a pain measuring device.

* * *

It only measures abnormalities in the outflow of the nerve fibers * * * from the sympathetic spinal chain along the spinal nerve roots to the surface of the skin.

(Tr. at 899-901)

Dr. Longmire testified that the results of STC testing can be used to locate where further diagnosis studies, such as MRI, should be performed. Moreover, Dr. Longmire noted that STC testing can locate an area of abnormality if the patient has sympathetically referred pain. (Tr. at 901-902)

80. Dr. Longmire testified that humidity does not alter the results of STC testing because the test measures relative values of different areas of the body, and that all areas of the body are exposed to the same humidity level. (Tr. at 887-889)

81. Dr. Longmire testified concerning FDA classification of the STC device:

The device has been classified as regulatory class 2, and it's been classified by the FDA twice. * * *

Initial classification as a selective tissue conductance meter was in 1988. It has subsequently been re-evaluated in the last two years and reclassified under the same category.

(Tr. at 880)

Dr. Longmire further testified that the operational definition as submitted to the United States Food and Drug Administration [FDA] and other governmental authorities is:

Selective tissue conductance, abbreviated as STC, is the relative ability of biological tissue to conduct a weak, direct current, electrical signal, which is applied for a selected period of time to a selected, limited, and restricted surface area of that tissue.

(Tr. at 872)

Testimony and Written Reports of Dr. Chelimsky

82. Dr. Chelimsky testified that the autonomic nervous system controls most involuntary functions. Dr. Chelimsky further testified that, for example, if a person is frightened, the person flushes and the blood pressure and heart rate go up. Dr. Chelimsky testified that all of those reactions are controlled by the autonomic nervous system. (Tr. at 1489-1490)

Dr. Chelimsky testified that, during his fellowship in autonomic research, he had learned how to test the autonomic nervous system, and how the autonomic nervous system interacts with pain in a condition known as reflex sympathetic dystrophy or complex regional pain syndrome, a severely painful condition that is difficult to treat. Dr. Chelimsky further testified that he is considered an expert in that area, and that there are less than 20 neurologists in the country who are so recognized. (Tr. at 1490, 1498)

Dr. Chelimsky testified that there are several available methods to test sudomotor function and that he uses two. The first, called the axon reflex test, involves applying a small capsule to the skin and passing an electric current through a solution in the capsule. The amount of sweat produced is then measured. The other test used by Dr. Chelimsky is called the thermoregulatory sweat test, nicknamed the "shake and bake" test. The test involves putting the patient in a sauna-like structure and applying a dye on the patient's skin. Areas where the patient sweats turn purple; areas where the patient doesn't sweat stay orange. Dr. Chelimsky testified, "[T]hat gives you a map of the nerves through the body, what's sweating, what's not sweating." (Tr. at 1495-1496)

83. Dr. Chelimsky stated in his written report that STC testing “is an entirely unproven diagnostic tool and its performance under any circumstance is intrinsically below [the] minimal standard of care. The results make no scientific sense, as the axes are unlabeled.” (St. Ex. 28 at 2) Dr. Chelimsky further wrote that the results made no clinical sense, either. Referring to Patient 21, Dr. Chelimsky commented on the following examples:

- On July 13, 2001, Patient 21 received chemoneurolytic injections in the cervical region. Chemoneurolytic injections are one of the interventional techniques utilized by PCC, and will be described in greater detail later in this report. They are intended to relieve pain by destroying or impairing the ability of nerve tissue to relay pain information to the brain. Pre- and post-injection STC testing of Patient 21’s cervical region was performed. Dr. Griffin interpreted the results. (St. Ex. 21 at 600-605; Tr. at 1574)

- The results of the pre-injection STC test were as follows:

“The C3 (Third Occipital Nerve) is not clinically significant.
“The C4 has a greater than 51% chance of clinically significant disease.
“The C5 has a greater than 51% chance of clinically significant disease.
“The C6 is not clinically significant.”

(St. Ex. 21 at 602)

The results of the post-injection STC test were as follows:

“The C3 (Third Occipital Nerve) has significant pathology.
“The C4 has a greater than 51% chance of clinically significant disease.
“The C5 has severe pathology.
“The C6 has significant pathology.”

(St. Ex. 21 at 605)

Dr. Chelimsky indicated in his report that the STC tests performed on the same area before and after a chemoneurolytic injection “showed that C3-C6 were normal pre-treatment but post-treatment there was now C5 severe involvement.” (St. Ex. 21 at 600-605; St. Ex. 28 at 2)

- The results of an STC test on Patient 21 on September 27, 2001, yielded the following results, interpreted by Dr. Griffin:

“The C3 (Third Occipital Nerve) has significant pathology.
“The C4 has a greater than 51% chance of clinically significant disease.

“The C5 has a greater than 51% chance of clinically significant disease.

“The C6 has a greater than 51% chance of clinically significant disease.”

(St. Ex. 21 at 598)

The following day, Patient 21 was tested again. The record does not state whether the test occurred before or after the trigger point injection⁹ she received that day. The results of the September 28, 2001, STC were:

“The C3 (Third Occipital Nerve) has severe pathology.

“The C4 has severe pathology.

“The C5 has severe pathology.

“The C6 has significant pathology.”

Dr. Chelimsky commented that on September 27, 2001, STC tests “showed that C3-C6 were mildly diseased, but on [September 28, 2001], one day later, it showed a different pattern[.]” (St. Ex. 28 at 594-599; St. Ex. 28 at 2)

- On October 12, 2001, Patient 21 received another trigger point injection in her cervical region. Pre- and post-injection STC testing of Patient 21’s cervical region was performed. Dr. Griffin interpreted the results. (St. Ex. 28 at 587-592)

“The C3 (Third Occipital Nerve) is not clinically significant.

“The C4 is not clinically significant.

“The C5 is not clinically significant.

“The C6 has a greater than 51% chance of clinically significant disease.”

(St. Ex. 21 at 588)

The results of the post-injection STC test were as follows:

“The C3 (Third Occipital Nerve) has a greater than 51% chance of clinically significant disease.

“The C4 has a greater than 51% chance of clinically significant disease.

“The C5 has significant pathology is not clinically significant.

“The C6 is not clinically significant.”

(St. Ex. 21 at 591)

⁹ A trigger point injection is another interventional technique utilized by PCC that will be discussed in detail later in this report. A trigger point injection involves the injection of anesthetic, sometimes combined with a steroid, to relieve pain. (Tr. at 1572-1574)

Dr. Chelimsky stated that the October 12, 2001, STC testing indicated that “C6 was diseased pre-block and [post-block] there was new disease at C3-C5 that wasn’t present before the block.” (St. Ex. 21 at 587-592; St. Ex. 28 at 2)

Dr. Chelimsky further wrote that the large numbers of nerves tested by Dr. Leak at any single visit virtually guaranteed that some would be abnormal based on statistical grounds alone. Moreover, Dr. Chelimsky wrote:

These results are meaningless since they do vary so randomly from one session to the next in the same patient at the same level and do not change consistently or reliably after the intervention procedures. The record reflects that even the ordering physicians themselves did not alter their plan of care in any way based on the results.

(St. Ex. 28 at 2)

84. Dr. Chelimsky testified that “for a test to have any reliability, it should be reproducible.” However, Dr. Chelimsky testified that STCs are not reproducible “because skin conductions change from day to day.” (Tr. at 1590-1592)

Even if the test was reproducible, Dr. Chelimsky testified that he has “a hard time understanding what it’s really telling you.” Dr. Chelimsky testified that, “even on theoretical grounds, it would be hard to understand how this would anatomically connect.” (Tr. at 1592) Dr. Chelimsky testified that there is no relationship between sweating and pain because the autonomic nerve fibers do not travel along the same paths as the sensory and motor nerves. Dr. Chelimsky explained that the autonomic nerves run alongside and outside of the spine, and that the autonomic nerves to a particular area may originate at a different level from a sensory pain nerve to that same area. Dr. Chelimsky testified that there is no way to know that damage to the autonomic nervous system at a particular level corresponds to sensory nerve root damage at the same level—that there is no reason to believe that a change in skin conductance at L5 reflects a problem with the sensory nerve root at L5. The problem could be anywhere, or there could be no problem at all; the results may only reflect a change in the patient’s sweating that day. (Tr. at 1590-1592, 1947-1950)

85. In addition to a test being reproducible and anatomically reliable, Dr. Chelimsky testified that a test should be valid. A valid test means that “the test tells you something meaningful about the disease.” However, Dr. Chelimsky testified that, in the case of STCs, “you don’t have reproducibility, you don’t have reliability, and you don’t have validity.” Furthermore, Dr. Chelimsky testified that, in his opinion, STC is an experimental procedure but that Dr. Leak is using it “clinically, not experimentally.” Finally, Dr. Chelimsky reiterated his opinion that STC is an unproven diagnostic tool and that its use is below the minimal standard of care. (Tr. at 1592-1594)

86. When asked if changes in the skin's electrical resistance can be used to locate where pain is radiating from, or damage to a nerve, Dr. Chelimsky replied: "No, not at all. This is totally—this is a fraud. There's absolutely nothing to this." (Tr. at 1950)
87. Dr. Chelimsky testified that Dr. Longmire's 2006 article in *Pain Physician* was a review article, which "is basically an opinion of a physician that has been published in a journal." A review article differs from a peer-reviewed article in that the peer-reviewed article has been subjected to a rigorous review by at least two other physicians "who actually look at the data, determine its validity, and determine the publishability of the information. A review article is simply published at an editor's discretion." (St. Ex. 213L; Tr. at 1795)

Dr. Chelimsky further testified concerning the substance of Dr. Longmire's article: "[M]y impressions are that this is a nice set of theories, but there is really nothing in this article that validates the procedure of selective tissue conductance. So they do have an FDA device approved, but that simply tells you about safety. It doesn't tell you about validity." (Tr. at 1796)

In addition, Dr. Chelimsky testified that he had performed a search using "Pub Med," an Internet search engine that will return any peer-review article published since 1966. Dr. Chelimsky testified:

"[F]rom 1966 until now, there was no peer-reviewed publication if one puts in the words selective tissue conductance or puts in [either Dr. Longmire or Dr. Woolsey as author], except for this article right here.

And the only reason that's in Pub Med is because that journal just got listed with Pub Med in the last year. So prior to that, *Pain Physician* was not listed with Pub Med. But whether it's listed in Pub Med is irrelevant. The issue is whether there's a peer-reviewed scholarly discussion of a technique, and there is none.

(Tr. at 1796-1797)

Testimony of Dr. Jay

88. In his March 21, 2007, written report, Dr. Jay stated, in pertinent part:

My medical opinion regarding the use of Selective Tissue Conductance in Pain Medicine is that it is valuable, reproducible and when used correctly it is useful in the diagnosis of chronic non-cancer pain diatheses. Medically it would certainly be within the standard of care to use this tool in the diagnosis of such patients. I think that the fact that there is a CMS originated CPT code also speaks for its legitimacy.

(Resp. Ex. 156)

During hearing, Dr. Jay could not recall the CPT code used to bill for STC testing, and acknowledged that STC testing might be billed using a code that is not specifically for STC testing.¹⁰ (Tr. at 2839)

89. Dr. Jay testified that Medicare has approved the use of STC, as has the State of Colorado. (Tr. at 2831-2832)
90. Dr. Jay testified that he has been using STC testing since 1992 or 1993. Dr. Jay further testified that STC is “a fairly objective way to look at regional sympathetic sudomotor or sweat dysfunction.” Dr. Jay further testified that other tests that study the same thing are more expensive, inconvenient, and uncomfortable for the patient. Moreover, Dr. Jay testified that one would expect to see the same results repeated in testing the same person with the same disease, and that STC is reproducible, reliable, and valid. However, Dr. Jay did not discuss PCC’s medical records and the seemingly inconsistent and unreliable results. Finally, Dr. Jay testified that, in his opinion, the use of STC testing is within the standard of care for pain practitioners. (Tr. at 2815-2818, 2829, 2832-2833, 2836)
91. Dr. Jay noted that STC testing can be used pre- and post-block to see whether it affected the targeted area “[o]nly if it’s an autonomic block.” (Tr. at 2822) (Emphasis added)

Testimony of Dr. Bressi

92. Dr. Bressi testified that the sympathetic nervous system is affected by the sensory nerves. Dr. Bressi further testified: “When you’re hot, the sympathetics dilate your blood vessels in your skin to let heat go. And when you’re cold, they do the opposite; they constrict the blood vessels to keep heat in. So they are part of the nerves that go to the skin and they can be affected by various problems, including pain.” (Tr. at 2939-2940)
93. Dr. Bressi testified that he does not use STC testing in his practice. (Tr. at 2377, 2995)

Testimony of Dr. Boswell

94. Dr. Boswell testified that he is familiar with selective tissue conductance, and that he has employed that modality in his practice using a device that had been provided to him by Dr. Longmire. (Tr. at 40) Dr. Boswell further testified:

I have used a hand-held device on some patients, not routinely. I have trialed the device. I have used the device on patients with radiculopathy in clinic. I was loaned the machine for a few months. I used it while I was doing anesthesia for electroconvulsive therapy and found extreme results after

¹⁰ Dr. Chelimsky disagreed that there is a CPT code for STC testing. Dr. Chelimsky testified that the CPT code being discussed covers other types of sudomotor testing but not STC. (Tr. at 1653-1654) Further, in an April 27, 2007, report, Dr. Chelimsky stated that “CPT Code 95923: Evaluation of Sudomotor Function” is not to be used for STC testing but can be used for other sudomotor function tests such as the axon reflex test and the thermoregulatory sweat test. (St. Ex. 53)

electrical induced seizures during therapy for depression. So I'm familiar with the device.

(Tr. at 62)

Testimony of Dr. Leak

95. Dr. Leak testified that a selective tissue conductance test is “part of an electrodiagnostic battery of studies used to provide objective data that there is, in fact, some dysfunction that we would perceive as anomalous. Anomalous, meaning not normal or that’s consistent with the patient’s complaint of pain.” Dr. Leak further testified that “it does not allow the patient to alter the results” because “we average repeated numbers.” (Tr. at 493-494)

Moreover, Dr. Leak testified that using STC “is a very, very reliable method for getting information that will or will not match the patient’s complaint * * *.” Dr. Leak testified that STC testing provides objective results. Dr. Leak stated that the results of some other tests, such as a straight leg test for a patient who complains of back pain, can be intentionally influenced by the patient. (Tr. at 494-496)

96. Dr. Leak testified concerning the STC tests referenced in Dr. Chelimsky’s written report; in particular, the STC tests that were performed on Patient 21 on July 13, 2001, before and after trigger point injections. (St. Ex. 21 at 600-605) Dr. Leak testified:

These are limited selective tissue tests. In other words, we have a person that is complaining of a confined area of discomfort. She has had treatment. We are determining whether or not—if she has active sympathetic manifestation of disease after local anesthetic injection, do we prove that we are able to change the amount of autonomic activity?

On—if you look at [State’s Exhibit 21 at] page 602, the four nerves that were evaluated prior to injection were the C3-C4, C5-C6. The same after injection—that’s what the post means. Postinjection. And we see the contralateral activity, or due to neural blockade, there’s increased sympathetic output, meaning that there has been a successful block. * * *

(Tr. at 2848-2849)

In addition, Dr. Leak explained that, if a nerve block is administered on one side, there should be an increase in autonomic activity on the contralateral side. Dr. Leak testified that that occurs because the contralateral side is “unimpeded and you have an increased outflow of sympathetic activity, because you’ve blocked the side with local anesthetic.” (Tr. at 2850-2851; see also 2917-2918) [Note, however, that the July 13, 2001, Procedural Note states that the injections were performed bilaterally. (St. Ex. 21 at 324)]

Testimony of Dr. Griffin

97. Dr. Griffin testified that STC is “a great theory. It wasn’t the best test we did. * * * But then again, we didn’t really have much to do, so we did the best we could to try and get objective evidence.” Dr. Griffin testified that he and Dr. Leak had worked with the test over a period of time to improve the reproducibility of the results, but that it is still not very reliable. Dr. Griffin added that the results of STC testing had influenced what he and Dr. Leak did with patients, “but we wouldn’t hang our hat on the study.” (Tr. at 3067-3068)
98. Dr. Griffin testified that he has not ordered or performed STC studies since leaving PCC in December 2003. (Tr. at 3083)

Table of EDX Studies Performed or Ordered by Dr. Leak and/or Dr. Griffin

99. The medical records indicate that Dr. Leak and/or Dr. Griffin performed or ordered the following tests. All tests were performed bilaterally.

Pt	Date	Physician	Test	SSEP: Nerve Root Level(s) Tested NCS: Nerves Tested STC: Level(s)/Dermatome(s) Tested	Med Rcd Page No.
1	07/18/01	Griffin	STC	C3-C6	229-231
	07/23/01	Leak	SSEP	Cervical, ¹¹ including C4 and C5	227-228
	07/23/01	Leak	NCS	Median and ulnar, sensory and motor	227-228
	07/24/01	Leak	STC	C3-C6, upper extremities	222-226
	07/25/01	Leak	STC	L1-S5, lower extremities	216-221
	07/26/01	Griffin	SSEP	Lumbar, ¹² including L2 and L3 ¹³	214-215
	07/26/01	Griffin	NCS	Sural sensory, peroneal and tibial motor	214-215
	08/22/01	Griffin	STC	C3-C6, pre-injection	208-213
	08/22/01	Griffin	STC	C3-C6, post-injection	208-213
	08/28/01	Griffin	STC	C3-C6, pre-injection	201-206
	08/28/01	Griffin	STC	C3-C6, post-injection	201-206
	09/18/01	Griffin	STC	C3-C6, pre-injection	194-200
	09/18/01	Griffin	STC	C3-C6, post-injection	194-200
	10/02/01	Griffin	STC	C3-C6, pre-injection	188-193
	10/02/01	Griffin	STC	C3-C6, post-injection	188-193
	10/12/01	Griffin	STC	C3-C6, pre-injection	182-187
	10/30/01	Griffin	STC	C3-C6, pre-injection	176-181
	10/30/01	Griffin	STC	C3-C6, post-injection	176-181
	11/16/01	Griffin	STC	L1-L4, pre-injection	170-175

¹¹ SSEPs of cervical nerve root levels always included C4-C8.

¹² Except for the cases of Patient 8 and the October 7, 1999, SSEP of Patient 11, SSEPs of lumbar nerve root levels always included L2 – L5 and S1.

¹³ Dr. Katirji testified that SSEP studies at L-2 and L-3 do not have normal ranges because they are not ordinarily performed. Dr. Katirji explained that SSEP studies at L-2 and L-3 involve “stimulating the groin and recording [the results] from that.” (1073-1074)

Pt	Date	Physician	Test	SSEP: Nerve Root Level(s) Tested NCS: Nerves Tested STC: Level(s)/Dermatome(s) Tested	Med Rcd Page No.
	11/16/01	Griffin	STC	L1-L4, post-injection	170-175
	11/28/01	Griffin	STC	L1-L4, pre-injection	164-169
	11/28/01	Griffin	STC	L1-L4, post-injection	164-169
	12/12/01	Griffin	STC	T1-T12	161-163
	12/13/01	Griffin	SSEP	Thoracic, ¹⁴ including T8, T10, and T12	159-160
2	01/02/01	Griffin	STC	T1-T12	357-359
	01/08/01	Leak	SSEP	Lumbar, including L2 and L3	355-356
	01/08/01	Leak	NCS	Sural sensory, peroneal and tibial motor	355-356
	01/11/01	Leak	SSEP	Cervical, including C4 and C5	353-354
	01/11/01	Leak	NCS	Median and ulnar, sensory and motor	353-354
	01/26/01	Griffin	STC	L1-S5, lower extremities	346-349
	07/23/01	Leak	STC	L1-L4	343-345
	10/16/01	Griffin	STC	L3-L5, pre-injection	337-342
	10/16/01	Griffin	STC	L3-L5, post-injection	337-342
	10/30/01	Griffin	STC	L1-L4, pre-injection	331-336
	10/30/01	Griffin	STC	L1-L4, post-injection	331-336
	11/13/01	Griffin	STC	L1-L4, pre-injection	325-330
	11/13/01	Griffin	STC	L1-L4, post-injection	325-330
3	04/24/01	Griffin	STC	L1-L5	334-336
	04/25/01	Griffin	SSEP	Lumbar, including L2 and L3	332-333
	04/25/01	Griffin	NCS	Sural sensory, peroneal and tibial motor	332-333
	07/16/01	Griffin	STC	L3-L5	329-331
	09/14/01	Griffin	STC	T11-L2, pre-injection	322-328
	09/14/01	Griffin	STC	T11-L2, post-injection	322-328
	09/28/01	Griffin	STC	T11-L2, pre-injection	314-327
	09/28/01	Griffin	STC	T11-L2, post-injection	314-327
	10/17/01	Griffin	STC	T11-L2, pre-injection	307-313
	10/17/01	Griffin	STC	T11-L2, post-injection	307-313
	11/13/01	Not documented	STC	T11-L2, pre-injection	300-306
	11/13/01	Not documented	STC	T11-L2, post-injection	300-306
	12/06/01	Leak	STC	T7-T9 and L4-S1, pre-injection	292-299
	12/06/01	Leak	STC	T7-T9 and L4-S1, post-injection	292-299
4	05/26/00	Leak	SSEP	Cervical, including C4 and C5	404-405
	05/26/00	Leak	NCS	Median and ulnar, sensory and motor	404-405
	06/05/00	Not documented	STC	C3-C6, upper extremities	400-403
	06/06/00	Not documented	STC	T1-T12	393-395
	06/08/01	Leak	SSEP	Thoracic, including T8, T10, and T12	391-392
	10/30/01	Griffin	STC	T3-T6, pre-injection	381-387
	10/30/01	Griffin	STC	T3-T6, post-injection	381-387
	11/06/01	Griffin	STC	T3-T6, pre-injection	374-379
	11/06/01	Griffin	STC	T3-T6, post-injection	374-379
	11/20/01	Griffin	STC	T3-T6, pre-injection	368-373

¹⁴ Except for the October 8, 1999, SSEP of Patient 11, SSEPs of thoracic nerve root levels always included T2, T4, T6, T8, T10, and T12.

Pt	Date	Physician	Test	SSEP: Nerve Root Level(s) Tested NCS: Nerves Tested STC: Level(s)/Dermatome(s) Tested	Med Rcd Page No.
	11/20/01	Griffin	STC	T3-T6, post-injection	368-373
5	08/10/99	Not documented	STC	L1-S5, lower extremities	326-331
	08/11/99	Leak	SSEP	Lumbar, including L2 and L3	324-325
	08/11/99	Leak	NCS	Sural sensory, peroneal and tibial motor	324-325
	04/05/00	Not documented	STC	C3-C6, upper extremities	318-323
	04/06/00	Leak	SSEP	Cervical, including C4 and C5	316-317
	04/06/00	Leak	NCS	Median and ulnar, sensory and motor	316-317
	04/07/00	Leak	SSEP	Thoracic, including T8, T10, and T12	314-315
	04/10/00	Not documented	STC	T1-T12	309-313
	06/22/01	Griffin	STC	T6-T10, pre-injection	303-308
	06/22/01	Griffin	STC	T6-T10, post-injection	303-308
	06/29/01	Griffin	STC	L1-L3, pre-injection	297-302
	06/29/01	Griffin	STC	L1-L3, post-injection	297-302
	07/13/01	Griffin	STC	T6-T10, pre-injection	292-296
	07/13/01	Griffin	STC	T6-T10, post-injection	292-296
	07/20/01	Griffin	STC	L1-L4, pre-injection	286-291
	07/20/01	Griffin	STC	L1-L4, post-injection	286-291
	10/10/01	Griffin	STC	T4-T7, pre-injection	280-285
	10/10/01	Griffin	STC	T4-T7, post-injection	280-285
	10/12/01	Griffin	STC	L1-L4, pre-injection	274-279
	10/12/01	Griffin	STC	L1-L4, post-injection	274-279
	10/19/01	Griffin	STC	T4-T7, pre-injection	267-273b
	10/19/01	Griffin	STC	T4-T7, post-injection	267-273b
	10/30/01	Griffin	STC	L1-L3, pre-injection	261-266
	10/30/01	Griffin	STC	L1-L3, post-injection	261-266
	11/13/01	Griffin	STC	L1-L3, pre-injection	255-260
	11/13/01	Griffin	STC	L1-L3, post-injection	255-260
	11/21/01	Griffin	STC	T4-T7, pre-injection	249-254
	11/21/01	Griffin	STC	T4-T7, post-injection	249-254
6	11/28/00	Not documented	STC	L1-S5, lower extremities	159-162
	12/27/00	Leak	SSEP	Lumbar, including L2 and L3	153-154
7	11/21/00	Not documented	STC	L1-S5, lower extremities	379-384
	11/28/00	Leak	SSEP	Lumbar, including L2 and L3	377-378
	11/28/00	Leak	NCS	Sural sensory, peroneal and tibial motor	377-378
	06/01/01	Griffin	SSEP	Thoracic, including T8, T10, and T12	375-376
	06/05/01	Griffin	STC	T1-T12	369-374
	06/26/01	Griffin	STC	L1-L5, pre-injection	363-368
	06/26/01	Griffin	STC	L1-L5, post-injection	363-368
	07/18/01	Griffin	STC	L1-L5, pre-injection	357-362
	07/18/01	Griffin	STC	L1, L4, post-injection	357-362
	08/01/01	Leak	STC	L4-S2, pre-injection	351-356
	08/01/01	Leak	STC	L4-S2, post-injection	351-356
	08/14/01	Griffin	STC	L4-S1, pre-injection	343-350
	08/14/01	Griffin	STC	L4-S1, post-injection	343-350
	09/11/01	Griffin	STC	L4-S1, pre-injection	337-342

Pt	Date	Physician	Test	SSEP: Nerve Root Level(s) Tested NCS: Nerves Tested STC: Level(s)/Dermatome(s) Tested	Med Rcd Page No.
	09/11/01	Griffin	STC	L4-S1, post-injection	337-342
	09/21/01	Griffin	STC	L1-L4, pre-injection	331-336
	09/21/01	Griffin	STC	L1-L4, post-injection	331-336
	10/02/01	Griffin	STC	L1-L4, pre-injection	325-330
	10/02/01	Griffin	STC	L1-L4, post-injection	325-330
	12/04/01	Griffin	STC	T6-T8, pre-injection	319-324
	12/04/01	Griffin	STC	T6-T8, post-injection	319-324
	12/11/01	Griffin	STC	T6-T8, pre-injection	313-318
	12/11/01	Griffin	STC	T6-T8, post-injection	313-318
8	10/13/99	Not documented	STC	L1-S5, lower extremities	535-541
	10/14/99	Leak	SSEP	L4-S1	542-543
	10/14/99	Leak	NCS	Sural sensory, peroneal and tibial motor	542-543
	04/17/00	Not documented	STC	L1-S5, lower extremities	529-534
	08/15/01	Griffin	STC	C3-C6, upper extremities	523-528
	08/22/01	Leak	SSEP	Cervical, including C4 and C5	521-522
	08/22/01	Leak	NCS	Median and ulnar, sensory and motor	321-322
	10/26/01	Griffin	STC	L3-S1	518-520
	10/26/01	Griffin	STC	C4-C6	515-517
9	06/05/00	Leak	SSEP	Lumbar, including L2 and L3	321-322
	06/05/00	Leak	NCS	Sural sensory, peroneal and tibial motor	321-322
	06/08/00	Not documented	STC	L1-S5, lower extremities	315-318
	06/21/01	Griffin	STC	L1-S1	311-313
	07/19/01	Griffin	STC	L2-S1	308-310
10	04/06/01	Griffin	STC	L1-S5, lower extremities	103-108
11	10/06/99	Not documented	STC	C3-C6, upper extremities	601-607
	10/07/99	Leak	SSEP	L4-S1	624-624
	10/07/99	Leak	NCS	Sural sensory, peroneal and tibial motor	624-625
	10/08/99	Leak	SSEP	T4, T6, T8, and T10	622-623
	10/14/99	Not documented	STC	L1-S5, lower extremities	608-611
	05/15/00	Not documented	STC	Thoracic	596-600
	10/04/00	Not documented	STC	C3-C6, upper extremities	590-595
	10/06/00	Not documented	STC	L1-S5, lower extremities	580-585
	10/18/00	Leak	SSEP	Thoracic, including T8, T10, and T12	588-589
	11/03/00	Leak	SSEP	Lumbar, including L2 and L3	586-587
	11/03/00	Leak	NCS	Sural sensory, peroneal and tibial motor	586-597
	11/10/00	Leak	SSEP	Cervical, including C4 and C5	577-578
	11/10/00	Leak	NCS	Median and ulnar, sensory and motor	577-578
	07/18/01	Griffin	STC	T5-T9, pre-injection	571-576
	07/18/01	Griffin	STC	T5-T6, post-injection	571-576
	08/08/01	Griffin	STC	T4-T7, pre-injection	565-570
	08/08/01	Griffin	STC	T4-T8, post-injection:	565-570
	08/28/01	Not documented	STC	T4-T7, pre-injection	558-564
	08/28/01	Not documented	STC	T4-T7, post-injection	558-564
	09/18/01	Griffin	STC	T4-T7, pre-injection	552-557

Pt	Date	Physician	Test	SSEP: Nerve Root Level(s) Tested NCS: Nerves Tested STC: Level(s)/Dermatome(s) Tested	Med Rcd Page No.
	09/18/01	Griffin	STC	T4-T7, post-injection	552-557
	10/02/01	Griffin	STC	T4-T7, pre-injection	546-551
	10/02/01	Griffin	STC	T4-T7, post-injection	546-551
	10/23/01	Griffin	STC	T6-T10, pre-injection	540-545
	10/23/01	Griffin	STC	T6-T10, post-injection	540-545
	11/06/01	Griffin	STC	T4-T7, pre-injection	534-539
	11/06/01	Griffin	STC	T4-T7, post-injection	534-539
12	11/10/00	Not documented	STC	C3-C6, upper extremities	326-331
	11/28/00	Not documented	STC	L1-S5, lower extremities	320-325
	11/29/00	Not documented	STC	T1-T12	315-319
	11/30/00	Leak	SSEP	Cervical, including C4 and C5	313-314
	11/30/00	Leak	NCS	Median and ulnar, sensory and motor	313-314
	12/01/00	Leak	NCS	Sural sensory, peroneal and tibial motor	334-335
	12/01/00	Leak	SSEP	Lumbar, including L2 and L3	334-335
	12/05/00	Leak	SSEP	Thoracic, including T8, T10, and T12	332-333
13	06/29/00	Not documented	STC	L1-S5, lower extremities	171-173, 177
	07/05/00	Leak	SSEP	Cervical, including C4 and C5	170, 174
	07/05/00	Leak	NCS	Median and ulnar, sensory and motor	170, 174
	07/06/00	Not documented	STC	T1-T12	175-176
	07/10/00	Leak	SSEP	Thoracic, including T8, T10, and T12	168-169
	09/01/00	Leak	SSEP	Lumbar, including L2 and L3	166-167
	09/01/00	Leak	NCS	Sural sensory, peroneal and tibial motor	166-167
14	02/28/01	Griffin	STC	C3-C6, upper extremities	211-216
	03/06/01	Griffin	STC	T1-T12	202-204, 207-208
	03/07/01	Leak	SSEP	Cervical, including C4 and C5	209-210
	03/07/01	Leak	NCS	Median and ulnar, sensory and motor	209-210
	03/15/01	Leak	SSEP	Thoracic, including T8, T10, and T12	205-206
	06/22/01	Griffin	STC	T1-T3, pre-injection	196-201
	06/22/01	Griffin	STC	T1-T3, post-injection	196-201
	06/29/01	Griffin	STC	C3-C6, pre-injection	190-195
	06/29/01	Griffin	STC	C3-C6, post-injection	190-195
15	04/10/00	Not documented	STC	L1-S5, lower extremities	253-258
	04/19/00	Leak	SSEP	Lumbar, including L2 and L3	251-252
	04/19/00	Leak	NCS	Sural sensory, peroneal and tibial motor	251-252
	06/28/01	Griffin	STC	L1-L2	248-250
16	05/25/01	Griffin	SSEP	Lumbar, including L2 and L3	149-150
	05/25/01	Griffin	NCS	Sural sensory, peroneal and tibial motor	149-150
	05/28/01	Griffin	STC	L1-S5, lower extremities	143-148
	06/25/01	Griffin	STC	Lower extremities	140-142
	07/23/01	Leak	STC	Lower extremities	137-139

Pt	Date	Physician	Test	SSEP: Nerve Root Level(s) Tested NCS: Nerves Tested STC: Level(s)/Dermatome(s) Tested	Med Rcd Page No.
17	06/25/00	Not documented	SSEP	Cervical, including C4 and C5	318
	06/25/00	Not documented	NCS	Median and ulnar, sensory and motor	318
	07/28/00	Not documented	STC	C3-C6, upper extremities	312-317
	08/14/00	Leak	SSEP	Thoracic, including T8, T10, and T12	310-311
	08/23/00	Leak	SSEP	Lumbar, including L2 and L3	308-309
	08/23/00	Leak	NCS	Sural sensory, peroneal and tibial motor	308-309
	06/29/01	Griffin	STC	T5-T7, pre-injection	302 -307
	06/29/01	Griffin	STC	T5-T7, post-injection	302 -307
	08/27/01	Griffin	STC	T7-T10, pre-injection	296-301
	08/27/01	Griffin	STC	T7-T10, post-injection	296-301
	08/07/01	Griffin	STC	T6-T8, pre-injection	290-295
	08/07/01	Griffin	STC	T6-T8, post-injection	290-295
	07/24/01	Leak	STC	T5-T7, pre-injection	285-289
	07/24/01	Leak	STC	T5-T7, post-injection	285-289
	08/31/01	Griffin	STC	T7-T10, pre-injection	279-284
	08/31/01	Griffin	STC	T7-T10, post-injection	279-284
	09/28/01	Griffin	STC	L1-L5, pre-injection	269-275
	09/28/01	Griffin	STC	L1-L5, post-injection	269-275
	10/12/01	Griffin	STC	L1-L5, pre-injection	263-268
	10/12/01	Griffin	STC	L1-L5, post-injection	263-268
	11/16/01	Leak	STC	L1-S1	259-262
18	02/28/01	Griffin	STC	L1-S5	149, 151-152, 281
	03/13/01	Leak	SSEP	Lumbar, including L2 and L3	279-280
	03/13/01	Leak	NCS	Sural sensory, peroneal and tibial motor	279-280
19	09/20/00	Leak	SSEP	Lumbar, including L2 and L3	186-187
	09/20/00	Leak	NCS	Sural sensory, peroneal and tibial motor	186-187
	09/22/00	Not documented	STC	L1-S5	180-185
20	08/25/00	Leak	SSEP	Lumbar, including L2 and L3	358, 365
	08/25/00	Leak	NCS	Sural sensory, peroneal and tibial motor	358, 365
	08/30/00	Not documented	STC	L1-S5	359-364
21	08/29/00	Not documented	STC	C3-C6, upper extremities	616-621
	08/30/00	Not documented	STC	L1-S5, lower extremities	610-615
	09/18/00	Leak	SSEP	Lumbar, including L2 and L3	608-609
	09/18/00	Leak	NCS	Sural sensory, peroneal and tibial motor	608-609
	09/22/00	Leak	SSEP	Cervical, including C4 and C5	606-607
	09/22/00	Leak	NCS	Median and ulnar, sensory and motor	606-607
	07/13/01	Griffin	STC	C3-C6, pre-injection	600-605
	07/13/01	Griffin	STC	C3-C6, post-injection	600-605
	09/27/01	Griffin	STC	C3-C6	597-599
	09/28/01	Griffin	STC	C3-C6	594-596
	10/12/01	Griffin	STC	C3-C6, pre-injection	587-593
	10/12/01	Griffin	STC	C3-C6, post-injection	587-593

Pt	Date	Physician	Test	SSEP: Nerve Root Level(s) Tested NCS: Nerves Tested STC: Level(s)/Dermatome(s) Tested	Med Rcd Page No.
22	03/05/01	Leak	SSEP	Cervical, including C4 and C5	342-343
	03/05/01	Leak	NCS	Median and ulnar, sensory and motor	342-343
	03/06/01	Griffin	STC	C3-C6, upper extremities	336-341
	03/09/01	Griffin	STC	T1-T12	330-335
	03/13/01	Not documented	STC	L1-S5, lower extremities	325-329
	03/14/01	Leak	SSEP	Thoracic, including T8, T10, and T12	323-324
	03/19/01	Leak	SSEP	Lumbar, including L2 and L3	321-322
	03/19/01	Leak	NCS	Sural sensory, peroneal and tibial motor	321-322
	06/26/01	Griffin	STC	L4-S2	317-319
	07/12/01	Griffin	STC	L4- S2, pre-injection	311-316
	07/12/01	Griffin	STC	L4- S2, post-injection	311-316
	07/25/01	Leak	STC	T4-T9, pre- post-injection	305-310
	07/25/01	Leak	STC	T4-T9, post-injection	305-310
	07/31/01	Not documented	STC	T4-T8, pre-injection	299-304
	07/31/01	Not documented	STC	T4-T8, post-injection	299-304
	08/03/01	Leak	STC	T2-T7, pre-injection	293-298
	08/03/01	Leak	STC	T2-T7, post-injection	293-298
	09/19/01	Griffin	STC	T4-T7, pre-injection	287-292
	09/19/01	Griffin	STC	T4-T7, post-injection	287-292
	09/28/01	Griffin	STC	T4-T7, pre-injection	280-286
	09/28/01	Griffin	STC	T4-T7, post-injection	280-286
	10/19/01	Griffin	STC	T4-T7, pre-injection	274-279
	10/19/01	Griffin	STC	T4-T7, post-injection	274-279
23	03/30/01	Griffin	STC	L1-S5, lower extremities	101-106
	04/05/01	Leak	SSEP	Lumbar, including L2 and L3	99-100
	04/05/01	Leak	NCS	Sural sensory, peroneal and tibial motor	99-100

Allegation (1)(c):

100. In its August 9, 2006, notice of opportunity for hearing, the Board alleged in Allegation (1)(c) as follows:

[Dr. Leak] improperly performed and/or caused to be improperly performed somatosensory evoked potentials testing. For example, the latencies purportedly observed for Patient 1 differ by far more than could be true clinically.

(St. Ex. 54C)

101. In his January 31, 2005, written report, Dr. Chelimsky stated, in part:

In many cases, the [SSEP] simply made no sense and appeared to have been itself performed technically below minimal standard of care, for example in the case of [Patient 1] p 159, the latencies differ by far more than could be true clinically.

(St. Ex. 28 at 2)

102. The following are the results of a December 13, 2001, SSEP study on Patient 1 performed or interpreted by Dr. Leak:

SSEP Nerve Tested	Normal Range in ms	Right (N-19) in msec	Left (N-19) in msec	Differential >3.0 ms
T2 DEP	19.2 – 25.8	23.96	20	3.96
T4 DEP	17.6 – 24.8	27.71	27.46	0.25
T6 DEP	19.2 – 25.8	26.25	27.29	1.04
T8 DEP		22.71	22.5	0.21
T10 DEP		25.42	27.5	2.08
T12 DEP		27.92	28.12	0.2

(St. Ex. 1 at 159)

Allegation (1)(e)

103. In its August 9, 2006, notice of opportunity for hearing, the Board alleged in Allegation (1)(e) as follows:

Assuming, *arguendo*, that EDX studies on Patients 1, 2, 4-9, 11-23 were necessary, [Dr. Leak] failed to perform or recommend and/or document the performance or recommendation of a needle EMG examination.

(St. Ex. 54C)

Use of Needle EMG

Testimony of Dr. Katirji

104. Dr. Katirji testified that needle EMG is performed by placing a needle into any of various muscles in the limbs. Dr. Katirji further testified, “[T]he patient is asked to activate the muscle, and then the size of the motor units are looked at.” Dr. Katirji testified, “[Y]ou can look at muscle disease by the needle EMG, but also you can look at nerve disease because if

the nerve's lost to that muscle, you'll see changes in that muscle that tell you that the axons on that muscle have disintegrated." (Tr. at 1022-1023)

105. Dr. Katirji testified that needle EMGs are about 85 percent accurate. Dr. Katirji testified that that means if a nerve is compressed in the back, as would be the case with radiculopathy, 85 percent of patients will have an abnormal result with needle EMG. (Tr. at 1154-1155; 1209-1212)
106. Dr. Katirji testified that needle EMG is nearly always performed in conjunction with a nerve conduction study. Dr. Katirji further testified that needle EMG *must* be performed in conjunction with nerve conduction studies in order to diagnose radiculopathy. That is because, in cases of radiculopathy, "the root lesion is at the spine level, and the nerve conduction studies do not really test the roots. They just test the limbs." Dr. Katirji further testified that, in order to diagnose radiculopathy, the results of the nerve conduction studies must be normal and the needle EMG abnormal. Moreover, if a patient has nerve compression in a limb rather than radiculopathy, as with carpal tunnel syndrome, the needle EMG result would be nearly normal. (Tr. at 1021-1023, 1154-1155, 1210-1212)

Dr. Katirji further testified that nerve conduction studies may be performed *without* needle EMG for conditions other than radiculopathy, such as peripheral neuropathy, carpal tunnel syndrome, myasthenia gravis, and Lou Gehrig's disease. Further, they may be performed without needle EMG in the event of an acute case when the patient has had the problem for less than a week. With regard to radiculopathy, however, Dr. Katirji testified that needle EMG must be performed because, in cases of radiculopathy, nerve conduction study results "are normal by definition." (Tr. at 1011-1012, 1157-1158)

107. In his August 8, 2006, report, and in his testimony at hearing, Dr. Katirji indicated that, of the medical records for Dr. Leak's patients that Dr. Katirji reviewed, about one-third of the patients suffered from radicular pain.¹⁵ All of those patients received nerve conduction studies, but none received needle EMG. Dr. Katirji testified that performing nerve conduction studies without needle EMG in patients who suffer from such symptoms falls below the minimal standard of care. Patients who exhibited radicular pain were:

- Patient 8. (St. Ex. 8 at 521-522, 542-543; St. Ex. 31; Bd. Ex. H; Tr. at 1079-1081)
- Patient 9. (St. Ex. 9 at 321-322; St. Ex. 31; Bd. Ex. H; Tr. at 1082-1083)
- Patient 11.¹⁶ (St. Ex. 11 at 577-578, 586-587, 624-625; St. Ex. 31; Bd. Ex. H; Tr. at 1092-1094)
- Patient 12. (St. Ex. 12 at 313-314, 334-335; St. Ex. 31; Bd. Ex. H; Tr. at 1096-1097)
- Patient 13. (St. Ex. 13 at 166-167; St. Ex. 31; Bd. Ex. H; Tr. at 1101-1102)
- Patient 14. (St. Ex. 14 at 209-210; St. Ex. 31; Bd. Ex. H; Tr. at 1106)
- Patient 18. (St. Ex. 18 at 279-280; St. Ex. 31; Bd. Ex. H; Tr. at 1116-1117)

¹⁵ Dr. Katirji testified that radiculopathy is characterized in part by pain radiating from the back or neck into a limb, and not by pain localized in a joint or limb. (Tr. at 1057)

¹⁶ Note that a needle EMG had been performed on Patient 11 on July 6, 1999, but the test had not been ordered by Dr. Leak or Dr. Griffin. (St. Ex. 11 at 626)

- Patient 19. (St. Ex. 19 at 186-187; St. Ex. 31; Bd. Ex. H; Tr. at 1118)
- Patient 20. (St. Ex. 20 at 365; St. Ex. 31; Bd. Ex. H; Tr. at 1119-1120)
- Patient 22. (St. Ex. 22 at 321-322, 342-343; St. Ex. 31; Bd. Ex. H; Tr. at 1119-1120)

Furthermore, Dr. Katirji testified that the remaining patients had complained only of joint pain or pain localized to the back. Dr. Katirji testified that those patients had not needed SSEPs or nerve conduction studies but nevertheless received them. Dr. Katirji testified that, accordingly, patients with radicular symptoms had had incomplete testing, and patients who did not have radicular symptoms had had unnecessary testing. (Tr. at 1142-1143, 1203-1208)

Testimony of Dr. Chelimsky

108. Dr. Chelimsky provided further testimony concerning the reasons that a needle EMG must be performed in conjunction with nerve conduction studies:

[T]he needle examination tells you whether the lesion is a demyelinating or an axonal lesion. It also tells you whether the lesion is occurring up at the root level or down at the nerve level. It fully complements—the nerve conduction study essentially gives you something is normal or something is abnormal, but it doesn't really do a very good job of localizing because you could have an abnormality anywhere along that nerve between the point you stimulate and the point you record, and you would have an abnormality. You need the needle examination to tell you the relevance of the finding.

* * * [I]f you're assessing a nerve root, you need to do both a motor and a sensory conduction. The reason for this is that the dorsal roots—how do I put this? The cell body is connected to the nerve, and the cell body is what determines whether a nerve dies or not.

Now, the cell bodies that belong to feeling or sensory neurons turn out that they're outside the spine. So if you have some problem like a disc or some other problem pushing on the nerve roots inside the spine, the sensory conduction will be fine. * * * Only the motor conduction will be affected because the cell body of the motor nerve is actually in the spinal cord.

* * * [I]n order for a nerve to die, you have to actually separate the cell body from the nerve axon. So because the sensory cell bodies are outside the spine, you will never get damage to a sensory nerve from a problem inside the spine. You just—they're too far away. They're about a half an inch away. But you will get damage to the motor. So you have to do motor and sensory conductions, and you have to have the needle examination to go with it.

(Tr. at 1585-1587) Moreover, Dr. Chelimsky testified that the standard of care requires performing a needle EMG along with nerve conduction studies: “To have nerve conduction studies by themselves is meaningless.” (Tr. at 1587)

Testimony of Dr. Bressi

109. Dr. Bressi testified that he does not believe that nerve conduction studies must be performed in conjunction with needle EMG at all times. However, Dr. Bressi did not address whether Dr. Leak's use of nerve conduction studies had required concomitant use of needle EMG. (Tr. at 2376-2377)

Testimony of Dr. Leak

110. Referring to the July 23, 2001, EDX studies performed on Patient 1, Dr. Leak was asked why he had not performed or ordered needle EMG along with the SSEPs and nerve conduction studies. Dr. Leak replied that he had not performed needle EMG on Patient 1 because it had been unnecessary to do so. Dr. Leak further testified that EMGs do not provide any useful information concerning a patient's complaint of pain. Moreover, Dr. Leak testified:

The patient's complaint was one of subjective pain, and that's what we needed to prove.

The patient * * * had nerve conduction studies that indicated that there was already evidence of motor pathology. Nerve conduction studies are done independent of EMGs and independent of [SSEPs] as a matter of standard.

The need for EMG was not relevant to us because we had proven without doubt that the patient had sensory or painful pathology and, therefore, the EMG was not needed * * *. Pain is a sensory response. [If the] patient had developed a scenario of loss of function, motor function—that is, the capacity to move or to lift the arms, something like that—that would have been a different story. But for his complaint of pain, the EMG was not something that we considered as indicated, since we already had a good body of electrodiagnostic studies that gave us the answer.

(Tr. at 571-572) When asked if needle EMG would have provided a more accurate assessment of the nerve or nerve root, Dr. Leak replied:

Absolutely not. Needle EMGs look at muscle pathology per the nerve. And each muscle is supplied by multiple nerves. There's a paper that we're publishing on a patient that had four EMGs in this community by four different doctors. All of the results were different.

[P]art of the concern of EMG is the fact that if the patient doesn't relax, and it's not that easy to relax when somebody pokes you with a needle, then that will look like abnormal pathology. If they're shivering or being cold, and part of the EMG study is not easy to control the ambient environment, that can give variance to the results.

So, no, it is because of the wide variety of results in the same patients having the alleged same study, even in our community, which ha[s] relatively efficient electromyographers, we find the study not to be superior. In fact, it's non-contributory just for pain.

(Tr. at 573)

Testimony of Dr. Griffin

111. Dr. Griffin testified as follows concerning the necessity of needle EMG:

[I]t's essentially a fairly crude test for pain. It's good for motor, but motor is not sensory. Motor's motor. Pain is sensory. Pain, with a signal coming from the injury or chronic pain site to the spinal cord and going up, that's sensory afferent pain.

If you order an EMG, you're getting strictly outgoing signal to the muscle and the response of the muscle. So you're not getting—it's a little bit of a large leap to say that that is an indicator for pain. It's not.

So the SSEP came along, which was a real—it was a scientific attempt to get pain measurement. It doesn't measure pain, but it does measure injury to the nerve or nerve inadequacy. So that procedure is an afferent study for an afferent problem, so that makes more sense than an afferent study for an efferent system, which is just an outgoing study of one system for another.

The SSEP is a refinement. And for those of us that trained on EMGs or with the EMGs as the standard of the time, we had to kind of relearn the electrodiagnostic stuff with the SSEP now being the benchmark, so to speak. And it's a good test. It's not perfect, by any stretch of the imagination, but it's real good if you're trying to show that this patient's not lying to us or there's more to that problem than we suspected.

(Tr. at 3024-3025)

Dr. Griffin added that he has two patients who insist that their pain level actually increased as a result of having had needle EMGs performed. (Tr. at 3026)

Testimony of Dr. Boswell

112. Dr. Boswell believes that nerve conduction studies are valuable even if performed separately from a needle EMG. Dr. Boswell further testified that in individual circumstances it may be valuable to perform one or both. (Tr. at 58-61)

Allegation (1)(f)

113. In its August 9, 2006, notice of opportunity for hearing, the Board alleged in Allegation (1)(f) as follows:

[Dr. Leak] failed to identify and/or document an appropriate indication for the use of the EDX studies on Patients 1, 2, 4, 5, 7-9, 11-23.

(St. Ex. 54C)

Indications for the Use of EDX Studies

Testimony of Dr. Katirji

114. Dr. Katirji criticized Dr. Leak and Dr. Griffin for failing to document the indications for performing EDX studies. Dr. Katirji testified: “Usually you suspect something. You say I’m worried about this, lets do the test to look for that.” However, Dr. Katirji could find no progress notes concerning why the EDX studies in question had been performed. Moreover, Dr. Katirji testified that there had been no mention in the progress notes of the results of the EDX studies. (Tr. at 1041-1044)

115. Dr. Katirji further testified that a statement that appeared in many of the medical records, that Dr. Leak or Dr. Griffin would “plug [the patient] into [their] very extensive diagnostic process,” implies that tests were ordered without any thought process. (St. Ex. 31; Tr. at 1044, 1226-1227; See, e.g., St. Ex. 1 at 136; St. Ex. 2 at 231; St. Ex. 12 at 271)

116. With regard to a statement in his written report that EDX studies “were clearly performed with a ‘cookbook’ approach as evidenced by identical[] SSEPs and NCSs done on all patients regardless of symptoms,” Dr. Katirji testified :

What I meant in here is * * * within the nerve conduction studies * * * exactly the same set of conductions are done. We don’t do the same conductions on every patient the same way and we don’t need to do both sides in a person who has unilateral limb symptoms.

* * *

If you look at every upper limb, it’s exactly the same. Every lower limb, it’s exactly the same. [With regard to nerve conduction studies only, t]hey’re done bilaterally, the same number of nerves, the same number of reflexes. If you have limb pain on the left, why was the right done when the right was normal? So that’s what I’m talking about cookbook. And the nerves are the same. There are more nerves than are tested here. The exactly same nerve is done.

(Tr. at 1233-1235) Moreover, Dr. Katirji testified:

Obviously a technician did [the nerve conduction studies] and was told to do these nerves regardless of the problem. There's no thought process in it at all. It was done just like a cookbook. * * *

(Tr. at 1235)

Furthermore, with regard to SSEP studies, Dr. Katirji testified that, for example, if a patient complained of pain at the T6 level, the patient was tested at T2, T4, T6, T8, and T10. Moreover, Dr. Katirji testified that, at the cervical and lumbar spines, the same levels were always tested. Finally, Dr. Katirji testified that tests "have to be individualized. You can't just do exactly the same on everybody every time whatever the problem is." (St. Ex. 31; Tr. at 1041, 1236-1238)

117. Dr. Katirji testified that electrodiagnostic studies should be a continuation of the examination, and should only be performed based on a patient's symptoms and the limb affected. Moreover, Dr. Katirji testified that the performance of studies in limbs that were not part of the patient's complaint had been a deviation from the standard of care. Finally, Dr. Katirji testified that performing EDX tests on patients when such tests are not indicated constitutes a deviation from the standard of care. (Tr. at 1044-1045)

Testimony of Dr. Bressi

118. Dr. Bressi testified that pain is completely subjective and that physicians have to "validate the patient's subjective impression of their pain." Dr. Bressi further testified that validating a patient's subjective complaint of pain is "part of the art of medicine" and "a work in progress." It involves taking the patient's history and talking with the patient, a physical examination, and ordering diagnostic studies or reviewing records of past diagnostic evaluations. Moreover, Dr. Bressi testified that diagnostic tests "never are there to define the diagnosis. They're there to either support it or not support it * * *." (Tr. at 2265-2268)

Dr. Bressi testified that that would not be unusual for an interventional pain management physician to use diagnostic tests to determine whether a patient actually has pain. (Tr. at 2270)

119. Dr. Bressi testified that it is above the minimal standard of care for a physician to perform or order "broad testing to find out answers" concerning complex chronic pain patients. Dr. Bressi further noted that many of the patients he reviewed in this matter had pain issues that emanated from more than one location or condition. (Tr. at 2446)

Testimony of Dr. Griffin

120. Dr. Griffin disagreed with the allegation that he had utilized EDX studies without identifying or documenting an appropriate indication. Dr. Griffin testified that the need for the studies had been determined shortly after the patient's first visit when the treatment plan was formed. (Tr. at 3022-3024)

Dr. Griffin further disagreed that he had ordered unnecessary tests on patients. Dr. Griffin testified that the studies had been ordered to obtain objective evidence of the patients' subjective complaints of pain. Dr. Griffin further testified that the tests "never made the diagnosis." Dr. Griffin testified, "You've got a large amount of data that has to be included in the process of working out a differential diagnosis." (Tr. at 3020-3022)

Standing Orders for EDX Studies

Testimony of Dr. Griffin

121. Dr. Griffin testified that Dr. Leak had established standing orders to perform SSEPs, nerve conduction studies, and STCs on patients to determine, to the extent it was possible, whether "there was pathology to match the patient pain complaint." Dr. Griffin further testified that, if a patient was going to have a trigger point or chemoneurolytic injection, staff was to perform pre- and post-injection STC tests. (Tr. at 694-695, 765-766, 3013-3014)

Testimony of Dr. Chelimsky

122. Concerning standing orders for each patient to be tested with SSEPs, nerve conduction studies, and STCs, Dr. Chelimsky agreed that the medical records "certainly would reflect that, that every patient got the same diagnostic testing." (Tr. at 1607-1608) Dr. Chelimsky further testified:

[T]he core part of being a physician is selecting those diagnostic tests which are going to provide meaningful information in that patient's care. There are no two patients alike, let alone 24 patients who are alike. So it would reflect absence of conceptualization of patient problems to order the exact same diagnostic tests on 24 patients.

(Tr. at 1608)

Allegations (1)(g), (1)(h)

123. In its August 9, 2006, notice of opportunity for hearing, the Board alleged as follows:

Allegation (1)(g):

[Dr. Leak] failed to properly document an appropriate comment on purported abnormal EDX study results for Patients 1, 5-9, 11-14, 17-19, 21 and 22.

Allegation (1)(h):

[Dr. Leak] failed to change and/or document a change in treatment or management of Patients 1, 5-9, 11-14, 17-19, 21 and 22 based on the abnormal results of EDX studies.

(St. Ex. 54C)

*Comments on Abnormal EDX Study Results*Dr. Katirji's Testimony and Report

124. Dr. Katirji's written report and testimony indicates that a number of SSEP studies yielded abnormal results; however, with one exception,¹⁷ Dr. Leak and Dr. Griffin failed to comment in their progress notes concerning the abnormal results. Dr. Katirji testified that such lack of comment deviated from the standard of care. (Tr. at 1043-1044)

The hearing record contains the following information concerning abnormal results obtained from SSEP studies:

Pt¹⁸	Date	Abnormal Results	Physician¹⁹	Citation to Hearing Record²⁰
1	07/26/01	L5 and S1 left	Dr. Griffin	St. Ex. 1 at 214-215; Tr. at 1050
3	04/25/01	L4 and L5 bilaterally	Dr. Griffin	St. Ex. 3 at 332-333; Tr. at 1064
6	12/27/00	L4 left, L5 & S1 bilaterally	Dr. Leak	St. Ex. 6 at 153-154; Tr. at 1071-1072
7	11/28/00	L5 and S1 bilaterally	Dr. Leak	St. Ex. 7 at 377-378; Tr. at 1073
8	10/14/99	L5 and S1 bilaterally	Dr. Leak	St. Ex. 8 at 542-543; Tr. at 1076-1079
9	06/05/00	L5 and S1 bilaterally	Dr. Leak	St. Ex. 9 at 321-322; Tr. at 1081-1082
11	10/07/99	L4 left	Dr. Leak	St. Ex. 11 at 624-625; Tr. at 1086
11	10/08/99	T6 and T8 right	Dr. Leak	St. Ex. 11 at 622-623; Tr. at 1086
11	10/18/00	T2, T4, and T6 bilaterally	Dr. Leak	St. Ex. 11 at 588-589; Tr. at 1085
11	11/03/00	L4 left, L5 & S1 bilaterally	Dr. Leak	St. Ex. 11 at 586-587; Tr. at 1084
12	11/30/00	C4 – C6 right	Dr. Leak	St. Ex. 12 at 313-314; Tr. at 1094-1095
12	12/05/00	T2, T4, and T6 bilaterally	Dr. Leak	St. Ex. 12 at 332-333; Tr. at 1095

¹⁷ Dr. Katirji testified with regard to Patient 1's December 13, 2001, thoracic SSEP that a comment concerning the abnormal results had been documented in the chart. (St. Ex. 1 at 159-160; Tr. at 1048) That study was not included in this list.

¹⁸ These are the patient numbers as used in the Master Patient Key. The numbers differ from those used by Dr. Katirji in his written report. (St. Exs. 26, 31) See Board Exhibit H, which matches Dr. Katirji's patient numbers to the Master Patient Key.

¹⁹ This is the name of the physician who ordered, performed, or interpreted the test.

²⁰ State's Exhibit 31 and Board Exhibit H also apply to all cases in the table.

Pt¹⁸	Date	Abnormal Results	Physician¹⁹	Citation to Hearing Record²⁰
12	12/01/00	L4 right, L5 & S1 bilaterally	Dr. Leak	St. Ex. 12 at 334-335; Tr. at 1096
13	07/10/00	T8 right could not be obtained	Dr. Leak	St. Ex. 13 at 168-169; Tr. at 1099
13	07/05/00	C6 and C7 left	Dr. Leak	St. Ex. 13 at 170-171; Tr. at 1099-1101
14	03/07/01	C8 right	Dr. Leak	St. Ex. 14 at 209-210; Tr. at 1103
14	03/15/01	T2, T4, and T6 right	Dr. Leak	St. Ex. 14 at 205-206; Tr. at 1102-1103
17	08/14/00	T6 bilaterally	Dr. Leak	St. Ex. 17 at 310-311; Tr. at 1113-1114
18	03/13/01	L4 and L5 left	Dr. Leak	St. Ex. 18 at 279-280; Tr. at 1116
19	09/20/00	L5 and S1 left	Dr. Leak	St. Ex. 19 at 186-187; Tr. at 1117-1118
21	09/18/00	S1 bilaterally	Dr. Leak	St. Ex. 21 at 608-609; Tr. at 1121
22	03/19/01	S1 left	Dr. Leak	St. Ex. 22 at 321-322; Tr. at 1123
22	03/14/01	T6 bilaterally	Dr. Leak	St. Ex. 22 at 323-324; Tr. at 1124

Testimony of Dr. Griffin

125. Dr. Griffin disagreed that he had failed to document an appropriate comment concerning abnormal test results. Dr. Griffin testified:

[I]deally, yes, you document what you do, but at the same time, you—I mean, that’s in the chart. It’s available. All you’ve got to do is look at it and it’s got an interpretation on it. So it seems a little silly to say the same thing over again when we have a clear pattern. Like a second visit is a diagnostic review. We go through all the material that’s ordered and some of the past material.

So it’s possible, I suppose, that we would not make a direct comment about it, but it was always looked at and always included in the process of working out a differential diagnosis.

(Tr. at 3026-3027)

Change in Management Based on the Abnormal Results of EDX Studies

Dr. Katirji’s Testimony

126. Dr. Katirji stated that he could find no evidence of any change in the course of treatment or management of the patients based upon abnormal SSEP results. (Tr. at 1143)

127. Dr. Katirji acknowledged that, if EDX testing confirms a suspected diagnosis, and “[i]f it confirms the exact level that you’ve treated,” it is not necessary to alter treatment based on the abnormal test results. (Tr. at 1266-1267)

Allegation (1)(i):

128. In its August 9, 2006, notice of opportunity for hearing, the Board alleged in Allegation (1)(i) as follows:

[Dr. Leak] failed to form and/or document the formation of an individualized clinical impression for Patients 1-10 and 12-24.

(St. Ex. 54C)

Lack of Overall Clinical impression

Testimony and Written Report of Dr. Chelimsky

129. In his January 31, 2005, written report, Dr. Chelimsky offered the following opinion concerning the care rendered by Drs. Griffin and Leak as documented in the medical records for Patients 1 through 24:

The history was difficult to locate in the chart. It consisted usually of some nurse’s notes, a patient questionnaire that was extensive but not annotated or referenced (in its content) by either the nurse or the physician and usually a brief dictated note which referenced the presence of a history and physical examination in the chart but detailed little history or examination findings itself. The physical examination consisted of a pre-printed form with hand-written notations of normal and abnormal findings by which one could reasonably ascertain the results of the examination.

However, a major downfall occurs in the impression and plan. One cannot find a handwritten or typed formulation, impression, or differential diagnosis, and there is no documentation of synthesis of the clinical facts. A similar comment applies to the diagnostic and therapeutic management plan, which most often simply states, “the patient will undergo our extensive diagnostic testing.” The record reflects no reconstruction of the available information into a cohesive clinical picture. Since such an evaluative process forms the basis of the practice of medicine and surgery in Ohio, its absence clearly constitutes a great violation of minimal standard of care. This was true in every single record reviewed, except that of [Patient 11], where a reasonable impression was dictated by Dr. Griffin. * * *

(St. Ex. 28 at 1)

Moreover, Dr. Chelimsky testified that the standard of care requires that a physician document in the medical record “some kind of thinking expressed by the physician about what the problem is and how they plan to address it.” (Tr. at 1583)

130. Dr. Chelimsky testified that the plan for each patient had always been the same. Dr. Chelimsky explained: “The patient would undergo extensive diagnostic testing. It wasn’t clear what for. And then it’s not clear how that was being used.” Furthermore, Dr. Chelimsky testified that the treatment documented in the medical records seemed like

a series of disconnects. The patient would present, then there was a disconnect between the presentation and the impression, a disconnect between the impression and the plan, which is the extensive diagnostic testing, and then a disconnect between the test results and what was done afterwards. So everything’s disconnected. I’m talking about conceptually disconnected, not physically in the chart.

(Tr. at 1584)

Testimony of Dr. Bressi

131. Dr. Bressi testified with regard to PCC’s medical recordkeeping that, although the records were not perfect, they included the necessary information concerning diagnoses, consent forms, medications, and the doctors’ reasons for putting patients on pain medications and for changing patients’ medications. Dr. Bressi testified that he had had no difficulty in locating the patient histories in the 24 charts that he reviewed, although he acknowledged that he had not been familiar with Dr. Leak’s and Dr. Griffin’s recordkeeping and had to “hunt and peck” his way around the charts. However, Dr. Bressi testified that there was no standard of care from 1999 to 2001 that required medical records to be kept in any particular order. (Tr. at 2309, 2347)

Dr. Bressi further testified that he had found an impression and plan in each of the patient records that he reviewed. Dr. Bressi further testified that the impressions and plans recorded were “well within the minimal standards of care.” Dr. Bressi explained: “They listed diagnoses. They listed plans. They thoroughly introduced the patient to what was expected of them and what they should expect of the chronic pain team. They wrote down diagnostic lists, and they had inclusions in the charts of results or test results that helped them form their diagnostic lists.” (Tr. at 2348-2349)

Testimony of Dr. Leak

132. Dr. Leak believes that the experts who reviewed his charts for the State misunderstood his medical records. Dr. Leak further testified that that is understandable because the patient record exhibits do not look like his medical records. Dr. Leak testified:

In our medical chart, we have dividers that will tell you what’s where, so it’s sort of easy on a given day to go to this section on admission, this section on

the discharge note, this section on the procedure note, this section on our office note.

In this—these are my records and I have a little challenge finding things because it doesn't look like a chart, like a medical chart. So if things are all separated by hundreds of pages, one might see how someone could be mistaken. But that just means you have to look a lot harder.

(Tr. at 2878)

Testimony of Dr. Griffin

133. Dr. Griffin testified that he “completely disagree[s]” with the allegation that he had failed to form or document forming an overall clinical impression of certain patients. Dr. Griffin added that “[t]hat is an amazing allegation” because every chart had a treatment plan in it. (Tr. at 3029-3030)

Medical Records

134. The majority of the medical records contain a single-page, handwritten flowchart labeled as a treatment plan. For example, the treatment plan for Patient 5 states “TX PLAN” at the top, underlined, below which “SPINAL DIFF” was written. Three arrows were drawn below that pointing toward the left, directly below, and toward the right.

- Beneath the left arrow is written “LUMBAR.” Nothing else is written below that.
- Beneath the center arrow is written “THORACIC,” below which is written “PROV DISCO T9 10 T12L1,” and “DONE,” below which is an arrow pointing to the right. Nothing appears at the end of that arrow. Another arrow points down to “3 STAGE” and “DONE,” and yet another arrow points down to nothing.
- Beneath the right arrow is written “CERVICAL” below which is written “PROV DISC C₃₄ C₆₇.” An arrow points down from there to “Z JOINTS C₃₄ – C₆₇.” An arrow points down from there to nothing.

(St. Ex. 5 at 30) Other documents labeled as treatment plans may be found at St. Ex. 2 at 19a; St. Ex. 3 at 13a; St. Ex. 4 at 20; St. Ex. 7 at 8a; St. Ex. 8 at 51, 54; St. Ex. 9 at 14a; St. Ex. 11 at 22, 25; St. Ex. 12 at 16a; St. Ex. 13 at 9; St. Ex. 14 at 15, (at 19 labeled “Dx Review”); St. Ex. 15 at 13; St. Ex. 16 at 13; St. Ex. 17 at 9; St. Ex. 18 at 23; St. Ex. 19 at 13b; St. Ex. 20 at 9a; St. Ex. 21 at 18; St. Ex. 22 at 19; and St. Ex. 23 at 10a. Some are dated, others are not; none are signed or identified as the product of any particular physician.

Allegation (1)(a)

135. In its August 9, 2006, notice of opportunity for hearing, the Board alleged in Allegation (1)(a) as follows:

[Dr. Leak] failed to refer or timely refer and/or document the referral or timely referral of Patients 1-4, 9, 11-21, 23 and 24 for psychological consultation.

(St. Ex. 54C)

Referral for Psychological Consultation

Testimony and Report of Dr. Chelimsky

136. In his January 31, 2005, report, Dr. Chelimsky stated that the “minimal standard of care for chronic pain is early involvement of a psychologist in all cases.” (St. Ex. 28 at 3)

At hearing, Dr. Chelimsky testified that, in chronic pain patients, the standard of care requires that a referral for a psychological examination be made within three months of the patient presenting to the practice, and that the referral be documented in the medical record. (Tr. at 1602-1603) Moreover, Dr. Chelimsky testified:

One would expect to do it more quickly because 90 percent of these patients are depressed, so, you know, the ten percent who aren't, you're not going to do them any harm by getting an evaluation, and you may be wrong. I've often been wrong about thinking who's depressed and who isn't. But 90 percent, you're surely going to help.

(Tr. at 1603)

Testimony of Dr. Bressi

137. Dr. Bressi testified that there is no standard or requirement that every pain patient be referred for a psychological consult within a certain period of time, and that it is within the physician's discretion to refer or not refer patients. Dr. Bressi further testified that chronic pain patients are often already being treated for depression, and they are often being treated for that condition by their family doctor rather than by a psychiatrist or psychologist. Moreover, Dr. Bressi testified that, in his opinion, Dr. Leak and Dr. Griffin met the standard of care in their referrals of patients for psychological consults. (Tr. at 2314-2315, 2317-2318, 2383-2384)

Dr. Bressi testified that, among the 24 patient records he reviewed, he found no patient whom Dr. Leak or Dr. Griffin failed to refer for a psychological consult when there should have been such a referral. (Tr. at 2385)

Testimony of Dr. Leak

138. Dr. Leak testified that the situation in which a behavioral medicine consultation is “absolutely, positively” required, by protocol and policy, are “patients in which there are neuromodulation devices being used. And there’s a specific standard by which that is required.” Dr. Leak testified that all other cases are within the judgment of the physician. (Tr. at 2750-2751)

Dr. Leak further testified that a patient who is threatening suicide is clearly in need of psychological help. However, a patient who simply asks for relief from pain may not need a psychological consultation. (Tr. at 2754-2755)

Moreover, Dr. Leak testified that he is unaware of a standard of care that requires a behavioral consult for all pain patients. Finally, Dr. Leak testified that, like the use of any other type of consultations, behavioral consultations should be utilized on a patient-by-patient basis depending upon each patient’s individual condition. (Tr. at 2757)

Testimony of Dr. Griffin

139. In contradiction of Dr. Leak’s testimony, Dr. Griffin testified, “It was a standing order at the first visit that a consult was made to behavioral medicine.” Dr. Griffin testified that that was the case with every patient. When asked if that information had been documented in the medical records, Dr. Griffin testified: “Sometimes it [was] not. We’ve got a lot of information coming and going, and it’s hard to remember to put every single drivel of information into the chart.” (Tr. at 782-783)

Dr. Griffin testified that “[e]very single patient that came in the door was given a referral to a psychologist who had kind of a specialty in pain management, even to the point of knowing some of what we did interventionally.” (Tr. at 3017)

Patient-Specific Evidence re: Psychological Referrals

140. Evidence concerning psychological referrals for specific patients includes the following:

- **Patient 1:** On the form for Patient 1’s May 23, 2001, initial consultation and evaluation, the following notation appears next to the heading Psychiatric Admissions/Outpatient Evaluations: “Dr. Wallenbrock - gave [patient] antidepressants/sleep aide/depression.” (St. Ex. 1 at 253)

Dr. Leak testified that, at the time Patient 1 had first come to him, Patient 1 was being treated for depression and sleep deprivation by another practitioner. Accordingly, Dr. Leak did not feel a need to refer Patient 1 for a psychiatric consultation. However, Dr. Leak acknowledged that his medical record does not indicate when Patient 1 had received the referenced psychiatric treatment. (Tr. at 576-578)

Dr. Leak further testified that he had interpreted the results of Patient 1's "McGill examination" and concluded that Patient 1 did not require a psychological referral. (St. Ex. 1 at 247; Tr. at 577-578)

- **Patient 2:** Dr. Leak testified that he believes that Patient 2 had been referred for psychological counseling, but that that had occurred outside the time period relevant to this hearing. (Tr. at 603-604)
- **Patient 3:** The regional workup sheet, a document that lists the tests and consults ordered, can be found in each patient's medical record. The regional workup sheet for Patient 3 has check marks that indicate that Patient 3 had been referred for a behavioral medicine consult and that the consult had been completed. However, the dates were not noted and no psychological report is included in the chart. (St. Ex. 3 at 18; See also Tr. at 603-604)
- **Patient 4:** Dr. Leak's medical records indicate that a psychological consult had been ordered for Patient 4, but do not indicate that the consult was completed. (St. Ex. 4 at 19; Tr. at 612-613)
- **Patient 7:** The initial evaluation of Patient 7 took place on May 31, 2000, and he was referred for psychological consultation on August 18, 2000, about 2 1/2 months later. Dr. Chelimsky stated that the standard of care requires a psychology referral within three months of the initiation of care for a patient with chronic pain. Accordingly, in Patient 7's case, the standard of care had been met. (St. Ex. 29 at 1)
- **Patient 8:** In his May 2, 2006, report, Dr. Chelimsky stated that the standard of care for psychological referrals had been met in the case of Patient 8. (St. Ex. 29 at 1)
- **Patient 9:** Dr. Leak acknowledged that there is no record that Patient 9 had been referred for psychological counseling. However, Dr. Leak testified that Patient 9 had suffered from "real pathology" and had not been in need of psychological services. (Tr. at 1350-1351)
- **Patient 10:** A nurse's note dated March 19, 2001, that involves a medication issue includes handwritten notations concerning psychological, dental, and nephrology care. Concerning psychological care, the note states, "Psych - Rebecca Ware OSU" and lists a telephone number. (St. Ex. 10 at 61)

On a consultation and evaluation form for Patient 10 dated March 27, 2001, it is noted that Patient 10 had been self-admitted for psychiatric care for five days in December 1999, and for seven days in March 2000. The consultation and evaluation form did not indicate the reasons for the admissions, the diagnoses, or treatment rendered. (St. Ex. 10 at 124)

The medical record contains no documentation that Patient 10 had been referred for a psychological consult. (St. Ex. 10)

- **Patient 11:** Patient 11's first visit to PCC occurred on August 31, 1999. (St. Ex. 11 at 716)

A July 30, 2001, discharge summary for Patient 11 includes a note referring Patient 11 for a neuropsychological consult. (St. Ex. 11 at 117a)

An August 15, 2001, letter from Dr. Marzella, a psychologist, and Ms. Schrim, a counselor, reports the result of their evaluation of Patient 11. Among other things, their letter states that Patient 11 "reports he currently attends psychotherapy with Moundbuilders in Heath, Ohio to address interpersonal difficulties." (St. Ex. 11 at 374)

In his May 2, 2006, written report, Dr. Chelimsky stated that the July 2001 referral had fallen below the standard of care because it had not been made until two years after Patient 11 had first been seen by PCC. (St. Ex. 29 at 1)

Dr. Griffin acknowledged that Patient 11's referral for a psychological consultation took place about two years after PCC started treating Patient 11. However, Dr. Griffin further testified that Patient 11 had been under the care of a psychologist already. Nevertheless, that information was not documented in the patient record prior to the August 2001 letter from Dr. Marzella and Ms. Schrim. (Tr. at 3106; St. Ex. 11)

- **Patient 12:** Patient 12 first visited PCC on October 25, 2000. Although a record of a psychological referral around the time of her first visit does not appear to be included in the medical record, a December 12, 2000, note by a medical assistant indicates that Patient 12 had canceled her appointment that week with Dr. Bryan, a psychologist. Subsequently, a discharge summary dated February 23, 2001, states in part that Patient 12 had asked to see a psychologist regarding depression. (St. Ex. 12 at 104a, 148, 381)

In his May 2, 2006, report, Dr. Chelimsky stated with regard to Patient 12: "[S]he was first seen [on October 25, 2000] and she was not referred [to a psychologist] until 2/23/01 about four months and this was only at the patient's request, not because the doctor felt this was necessary. This again fell below the standard as it exceeded 3 months." (St. Ex. 29 at 1)

Dr. Leak testified that PCC had attempted to schedule Patient 12 for a psychological consult but that Patient 12 had cancelled the appointment. Dr. Leak added that, on February 23, 2001, Patient 12 had been scheduled for another appointment with a psychologist. Dr. Leak acknowledged, however, that his records do not indicate whether Patient 12 attended the appointment. (St. Ex. 12 at 104a, 148; Tr. at 1389-1402)

- **Patient 13:** The medical record contains no documentation that Patient 13 had been referred for a psychological consult. (St. Ex. 13)

- **Patient 14:** Patient 14 first visited PCC on February 9, 2001. The regional workup sheet for Patient 14 indicates that Patient 14 was referred for a behavioral medicine consult on February 9, 2001, and that it had been completed March 9, 2001. (St. Ex. 14 at 18)
- **Patient 15:** The medical record for Patient 15 indicates that he had first been seen at PCC around March 3, 2000. A nurse's note dated March 3, 2000, states, among other things, "Dr. Darrel Brush, MD, Psych – appt Apr 7, 00." (St. Ex. 15 at 124a)
- **Patient 16:** Patient 16 first visited PCC around May 15, 2001. A document entitled *The Role of Psychologist in Behavioral Medicine*²¹ was signed by Patient 16 and dated May 15, 2001. The document advises Patient 16 of the frequent need for psychological services by patients who have chronic pain, and the services that are offered. The name of the psychologist that the document refers to does not appear on the document. There is no indication that Patient 16 was ever specifically referred to psychological services or that he actually received psychological services. (St. Ex. 16 at 133)
- **Patient 17:** In his May 2, 2006, report, Dr. Chelimsky stated that the psychological aspect of Patient 17's case was not addressed in the medical record until one year after her care began. Nevertheless, no referral was made even at that time. Dr. Chelimsky stated that that had fallen below the standard of care. (St. Ex. 29 at 1)
- **Patient 18:** Patient 18 first visited PCC on or about October 7, 1998. A regional workup sheet for Patient 18 indicates that she was referred for a behavioral medicine consult on February 14, 2001, and that that had been completed March 7, 2001. (St. Ex. 18 at 14, 273, 275)

Dr. Chelimsky testified that Patient 18 did not receive a referral for psychological care until almost three years after she began treatment by PCC. Dr. Chelimsky further testified that Patient 18 had clearly been depressed and was in need of those services. (Tr. at 1762) In his May 2, 2006, report, Dr. Chelimsky stated that this had been "well below the standard of care." (St. Ex. 29 at 1)

Dr. Bressi testified that the medical record for Patient 18 states that, on September 15, 1998, she was referred for psychological services. (Tr. at 2409-2411) The document that Dr. Bressi referred to was from The Ohio State Pain Center and not from Dr. Leak or Dr. Griffin. However, it does appear that she had been referred by someone to psychological services at that time. (St. Ex. 18 at 134-136; See St. Ex. 18 at 135 under "Treatment")

²¹ This document purports to be a message to a generic patient from an unnamed psychologist or psychiatrist. The document discusses the association between chronic pain and the need for psychological intervention in a very general way. It also suggests that the services of the unidentified author are available should the generic patient so desire.

- **Patient 19:** Patient 19 was first seen by PCC on or about June 27, 2000. The document entitled The Role of Psychologist in Behavioral Medicine was signed by Patient 19 and dated June 27, 2000. The document advises Patient 19 of the frequent need for psychological services by patients who have chronic pain, and the services that are offered. The name of the psychologist that the document refers to does not appear on the document. There is no indication that Patient 19 was ever specifically referred to psychological services or that he actually received psychological services. (St. Ex. 19 at 176)
- **Patient 20:** Patient 20 was first seen by PCC on or about November 8, 1999. (St. Ex. 20 at 467)

In his May 2, 2006, report, Dr. Chelimsky stated that Patient 20 had not been referred to a psychologist until 1 1/2 years after he began treatment with PCC. Dr. Chelimsky testified that this falls below the minimal standard of care. (St. Ex. 28 at 3; St. Ex. 29 at 1)

- **Patient 21:** Dr. Leak testified that, during his treatment of Patient 21, Patient 21 had been referred for a behavioral medicine consultation. (Tr. at 2857-2858) It is difficult to tell from the medical record when Patient 21 had first visited PCC. However, she had been treated at PCC since at least September 9, 1999. (St. Ex. 21 at 310a-311b)

The regional workup sheet for Patient 21 is blank concerning behavioral medicine referrals. However, a series of psychology case notes authored by Dr. Bryan begin on April 13, 2001. The first note states that Patient 21 had been seen on an emergency basis at the request of Dr. Griffin. (St. Ex. 21 at 684-690)

- **Patient 23:** Patient 23 was first seen by PCC around February 9, 2001. The document entitled The Role of Psychologist in Behavioral Medicine was signed by Patient 23 and dated February 9, 2001. The document advises Patient 23 of the frequent need for psychological services by patients who have chronic pain, and the services that are offered. The name of the psychologist that the document refers to does not appear on the document. There is no indication that Patient 23 was ever specifically referred to psychological services or that he actually received psychological services. (St. Ex. 23 at 87, 97)
- **Patient 24:** Patient 24 was first seen by PCC on August 30, 2000. A discharge summary dated August 30, 2000, indicates that Patient 24 had been referred for a behavioral medicine consultation with Dr. Bryan. The record contains no other information regarding that referral. (St. Ex. 24 at 80b)

Allegation (1)(b):

141. In its August 9, 2006, notice of opportunity for hearing, the Board alleged in Allegation (1)(b) as follows:

[Dr. Leak] failed to refer Patients 20 and 23 to an addiction medicine specialist and/or obtain toxicology screens despite signs of drug abuse and/or diversion.

(St. Ex. 54C)

Evidence Specific to Patient 20

Drug-Seeking Behavior

142. A copy of a report from the Obetz Police Department states that on February 18, 2001, Patient 20 had reported to police that he had lost his medication, consisting of 25 tablets of OxyContin. The report also states, "Doctor will not refill his prescription without a report." Finally, it indicates that, a few days later, Patient 20 reported the event to PCC on February 23, 2001. (St. Ex. 20 at 42)

A handwritten, undated note on a copy of two prescriptions issued by Dr. Hoogendoorn on February 19, 2001, states: "Opioid Transition Pack. 'Meds lost.' 'Police won't take report.' Lost or overtook meds in January." (St. Ex. 20 at 38) (Emphasis in original)

A Discharge Summary dated February 21, 2001, states, "We will not prescribe opioids until we have a police report and we may change your medication." (St. Ex. 20 at 99a) A written note by Dr. Griffin describes the episode in greater detail. (St. Ex. 20 at 175) Similarly, a nursing assessment that date concerned Patient 20's effort to get a police report. (St. Ex. 20 at 100a)

143. Subsequently, on February 23, 2001, Patient 20 and his spouse saw Harry Bryan, Ph.D. Dr. Bryan's Psychology Case Note primarily concerns Patient 20's marital problems, but Dr. Bryan also noted that Patient 20 had brought a copy of the police report. Dr. Bryan further noted that that had been a second occurrence of lost medication for Patient 20. (St. Ex. 20 at 177)

144. A progress note dated March 15, 2001, states that Patient 20 had been seen that date for a follow-up. The note further states, in part:

Unfortunately for [Patient 20] he has increased his methadone [a] couple of tablets here and there and he ran out two days ago. This is becoming a pattern for him. He states that he did not realize that it was self-endangering, and the increase did not seem to help. He also is stating that he is not sleeping well

and he also states that he has not been taking his Vioxx and he has run out of his Doxepin today. * * *

(St. Ex. 20 at 183)

The note further indicates that Dr. Hoogendoorn, under the supervision of Dr. Griffin, had discussed with Patient 20 his excessive use of prescribed opioid medication. His treatment regimen was adjusted and the note states that he was verbally reprimanded for mismanaging his medications and thereby endangering himself. (St. Ex. 20 at 183)

Testimony of Dr. Chelimsky

145. Dr. Chelimsky testified that after Patient 20 had reported losing his medication and increasing his medication on his own he should have had a toxicology screen and been referred to an addiction specialist. Dr. Chelimsky further testified that neither was documented. Dr. Chelimsky testified that that deviates from the standard of care. (Tr. at 1767-1769)

146. Regarding the necessity for addictionology consult, Dr. Chelimsky testified:

I think it's very hard as a single practitioner to both be the prescribing doctor and the assessing doctor. You need somebody, another pair of eyes, to take a look at this person and get another perspective and see what's really happening here. And I think a lot of these patients, a psychologist can unearth issues about addiction that you cannot. You feel for them and you want to do what's right for them, so you get bamboozled, I think.

(Tr. at 1625)

Testimony of Dr. Leak

147. Dr. Leak acknowledged that it would appear from the medical record that Patient 20 either had a diversion issue or pseudoaddiction. When asked why Patient 20 had not been referred to an addiction medicine specialist, Dr. Leak replied that the problem presented by Patient 20 had been within the scope of PCC's management. Dr. Leak further testified that he believes that Drs. Griffin and Hoogendoorn had handled the situation appropriately. Moreover, Dr. Leak testified that, in 2001, "referral for pain and addiction medicine specialists in this community would be like sending a text message. There would be nowhere for it to go because the technology had not been developed or the capacities to handle these issues were not well defined." Finally, Dr. Leak testified that he does not believe that a toxicology screen had been required under Patient 20's circumstances. (Tr. at 1435-1438)

148. Dr. Leak testified that, if he believes that a patient may be diverting his or her medication, the patient is given an "opioid transition pack" to move them off of opioid medication. (Tr. at 1434)

*Evidence Specific to Patient 23*Drug-Seeking Behavior

149. Patient 23 first visited PCC on February 14, 2001. He filled out a patient history form that states, among other things, that he is a “recovering cocaine addict.” In the space labeled “How Long Ago,” he responded “15 yrs.” In addition, under the heading, “Methadone/Detox Programs,” Patient 23 responded, “Recovering alcoholic for 3 yrs, 1998. 1986: cocaine.” Finally, Patient 23 indicated that he “smokes marijuana seldom,” once per month. (St. Ex. 23 at 116-117)

A nursing assessment dated February 14, 2001, states, among other things, that Patient 23’s history of marijuana use was discussed. A urine toxicology screen was evidently discussed or ordered as well; the note states, “tox screen at Leak Labs.” (St. Ex. 23 at 60a) However, the results of the toxicology screen are not included in the medical record. (St. Ex. 23; Tr. at 1468)

150. A note dictated by Dr. Griffin concerning an April 3, 2001, visit states that Patient 23 had “fallen short with his Vicodin” by two days. The note further stated that Patient 23 had recently been through treatment adherence training [TAT]. The note states that Dr. Griffin discussed with Patient 23 the laws of the State and the requirements of PCC. Moreover, the note states that the Patient 23 is aware that he cannot increase his medication without Dr. Leak’s or Dr. Griffin’s approval. Finally, the note states:

[A]t this point in a humane effort to manage his pain better, we will keep him on the Norco for breakthrough and add OxyContin 10 mg [twice per day] as a better base. This might make him more comfortable. He is trying to continue to work and we also recommended a kneepad to him. He has forward movement and has been making good efforts. He knows he has to maintain forward progress.

(St. Ex. 23 at 67)

151. A nursing assessment dated April 24, 2001, states, among other things, that Patient 23 had reported losing a prescription for OxyContin #46 given to him during a previous visit on April 12, 2001. The note states that Patient 23 had also visited the office on April 17, 2001, but had not mentioned the loss of his script at that time out of fear that he would “get in trouble.” In addition, the note states that that had been the second time that Patient 23 had reported losing a prescription. (St. Ex. 23 at 39b)

Moreover, the discharge summary for that visit states that Patient 23 was instructed “to bring script for OxyContin to next visit. Bring in police report. No further opioids will be given.” The discharge summary was signed by Dr. Griffin, among others. (St. Ex. 23 at 40b)

152. On the first page of the medical record for Patient 23 there is a note with the heading, "MEDICAL ALERT," that states "*OPIOID WARNING" and "4/2/01 – SHORT." It also indicates that the patient lost prescriptions twice and that both prescriptions were found. (St. Ex. 23 at 1a; Tr. at 2964-2965)

153. Dr. Leak testified that PCC had treated Patient 23 for only three months. (Tr. at 1468)

Testimony of Dr. Chelimsky

154. Dr. Chelimsky testified that, in the specialty of pain management, all physicians have to deal with the issue of determining which patients are seeking narcotics for illegitimate purposes. Dr. Chelimsky noted that it is a very difficult problem for any physician to deal with. (Tr. at 1622-1623) However, Dr. Chelimsky testified:

I think there were certain red flags in these charts, people losing prescriptions over and over, not taking the other prescribed medications. There was evidence that potentially these patients were actually diverting medications, not using them themselves, but using them to sell them or whatever. So there should have been either a psych referral or a tox screen or both done whenever the realization occurs.

(Tr. at 1623) Dr. Chelimsky further testified, however, that he could find no documentation in the medical records for Patients 20 or 23 that either had been seen by a psychologist or had submitted to toxicology screens. (Tr. at 1623-1624)

155. When asked what the standard of care requires if a patient refuses to see an addictionologist or psychologist, Dr. Chelimsky replied:

[O]nce you've requested them to do that, then you need to stop the opiates if they refuse to do what it is you've asked them to do. If they go, then that's fine, then you can continue the opiates until they've either been cleared from an addiction issue or until they've been found to be addicted, in which case you're going to stop it anyway. But anytime there's a suspicion of diversion, then you need to take action. That would be those things I've described. And if they refuse, then you would stop the opiate.

You have a choice as to how to stop the opiate. You can either stop it cold and give them some Clonidine and some other medications for withdrawal, or you can hospitalize them and put them on some buprenorphine taper. But you need to stop it relatively immediately.

(Tr. at 1625-1626)

156. Dr. Chelimsky testified that Patient 23 was at a very high risk for drug abuse and possibly diversion due to his past substance abuse problems. Following Patient 23's overuse of his Vicodin, a toxicology screen should have been obtained and either opiate prescribing should

have ceased or the patient should have been referred to an addiction specialist. Dr. Chelimsky testified that neither of those things occurred. (Tr. at 1785-1786)

Testimony of Dr. Bressi

157. Dr. Bressi testified that he runs one of the largest pain centers in the country, and that his practice issues thousands of prescriptions per week. Dr. Bressi testified that most of the time when a patient who comes in for an initial evaluation, he or she will get a urine screen. Urine screens are also performed periodically when the provider feels the need to do one. Dr. Bressi testified that urine screens on established patients should show the medications that are being prescribed, and should not show illegal substances. In addition to urine screens, Dr. Bressi testified that his pain center does pill counts. Patients are asked to bring their medications to the office and the pills are counted to determine if the patients are adhering to the prescription policy. (Tr. at 2311-2312)

However, Dr. Bressi noted that a pill count that does not come out exactly right does not necessarily mean the patient is misusing medication. Likewise, a urine screen that fails to show a medication that the patient is taking does not necessarily mean that the patient is noncompliant or diverting the medication. It *does* mean, however, that there is an issue that the provider must discuss with the patient. (Tr. at 2312-2314)

158. Dr. Bressi testified that a patient losing a prescription once is not necessarily a sign of diversion. However, if it happens twice, it is a problem, and the physician must determine the best way to approach it. Dr. Bressi testified to the effect that the physician needs to discuss the issue with the patient to determine the reason why the patient is inappropriately seeking medication. (Tr. at 2455-2457)

159. Dr. Bressi was asked with regard to the period 1999 to 2001 whether there had been standards to ensure that patients were not “gaming the system to get more meds.” He replied that there was no standard, and that it was up to the physician to determine whether something needed to be investigated further. (Tr. at 2314)

Dr. Bressi testified that toxicology screens are somewhat controversial in pain medicine because of the possibility of false negatives for medications the patient is supposed to be taking. This can lead to a false conclusion that the patient is diverting the medication. Dr. Bressi further testified:

[A]round the country innocent patients have been discharged [from physicians’ practices] because of being negative on a urine drug screen, for instance, for Percocet or Hydrocodone, which are short-acting, narcotic-based pain medicines. The problem is that it clears so fast that by the time they take the medicine and then go down and do the urine drug screen, whatever time that is, the medicine may have passed through and may not be in the urine. So they may be legitimately taking the medicine, but it’s not in the urine.

(Tr. at 2312-2313) Dr. Bressi testified that toxicology screens are therefore not used by all pain medicine physicians, and are not required by the standard of care. (Tr. at 2314)

160. Dr. Bressi testified that, in his opinion, Dr. Leak and Dr. Griffin referred patients to addiction services in accordance with the standard of care. (Tr. at 2316)
161. Dr. Bressi testified that, despite the history of drug abuse, losing prescriptions, and increasing his dosage without approval, Patient 23 did “not necessarily” require a consultation with an addictionologist. Dr. Bressi noted that recovering addicts have often already been through treatment and counseling. Dr. Bressi further testified that the treatment of such patients for chronic pain is very complex, and that many physicians would refer such a patient for addiction services; however, depending on the physician and the physician’s interaction with the patient, it is not absolutely required. (Tr. at 2944-2945)
162. Dr. Bressi testified that a patient reporting occasional use of marijuana would not stop him from providing pain management services, especially if the patient was honest and up-front about it. However, Dr. Bressi testified that he will not continue to treat a patient who continues to use illegal substances. If such a patient wishes to remain a patient at Dr. Bressi’s pain center, the patient must quit using illegal substances. (Tr. at 2461-2462)

Testimony of Dr. Leak

163. In light of Patient 23’s previous struggles with alcohol and cocaine and his then-current use of marijuana, Dr. Leak was asked why Patient 23 had not been referred to an addiction medicine specialist. Dr. Leak replied that they had treated Patient 23 as someone who suffered from pain. Dr. Leak further testified: “There has to be some tolerance and personal understanding with people. And before you label and get an individual who has a job and private insurance labeled as an addict again, which has dire consequences, you attempt to give them enough rope and give them credit for the possibility of pseudoaddiction.” (Tr. at 1460) Dr. Leak further testified:

[Considering] the intensity with which Dr. Griffin handled this, that it was within the scope of our practice and within the scope of pain medicine as we were expected also to be able to monitor and medicate in the addicted patient.

* * * This gentleman needed an enormous amount of education, and it looks as though that was afforded to him in a very appropriate manner.

(Tr. at 1461)

164. Dr. Leak testified that he interprets Dr. Griffin’s April 3, 2001, note to mean that Patient 23 potentially had signs of diversion, but also that he may have pseudoaddiction and require re-education. Dr. Leak further testified that pseudoaddiction occurs when a patient is treated for pain but not given enough medication to control the pain. Under those circumstances, patients can start to behave like addicts when, in fact, they are not. Dr. Leak opined that

Dr. Griffin had treated Patient 23 as having pseudoaddiction, and attempted to better control Patient 23's pain and educate him. (Tr. at 1458-1463)

165. With regard to Patient 23's ongoing use of marijuana, Dr. Leak testified: "As subspecialists, we end up having to treat the addicted patient for pain. In this scenario, marijuana alone is not a stopping point. Cocaine and heroin would have made a significant difference if he had indicated that was an ongoing concern." (Tr. at 1462)

Further Testimony of Dr. Chelimsky

166. Dr. Chelimsky testified that the term "pseudoaddiction" refers to a patient who behaves as though he or she is addicted when in fact there is another cause for the behavior. Dr. Chelimsky testified that the cause is usually an escalating level of pain, increasing tolerance to the opiate's pain-relieving effect, or a desire for more pain relief. However, Dr. Chelimsky testified that some studies show that patients who exhibit pseudoaddiction do not report that they have lost a prescription or their medication. They are much more likely to be straightforward and ask the physician for more pain medication. The physician then must determine if the patient is addicted or actually has a legitimate medical need for more medication. (Tr. at 1627-1628)

Further Testimony of Dr. Bressi

167. Dr. Bressi testified that pseudoaddiction occurs when a patient's pain is not controlled well enough and the patient seeks to get control. Dr. Bressi further testified that, once pain control is obtained, the patient stops engaging in that behavior. Moreover, Dr. Bressi testified that "pseudo addiction is probably the most common behavior pattern that causes suspicion and alarm. Addiction is much rarer. (Tr. at 2315-2316)

Testimony of Dr. Griffin

168. Dr. Griffin testified that PCC relied more upon its in-house psychologist²² than referrals to an addiction medicine physician. Dr. Griffin testified, "We had great difficulty getting anybody to any of the M.D. addictionology people to do an assessment on the patients." (Tr. at 793-794)
169. Dr. Griffin testified that the toxicology screen mentioned in the February 14, 2001, note was based on a "[s]tanding order for labs." However, Dr. Griffin further testified that the results of toxicology screens were not always recorded in the medical record. Dr. Griffin further testified, "I think one of the great weaknesses of the practice was the inability to get all the information into the record." (Tr. at 791-793)
170. Dr. Griffin testified that a patient who smokes marijuana can be treated in a pain medicine practice. Dr. Griffin added, "It doesn't mean we gave him medications, but we don't

²² Dr. Griffin was probably referring to Dr. Bryan. However, Dr. Leak testified that Dr. Bryan had his own office and was not an employee of PCC. (Tr. at 1403-1407)

necessarily deny them the opportunity to have their pain relieved by interventional techniques.” (Tr. at 795-796)

171. Dr. Griffin testified that if he obtained information that a patient was possibly misusing medication, the standard practice was to “discuss that with the patient and strongly recommend that they see an addictionologist.” However, Dr. Griffin testified that patients sometimes would simply not go. Dr. Griffin testified that, in those cases, the patients were not just dismissed from the practice. Dr. Griffin testified that PCC would wean the patient from opioids but would continue to treat the patient with interventional techniques. (Tr. at 3019-3020)
172. Dr. Griffin testified that prescriptions were typically issued to last one month with no refills. Dr. Griffin testified that they did so in order to maintain tight control on the patients’ medication and to give the physicians an opportunity to evaluate the patients for side effects. (Tr. at 3050-3051)

Allegation (1)(i):

173. In its August 9, 2006, notice of opportunity for hearing, the Board alleged in Allegation (1)(i) as follows:

[Dr. Leak] failed to provide critical individualization of treatment, and instead inappropriately engaged in a “cook-book” approach to pain management treatment.

(St. Ex. 54C)

Dr. Chelimsky’s Written Report

174. In his January 31, 2005, report, Dr. Chelimsky stated, in part:

The approach to pain management is uni-dimensional. Medications targeted primarily pain relief. The caregivers considered the management of sleep occasionally, while the management of depression occurred very rarely. Psychological services provided by Dr. Bryan seemed reasonable and it is a pity they were utilized only in a minority * * * of patients. * * * Several of the patients requested a rehabilitative approach to pain management, which was generally not pursued (although referrals to physical therapy occurred appropriately, there was no evidence of inclusion of this dimension of care into the overall approach). * * *

* * *

Conceptually the use of the treatment adherence-training (“TAT”) program is appealing. However, all of these reports have identical boilerplate language

with identical sign in and sign out times of 8 AM and 12 PM. They vary only in the small paragraphs surrounding the review of systems and vital signs.

* * * Overall, the documentation for this activity suggests a “cook-book” approach, not providing the critical individualization of treatment needed to satisfy minimal standard of medical care.

(St. Ex. 28 at 3)

Allegation (1)(j):

175. In its August 9, 2006, notice of opportunity for hearing, the Board alleged in Allegation (1)(j) as follows:

[Dr. Leak] inappropriately threatened to withhold prescriptions from Patients 5 and 12 unless they gave consent to perform diagnostic and/or invasive procedures.

(St. Ex. 54C)

Patient 5 Medical Records

176. The medical records for Patient 5 include a lengthy letter dated April 23, 2000, addressed to Dr. Leak from Patient 5. In that letter, Patient 5 complained that he had been “kicked to the curb” the last time he visited PCC. Moreover, Patient 5 stated, “I was given an ultimatum by nurse Marianne. I was informed that unless I had this procedure done (spinal tap differential), * * * I couldn’t get any more drugs from you guys.” Patient 5 asked that he be prescribed the medication he asked for—Ambien, Vicoprofen, and Remeron—and be allowed to schedule a consult to discuss the spinal differential procedure. (St. Ex. 5 at 220A-221B)

177. A nursing assessment dated April 17, 2000, Patient 5’s last visit before writing his letter, indicates that Patient 5 had been very nervous and reluctant to submit to the spinal differential. Among other things, Patient 5 is quoted as saying, ““You are scaring me to death. You are scaring me to death.”” The nursing assessment indicates that the spinal differential had been planned because Patient 5 “did not respond to opioids.” (St. Ex. 5 at 117b)

The discharge summary for Patient 5’s April 17, 2000, visit indicates that Patient 5 had refused to submit to the spinal differential. Under the heading Current Medications by PCC, it states, “Stop all medications on mailer.” Finally, the discharge instructions state, in part, “We will hold off on treatment until you schedule differential.” (St. Ex. 5 at 116a)

178. A May 11, 2001, letter addressed to the Master Clinic from Dr. Griffin states, in part:

[Patient 5] is at [PCC] today for his first visit in the last 11 months. He was previously a patient here and we had worked out a treatment plan for him that

involved a spinal differential. During spinal differential, we attempt to determine what medication will help his pain, whether he is a responder to opioids, local anesthetics, or is factitious. Last summer when we spoke of this, he was extremely reluctant to proceed and asked for a year off stating that he would rather lay around for three years with his pain waiting for it to go away than be stuck with a needle. At that time and now, that philosophy is not acceptable to this practice nor to the laws of the land and we divorced ourselves of further involvement with him until such time as he was ready to proceed along his designed treatment plan. * * *

(St. Ex. 5 at 218) Dr. Griffin further stated that Patient 5 had appeared for his appointment on May 11, 2001, and continued to be reluctant “to be stuck with needles.” Dr. Griffin went on to describe his interaction and plan for Patient 5. (St. Ex. 5 at 218-219)

Patient 12 Medical Records

179. A note dated January 18, 2001, dictated by Dr. Hoogendoorn states that Patient 12 had recently experienced increased pain that left her unable to work “for a couple of days.” He noted that Patient 12 had rated her pain as “5.” In addition, the note states, in part:

1. I advised the patient that we need to have the rest of her diagnostic studies completed within the next week after which time we will develop a treatment plan and do a diagnostic review and may perform an ablative procedure that will decrease the amount of toxic substances that were necessary to introduce into her body on a daily basis to maintain her activities of daily living and functioning.
2. I will increase her Norco to up to 4 times a day from 2 a day due to her increased pain. **I explained to her that she is required at this point to complete her diagnostics before we increase her pain medication.**

(St. Ex. 12 at 191) (Emphasis added)

180. The medical records for Patient 12 indicate that she had been scheduled for a second C2 dorsal root ganglion injection on March 29, 2001. (St. Ex. 12 at 96a-101b, 296-297)

A nurse’s note dated March 29, 2001, states:

[Patient 12] called numerous times on the after-hours mail. She missed her surgery this morning, “woke up in too much pain. I do not want to terminate my care with you, my right leg is hard to even move” and wants to reschedule her surgery, even though she was specifically instructed to have the procedure today that it would actually help with her myofacial pain. Called back several other times wanting to reschedule the surgery for Monday or Tuesday. She was not trying to get out of surgery. These calls were transferred to Sharon. She was rescheduled for Monday, 04/02/01. In the meantime, her mailer was

put on hold. The prescriptions are here; if she does come for her surgery as directed, then she will get the prescriptions.

(St. Ex. 12 at 172)

Testimony of Dr. Chelimsky

181. Dr. Chelimsky testified that, “under any circumstance, to withhold a medication for a procedure is inappropriate. * * * A patient always has the option to say no without any punishment, any adverse effect in their treatment, if they do not want a procedure. That’s standard of care.” (Tr. at 1700-1701) Dr. Chelimsky further testified that, if a physician believes a test is critical to the care of the patient, it may not be unreasonable to tell the patient that the physician cannot continue the patient’s care unless the patient has the test. However, Dr. Chelimsky testified that it is below the minimal standard of care to simply withhold medication until a patient submits to a test. (Tr. at 1961-1962)
182. Dr. Chelimsky distinguished the circumstances of Patients 5 and 12 from a situation where a physician withholds prescribing opiate medication until a patient submits to a toxicology screen. Dr. Chelimsky testified, “In that setting, there’s a direct relationship to the administration of the drug.” (Tr. at 1963-1964)
183. With regard to the treatment of Patient 5, Dr. Chelimsky stated in his January 31, 2005, report:

Medical care in this record (that of [Patient 5]) took on a particularly disturbing, coercive flavor. The patient would not be given opiates, unless he agreed to the procedures they wished to perform. These were themselves not indicated! For example he was told that a spinal differential block would help the providers select medications. This is simply not the case. A spinal differential block can help localize the pain source, but plays little if any role in medication selection. * * *

(St. Ex. 28 at 3) Dr. Chelimsky reiterated these statements at hearing. (Tr. at 1604-1606)

184. With regard to the treatment of Patient 12, Dr. Chelimsky testified that there is a “common theme” in both the January 18 and March 29 notes: “[T]he prescription of medications is contingent on the completion of either diagnostic or therapeutic procedures.” (Tr. at 1740)

Testimony of Dr. Bressi

185. Dr. Bressi testified regarding the allegation that Dr. Leak had coerced Patient 5 and Patient 12. Dr. Bressi testified that these episodes appear to have been “taken out of context” and that it had been unfair to use them to judge Dr. Leak and Dr. Griffin, particularly as it relates to the standard of care. Dr. Bressi testified that pain medicine is an

extremely stressful specialty, the practice environment is emotionally charged, and the patients sometimes can be very difficult to deal with. Dr. Bressi further testified:

To take that out of context and judge a pain practice that's been going X amount of years with large volume and treating multiple patients and training multiple residents, which one of the residents in my program completed his fellowship with Dr. Leak. It's just—I didn't understand the evaluation of what it had to do with standards of care.

(Tr. at 2470-2471; See also Tr. at 2394-2395, 2467-2469)

Finally, Dr. Bressi testified, in his opinion, the care provided to Patient 5 and Patient 12 had been appropriate and within the standard of care. (Tr. at 2412)

Testimony of Dr. Leak

186. Dr. Leak testified that if a patient is not cooperative he does not have to be coercive to get the patient to comply. Dr. Leak testified:

For the most part, we are dealing with independent thinking individuals. Some just have not had the proper cultural experience to help them appreciate what we're offering. So it requires some explanation so that—I mean, I see people constantly who say, I just came here to get my drugs. Well, I'm sorry, but let's see why you need these drugs and we will make a—we will give them a prescription.

(Tr. at 2880)

187. Dr. Leak testified that, in the case of Patient 12, the nurse had determined to withhold Patient 12's medication, and he could not recall if the matter had ever been brought to his attention. Dr. Leak further testified that his nurses have the latitude to exercise "nursing judgment" when dealing with patients. Dr. Leak added that if a patient does not adhere to his or her treatment plan "the treatment plan is interrupted until there is a conference to determine where we will continue to go with the treatment plan." Dr. Leak denied that the nurse had tried to coerce the patient. Dr. Leak added that the note does not indicate that Patient 12 had been out of medication at the time. (Tr. at 1382-1387)

Allegation (1)(l):

188. In its August 9, 2006, notice of opportunity for hearing, the Board alleged in Allegation (1)(l) as follows:

[Dr. Leak] engaged in and/or supervised the excessive use of invasive techniques and blocks, including: chemoneurolytic and other injections and/or radiofrequency lesioning; and/or spinal decompression; and/or discography or

provocative discography; and/or thoracic decompression; and/or root ganglion injections in Patients 2-5, 7-9, 11, 12, 14, 15, 17, 18 and 20-22.

(St. Ex. 54C)

Testimony and Written Report of Dr. Chelimsky

189. In his January 31, 2005, report, Dr. Chelimsky wrote, “Interventions played an inappropriately prominent role in the treatment of the patient[s] in this practice and the use of invasive techniques and blocks is clearly excessive.” (St. Ex. 28 at 3)
190. With regard to Dr. Leak’s and Dr. Griffin’s use of interventional modalities such as trigger point injections, chemoneurolytic injections, and radiofrequency lesioning, Dr. Chelimsky testified:

[I]nterventions in and of themselves are entirely appropriate to use in chronic pain, and the issue is how do you use them and how many. And so in general * * * the most effective gain for the patients from an intervention will occur if it’s done in the context of a functional goal.

So you want to have a specific—like something simple. I can’t stand up at my sink and wash my dishes. I want to wash my dishes for 15 minutes at a time instead of three minutes at a time. That’s a specific functional goal that you agree to. But I think even more than that, certainly for an intervention, you need to have some kind of pain relief goal. How long? How much? How much pain is acceptable? How much pain relief is acceptable? What are we going to call success? What are we going to call a failure?

The notes primarily reflected, well, the person liked the block, didn’t like the block, but there’s no sense of even some kind of objectivization of, okay, they could do such and such afterwards which they couldn’t do before or their pain dropped so much. I mean, I think there were occasions. I’m not saying every single case they didn’t measure pain, but in general, that was not objectivized.

So those are the points that address how the blocks were done. They were just done in a way—in an almost seemingly haphazard way in relation to function. The other point is there were huge numbers of blocks done, enormous numbers of blocks done.

(Tr. at 1612-1613)

Furthermore, Dr. Chelimsky testified that, if a patient simply receives pain-relieving injections every one or two weeks for two years: “at the end of the two years, you’re in exactly the same place you started from. You haven’t actually done anything for the patient. So that’s why coupling with function is so critical.” (Tr. at 1614)

Procedures – Trigger Point Injections

191. Dr. Chelimsky testified that a trigger point is a place on the body that, if pressed, triggers pain that is felt in a different area than that being pressed. For example, a trigger point in the shoulder, if pressed, can cause pain that travels into the elbow and finger. Dr. Chelimsky testified that a trigger point injection is an injection of anesthetic, and possibly a steroid or other anti-inflammatory agent, into a trigger point. Dr. Chelimsky further testified that a physician needs to perform a physical examination to find trigger points. The physician palpates areas that are likely to have trigger points, which includes the shoulder areas, over the shoulder blades, along the mid-portion of the spine, and the hip and buttock regions. The physician can distinguish between trigger points and tender points by asking the patient if the pain travels. Further, Dr. Chelimsky testified that a trigger point “will usually have a little bit of an indurated feel to it.” (Tr. at 1572-1574)

Dr. Chelimsky testified that trigger points are different from tender points. Tender points are areas of localized pain that, if pressed, do not produce pain in other areas of the body. Dr. Chelimsky believes that many of the procedures documented as trigger point injections in the patient records were actually tender point injections. Dr. Chelimsky testified that the records do not document searches for trigger points, and that no patient could have 30 or 40 trigger points as some of the procedure notes would indicate. (Tr. at 1573, 1618-1619)

192. In addition, Dr. Chelimsky testified that an excessive number of injections had been administered. Moreover, with regard to injections that contained a steroid such as Depo-Medrol, Dr. Chelimsky testified that the amount of steroid required to give, for example, 40 injections, at a quarter to a half of a cc per injection, becomes a very large combined dosage. (Tr. at 1618-1620)

Dr. Chelimsky testified that the amount of steroid that a patient receives over a period of time must be limited. Giving an excessive amount of steroids can cause suppression of the body’s ability to make its own cortisone, increase the risk of osteoporosis, and/or create the risk of infection. (Tr. at 1615-1616)

When asked how many steroid-containing trigger point injections would approach the limit of the standard of care, Dr. Chelimsky replied, “Well, certainly doing 30 or 40 in a person would be below the standard of care * * * [i]n the time frame of a month or two, in the time frame of a year, even. One wouldn’t do that many injections.” (Tr. at 1616-1617)

Testimony of Dr. Bressi

193. The testimony of Dr. Bressi concerning the issue of trigger points versus tender points was largely consistent with that of Dr. Chelimsky. Dr. Bressi also testified that trigger points are typically near the places where muscles insert onto bone. (Tr. at 2250-2251)

Dr. Bressi testified that tender points are more often felt in the belly of a muscle rather than near an insertion point. Dr. Bressi noted that tender points are characteristic of fibromyalgia, which is a syndrome that “is still very controversial in the medical field.”

Dr. Bressi stated that the techniques for performing trigger point and tender point injections are essentially the same. (Tr. at 2318-2319, 2440-2441)

Testimony of Dr. Leak

194. When asked for a description of a tender point, Dr. Leak replied:

A tender point is a—an amorphously described area when people don't agree on whether it's a trigger point or not. Trigger points have not exactly been ubiquitous in their definition. And when people talk about tender point versus trigger point, contrary to some, the treatment is pretty much the same.

(Tr. at 2921)

Dr. Leak further testified that it is “absolutely” appropriate to inject tender points “if it takes the pain away[.]” (Tr. at 2921)

Testimony of Dr. Griffin

195. Dr. Griffin disagreed that he had utilized or supervised the excessive use of invasive techniques and blocks in his patients. Dr. Griffin testified that, when faced with a patient in pain, he would not withhold helpful treatment. (Tr. at 3030-3031)

196. Dr. Griffin testified that the term “trigger point injection” as used in the patient records had been “used a little bit loosely.” Dr. Griffin further testified that, although there are actual trigger points, the term was also used to describe injections into tender muscle areas. The purpose was to anesthetize the chronic pain area and stop the “pain cycle.” (Tr. at 670)

Procedures – Excessive Number of Trigger Point Injections – Respondent's Defense – “Fanning the Needle”

Testimony of Dr. Leak

197. Dr. Leak testified that, when a trigger point injection is made, the needle is inserted and then pointed north, then south, then east, then west. Medication is injected in each direction without removing the needle. Dr. Leak further testified that his fellows had been instructed to count each movement of the needle as one injection, so that this would have been documented as four injections. (Tr. at 2875-2876)

Dr. Leak further testified that, for example, with regard to injections for neck pain, there are three layers of muscles around the neck, and each layer would be injected in four directions, totaling twelve injections. Moreover, Dr. Leak testified that one needle placement could result in 20 injections, as the needle is “fanned out” at each muscle layer. Further, Dr. Leak testified that a procedure note indicating that 40 injections had been made could have resulted from two or three sites of entry. (Tr. at 2876-2878)

198. Dr. Leak testified that the fanning of the needle and injecting of different layers through a single needle entry may not have been documented. (Tr. at 2922-2923)

Testimony of Dr. Bressi

199. Dr. Bressi testified that, when he performs trigger point injections, he uses the four-quadrant approach described by Dr. Leak. (Tr. at 2961-2962)

Procedures – Chemoneurolytic Injections

Testimony of Dr. Chelimsky

200. Dr. Chelimsky testified that chemoneurolysis is the use of agents to destroy nerve tissue. Dr. Chelimsky further testified: “It’s sometimes used for an attempt to relieve pain, the concept being that if the pain is actually being generated by the nerve, destruction of the nerve would make the pain go away. It’s not been studied in any rigorous way, although it’s been reported many times.” (Tr. at 1574)

Dr. Chelimsky further testified that some of the records indicate that the chemoneurolytic injections were made into muscle tissue. For example, the medical record for Patient 2 indicates that on April 4, 2001, Dr. Hoogendoorn, under the supervision of Dr. Griffin, had performed “chemoneurolysis of the right levator scapulae muscle and sensory fibers” using Sarapin and bupivacaine. (St. Ex. 2 at 186; Tr. at 1683) Dr. Chelimsky testified:

This is a chemoneurolysis. One would normally do that in the neighborhood of a nerve. I don’t see that a particular nerve was really injected. I think the assumption here is that they’re just getting fibers, they’re getting nerve fibers that are coursing through the muscle in this area. This is, I would say, a relatively unproven way to approach this.

(Tr. at 1683)

Testimony of Dr. Leak

201. Dr. Leak testified that there are two categories of chemoneurolytics: nondestructive agents such as Sarapin, which is used to neutralize nerve fibers and is “the same as injecting a local anesthetic or * * * a bunch of [lidocaine] which is chemodenervation”; and destructive chemoneurolytic agents such as phenol which actually destroy nerve tissue. Dr. Leak testified that, unlike Sarapin, the use of phenol as a chemoneurolytic agent requires using an operating room and fluoroscopic guidance. (Tr. at 446-447) Dr. Leak testified that, unlike destructive agents, Sarapin “is a slow, slow-moving agent that goes with local anesthetic. And it’s just like—it’s literally an intramuscular injection that will hopefully neutralize the nerve fibers that penetrate the muscle.” (Tr. at 446-448)

Testimony of Dr. Griffin

202. Dr. Griffin testified that Sarapin is derived from the pitcher plant and is “the most benign chemoneurolytic agent[.]” Dr. Griffin further testified that it is supposed to destroy nerve tissue, but that “it’s not aggressive enough to suit [him].” When asked if Sarapin actually destroys nerve tissue, Dr. Griffin replied, “It is supposed to.” (Tr. at 701)

*Procedures – Radiofrequency Lesioning*Testimony of Dr. Chelimsky

203. Dr. Chelimsky testified that radiofrequency lesioning [RFL] is an alternative method of performing neurolysis. He further testified that it is performed by placing a special type of needle that is used to heat the nerve to either disrupt its activity or to destroy it. (Tr. at 1647-1648)

Testimony of Dr. Leak

204. Dr. Leak testified that he had performed “stereotactic radiofrequency lesioning.” Dr. Leak further testified that the term “stereotactic” refers to the use of “calculated axes to hit a neural target.” Dr. Leak noted that it is performed in an operating room under fluoroscopy. The purpose is to carefully place a probe into an area of sensory nerve tissue along the neural pathway of a painful area of the patient’s body. Once the proper location is reached, a radiofrequency current is sent through the probe to destroy some of the nerve tissue. (Tr. at 581-585)

Dr. Leak testified that, because radiofrequency lesioning is a destructive procedure, it is only used after a patient has first received diagnostic or prognostic injections of anesthetic into the target area and reported relief from pain. (Tr. at 585-586)

205. Dr. Leak testified that the results of radiofrequency lesioning last forever in some patients; in others it is ineffective. (Tr. at 585)

Additional Procedures Performed by Dr. Leak

206. Dr. Leak testified that provocative discography is an invasive radiographic study that involves placing a needle into a disc and injecting contrast fluid. The purpose is for “determining whether there’s a painful disc or an errant disc morphology. Whether the disc looks ugly, looks bad, leaks, or where it hurts.” In addition, the purpose is to determine whether the patient experiences pain “when that additional fluid is injected into the disc.” (Tr. at 1349-1350)
207. Dr. Leak testified that a zygapophyseal arthrogram is performed by placing a needle into a zygapophyseal joint and injecting contrast fluid followed by anesthetic. If the patient experiences pain relief, “then you see how long it lasts.” Dr. Leak testified that the

procedure is diagnostic. If the procedure is effective in relieving pain, it becomes prognostic. (Tr. at 594-596)

208. Dr. Leak testified that a vertebral corpectomy is the removal of a portion of a vertebra. (Tr. at 606)
209. Dr. Leak testified that an aspiration nucleotomy is performed to reduce the size of a herniated disc. Dr. Leak further testified that it is performed by placing a trocar into the herniated disk to “pull the nucleus out.” Dr. Leak further testified that a radiofrequency probe is then placed in the disc to create a burn lesion, which increases the blood flow to the disc and causes it to heal faster. Dr. Leak testified that, in performing the radiofrequency lesioning, “you do it in an effort not to hit the spinal fluid and not to hit the nerves and not to hit the aorta or bladder or other targets which you don’t want to encounter.” (Tr. at 609-610)
210. Dr. Leak testified that arthrodesis is a procedure to treat pain that is “associated with an anatomic anomaly that would either be cancer of a bone or collapse of a bone or post-radiation disease of a bone.” The procedure involves the injection of an acrylic, polymethylmethacrylate, into a vertebra. Within ten minutes, it hardens into a material that is harder than the bone itself. (Tr. at 607-608)

Dr. Leak further described arthrodesis:

[The] application [of] an internal device which stiffens or reduces the articulation; meaning that if I have two bones, and bones are not dead tissue. They are live and they are tympanic, like a tympani drum. So if I stiffen one, then the adjacent joints above and below are then reduced in their capacity to create tympanic motion, which is the presumption of the mechanism of pain in people who have collapsed vertebrae.

(Tr. at 606-607)

211. In his January 31, 2005, report, Dr. Chelimsky opined that “Dr. Leak should not be performing arthrodesis ([Patient 3], 5/3/01, p. 237), this is the province of an orthopedic surgeon.” (St. Ex. 28 at 4)

212. The following is a table of the invasive procedures engaged in or supervised by Dr. Leak or Dr. Griffin:

Pt	Date	Procedure Type/ Medication²³	Physician(s)	Location of Procedure (Number of Injections, if Documented)	Medical Rcd. Pg.
1	08/22/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn/ Griffin	Bilateral deltoids, superior margin of trapezius, splenius capitis, levator scapulae bilaterally, (15 injections)	144
	08/29/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Griffin	Splenius capitis, trapezius, supraspinatus, and levator scapula bilaterally	143
	10/02/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Dorsal cutaneous innervation of splenius capitis, levator scapula, trapezius, and erector spinae	108
	11/29/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Griffin	Erector spinae, latissimus dorsi, gluteus maximus	142
2	02/21/01	Provocative discography, psoas injection	Leak	Provocative discography at L2-3, L3-4, L4-5, and L5-S1. Psoas injection at L2-S1, right.	298-299
	02/28/01	Trigger point injection/ <i>bupivacaine</i>	Griffin	Levator scapulae bilaterally	290
	03/06/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Levator scapulae bilaterally	289
	03/13/01	Trigger point injection/ <i>Solu-Medrol, bupivacaine</i>	Griffin	Trapezius, right	314
	03/16/01	Trigger point injection/ <i>Solu-Medrol, bupivacaine</i>	Griffin	Levator scapulae, supraspinatus, and trapezius, left	187
	03/21/01	Zygapophyseal arthrogram	Leak	L3-L4, L4 -L5, L5-S1, bilaterally	282-283
	04/04/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	“[R]ight levator scapulae muscle”	186
	04/12/01	Zygapophyseal arthrogram	Leak	L3-L4, L4-L5, right; L3-L4, L4-L5, left	266
	04/25/01	RFL, lumbar plexus injection	Leak	RFL of dorsal root ganglion at L2, L3, and L4; RFL of the medial branches at L2, L3, L4, right; lumbar plexus injection at L2, L3, L4, L5.	256-258
	05/15/01	RFL	Leak	Dorsal ganglia at L2, L3, L4, left; medial branch, posterior primary ramus of the spinal nerve L2, L3, L4, left	236-238
	05/16/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Griffin	Levator scapula	315
	06/13/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Griffin	Cervical region with trapezius, splenius capitis, and serratus posterior superior	313
	10/16/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn/ Griffin	Lumbar erector spinae, latissimus dorsi	177
3	03/12/01	Chemoneurolysis/ <i>Phenol</i>	Leak	“[S]ympathetic chain to rami communicans at L2-L3”	255-256
	04/05/01	Aspiration nucleotomy, RFL at L3-L4	Leak	L3-L4	265-266

²³ Medications are identified in this table for trigger point and chemoneurolytic injections only.

Pt	Date	Procedure Type/ Medication ²³	Physician(s)	Location of Procedure (Number of Injections, if Documented)	Medical Rcd. Pg.
	04/19/01	Aspiration nucleotomy, RFL at L4-L5	Leak	L4-L5	268-270
	05/03/01	Arthrodesis	Leak	L3	237-238
	10/17/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Erector spinae and latissimus dorsi, right	156
	11/13/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Thoracic and lumbar latissimus dorsi	152
4	10/04/00	Provocative discography	Leak	C2-C6	335-336
	10/11/00	RFL	Leak	C2-C3	326-327
	11/28/00	Zygapophyseal arthrogram	Leak	C2-C6, bilaterally	248
	12/13/00	RFL	Leak	Medial branches at the cervical level, left	277-278
	12/27/00	RFL	Leak	Dorsal ganglion in medial branch at C2-C7, right	258-259
	01/10/01	Lumbar sympathetic block	Leak	Lumbar, bilaterally	231-232
	02/14/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn/ Leak	Intraspinal, ²⁴ paraspinal muscles (five injections)	153
	03/02/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Erector spinae muscle group, bilaterally	146
	03/16/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Erector spinae muscle groups, lumbar	145
	05/01/01	Myelography, epidural	Leak	T3-T4	235-237
	11/05/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Griffin	"[S]uperior and posterior serratus, the insertions of the levator scapula bilaterally with thoracic, erector spinae group, and trapezius"	226a
	11/20/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Griffin	Trapezius, superior serratus, erector spinae, and levator scapula, left	225
5	05/25/01	Chemoneurolytic injection	Griffin	The paraspinal musculature, cervical region, trapezius, levator (dictation ended)	166
	06/01/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Paraspinal muscles of the thoracic region ("The needle was * * * introduced into the skin at 24 separate locations")	164
	06/08/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Cutaneous nerves to the erector spinae muscle complex and intraspinal ligament	163
	06/15/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Dorsal cutaneous nerves of the erector spinae, paraspinal muscles, levator scapula, and splenius capitis (injections into each of 10 areas of maximal tenderness")	162

²⁴ Dr. Hoogendoorn disagreed with a statement in the procedure report, which he testified had been dictated by Dr. Leak (although Dr. Hoogendoorn's name and initials are printed at the bottom). Dr. Hoogendoorn acknowledged that he had performed trigger point injections into the *paraspinal* muscles, but denied that he had performed injections into the *intraspinal* muscles. Dr. Hoogendoorn further testified that, although he has no memory of this particular procedure, he remembers that he "never injected any intrathecal or intraspinal medications." (Tr. at 144-150)

Pt	Date	Procedure Type/ Medication²³	Physician(s)	Location of Procedure (Number of Injections, if Documented)	Medical Rcd. Pg.
	06/29/01	Chemoneurolytic injection/ <i>Sarapin, Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Cutaneous nerves of the erector spinae group, lumbar region (20 injections)	160
	07/06/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Griffin	“[A]long the paravertebral region from the nuchal line down to the midscapular line down across the tops of the trapezius into the insertion of levator scapula”	229
	07/13/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Griffin	“[A]long the paraspinal group and then out into the subscapularis and latissimus even involving the rhomboids in the trapezius additionally,” bilaterally	230
	10/10/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Dorsal cutaneous innervation of left thoracic erector spinae musculature	158
	10/19/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Dorsal cutaneous innervation to thoracic erector spinae muscle group	157
	11/21/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Griffin	Trapezius, serratus posterior and superior, rhomboids, erector spinae group, and subscapularis	228
7	08/15/00	Sacroiliac arthrogram	Leak	Sacroiliac joint	293-294
	00/00/00	Sacroiliac arthrogram ²⁵	Leak	Sacroiliac joint	274-275
	11/08/00	RFL	Leak	S2-S4, left	233-234
	06/19/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn/ Leak	Bilateral erector spinae and latissimus dorsi, lumbar region (eight injections)	158
	06/26/01	Trigger point injection/ <i>No medication noted</i>	Griffin	Latissimus dorsi, and gluteus maximus, bilaterally	157
	07/02/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Griffin	Latissimus dorsi, gluteus maximus, erector spinae group	156
	07/18/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Dorsal cutaneous nerves of the erector spinae and latissimus dorsi, right lumbar region (six injections)	154
	08/01/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Leak	Dorsal cutaneous innervation of the left latissimus dorsi and erector spinae muscle group (seven injections)	153
	08/14/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Dorsal cutaneous innervation of the interspinous ligament, erector spinae, and paraspinal musculature, left (five injections)	152
	09/21/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Erector spinae and latissimus dorsi, lumbar region	150
	10/02/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Dorsal cutaneous innervation of the lumbar erector spinae and latissimus dorsi	149

²⁵ The language of this operative report differs from the August 15, 2000, procedure, and therefore does not appear to be a duplicate. (St. Ex. 7 at 274-275, 293-294)

Pt	Date	Procedure Type/ Medication²³	Physician(s)	Location of Procedure (Number of Injections, if Documented)	Medical Rcd. Pg.
8	02/20/01	“L5-S1 right-sided decompression, adhesion, and excision of scar, chemoneurolysis 10% sodium chloride and 6% phenol with a 50x microscope”	Leak	L5-S1, right	430-431
	02/21/01	Decompression adhesiolysis	Leak	L5-S1	428
	05/01/01	Psoas compartment lumbar plexus injection	Leak	L3-L5, right	407-408
	10/26/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn/ Griffin	Splenius capitis, levator scapula	261
9	07/12/00	Discography	Leak	T12-S1	288-289
	10/18/00	Nucleotomy and RFL	Leak	L3-S1	266-267
	02/09/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Right greater trochanter area (seven injections)	260
	02/16/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Leak	Right greater trochanter area and gluteal area (six injections)	170
	03/09/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Right greater trochanter area (four injections)	169
11	03/29/00	Mechanical decompression	Leak	T7-T8	432-433
	05/28/01	Trigger point injection/ <i>Sarapin, Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Erector spinae complex, thoracic region (approximately eight injections)	246
	06/08/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Erector spinae muscle group, lumbar thoracic region (approximately 20 separate locations)	245
	06/19/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Dorsal cutaneous nerves of the erector spinae group (six injections)	244
	08/09/01	Trigger point injection/ <i>bupivacaine</i>	Griffin	Erector spinae group, rhomboids, latissimus dorsi, trapezius, right	428
	08/28/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Right erector spinae, trapezius	239
	10/02/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	“Dorsal cutaneous innervation of thoracic, erector spinae, and trapezius”	238
	10/23/01	Chemoneurolytic injection/ <i>bupivacaine</i>	Griffin	Dorsal cutaneous nerves, right posterior thorax	427
12	03/12/01	Dorsal ganglion injection	Leak	C2	296-297
	04/02/01	Dorsal root ganglion injection	Leak	C2	289-291
14	04/05/01	Ganglion injection	Leak	C2, right	166-167
	04/19/01	Ganglion injection	Leak	C2, right	145-146
	04/24/01	Trigger point injection/ “analgesia and steroid”	Griffin	Levator scapula, trapezius	105
	05/01/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Right erector spinae complex, rhomboids, and trapezius	103

Pt	Date	Procedure Type/ Medication²³	Physician(s)	Location of Procedure (Number of Injections, if Documented)	Medical Rcd. Pg.
	05/08/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Right trapezius, erector spinae, and rhomboid (injections into 10 areas of maximal tenderness)	102
	05/22/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Right levator scapula, rhomboids, and trapezius (six injections)	101
	06/05/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Griffin	Trapezius, levator scapula, splenius capitis, and supraspinatus	143
	06/15/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Right levator scapula, latissimus dorsi, splenius capitis, and rhomboid (approximately 15 separate injections)	100
	06/22/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Levator scapula, erector spinae, rhomboid, and trapezius, right (approximately 11 separate injections)	99
	07/06/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Griffin	Levator scapula, splenius capitis, trapezius, and supraspinatus	98
15	08/07/00	Provocative discography, psoas injection	Leak	L2-S1	217-218
17	01/19/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn	Paraspinal muscles, thoracic region (10 separate injections)	175
	01/26/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn	Erector spinae muscle groups bilaterally, thoracic lumbar region	174
	02/06/01	Chemoneurolytic injection ²⁶ / <i>Sarapin,</i> <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	“Trigger point injections with Sarapin, thoracic and lumbar spine, most specifically the erector spinae muscles” (20 separate injections)	173
	02/09/01	Chemoneurolytic injection/ <i>Sarapin, Depo-Medrol,</i> <i>bupivacaine</i>	Hoogendoorn/ Griffin	Erector spinae muscle group bilaterally (approximately 20 separate injections at 1 cm intervals along each side of spine totaling approximately 40 injections)	171
	02/16/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Leak	Paraspinal muscle group (40 separate injections)	170
	02/23/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Bilateral erector spinae musculature from midscapular to lumbosacral region (40 separate injections)	169
	03/02/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Erector spinae muscle groups bilaterally (40 separate injections)	167
	03/09/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Erector spinae muscle group (40 separate injections)	166
	03/23/01	Trigger point injection/ <i>Solu-Medrol, bupivacaine</i>	Griffin	Erector spinae group	165
	04/04/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Erector spinae muscle group (approximately 40 separate injections)	162

²⁶ Many of the procedural notes for Patient 17 indicate that a trigger point injection was performed; however, Sarapin, a mild chemoneurolytic agent, was used. Accordingly, these procedures have been identified in this table as chemoneurolytic injections. (St. Ex. 17 at 173; see also pages 169-171)

Pt	Date	Procedure Type/ Medication²³	Physician(s)	Location of Procedure (Number of Injections, if Documented)	Medical Rcd. Pg.
	04/11/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Erector spinae muscle complex, thoracic and lumbar region (approximately 40 separate injections)	161
	04/18/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Erector spinae muscle group: “20 injections with approximately 0.5 cc each were injected along the vertebral column in the erector spinae muscle complex and rhomboid area”	160
	04/25/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Erector spinae muscle complex bilaterally (approximately 40 separate injections)	159
	05/04/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Erector spinae muscle complex, lumbar and thoracic regions bilaterally (approximately 40 separate injections)	158
	05/16/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Erector spinae muscle complex, lumbar and thoracic regions bilaterally (approximately 40 separate injections)	157
	06/20/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Dorsal cutaneous nerves of the erector spinae muscle groups, lumbar and thoracic regions (approximately 20 separate injections)	156
	06/29/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Dorsal cutaneous nerves of the erector spinae muscle groups, lumbar and thoracic region, bilaterally (approximately 40 injections)	155
	07/09/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Dorsal cutaneous nerves of the paraspinals in the erector spinae muscle complex bilaterally, thoracic and lumbar regions (approximately 40 separate injections)	154
	07/24/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Leak	Dorsal cutaneous innervation of the erector spinae complex, lumbar, cervical, and thoracic regions	152
	08/07/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Dorsal cutaneous innervation of the erector spinae complex, low cervical, thoracic, and lumbar regions	151
	09/28/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	“[E]rector spinae in the cervical, lumbar and thoracic regions as well as trapezius, rhomboids, and latissimus dorsi, their dorsal cutaneous innervation”	149
18	01/11/99	Decompression adhesiolysis	Leak	L5-S1, left	236-237
20	10/05/00	Zygapophyseal arthrogram	Leak	L2-L3 bilaterally, L3-L4 right, L4-L5 and L5-S1 bilaterally	336-338
	10/23/00	Zygapophyseal arthrogram	Leak	Right L4-L5 and L5-S1 and left L3-L4, L4-L5, and L5-S1	327
	11/14/00	RFL	Leak	Dorsal ganglia and medial branches of right L3, L4, L5, S1, and left L2, L3, L4, L5, and S1	301-302

Pt	Date	Procedure Type/ Medication²³	Physician(s)	Location of Procedure (Number of Injections, if Documented)	Medical Rcd. Pg.
21	10/23/00	Provocative discography	Leak	C2-C7	343
	10/30/00	RFL	Leak	C4-C5	506-507
	05/23/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn/ Griffin	Splenius capitis, erector spinae, and levator scapula, bilaterally (10 separate injections)	328
	06/01/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Levator scapula, splenius capitis, and trapezius, right side (approximately 10 separate injections)	327
	06/08/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Levator scapula, splenius capitis, and trapezius, bilaterally (approximately 20 separate injections)	326
	07/13/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Dorsal cutaneous nerves of the splenius capitis and superior trapezius, bilaterally (approximately 20 separate injections)	324
	09/28/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn/ Griffin	Levator scapula and splenius capitis, right	319
	10/12/01	Trigger point injection/ <i>bupivacaine</i>	Griffin	Trapezius, splenius capitis, and levator scapula, cervical region	500
22	07/25/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn/ Leak	Thoracic and cervical trapezius and erector spinae muscle group (approximately 20 separate injections)	188
	07/31/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Leak	Rhomboids and erector spinae groups, bilaterally (20 separate injections)	187
	09/07/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn/ Griffin	Bilateral splenius capitis, erector spinae, levator scapula, and trapezius (approximately 10 separate injections)	185
	09/19/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn	Thoracic erector spinae, rhomboids, and trapezius	183
	09/28/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Thoracic rhomboid, erector spinae, and trapezius	182
	10/19/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Bilateral erector spinae, latissimus dorsi, and trapezius, thoracic region	181

Allegation (1)(d):

213. In its August 9, 2006, notice of opportunity for hearing, the Board alleged in Allegation (1)(d) as follows:

Despite test results reflecting abnormal findings related to the purported area of involvement, the left L5 nerve root, [Dr. Leak] failed to limit treatment to the left L5 nerve root of Patient 20 and, in fact, he performed blocks on all of Patient 20's lumbar nerve roots.

(St. Ex. 54C)

August 25, 2000, SSEP for Patient 20

214. The following are the results of an August 25, 2000, SSEP study performed or ordered by Dr. Leak on Patient 20's lumbar and sacral spine:

SSEP Nerve Tested	Normal Range	Right (P-37) in msec	Left (P-37) in msec	Differential >5.0 ms
L4 DEP	36.8-50.0 ms	42.92	42.08	0.84
L5 DEP	34.5-45.3 ms	43.33	50.83	7.50
S1 DEP	37.9-46.3 ms	45.00	42.92	2.08
L2 DEP		40.42	40.00	0.42
L3 DEP		41.67	41.25	0.42

(St. Ex. 20 at 365)

Dr. Leak made the following comment concerning the results: "The dermatomal SEPs show a relative interpeak latency prolongation on the left at the L5 sensory nerve pathway consistent with the presence of partial conduction block at that level as would be seen with the existence of lumbar radiculopathy or radiculitis." (St. Ex. 20 at 358)

Testimony and Report of Dr. Katirji

215. Dr. Katirji stated that the results of an August 25, 2000, SSEP study yielded abnormal results for L5 on the left side. (St. Ex. 20 at 365; Tr. at 1119)

Report of Dr. Chelimsky

216. In his January 31, 2005, report, Dr. Chelimsky stated that, "in the case of [Patient 20] there were abnormalities restricted to the left L5 nerve root yet the procedures performed blocked all lumbar nerve roots." (St. Ex. 28 at 2)

Procedures Performed

217. On October 5, 2000, Dr. Leak performed on Patient 20 a zygapophyseal joint arthrogram and analgesic injection at L2-L3 bilaterally, L3-L4 right, L4-L5 and L5-S1 bilaterally. (St. Ex. 20 at 336, 338) Dr. Leak concluded in his operative report that Patient 20 "had suspicious joints for nociception²⁷ at the left L3-4, the left L4-5, which is substantially positive and left L5-S1. On the right side, the patient had a positive for nociception at the +/- at L4-5 and definitely positive at L5-S1."

²⁷ Dorland's Illustrated Medical Dictionary, 27th Edition (W.B. Saunders Co., 1988), defines "nociceptive" thusly: "receiving injury; said of a receptive neuron for painful sensation."

On October 23, 2000, Dr. Leak performed on Patient 20 a zygapophyseal joint arthrogram and analgesic injection at right L4-L5 and L5-S1 and left L3-L4, L4-L5, and L5-S1. (St. Ex. 20 at 327)

On November 14, 2000, Dr. Leak performed on Patient 20 an RFL of the dorsal ganglia and medial branches of L3-S1 on the right and L2-S1 on the left. (St. Ex. 20 at 301-302)

Testimony of Dr. Bressi

218. Dr. Bressi testified that the L5 nerve root can be problematic because it is “one of the biggest nerves with one of the smallest natural bony canals to exit from the spine.” Compared to other levels, smaller amounts of inflammation at L5 may cause problems for the patient. (Tr. at 2362)

Dr. Bressi testified that it had been appropriate for Dr. Leak to treat all the lumbar nerve roots rather than just L5. Dr. Bressi further testified that CT scan and myelogram “showed multiple areas of degeneration.” Moreover, Dr. Bressi testified that a visible problem at only one location may not tell the whole story. (Tr. at 2363-2364)

219. Dr. Bressi testified that, in his opinion, the care rendered to Patient 20 by Dr. Leak and Dr. Griffin met the minimal standard of care. Dr. Bressi further testified, “I think these doctors were trying to do the best job they could with a very challenging patient clientele.” (Tr. at 2366)

Testimony of Dr. Leak

220. At hearing, when asked if there had been evidence of problems with vertebrae other than L5, Dr. Leak reviewed the record and referred to a February 2001 radiology report (that post dates the procedure) as well as an August 30, 2000, STC test. He replied that the patient had had “a plethora of pathology” throughout his lumbar spine. (St. Ex. 20 at 359-364, 370)

However, along with the February 2001 radiology report, the medical record for Patient 20 includes an earlier radiology report. An August 29, 2000, radiology report regarding a CT scan of the lumbar spine performed August 27, 2000, states, under the heading “Impression”:

1. Severe degenerative disc disease at L5-S1 with a vacuum disc phenomenon and large broad posterior, anterior, and right anterolateral components, also severe facet hypertrophy. Severe lateral recess narrowing is seen bilaterally, much greater on the right, where exiting L5 nerve root sleeve compression is probable (exiting left L5 nerve root sleeve compression is not excluded).
2. Small broad posterior and anterior disc protrusions at L4-5 with associated marked facet hypertrophy. Mild left lateral recess narrowing is seen at L4-5 but obvious exiting nerve root sleeve compression is not seen.
3. Small broad posterior and anterior disc protrusions at L3-4 with associated moderate facet hypertrophy.

4. Small broad posterior and anterior disc protrusions at L2-3 with a moderately large right anterolateral component associated with osteophytes.

Allegation (1)(m):

221. In its August 9, 2006, notice of opportunity for hearing, the Board alleged in Allegation (1)(m) as follows:

[Dr. Leak] inappropriately performed and/or inappropriately ordered invasive techniques, including, but not limited to, discography in the L5-S1 area, three-stage injection and SI joint injections, a three-stage decompression, as well as a spinal cord stimulator screen and implant, and an intralink port placed presumably for some type of drug delivery system, within a three-month period of time on Patient 18, a morbidly obese patient who was a high risk candidate for general anesthesia.

(St. Ex. 54C)

Patient 18 Medical Records

222. Patient 18 is described in the medical record as a white female born in 1965. Her correct middle initial is "S."²⁸ She was further described on different dates as being 5'9", 5'9-1/2", and 5'10" tall. Her weight on November 6, 1998, was noted to be 220 pounds. (St. Ex. 18 at 2, 69b, 170, 176a, 178a, 333)

Between November 1998 and February 1999, Patient 18 underwent several surgeries. Documentation concerning those surgeries includes the following:

- On November 17, 1998, a physician named Dr. Ranieri performed the following procedure on Patient 18: "Stereotactic provocative lumbar discography of L3-4, L4-5, L5-S1 under fluoroscopic control." The anesthesia used was described thusly: "She received general anesthesia in the beginning. When the needles were placed, she received monitored anesthesia care and was fully awake for the provocative discography." (St. Ex. 18 at 245-246)

In the operative report, Patient 18 was described as "a 33-year-old white female, morbid obesity * * *." Her middle initial was incorrectly noted as "C." (St. Ex. 18 at 245-246)

- On January 11, 1999, Dr. Leak performed the following procedure on Patient 18: "Operative myelography, fluoroscopic interpretation, transsacral endoscopic procedure with sacral laminotomy per endoscopic decompression adhesiolysis with 50 power

²⁸ Patient 18's middle initial is of interest because it was frequently incorrect in various documents. In addition, Patient 18's age and race were also incorrect in some documents.

microscope, chemoneurolysis, left sided L5-S1.” The anesthesia used was “[g]eneral anesthesia, MAC.” (St. Ex. 18 at 236-237)

Patient 18’s age, race, and weight were not described in the operative report. Her middle initial was incorrectly noted as “F.” (St. Ex. 18 at 236-237)

- On January 12, 1999, Dr. Ranieri performed the following procedure on Patient 18: “Stage II decompression and adhesiolysis on the left side of L4, L5, and S1 with 10% sodium chloride solution and local anesthetic, chemo neurolysis with 6% phenol of L4, L5, and S1 on the left side, re-implantation of Interlink port, and lumbar myelography.” The anesthesia used was “[g]eneral.” (St. Ex. 18 at 233-234)

Patient 18 was described in the operative report as “a 34-year-old white female * * *.” Her correct middle name was noted on the report. (St. Ex. 18 at 233-234)

- On or about January 13, 1999, Dr. Ranieri performed the following procedure on Patient 18: “Stage three decompression and adhesiolysis bilaterally at L4, L5-S1, chemoneurolysis with 6% phenol bilaterally at L4, L5-S1, lumbosacral myelography, removal of intraspinal foreign body.” Patient 18 was given general anesthesia for the procedure. (St. Ex. 18 at 230-231)

Patient 18 was described in the operative report as “a 34-year-old white female * * *.” Her correct middle name was noted on the report. (St. Ex. 18 at 230-231)

- On January 28, 1999, Dr. Ranieri performed the following procedure on Patient 18: “Spinal cord stimulator screen and implant. Thoracic spinal myelography.” The anesthesia used was “MAC.” (St. Ex. 18 at 239-240)

In the operative report, Patient 18 was described as “a 34-year-old white female, morbid obesity * * *.” Her middle initial was incorrectly noted as “C.” (St. Ex. 18 at 239-240)

- On February 11, 1999, Dr. Ranieri performed the following procedure on Patient 18, described thusly in the operative report: “Removal of dysfunctional spinal cord stimulator screen but with eventual removal because of inability to adequately place the spinal cord stimulator, and removal of Itrel 3 pulse generator.” The anesthesia used was a “[c]ombination of general anesthesia and MAC.” (St. Ex. 18 at 212-213)

In the operative report, Patient 18 was incorrectly described as “a 63-year-old African American female * * *.” No middle name or initial was noted on the report. (St. Ex. 18 at 212-213) Despite the incorrect description of Patient 18, the procedure performed appears consistent with another note concerning that procedure elsewhere in the medical record: a February 14, 2001, document entitled “Chart Protocols” correctly notes Patient 18’s full name and states, among other things, “Removal SCS 2/11/99.” (St. Ex. 18 at 16)

223. There is no evidence that specifically addresses the relationship between Dr. Ranieri and PCC. However, PCC letterhead on a facsimile cover sheet dated October 12, 1998, lists the name of Thomas Ranieri, M.D., directly below Dr. Leak's. Further, when discussing who at PCC may have reviewed the reports of fellows, Dr. Leak testified, "Dr. Ranieri became an attending * * *." (St. Ex. 28 at 271; Tr. at 2709, 2724, 2916)

January 31, 2005, Written Report of Dr. Chelimsky

224. In his January 31, 2005, report, Dr. Chelimsky stated with regard to the use of interventions on Patient 18:

[Patient 18] within a very short period of time received discography in L5 S1 3 stage injection and SI joint injection in November of 1998. Two months later in January of '99 she receive[d] a three-stage decompression as well as a spinal cord stimulator screen and implant and within the same time frame still in January of '99 she had an intralink port placed presumably for some type of drug delivery system which then ha[d] to be removed due to a manufacturing defect. This case is particularly flagrant because the record reflects that the patient is morbidly obese with a high risk of general anesthesia. None of the procedures were particularly effective in reducing her pain. She eventually left the practice a little bit later only to return in 2001.

(St. Ex. 28 at 3-4)

Testimony of Dr. Leak

225. When asked if he had been concerned about the number of procedures performed on a patient described as morbidly obese, Dr. Leak replied that he had not. Dr. Leak testified that the definition of morbid obesity "starts relatively low for America," and that many people fit that definition. Dr. Leak further testified: "As long as the instruments reach and it's considered safe by the anesthesiologist and safe by the physician performing the procedure, again, actual body weight is not so much the issue as is distribution and comorbid issues." (Tr. at 1427-1429)

Allegation (1)(o):

226. In its August 9, 2006, notice of opportunity for hearing, the Board alleged in Allegation (1)(o) as follows:

[Dr. Leak] inappropriately targeted and treated twelve roots in a single radio-frequency procedure on Patient 4 * * *.

(St. Ex. 54C)

Multiple Roots in a Single Radio-Frequency Procedure

Testimony and Written Report of Dr. Chelimsky

227. In his January 31, 2005, written report, Dr. Chelimsky stated with regard to Dr. Leak's treatment of Patient 4: "12 roots targeted in a single radio-frequency procedure on 11/28/00 p166a * * * prudent medicine would allow only 1-3 roots at a time on one side." (St. Ex. 28 at 4)

Patient 4 Medical Records

228. A progress note in Dr. Leak's medical record for Patient 4 indicates that on November 28, 2000, Dr. Leak had performed a zygapophyseal joint arthrogram at C2-3, C3-4, C4-5, and C5-6 bilaterally. The note further states that, "as he has pain relief, we would do radiofrequency lesioning to the medial branches C2, C3, C4, C5, C6, and C7 bilateral." (St. Ex. 4 at 166a)

However, although Dr. Leak did perform RFL of the medial branches at C2-C7, he did so in two separate procedures—the left side on December 13, 2000, and the right side on December 27, 2000. (St. Ex. 4 at 258-259, 277-278)

Allegation (1)(o) Part 2

229. In its August 9, 2006, notice of opportunity for hearing, the Board alleged in Allegation (1)(o) as follows:

[Dr. Leak] inappropriately targeted and treated * * * nine roots in a single radio-frequency procedure on Patient 20.

(St. Ex. 54C)

Multiple Roots in a Single Radio-Frequency Procedure

Patient 20 Medical Records

230. On November 14, 2000, Dr. Leak performed the following procedure on Patient 20: RFL of the dorsal ganglia and medial branches of the dorsal ganglia and medial branches of the right L3, L4, L5, S1, and left L2, L3, L4, L5, and S1. (St. Ex. 20 at 301-302)

Testimony and Written Report of Dr. Chelimsky

231. In his May 2, 2006, report, Dr. Chelimsky referred to the November 14, 2000, RFL procedure performed by Dr. Leak and stated, “injecting 9 roots at a single sitting as was done with [Patient 20] is below the standard of care.” (St. Ex. 29 at 3)

Dr. Chelimsky testified at hearing that the usual practice is to lesion one root that is thought to be responsible for pain, possibly two:

[B]ut it’s just beyond my imagination to lesion all of these roots.

Remember that the stereotactic radio frequency lesioning actually does damage to those roots, so they will be functioning poorly for a period of time. If there’s significant pain relief with that, I suppose one could do it, but it’s just not at all in the standard of practice to lesion this number of roots at any time for any reason.

(Tr. at 1766-1767)

Testimony of Dr. Leak

232. Dr. Leak testified that he had believed the November 14, 2000, RFL procedure to be indicated because Patient 20 had obtained relief from local anesthetic injections. (Tr. at 1439-1440)

Allegation (1)(n):

233. In its August 9, 2006, notice of opportunity for hearing, the Board alleged in Allegation (1)(n) as follows:

[Dr. Leak] inappropriately used, and/or supervised a podiatrist to engage in the use of, destructive modalities of treatment such as chemolytic agents indiscriminately on nerves and muscles on Patients 5, 7 and 17.

(St. Ex. 54C)

Supervising a Podiatrist to Engage in the Use of Destructive Modalities of Treatment

234. The medical records indicate that Dr. Leak used, or supervised Dr. Hoogendoorn in the use of, destructive modalities of treatment such as chemoneurolytic agents as follows:

Pt	Date	Procedure Type/ Medication	Physician(s)	Location of Procedure (Number of Injections, if Documented)	Medical Rcd. Pg.
7	08/01/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Leak	Dorsal cutaneous innervation of the left latissimus dorsi and erector spinae muscle group (seven injections)	153
17	02/16/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Leak	“* * * paraspinal muscle group totaling 40 injections in all”	170
	07/24/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Leak	Dorsal cutaneous innervation of the erector spinae complex, lumbar, cervical, and thoracic regions	152

235. No evidence was presented that Dr. Leak used, and/or supervised Dr. Hoogendoorn in the use, of destructive modalities of treatment such as chemoneurolytic agents in the treatment of Patient 5. (St. Ex. 5)

Testimony of Dr. Chelimsky

236. Dr. Chelimsky testified that chemoneurolytic injections are medical procedures that require the use of medical judgment, knowledge of the anatomic structure of muscles and blood vessels around the injection site, knowledge concerning the doses being injected, and knowledge of the potential risks that go along with the injections. Dr. Chelimsky further testified that chemoneurolytic and trigger point injections “require an individualized assessment of each patient, because trigger points vary from location to location in different patients. The risks also are different from patient to patient and the agent choice will vary from one patient to the next.” (Tr. at 1658-1663)

Testimony of Dr. Leak

237. Dr. Leak testified that there are two categories of chemoneurolytics: nondestructive agents such as Sarapin, which is used to neutralize nerve fibers and is “the same as injecting a local anesthetic or * * * a bunch of [lidocaine] which is chemodenervation”; and destructive chemoneurolytic agents such as phenol which actually destroy nerve tissue. Dr. Leak testified that, unlike Sarapin, the use of phenol as a chemoneurolytic agent requires using an operating room and fluoroscopic guidance. (Tr. at 446-447)

Testimony of Dr. Griffin

238. Dr. Griffin testified that Sarapin is derived from the pitcher plant and is “the most benign chemoneurolytic agent[.]” Dr. Griffin further testified that it is supposed to destroy nerve

tissue, but that “it’s not aggressive enough to suit [him].” When asked if Sarapin actually destroys nerve tissue, Dr. Griffin replied, “It is supposed to.” (Tr. at 701)

Allegation (2)(a):

239. In its August 9, 2006, notice of opportunity for hearing, the Board alleged in Allegation (2)(a) as follows:

During the period in or about August 2000 through in or about November 2001, [Dr. Leak] aided and abetted Kyle Elliott Hoogendoorn, D.P.M., in the unlawful practice of medicine and surgery by permitting and/or supervising Dr. Hoogendoorn in administering chemoneurolytic and other injections into the splenius capitis, levator scapulae, trapezius, superior trapezius, cervical erector spinae, thoracic erector spinae, lumbar erector spinae, latissimus dorsi, paraspinal, and/or rhomboid muscles, and/or the interspinous ligament, and/or greater trochanter, and/or gluteal area, and/or zygapophyseal joint of Patients 1-5, 7-9, 11, 14, 17, 20-22.

(St. Ex. 54C)

240. The medical records indicate that Dr. Leak permitted and/or supervised Dr. Hoogendoorn in administering chemoneurolytic and other injections into areas of patients’ bodies that would not be within the scope of practice of podiatric medicine:

The following is a table of the invasive procedures performed by Dr. Hoogendoorn: (The table includes procedures supervised by Dr. Griffin, because Dr. Leak, as medical director and head of the fellowship “permitted” Dr. Hoogendoorn to perform these procedures.)

Pt	Date	Procedure Type/ Medication	Physician(s)	Location of Procedure (Number of Injections, if Documented)	Medical Rcd. Pg.
1	08/22/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn/ Griffin	Bilateral deltoids, superior margin of trapezius, splenius capitis, levator scapulae bilaterally, (15 injections)	144
	10/02/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Dorsal cutaneous innervation of splenius capitis, levator scapula, trapezius, and erector spinae	108
2	03/06/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Levator scapulae bilaterally	289
	04/04/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	“[R]ight levator scapulae muscle”	186
	10/16/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn/ Griffin	Lumbar erector spinae, latissimus dorsi	177
3	10/17/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Erector spinae and latissimus dorsi, right	156

Pt	Date	Procedure Type/ Medication	Physician(s)	Location of Procedure (Number of Injections, if Documented)	Medical Rcd. Pg.
	11/13/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Thoracic and lumbar latissimus dorsi	152
4	02/14/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn/ Leak	Intraspinal, ²⁹ paraspinal muscles (five injections)	153
	03/02/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Erector spinae muscle group, bilaterally	146
	03/16/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Erector spinae muscle groups, lumbar	145
5	06/01/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Paraspinal muscles of the thoracic region (24 injections)	164
	06/08/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Cutaneous nerves to the erector spinae muscle complex and intraspinous ligament	163
	06/15/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Dorsal cutaneous nerves of the erector spinae, paraspinal muscles, levator scapula, and splenius capitis (10 injections)	162
	06/29/01	Chemoneurolytic injection/ <i>Sarapin, Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Cutaneous nerves of the erector spinae group, lumbar region (20 injections)	160
	10/10/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Dorsal cutaneous innervation of left thoracic erector spinae musculature	158
	10/19/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Dorsal cutaneous innervation to thoracic erector spinae muscle group	157
7	06/19/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn/ Leak	Bilateral erector spinae and latissimus dorsi, lumbar region (eight injections)	158
	07/18/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Dorsal cutaneous nerves of the erector spinae and latissimus dorsi, right lumbar region (six injections)	154
	08/01/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Leak	Dorsal cutaneous innervation of the left latissimus dorsi and erector spinae muscle group (seven injections)	153
	08/14/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Dorsal cutaneous innervation of the interspinous ligament, erector spinae, and paraspinal musculature, left (five injections)	152
	09/21/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Erector spinae and latissimus dorsi, lumbar region	150
	10/02/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Dorsal cutaneous innervation of the lumbar erector spinae and latissimus dorsi	149

²⁹ Dr. Hoogendoorn disagreed with a statement in the procedure report, which he testified had been dictated by Dr. Leak (although Dr. Hoogendoorn's name and initials are printed at the bottom). Dr. Hoogendoorn acknowledged that he had performed trigger point injections into the *paraspinal* muscles, but denied that he had performed injections into the *intraspinal* muscles. Dr. Hoogendoorn further testified that, although he has no memory of this particular procedure, he remembers that he had "never injected any intrathecal or intraspinal medications." (Tr. at 144-150)

Pt	Date	Procedure Type/ Medication	Physician(s)	Location of Procedure (Number of Injections, if Documented)	Medical Rcd. Pg.
8	10/26/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn/ Griffin	Splenius capitis, levator scapula	261
9	02/09/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Right greater trochanter area (seven injections)	260
	02/16/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Leak	Right greater trochanter area and gluteal area (six injections)	170
	03/09/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Right greater trochanter area (four injections)	169
11	05/28/01	Trigger point injection/ <i>Sarapin, Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Erector spinae complex, thoracic region (approximately eight injections)	246
	06/08/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Erector spinae muscle group, lumbar thoracic region (approximately 20 injections)	245
	06/19/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Dorsal cutaneous nerves of the erector spinae group (six injections)	244
	08/28/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Right erector spinae, trapezius	239
	10/02/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	"Dorsal cutaneous innervation of thoracic, erector spinae, and trapezius"	238
14	05/01/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Right erector spinae complex, rhomboids, and trapezius	103
	05/08/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Right trapezius, erector spinae, and rhomboid (10 injections)	102
	05/22/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Right levator scapula, rhomboids, and trapezius (six injections)	101
	06/15/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Right levator scapula, latissimus dorsi, splenius capitis, and rhomboid (approximately 15 injections)	100
	06/22/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Levator scapula, erector spinae, rhomboid, and trapezius, right (approximately 11 injections)	99
17	01/19/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn/ Griffin	Paraspinal muscles, thoracic region (10 injections)	113a, 175
	01/26/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Erector spinae muscle groups bilaterally, thoracic lumbar region	110a, 174
	02/06/01	Chemoneurolytic injection ³⁰ / <i>Sarapin, Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	"Trigger point injections with Sarapin, thoracic and lumbar spine, most specifically the erector spinae muscles" (20 injections)	173

³⁰ Many of the procedural notes for Patient 17 indicate that a trigger point injection was performed; however, Sarapin, a mild chemoneurolytic agent, was used. Accordingly, these procedures have been identified in this table as chemoneurolytic injections. (St. Ex. 17 at 173; see also pages 169-171)

Pt	Date	Procedure Type/ Medication	Physician(s)	Location of Procedure (Number of Injections, if Documented)	Medical Rcd. Pg.
	02/09/01	Chemoneurolytic injection/ <i>Sarapin, DepoMedrol, bupivacaine</i>	Hoogendoorn/ Griffin	Erector spinae muscle group bilaterally (approximately 40 injections)	171
	02/16/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Leak	"* * * paraspinal muscle group totaling 40 injections in all"	170
	02/23/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Bilateral erector spinae musculature from midscapular to lumbosacral region (40 injections)	169
	03/02/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Erector spinae muscle groups bilaterally (40 injections)	167
	03/09/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Erector spinae muscle group (40 injections)	166
	04/04/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Erector spinae muscle group (approximately 40 injections)	162
	04/11/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Erector spinae muscle complex, thoracic and lumbar region (approximately 40 injections)	161
	04/18/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Erector spinae muscle group: "20 injections with approximately 0.5 cc each were injected along the vertebral column in the erector spinae muscle complex and rhomboid area"	160
	04/25/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Erector spinae muscle complex bilaterally (approximately 40 injections)	159
	05/04/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Erector spinae muscle complex, lumbar and thoracic regions bilaterally (approximately 40 injections)	158
	05/16/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Erector spinae muscle complex, lumbar and thoracic regions bilaterally (approximately 40 injections)	157
	06/20/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Dorsal cutaneous nerves of the erector spinae muscle groups, lumbar and thoracic regions (approximately 20 injections)	156
	06/29/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Dorsal cutaneous nerves of the erector spinae muscle groups, lumbar and thoracic region, bilaterally (approximately 40 injections)	155
	07/09/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Dorsal cutaneous nerves of the paraspinals in the erector spinae muscle complex bilaterally, thoracic and lumbar regions (approximately 40 injections)	154
	07/24/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Leak	Dorsal cutaneous innervation of the erector spinae complex, lumbar, cervical, and thoracic regions	152
	08/07/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Dorsal cutaneous innervation of the erector spinae complex, low cervical, thoracic, and lumbar regions	151

Pt	Date	Procedure Type/ Medication	Physician(s)	Location of Procedure (Number of Injections, if Documented)	Medical Rcd. Pg.
	09/28/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	“[E]rector spinae in the cervical, lumbar and thoracic regions as well as trapezius, rhomboids, and latissimus dorsi, their dorsal cutaneous innervation”	149
21	05/23/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn/ Griffin	Splenius capitis, erector spinae, and levator scapula, bilaterally (10 injections)	328
	06/01/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Levator scapula, splenius capitis, and trapezius, right side (approximately 10 injections)	327
	06/08/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Levator scapula, splenius capitis, and trapezius, bilaterally (approximately 20 injections)	326
	07/13/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Dorsal cutaneous nerves of the splenius capitis and superior trapezius, bilaterally (approximately 20 injections)	324
	09/28/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn/ Griffin	Levator scapula and splenius capitis, right	319
22	07/25/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn/ Leak	Thoracic and cervical trapezius and erector spinae muscle group (approximately 20 injections)	188
	07/31/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Leak	Rhomboid's and erector spinae groups, bilaterally (20 injections)	187
	09/07/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn/ Griffin	Bilateral splenius capitis, erector spinae, levator scapula, and trapezius (approximately 10 injections)	185
	09/19/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn/ Griffin	Thoracic erector spinae, rhomboids, and trapezius	94a, 183
	09/28/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Thoracic rhomboid, erector spinae, and trapezius	182
	10/19/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Bilateral erector spinae, latissimus dorsi, and trapezius, thoracic region	181

Testimony and January 31, 2005, Report of Dr. Chelimsky

241. Dr. Chelimsky testified that Dr. Hoogendoorn had performed procedures that were beyond the scope of practice of a podiatric physician. Dr. Chelimsky testified that chemoneurolytic and trigger point injections require the exercise of judgment based on medical knowledge. Dr. Chelimsky further testified that they require an individual assessment of each patient because trigger points vary in location from patient to patient, the risks are different from patient to patient, “and the agent choice will vary from one patient to the next.” Dr. Chelimsky further testified that they cannot be performed without a need for complex observations or critical decisions. Finally, such procedures “require repeated medical assessments to look at the results of the injection as far as pain is concerned, and also to make sure there hasn’t been a serious complication.” (Tr. at 1634, 1657-1665)

Finally, Dr. Chelimsky testified concerning Dr. Hoogendoorn's performance of injection procedures that his opinion does not change if Dr. Hoogendoorn had been performing these injections as a fellow because "that would imply he's training to perform it, eventually.

* * * The point of a fellowship program is to train somebody to do what they're eventually going to do." (Tr. at 1648-1649)

Testimony of Dr. Bressi

242. Dr. Bressi believes that it had been appropriate for Dr. Hoogendoorn to administer trigger point and chemoneurolytic injections in the context of his pain fellowship. Dr. Bressi testified: "For podiatry it is extremely important that they get a handle on chronic pain because * * * many, if not the bulk, of their problems deal with pain in the feet. But not all the pain in the feet comes from the feet, and they have to be familiar with generalized systems." (Tr. at 2320-2323, 2479-2480)

243. Dr. Bressi testified that trigger point injections "could be catastrophic if you're not careful." For example, "in the thoracic area you have to watch that you don't go too deep because you can collapse a lung[.]" Further, "[y]ou don't want to get a [blood] vessel. You can have a seizure or somebody can stroke." Dr. Bressi further testified that either Dr. Leak or Dr. Griffin had to have been in the room with Dr. Hoogendoorn at first to show him how they are done and observe his performance. After that, they would not necessarily have to be in the room with him. (Tr. at 2480-2482)

Dr. Bressi further testified that, in his opinion, Dr. Hoogendoorn had been competent to perform trigger point injections and chemoneurolytic injections under the supervision of Dr. Leak or Dr. Griffin. (Tr. at 2486)

244. Dr. Bressi testified that, in his opinion, Dr. Hoogendoorn had not practiced medicine without a certificate by performing injections under the supervision of Dr. Leak or Dr. Griffin. Dr. Bressi testified that the basis of that opinion was that Dr. Hoogendoorn had been in a fellowship at the time he engaged in those activities. (Tr. at 2486-2487)

Testimony of Dr. Griffin

245. Dr. Griffin testified that Dr. Hoogendoorn had joined the fellowship when Dr. Griffin was a second-year fellow. Dr. Griffin testified that Dr. Leak had asked him, as a second-year fellow, to supervise and teach Dr. Hoogendoorn about pain medicine. Dr. Griffin noted that he had been aware that Dr. Hoogendoorn was a podiatrist. (Tr. at 3005-3007)

Dr. Griffin testified that he had supervised Dr. Hoogendoorn's performance of procedures because Dr. Hoogendoorn had been a fellow and was there to learn about pain medicine. Dr. Griffin further testified that he had done so based on "many, many discussions with Dr. Leak[.]" whom Dr. Griffin testified "ran a pretty tight ship." (Tr. at 647-648, 3006-3008)

Dr. Griffin added: “We were trying to teach him about pain management, [the] pharmacological side, and the interventional side as far as he could take it, with the idea that it was his choice as to how to implement that into a podiatry practice.” (Tr. at 815-816)

Testimony of Dr. Hoogendoorn

246. Dr. Hoogendoorn testified that he had believed that the procedures he performed that were beyond his podiatric scope of practice had been performed under the scope of practice of the attending physician. Dr. Hoogendoorn further testified that he had recognized both Dr. Leak and Dr. Griffin as his attending physicians. (Tr. at 278)

Dr. Hoogendoorn further testified that every podiatric residency program in Ohio and in the country includes rotations through services that would be beyond the scope of podiatry, such as surgery, general medicine, and anesthesiology. Dr. Hoogendoorn added that residents in these programs are not just permitted but are required to scrub in on surgeries for non-podiatric conditions. Dr. Hoogendoorn testified that, although podiatrists’ practices are limited in scope, they need to become familiar with the body as a whole to recognize non-podiatric conditions that their patients may suffer from. (Tr. at 281-287)

247. Dr. Hoogendoorn testified as follows concerning the training he received at PCC prior to being allowed to perform injection procedures:

During that first period of several months of shadowing and even before—even after that, before any invasive procedure was ever done, whether a trigger point or chemoneurolytic injection, the attending would show me exactly how to do it; what we would have to know; what he would expect me to know; what medications were going in; why we were using those; why we were using certain local anesthetics versus others; if we’re adding anything to it, like a steroid, why that was being done; placement, choice of placement along the muscle or muscle belly or the insertion; how to prep the patients; gauge of syringe and needle to use. We’d go over it from top to bottom.

(Tr. at 2512)

248. Dr. Hoogendoorn testified that he had injected only soft tissue during his fellowship. Dr. Hoogendoorn further testified that he never performed spinal injections beyond the muscles that surround the spinal column. (Tr. at 2516-2517)

Dr. Hoogendoorn also testified that he never performed epidurals or placed spinal stimulators, although he had assisted in such procedures. When asked why he had been taught to perform some interventional pain management procedures but not others, Dr. Hoogendoorn replied:

Trigger point and chemoneurolytic injections are easily transferred from the back into the foot and ankle area in the soft tissues. The same principles apply.

* * *

It was never intended that for any reason I was going to be doing epidurals, sympathetic blocks; implant stimulators * * *. * * * It was more for me to learn technique, instrumentation, to develop that and bring it down to the foot and ankle where appropriate.

(Tr. at 2518-2519)

Level of Supervision of Dr. Hoogendoorn during Procedures

Testimony of Dr. Leak

249. Dr. Leak testified that it is possible that Dr. Hoogendoorn had been allowed to perform chemoneurolytic injections using Sarapin as the chemoneurolytic agent without an attending present in the same room. Dr. Leak further testified that Sarapin “is a slow, slow-moving agent that goes with local anesthetic. And it’s just like—it’s literally an intramuscular injection that will hopefully neutralize the nerve fibers that penetrate the muscle.” (Tr. at 446-448)

Later in the hearing, Dr. Leak testified that he had been present with Dr. Hoogendoorn whenever Dr. Hoogendoorn was performing trigger point or chemoneurolytic injections. Dr. Leak further testified that Dr. Griffin had spent more time with Dr. Hoogendoorn, and that Dr. Leak had left to Dr. Griffin’s judgment how Dr. Griffin “would staff” Dr. Hoogendoorn. (Tr. at 2768)

Testimony of Dr. Griffin

250. Dr. Griffin testified that, when he had supervised Dr. Hoogendoorn during a procedure, he had been “at [Dr. Hoogendoorn’s] elbow.” Dr. Griffin further testified that he doubts that there was any occasion when he had supervised a procedure performed by Dr. Hoogendoorn when he had not been present in the room. (Tr. at 671-672, 3059-3060)
251. Dr. Griffin added that, having had years of experience as a deputy sheriff, he had “absolutely not” believed that he was aiding and abetting Dr. Hoogendoorn in the commission of a crime. Moreover, Dr. Griffin testified that if he *had* been aware that he was aiding and abetting the commission of a crime he would not have supervised Dr. Hoogendoorn, even if that had meant leaving the fellowship. (Tr. at 3007-3009)

Testimony of Dr. Hoogendoorn

252. Dr. Hoogendoorn testified that Dr. Leak or Dr. Griffin had been in the room with him when he had performed a procedure “[t]he first couple times.” Dr. Hoogendoorn stated that after he had been “found to be capable of doing them from a prior experience,” then he would be permitted to perform such procedures without Dr. Leak or Dr. Griffin in the room. However, Dr. Hoogendoorn testified that at least one of them had always been present in the clinic when he performed non-podiatric procedures. (Tr. at 97-99)

Later in the hearing, Dr. Hoogendoorn testified that, whenever Dr. Griffin had supervised Dr. Hoogendoorn in performing an injection, Dr. Griffin had been at Dr. Hoogendoorn's elbow. Dr. Hoogendoorn further testified that, whenever Dr. Leak had supervised him performing an injection, Dr. Leak had been in the room with him. (Tr. at 2514-2515)

Allegation (2)(b):

253. In its August 9, 2006, notice of opportunity for hearing, the Board alleged in Allegation (2)(b) as follows:

During the period in or about August 2000 through in or about November 2001, [Dr. Leak] aided and abetted Kyle Elliott Hoogendoorn, D.P.M., in the unlawful practice of medicine and surgery by permitting and/or supervising Dr. Hoogendoorn in prescribing for the treatment of non-podiatric conditions controlled and noncontrolled medications, including, but not limited to, Nicotrol, Wellbutrin, Neurontin, Propranolol, Vioxx, Zyprexa, Ultram, Oxycontin, Clonazepam, Duragesic, Depakote, Senokot, Trazadone, hydrocodone, methadone, Transderm Scop, Celebrex, Zanaflex, Catapres, Zithromax, propoxyphene, Diflucan, oxazepam and/or methylphenidate to Patients 2, 7, 11-14, 18, 20, 21, 23 and 24.

(St. Ex. 54C)

Dr. Hoogendoorn's Prescribing of Medications for Non-Podiatric Patients

254. The medical records indicate that Dr. Hoogendoorn issued the following prescriptions to patients for non-podiatric conditions:

Pt	Date	Supervising Physician	Discharge Summary Signed?/Name/ Page Number	Medication and Strength	Medical Rcd. Pg.
2	01/23/01	Griffin ³¹	Yes/Griffin/148a	propranolol HCL 10 mg #60	79, 148a
				Neurontin 300 mg #360	80, 148a
				Vioxx 25 mg #60	80, 148a
				Zyprexa 5 mg #60	81, 148a
				Ultram 50 mg #80	81, 148a
	03/06/01	Griffin	Yes/Griffin/136a	"Nicotrol 15MG/16HR PT24" #1 box of 14 patches	75, 289
				Wellbutrin SR 150 mg #60	76, 289
7	02/20/01	Griffin	No	OxyContin 40 mg #90	37, 164

³¹ Although Dr. Hoogendoorn's January 23, 2001, progress note does not mention a supervisor, the discharge summary appears to bear Dr. Griffin's initial "G." (St. Ex. 1 at 148a, 189)

Pt	Date	Supervising Physician	Discharge Summary Signed?/Name/ Page Number	Medication and Strength	Medical Rcd. Pg.
				clonazepam 0.5 mg #30	37, 164
11	10/18/00	Griffin ³²	Yes/Griffin/154	Zithromax 250 mg #2 Z-Paks	64, 154
12	11/16/00	Griffin	Yes/Griffin/139a	Neurontin 100 mg #60	70, 203
	01/18/01	Griffin	Yes/Griffin/118a	hydrocodone APAP 10/325 mg #16	53, 191
	02/08/01	Griffin	Yes/Griffin/110a	OxyContin 80 mg #42	47, 188
				OxyContin 20 mg #30	46, 188
	02/16/01	Griffin	Yes/Leak/108a	Duragesic 50 mcg/hr #1 box of 5 patches	34, 186
	02/19/01	Leak	Yes/Leak/106a	Duragesic 50 mcg/hr #1 box of 5 patches	46, 184
				Trazodone HCL 50 mg #60	45, 184
				Senokot Xtra 374 mg tabs #120	45, 184
				Vioxx 50 mg #30	44, 184
				propranolol HCL 10 mg #30	44, 184
				Neurontin 100 mg #240	43, 184
				Depakote 250 mg #90	43, 184
13	02/16/01	Leak	No	methadone HCL 10 mg #60	16, 99
14	02/23/01	Griffin	Yes/Leak/86a	Vioxx 12.5 mg #30	36, 108
				Duragesic 25 mcg/hr #2 boxes of 5 patches	37, 108
				Neurontin 300 mg #126	37, 108
				Zyprexa 2.5 mg #40	38, 108
18	02/14/01	Leak	Yes/Leak/70a	Zyprexa 2.5 mg #30	38, 119
				OxyContin 10 mg #45	38, 119
				OxyContin 40 mg #45	39, 119
				Zanaflex 2 mg #30	39, 119
20	02/19/01	Leak	No discharge summary found – prescriptions were called in	Catapres TTS 0.1 mg #1 box of 4 patches	38, 186
				propranolol HCL 10 mg #14	39, 186
				propoxyphene N-APAP 100/650 mg #28	40, 186
				oxazepam 30 mg #7	41, 186
23	02/14/01	Leak	Yes/Leak/59a	Celebrex 200 mg #40	28, 70

³² Although Dr. Hoogendoorn's October 18, 2000, progress note does not mention a supervisor, the discharge summary appears to bear Dr. Griffin's initial "G." Further, Dr. Hoogendoorn testified that Dr. Griffin had directed him to issue this prescription. (St. Ex. 1 at 154, 265; Tr. at 202)

Pt	Date	Supervising Physician	Discharge Summary Signed?/Name/ Page Number	Medication and Strength	Medical Rcd. Pg.
				hydrocodone APAP 10/325 mg #60	28, 70
				Neurontin 300 mg #126	27, 70
				Zyprexa 2.5 mg #20	27, 70
	03/05/01	Griffin	Yes/Griffin/53a	hydrocodone APAP 10/325 #90	26, 68
				Neurontin 300 mg #240	26, 68
				Celebrex 200 mg #60	25, 68
				Zyprexa 2.5 #30	25, 68
24	01/25/01	Griffin	Yes/Griffin/47a	methylphenidate 10 mg #20	34, 47a, 88
	02/09/01	Griffin	No	Zanaflex 2 mg #10	33, 86
	02/16/01	Leak	Yes/Leak/43a	Duragesic 50 mcg/hr #3 boxes of 5 patches	32, 85
				Zanaflex 2 mg #30	32, 85

No refills were authorized for any prescription listed above.

Testimony of Investigator McCafferty

255. David Shawn McCafferty testified that he is an Investigator for the Board, and that he has been so employed for over twelve years. He testified that his duties include investigating complaints against the Board's licensees. (Tr. at 295-296)

Investigator McCafferty testified concerning his investigation of Dr. Hoogendoorn:

[On April 6, 2001], I met with Dr. Hoogendoorn and discussed his prescribing of Zyprexa, Ritalin, Oxycontin, and Methadone. Dr. Hoogendoorn advised me that he would prescribe Zyprexa for pain. He would also prescribe Ritalin for pain due to depression.

He would further prescribe Methadone as part of a weaning pack in an effort to control people from abusing drugs or people that he felt were misusing controlled medications. He would then turn around and then provide them with a wean pack to wean them off, which may include Methadone.

Dr. Hoogendoorn advised that he was doing this under a pain fellowship with Pain Net Incorporated. We concluded our conversation by him advising that he would send documentation to the Medical Board of his fellowship with Pain Net Incorporated, which he did at a later date.

(Tr. at 296-297)

256. Investigator McCafferty testified that Dr. Hoogendoorn advised that he had treated patients for various pain conditions under the supervision of Dr. Leak and Dr. Griffin as part of the PCC fellowship. (Tr. at 321-322)

Testimony of Dr. Chelimsky Concerning Medications Prescribed by Dr. Hoogendoorn

257. Dr. Chelimsky testified as follows concerning some of the medications that Dr. Hoogendoorn prescribed at PCC:

- Wellbutrin is used to treat depression, and the treatment of depression is beyond the scope of the practice of podiatry. Although some antidepressants are effective in treating chronic pain, Wellbutrin is not. (Tr. at 1675-1678)
- Neurontin is an anti-epileptic medication that can be used to manage pain, and its use constitutes the practice of medicine. (Tr. at 1678-1679)
- Zyprexa is a mild, sedating anti-psychotic medication used primarily to treat patients who suffer from hallucination. It is also useful as a sleep aid for chronic pain patients. Dr. Chelimsky is not aware of any use for Zyprexa to treat podiatric conditions. (Tr. at 1679-1680)
- Transderm-Scop is a medication used to treat nausea. Its use is not within the scope of practice for podiatry. (Tr. at 1741-1742)
- Duragesic patch contains the opiate Fentanyl, and is prescribed to relieve pain. (Tr. at 1743)
- “Zanaflex is an anti-spastic agent that’s sometimes used for chronic pain, sometimes used for migraine.” It could be used for podiatric conditions such as a muscle spasm in the foot or ankle. However, Dr. Chelimsky found no such symptoms in the medical records for Patients 18 and 20, the patients who had received Zanaflex from Dr. Hoogendoorn. (Tr. at 1754-1755)
- Catapres is a transdermal preparation of clonidine, an antihypertensive medication that Dr. Hoogendoorn had prescribed to Patient 9. Its use would be beyond the scope of podiatry unless prescribed for a neuroma in the foot or hand. This patient had no such complaint. (Tr. at 1763-1764)
- Propranolol is an antihypertensive medication which is used almost exclusively for the control of high blood pressure. Its use is beyond the scope of practice of podiatry. (Tr. at 1764)
- Methylphenidate is the generic for Ritalin, an amphetamine-like substance used to treat attention deficit disorder and narcolepsy. Its use is beyond the scope of practice of podiatry. (Tr. at 1787-1788)

Testimony of Dr. Hoogendoorn

258. Dr. Hoogendoorn testified that Catapres was used by PCC “for patients who were taken off their meds to transition from one med to another, to help decrease symptoms.”

Dr. Hoogendoorn further testified that he has not utilized Catapres in his podiatric practice. (Tr. at 247-248)

Dr. Hoogendoorn testified that Zithromax is a brand name for azithromycin, an antibiotic. Dr. Hoogendoorn testified that Dr. Griffin had directed him to prescribe two packages of Zithromax (Z-Paks) to Patient 11 to treat Lyme’s disease. Dr. Hoogendoorn noted that he has prescribed Zithromax to his podiatric patients for podiatric conditions since leaving the fellowship. (Tr. at 202-203, 206-207, 2525)

Dr. Hoogendoorn testified that Neurontin is a “neuromembrane stabilizer.”

Dr. Hoogendoorn further testified that “[i]t works to dampen the nervous system, in a sense, so it takes more stimulation for you to feel pain.” Dr. Hoogendoorn also stated that it is a centrally-acting drug that can affect memory and balance. He testified that he has prescribed Neurontin since leaving his fellowship for the purpose of controlling neuropathic pain in the foot and ankle. (Tr. at 118-119)

Dr. Hoogendoorn testified that Depakote is an anti-seizure medication. He stated that he has not utilized Depakote in his podiatric practice. (Tr. at 209)

Dr. Hoogendoorn testified that Senokot is a stool softener used to help patients on long-term medications avoid constipation. Dr. Hoogendoorn testified that he believes he has prescribed Senokot to his podiatric patients following surgery. (Tr. at 210-211)

Dr. Hoogendoorn testified that Trazodone is a medication used to control cramping or as a sleep aid. Dr. Hoogendoorn testified that he may have used Trazodone in his podiatric practice if a patient suffered from muscle spasms of the foot and ankle. (Tr. at 211)

Dr. Hoogendoorn testified that hydrocodone APAP is generic Vicodin, a combination of hydrocodone and acetaminophen, used to control pain. Dr. Hoogendoorn testified that he does utilize hydrocodone APAP in his podiatric practice to treat podiatric conditions. (Tr. at 213-214)

259. Dr. Hoogendoorn testified that, prior to issuing a prescription, he had seen and evaluated the patient and made recommendations to Dr. Leak or Dr. Griffin. He stated that Dr. Leak or Dr. Griffin had approved in advance all prescriptions that he issued. In addition, Dr. Hoogendoorn testified that either Dr. Leak or Dr. Griffin had reviewed each printed prescription to be sure it was printed correctly prior to the prescription being handed to a patient. (Tr. at 2508-2509)

Moreover, Dr. Hoogendoorn testified that one can tell from the medical record that either Dr. Leak or Dr. Griffin had approved a prescription by reviewing the discharge summary for

the patient visit. Dr. Hoogendoorn testified that the discharge summaries had been countersigned by either Dr. Leak or Dr. Griffin. (Tr. at 2509)

Further Testimony of Dr. Chelimsky

260. Dr. Chelimsky testified that the medical records reflect that Dr. Hoogendoorn had prescribed or changed medications that were utilized for non-podiatric conditions. Dr. Chelimsky further testified that, although Dr. Hoogendoorn had in many cases dictated progress notes indicating that he had prescribed these medications under the direct supervision of Dr. Leak or Dr. Griffin, there were no signatures on those progress notes from Dr. Leak or Dr. Griffin documenting their agreement with the new treatment. Dr. Chelimsky opined that Dr. Hoogendoorn had thus engaged in practice that was beyond the scope of his practice as a podiatrist. (St. Ex. 28 at 4-5; Tr. at 1632-1643)

Dr. Chelimsky subsequently testified that, in cases where Dr. Leak signed the discharge summary for a patient visit where Dr. Hoogendoorn had treated a patient, he would not consider it inappropriate. However, Dr. Chelimsky further testified that, if Dr. Griffin had signed the note and had also been a fellow at that time, he considers it inappropriate because the issuance of the prescription must be approved by an attending physician in charge of the patient. Dr. Chelimsky testified that one fellow cannot sign another fellow's notes. (Tr. at 2001-2003) Dr. Chelimsky further testified:

Either you have a fellowship with clearly defined fellows and clearly defined attendings and the attendings are teaching the fellows. If you have a fellowship program and a second-year fellow is signing a first-year fellow's note, that's not appropriate.

(Tr. at 2003)

Testimony of Dr. Bressi

261. Dr. Bressi testified that, as a fellow, if Dr. Hoogendoorn had recommended a particular prescription and gained approval from Dr. Griffin or Dr. Leak, Dr. Hoogendoorn could have signed the prescription himself because he was a licensed physician with a DEA registration. Dr. Bressi further testified that he did not find that to be inappropriate. (Tr. at 2478-2479)

Dr. Bressi further testified that he had reviewed the list of medications contained in the Board's notice letters to Dr. Leak, Dr. Griffin, and Dr. Hoogendoorn. Dr. Bressi testified that he did not find that any of those medications would have been inappropriate for Dr. Hoogendoorn to have prescribed under the supervision of Dr. Leak or Dr. Griffin in the context of Dr. Hoogendoorn's fellowship. (Tr. at 2482-2486)

Testimony of Dr. Leak

262. With regard to the supervision Dr. Hoogendoorn received when he wrote prescriptions for non-podiatric conditions, Dr. Leak testified:

Dr. Hoogendoorn would present a patient and make recommendations. That's the nature of training. If the attending makes all the decisions, there is very little hope that the trainee will absorb much of anything. So they—he would present and, if supported by the attending, those were the prescriptions that were written.

(Tr. at 448-449)

Dr. Leak further testified that Dr. Hoogendoorn had received training concerning the medications he prescribed and how they affected the body. (Tr. at 449)

Testimony of Dr. Griffin

263. With regard to Dr. Hoogendoorn's issuance of prescriptions for non-podiatric conditions, Dr. Griffin testified: "The patient would come into the clinic. The nursing staff would do vital signs, put them in a room. If [Dr. Hoogendoorn] saw the patient, he would go see the patient, do a history and physical, form a treatment plan, which included medications on occasion. And then he would bring it to me." Dr. Griffin would then examine the patient and, if he agreed with Dr. Hoogendoorn's treatment plan and choice of medication, he would approve the prescription(s) that Dr. Hoogendoorn had suggested. Dr. Griffin testified that Dr. Hoogendoorn had not issued prescriptions for non-podiatric conditions until Dr. Griffin or Dr. Leak had had a chance to examine the patient and determine whether the prescription was acceptable, and that, if a prescription "made it out of the building," either Dr. Leak or Dr. Griffin had approved it. (Tr. at 676, 807-809)
264. Dr. Griffin testified that for a short time Dr. Hoogendoorn had issued prescriptions under his own name, after the prescriptions had been approved by Dr. Griffin or Dr. Leak. Dr. Griffin further testified that, after about two weeks, during a regular meeting at PCC, Dr. Leak and Dr. Griffin determined they would rather issue the prescriptions under their names "because certainly we were responsible anyway[.]" (Tr. at 3051-3053)

Further Testimony of Dr. Hoogendoorn

265. Dr. Hoogendoorn testified that PCC had used a computerized prescription program and that his name had been added to the computer for only a short time, which allowed prescriptions to be issued under his name. Dr. Hoogendoorn testified that his name was later removed, however, because pharmacists had called the clinic wondering why the medication was being prescribed by a podiatrist. (Tr. at 2506-2507) Dr. Hoogendoorn further testified:

[T]hey were confused on why a podiatrist would be writing for—because it designated me as Kyle Hoogendoorn, D.P.M. They were confused on why a

podiatrist would be writing some of the medications that they directed me to write for. When they called the office, my understanding is they talked with the office manager or one of the attendings and explained, you know, he's a pain fellow, he's in a training program, that's what this is for.

And it seemed to cause a little bit of an issue. So rather than have that hold up clinic and people not get their prescriptions filled possibly and that kind of thing, they decided that we'd discontinue that form of training.

(Tr. at 2510)

Dr. Hoogendoorn testified that he had signed prescriptions for only a short time, in or about February and March 2001. After he discontinued, all prescriptions had been issued by Dr. Leak or Dr. Griffin. (Tr. at 2510)

266. No evidence was presented that Dr. Hoogendoorn had prescribed Diflucan to Patients 2, 7, 11-14, 18, 20, 23, or 24. (St. Exs. 2, 7, 11-14, 18, 20, 23, 24)

Dr. Griffin's Participation in the PCC Fellowship

Testimony of Dr. Griffin

267. Dr. Griffin testified that he had developed an interest in pain medicine as an emergency medicine physician. He further testified that he had made an effort to learn about that field and applied some of the techniques while practicing in the ER. Dr. Griffin stated that when he received the offer to join Dr. Leak's fellowship, he had "jumped on it." Dr. Griffin entered the fellowship in August 1999. Dr. Griffin further testified that, after he had completed his first year of fellowship, he had "begged" to stay a second year. Dr. Griffin testified that he remained in the fellowship until 2001. (Tr. at 800, 2995-2998, 3004)

Dr. Griffin testified that he had mostly received surgical training during his second year, which he described as the "true interventional side. * * * I really wanted what Dr. Leak was able to give me, which is truly an international level, expert level of pain management and interventional pain management." (Tr. at 3005)

268. Dr. Griffin testified that he had used the fellowship training he received at PCC to obtain ABMS-recognized specialty certification in pain medicine. (Tr. at 800-802)

As discussed earlier in this report, information obtained by the State from the ABMS World Wide Web site indicates that Dr. Griffin holds subspecialty certification in pain medicine through the American Board of Physical Medicine and Rehabilitation. (St. Ex. 57)

Testimony of Dr. Hoogendoorn

269. Dr. Hoogendoorn testified that, to his knowledge, Dr. Griffin had been a fellow in the PCC program from August 2000, when Dr. Hoogendoorn entered the fellowship, through November 2001. (Tr. at 2530)

Testimony of Dr. Katirji

270. Dr. Katirji was unaware that Dr. Griffin had been a fellow in Dr. Leak's program until being so advised during cross-examination at hearing. When asked whether his opinion concerning Dr. Griffin would change if the evidence shows that Dr. Griffin had been a fellow in Dr. Leak's program from 1999 to 2001, Dr. Katirji replied, "Well, if he's a fellow, he's technically following orders, I guess, somehow." (Tr. at 1286-1287)

*Dr. Hoogendoorn's Participation in the PCC Fellowship*Testimony of Dr. Hoogendoorn Concerning Podiatric Residency Training

271. Dr. Hoogendoorn opined that his performance during the PCC fellowship should be likened to podiatric residency training. Dr. Hoogendoorn testified that, during podiatric residency training, residents rotate through various services and participate in the management of patients who suffer from non-podiatric conditions. (Tr. at 85-92)

Dr. Hoogendoorn stated that, during his residency, he had rotated through various services including internal medicine, dermatology, anesthesiology, wound care, emergency medicine, and podiatric surgery. Dr. Hoogendoorn further stated that he had managed patients suffering from a variety of non-podiatric conditions, including emphysema and congestive heart failure. Moreover, Dr. Hoogendoorn testified that, during rotations at Columbus Community Hospital [CCH], he had performed a general surgery rotation wherein that he had assisted in various procedures such as laparoscopic "[g]allbladder excisions" during which he created portals, inserted instruments, stapled off arteries, and closed. Dr. Hoogendoorn added that he had assisted in thoracotomy. When asked what a thoracotomy is, Dr. Hoogendoorn replied: "It's an open heart procedure. The chest is actually opened. The ribs are separated. The pleural cavity is exposed." Dr. Hoogendoorn stated: "When we got to that level, I helped retract. I also closed on leaving. So [I] sutured ribs back together, deep tissues, skin." (Tr. at 85-92) (Note that Dr. Hoogendoorn spent only one year in podiatric residency. [Resp. Ex. 103H])

272. Dr. Hoogendoorn testified that, during his residency, he had been expected to do the same work during rotations as the allopathic and osteopathic residents. (Tr. at 2184-2185)

Testimony of Dr. Weiner Concerning Podiatric Residency Training

273. Richard D. Weiner, D.P.M., testified on behalf of the Respondents. Dr. Weiner obtained his podiatric medical degree from the Ohio College of Podiatric Medicine. He performed his residency at the California College of Podiatric Medicine, which is affiliated with the

University of Southern California Medical Center in Los Angeles. Since about 1997, Dr. Weiner has been the director of the podiatric residency program at OhioHealth Grant Medical Center in Columbus, and is also in private practice. (Tr. at 2089-2090, 2164)

274. Dr. Weiner testified that the Council of Podiatric Medical Education [CPME] mandates that podiatric residents be given exposure to a variety of medical conditions rather than limiting their training to conditions of the foot and ankle. (Tr. at 2094) Dr. Weiner explained: “The rationale is because the foot and ankle is connected to the rest of the body. It’s not an isolated structure. So in order to competently treat that, one must understand how what they’re doing affects the rest of the body.” (Tr. at 2120-2121)
275. Dr. Weiner testified that podiatric residency training in Ohio currently consists of either a two-year or three-year program. Dr. Weiner testified that, the first year, residents rotate through a number of different areas such as family medicine, internal medicine, radiology, emergency medicine, and endocrinology. During the second year the residents focus on foot and ankle both clinically and surgically, and also continue generalized rotations such as plastics and orthopedics. The third year is a continuation of the second and may include electives such as general surgery. (Tr. at 2091-2092)

Dr. Weiner testified that, when performing rotations, the residents function under the direct supervision of the podiatric, osteopathic, or allopathic physician who is in charge of the rotation. The residents also answer to the hospital’s graduate medical education committee and the bylaws of the hospital. (Tr. at 2093)

276. Dr. Weiner testified that all podiatric residents receive some training in either general surgery or some other surgical field such as vascular surgery or orthopedic surgery, depending on the institution. Moreover, Dr. Weiner testified that podiatric residents assist in all surgical procedures that their rotations cover, including non-podiatric surgeries. (Tr. at 2101-2102)

Testimony of Dr. Loftus Concerning Podiatric Residency Training

277. Todd C. Loftus, D.P.M., testified on behalf of the Respondents. Dr. Loftus obtained his podiatric medical degree in 2000 from the Ohio College of Podiatric Medicine. From 2000 to 2003, Dr. Loftus participated in a podiatric residency at Salt Lake City Veterans Hospital in Salt Lake City, Utah. Dr. Loftus testified that his residency had consisted of 12 months of medicine and 24 months of surgery. Dr. Loftus currently practices as a junior associate in a four-partner podiatric practice. (Tr. at 2544-2545)

Dr. Loftus testified that he is past central chapter president of the Ohio Podiatric Medical Association [OPMA]. Dr. Loftus further testified that he is familiar with the laws and rules that govern the practice of podiatry in Ohio. (Tr. at 2554)

278. Dr. Loftus’ testimony concerning his training as a podiatric resident was consistent with the testimony of Dr. Hoogendoorn and Dr. Weiner. (Tr. at 2551-2554)

Testimony of Dr. Bastawros Concerning Podiatric Fellowship Training

279. David S. Bastawros, D.P.M., testified on behalf of the Respondents. Dr. Bastawros testified that he had obtained his podiatric medical degree from the Ohio College of Podiatric Medicine in 1997, and, from 1997 to 1998, participated in a podiatric residency at the Veterans Administration Medical Center in Boston, Massachusetts. Dr. Bastawros further testified that his residency program had been affiliated with Harvard Medical School and Brigham and Women's Hospital. (Tr. at 2640-2641)

Dr. Bastawros testified that he is currently engaged in the solo practice of podiatric medicine and surgery in Richardson, Texas. In addition to his private practice, Dr. Bastawros is also a Physician Investigator for the Texas State Board of Podiatric Medical Examiners [Texas Board]. Dr. Bastawros has worked with the Texas Board since June 2002. Moreover, Dr. Bastawros is Chairman of the Patient Safety Committee at Richardson Regional Medical Center, and a member of the Executive Advisory Board for the North Texas Healthcare Fraud Working Group. (Resp. Ex. 109H; Tr. at 2640-2645)

Dr. Bastawros testified that he is licensed to practice podiatric medicine and surgery in Texas. (Tr. at 2643)

280. Dr. Bastawros testified that the scope of podiatric practice in Texas is limited to the treatment of the bone and joints in the foot and ankle and soft tissues "all the way up into the leg area." Dr. Bastawros further testified that, unlike Ohio, Texas podiatrists cannot treat superficial lesions of the hand. Moreover, Dr. Bastawros testified that he gained familiarity with the scope of podiatric practice in Ohio through his education at the Ohio College of Podiatric Medicine.³³ (Tr. at 2647-2648)

281. Dr. Bastawros testified that he is familiar with podiatric fellowship programs. Dr. Bastawros further testified that they have unaccredited as well as accredited podiatric fellowships in Texas, and that the issue of podiatrists training in an unaccredited fellowship has never been a basis for concern with the Texas Board. Dr. Bastawros indicated that it would not be of concern as long as the podiatric fellow is appropriately supervised. (Tr. at 2656-2660)

Dr. Bastawros testified concerning "appropriate supervision" of a podiatric fellow:

[A]s long as the fellow is being appropriately supervised by their attending, whether it's another podiatrist, whether it's a medical doctor, whether it's a

³³ During the hearing, counsel for the State raised an objection that the statute defining the scope of practice of podiatric medicine and surgery in Ohio, R.C. 4731.51, had been amended since Dr. Bastawros finished medical school in Ohio in 1998. (Tr. at 2648-2649)

The current version of R.C. 4731.51 became effective on April 10, 2001. The only changes from the previous version of the statute, which had been in effect since December 14, 1967, were to change "podiatry" to "podiatric medicine and surgery," and to change "he" to "the applicant." No substantive change was made to the scope of practice. (See Sub. H.B. 585, 123rd General Assembly [148 v H 585])

doctor of osteopathic medicine, that fellow must work under the direct orders of that physician. And as a fellow, they're receiving further training. They many times will be performing or providing care outside their initial scope of practice because they're working—if they're working under a medical doctor, as long as that medical doctor is comfortable and as long as that medical doctor is providing supervision and providing orders and feels comfortable with their care, then that fellow can—they're delegated the authority to provide whatever treatments are necessary, once again, as long as they're being appropriately supervised.

(Tr. at 2663-2664) Furthermore, Dr. Bastawros testified that the attending physician would decide the level of supervision required, such as direct or on-site. (Tr. at 2664-2665)

Dr. Bastawros further explained that, when a podiatrist is providing services as a fellow, he or she is actually practicing under the license of the attending physician, whether the physician is an allopath, osteopath, or podiatrist. (Tr. at 2665)

282. On cross-examination, Dr. Bastawros acknowledged that he and Dr. Hoogendoorn are good friends. Dr. Bastawros further acknowledged that he had gone to podiatric medical school with Dr. Hoogendoorn and that he talks to Dr. Hoogendoorn about once or twice per week. (Tr. at 2668-2669)

The PCC Fellowship

Testimony of Dr. Hoogendoorn

283. Dr. Hoogendoorn testified that he had been offered a position in the PCC fellowship in 2000. Dr. Hoogendoorn testified that Dr. Griffin, who was himself a fellow at that time, had recommended Dr. Hoogendoorn for the program. (Tr. at 2208-2209, 2215)
284. Dr. Hoogendoorn testified that he had entered the PCC fellowship in August 2000. He remained in the program until around November 2003. (Tr. at 2498, 2528)
285. When asked why he had been interested in joining the fellowship program, Dr. Hoogendoorn replied:

One, it was a fantastic opportunity for myself. Podiatry has always struggled to be accepted amongst M.D.s and D.O.s, and I worked with a lot of M.D.s while I was at the program and gained their confidence and worked with them very closely. So it kind of was exciting to be brought into that.

Also, there's a lot of things that they've done or currently still do that they may do in the low back; but I've also taken it now and do it down in the foot and ankle, which has proved to be very successful. The training was at that point one of a kind, so to speak; and I thought it was an excellent opportunity to

increase my base knowledge of pain and expand on it in the private practice within the podiatric scope.

(Tr. at 2209-2210)

286. Dr. Hoogendoorn testified that, after he entered the PCC program, he had sought and obtained accreditation for the program from the Council on Podiatric Medical Education [CPME]. Dr. Hoogendoorn further testified that CPME accreditation had required linking the program with the Ohio College of Podiatric Medicine. PCC and the OCPM entered into an agreement to that effect, dated September 13, 2001. (Resp. Ex. 119H; Tr. at 2218-2221)

By letter dated January 8, 2002, the CPME notified Dr. Leak that, effective January 1, 2002, the PCC fellowship program had been granted approval as a podiatric fellowship in pain management. (Resp. Ex. 121H)

287. Dr. Hoogendoorn testified that the CPME would not recognize or give credit for the time he had spent in the fellowship prior to January 8, 2002. Therefore, he repeated that time and remained in the fellowship until September 2003. (Tr. at 2222-2224, 2535)
288. Dr. Hoogendoorn testified that there had been no difference in the training he received at the PCC fellowship between the times prior to and after CPME accreditation. (Tr. at 2224)
289. Dr. Hoogendoorn described at length his responsibilities during the fellowship and his purpose in participating in the fellowship:

This was harder than my residency. You were required to have self-directed learning on top of directed learning. You were to evaluate as many patients as you can in clinic and present them to the attending and then the attending would ask you questions and then you would be given direction to look up new educational information or techniques or other things.

You would have to know pharmacology. You'd have to know nerve blocks, nerve roots, dermatomes, sclerotomes, why certain medications work and why some don't, some drug interactions. You would have to do research on topics. You were required—I believe I was required every two or three weeks to give a presentation and it was a PowerPoint presentation that you had to produce, a publication that had to be done by the end of your fellowship program or presented for publication, pretty much you had to know as much as you possibly could.

You also had to understand patient relations in the sense of, you know, not everybody [who] goes to a pain clinic is 100 percent legit; and we try to focus on how do we spot people who are faking, basically. Had to know why you ordered certain diagnostics, you had to know what certain diagnostics to order and when. You had to know how to come up with a treatment plan; how, you know, pain presents in the different ways and why. So it's a very hard question

to put a net around because the typical patient that would come to a pain management group has already seen at least four or five other people; and, surprisingly, I would say it was not—it wasn't far off—20 percent of them had chronic foot and ankle painful conditions.

So it's one of these things where it definitely had relevance to podiatry, definitely had application. It might—you know, doing this whole program, it was never the intent for me to come out after I was done to give epidurals, injections above and beyond the scope of practice for podiatry. It was to learn what they do; evaluate what can be brought down to the foot and ankle that we currently aren't using; for better techniques to treat patients with chronic painful conditions; and advance podiatry, so to speak, take it to another level that is currently not there.

And that's what I expected to learn and expected to do in this. You know, neither David Leak, Brian Griffin, or anybody else in the facility ever thought for a second I was going to come out and start doing epidural injections or selective nerve root injections or anything above and beyond the scope and practice of podiatry.

(Tr. at 2212-2214)

Testimony of Dr. Leak

290. Dr. Leak testified that, during the time that Dr. Hoogendoorn rotated through CCH as a podiatric resident, he had worked with Dr. Hoogendoorn and been impressed by Dr. Hoogendoorn's curiosity and desire to learn. He eventually invited Dr. Hoogendoorn to join the PCC fellowship. Dr. Leak testified that, after Dr. Hoogendoorn joined the PCC fellowship, Dr. Hoogendoorn had been limited in his activities only to the degree that he had wanted to be limited. Dr. Leak testified that, for example, Dr. Hoogendoorn had not been interested in learning how to implant spinal cord stimulators because he would not be doing those in his practice as a podiatrist. Aside from that, Dr. Hoogendoorn was put through the same curriculum as the other fellows. (Tr. at 384-386, 2762-2764)

When asked whether he had had any concerns that, while in the fellowship, Dr. Hoogendoorn would be practicing outside the scope of podiatry, Dr. Leak likened fellowship training to podiatric residency training wherein podiatric residents receive training that is beyond the scope of podiatry. Dr. Leak noted that he had gained exposure to podiatric residency training at CCH and that podiatric residents rotated through various services including anesthesiology and general surgery. Moreover, Dr. Leak testified that he had reviewed the curriculum for podiatric residents at CCH. Dr. Leak testified that that curriculum "was broad enough to include our service * * *" and that CCH administrators had asked that podiatric residents be allowed to rotate through Dr. Leak's pain medicine service. (Tr. at 385-386, 401-407) Dr. Leak further testified:

As a physician, in our world, it was a seamless progression, because the hospital which was in our community and accredited—we were working literally in the same place, so it did not occur that if he was operating with us and within our clinic on March 31st that he would not be able to operate in our clinic on April 5th, because it was the same continuum, same physical facility, and just more information that should have resulted in a better trained and educated individual.

We did have an expectation and an understanding that, just like all the other podiatry residents and surgical residents, that once they completed training with us, that they would then go back to what they understood and what we understood to be their scope of practice once they were outside our venue.

(Tr. at 385-386)

291. Dr. Leak testified that Dr. Hoogendoorn had been the only podiatrist who participated in the PCC fellowship. (Tr. at 384, 2767)

Testimony of Dr. Griffin

292. Dr. Griffin testified that when Dr. Hoogendoorn entered the PCC fellowship, Dr. Griffin had been a second-year fellow. Dr. Griffin acknowledged that he had supervised Dr. Hoogendoorn in the performance of tasks that were outside the scope of practice of podiatric medicine. However, Dr. Griffin testified that it had been his understanding that, while training as a fellow at PCC, Dr. Hoogendoorn had been allowed to perform medical tasks that were outside the scope of practice for podiatric medicine. (Tr. at 824)

With regard to his supervision of Dr. Hoogendoorn, Dr. Griffin testified:

It's tradition in teaching. It's just always been that way. It was that way for me. You start at the bottom and you've got to work your way up. They start off by doing histories and physicals, and then as they get—show [in]dependence, they get a little more involved with the patients. But we all went through that training process where you're low man on the totem pole until you step up a step, internship, residency, and then you teach the guy beneath you.

(Tr. at 824)

Testimony of Dr. Chelimsky

293. Dr. Chelimsky testified that he had had trouble understanding why Dr. Hoogendoorn was in the PCC fellowship because fellows “normally would be trained to do things they're going to do in the future.” However, Dr. Chelimsky testified that a podiatrist would not perform trigger point injections because there are no trigger points in the foot or the supporting structures of the foot. Dr. Chelimsky further testified that, if a technique would be beyond

the scope of a podiatrist's eventual practice, the podiatrist should not be taught that technique in a fellowship. Moreover, Dr. Chelimsky testified that the standard of practice is that a fellowship teaches only those things that may be used by the fellow in his or her area of licensure. (Tr. at 1838-1839, 1894, 1983)

In addition, Dr. Chelimsky testified that, if Dr. Griffin or Dr. Leak had always been at Dr. Hoogendoorn's side when he performed a procedure and had always reviewed and approved Dr. Hoogendoorn's treatment plans, it would not change his opinion concerning Dr. Hoogendoorn's participation in the fellowship. Dr. Chelimsky testified:

I think the fundamental question I have is was this just a way of getting more procedures done and just get more money passed through, or was there a true fellowship program happening with true education, some percentage of time allotted to Dr. Hoogendoorn that would be his fellowship time? The whole thing has a very unusual appearance to it, as best I can gauge from the notes, from '99 to 2001.

(Tr. at 1992)

Furthermore, Dr. Chelimsky testified that, the only attestation in the patient records concerning supervision had been a line dictated by Dr. Hoogendoorn that Dr. Leak or Dr. Griffin had been supervising. Dr. Chelimsky testified that "that would be entirely inadequate in any medical record review." Dr. Chelimsky testified that an attestation is required by the supervising physician that he or she was present at the time of the procedure. Ideally, the supervising physician's note would also include information concerning the patient's progress or "[s]ome evidence that there was some thought put in by the person doing the training." (Tr. at 1831-1834)

294. With regard to Dr. Chelimsky's knowledge of the PCC fellowship program, the following exchange took place:

Q. [By Mr. Graff] The fellowship program hours of Dr. Griffin were accepted by the American Board of Anesthesia for the purposes of board certification examination in pain medicine. Are you aware of that?

* * *

A. [By Dr. Chelimsky] No.

* * *

Q. That, in fact, the fellowship program of Dr. Leak was used for the purposes of providing the educational hours necessary for the subspecialty of pain medicine; are you aware of that?

A. I was not aware of that.

Q. And that those hours as certified during the period that is under review are those that were the basis to allow a physician to sit for examination who is now certified in the subspecialty of pain medicine; are you aware of that?

A. I thought I just said that.

- Q. Are you aware that the same program without change was certified the following year as an accredited fellowship by the Ohio College of Podiatric Medicine and certified the hours of Dr. Hoogendoorn?
- A. I was not aware of that.
- Q. Having this additional information available to you now, does it change your opinion?
- A. I think I would still need to look at the structure of the program to understand what the program's about and what the teaching hours were and so on.
- Q. So that your opinion as expressed in your testimony to date is lacking the foundation necessary, in your opinion, of the fellowship program itself to being fully accurate?
- A. As far as the structure of the fellowship program.
- Q. Correct.
- A. Yes.

(Tr. at 2008-2010)

Testimony of Dr. Bressi

295. Dr. Bressi testified that he does not believe that it had been inappropriate for Dr. Griffin, a second year fellow in Dr. Leak's program, to have supervised Dr. Hoogendoorn, a first year fellow, even though Dr. Hoogendoorn was a podiatrist. Dr. Bressi testified that "[i]t's perfectly reasonable and it does not deviate from any standard of care." (Tr. at 2432-2433)

Signed Discharge Summaries for Procedures

296. The following table lists the invasive procedures performed by Dr. Hoogendoorn, whether the discharge summary was signed, by whom it was signed,³⁴ and the medical record page number for the discharge summary:

Pt	Date	Procedure Type/ Medication	Physician(s)	Discharge Summary Signed By Dr. Leak or Dr. Griffin?/ Name	Dch.Sum at Page
1	08/22/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Griffin	67a
	10/02/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Griffin	68a
2	03/06/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Griffin	136a
	04/04/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	No	121a
	10/16/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Griffin	95a

³⁴ An example of Dr. Leak's signature appears at State's Exhibit 41 at 8. (Tr. at 455-460) An example of Dr. Griffin's signature appears at State's Exhibit 2 at 326. (Tr. at 673) An example of Dr. Hoogendoorn's signature appears at St. Ex. 9 at 97a, to the left of Dr. Griffin's initial "G." (Tr. at 200)

Pt	Date	Procedure Type/ Medication	Physician(s)	Discharge Summary Signed By Dr. Leak or Dr. Griffin?/ Name	Dch.Sum at Page
3	10/17/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Griffin	87a
	11/13/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Griffin	76a
4	02/14/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn/ Leak	Yes/Leak	214a
	03/02/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Griffin	85a
	03/16/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Griffin	83a
5	06/01/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	No	93a
	06/08/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	No	90a
	06/15/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	No	87a
	06/29/01	Chemoneurolytic injection/ <i>Sarapin, Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	No	78a
	10/10/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Griffin	65a
	10/19/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Griffin	59a
7	06/19/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn/ Leak	No	92a
	07/18/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Griffin	86a
	08/01/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Leak	Yes/Leak	84a
	08/14/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Griffin	82a
	09/21/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Griffin	75a
	10/02/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Griffin	73a
8	10/26/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Griffin	127a
9	02/09/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Griffin	76a
	02/16/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Leak	Yes/Griffin and Leak	74a
	03/09/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Griffin	72a

Pt	Date	Procedure Type/ Medication	Physician(s)	Discharge Summary Signed By Dr. Leak or Dr. Griffin?/ Name	Dch.Sum at Page
11	05/28/01	Trigger point injection/ <i>Sarapin, Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	No	132a
	06/08/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	No	129a
	06/19/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	No	127a
	08/28/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Griffin	113a
	10/02/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Griffin	109a
14	05/01/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	No	62a
	05/08/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Possibly/Griffin	60a
	05/22/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	No	58a
	06/15/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	No	54a
	06/22/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	No	52a
17	01/19/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn	Yes/Griffin	113a
	01/26/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn	Yes/Griffin	110a
	02/06/01	Chemoneurolytic injection ³⁵ / <i>Sarapin, Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Leak	107a
	02/09/01	Chemoneurolytic injection/ <i>Sarapin, Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Griffin	104a
	02/16/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Leak	Possibly/Leak	101a
	02/23/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Possibly/Leak	98a
	03/02/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Possibly/Leak	96a
	03/09/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Leak	94a
	04/04/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Griffin	90a
	04/11/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	No	88a

³⁵ Many of the procedural notes for Patient 17 indicate that a trigger point injection was performed; however, Sarapin, a chemoneurolytic agent, was used. Accordingly, these procedures have been identified in this table as chemoneurolytic injections. (St. Ex. 17 at 173; see also pages 169-171)

Pt	Date	Procedure Type/ Medication	Physician(s)	Discharge Summary Signed By Dr. Leak or Dr. Griffin?/ Name	Dch.Sum at Page
	04/18/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	No	86a
	04/25/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Griffin	84a
	05/04/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	No	82a
	05/16/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Griffin	80a
	06/20/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Griffin	77a
	06/29/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Griffin	75a
	07/09/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	No	73a
	07/24/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Leak	Possibly/Leak	69a
	08/07/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Griffin	67a
	09/28/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Griffin	54a
21	05/23/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn/ Griffin	No	170a
	06/01/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	No	166a
	06/08/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	No	163a
	07/13/01	Chemoneurolytic injection/ <i>Sarapin, bupivacaine</i>	Hoogendoorn/ Griffin	No	154a
	09/28/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Griffin	139a
22	07/25/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn/ Leak	Possibly/Griffin	110a
	07/31/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Leak	Yes/Leak	107a
	09/07/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Griffin	98a
	09/19/01	Trigger point injection/ <i>bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Griffin	94a
	09/28/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Griffin	92a
	10/19/01	Trigger point injection/ <i>Depo-Medrol, bupivacaine</i>	Hoogendoorn/ Griffin	Yes/Griffin	90a

Allegation (3):

297. In its August 9, 2006, notice of opportunity for hearing, the Board alleged in Allegation (3) as follows:

Despite the lapse of his malpractice insurance coverage during the period in or about August 2003 to in or about March 2004, [Dr. Leak] failed to:

- (a) provide written notice of his lack of malpractice insurance coverage [malpractice notice] to every patient seeing [him] for nonemergency professional services which provided a space for the patient to acknowledge receipt of the malpractice notice; and/or
- (b) obtain from every patient seeing [him] for nonemergency professional services the patients' signatures acknowledging receipt of the malpractice notice; and/or
- (c) maintain a signed written malpractice notice in the patient chart for every patient who saw [him] for nonemergency professional services.

(St. Ex. 54C)

*Dr. Leak's Interrogatory Responses*Second set of Interrogatories

298. By letter dated May 13, 2004, Board enforcement staff provided to Dr. Leak the Board's Second Set of Interrogatories Directed to William David Leak, M.D. Dr. Leak provided written responses to those interrogatories as instructed, signed the document on May 21, 2004, and delivered the completed, signed document to the Board the same day. (St. Ex. 41)

In response to the questions contained in the Board's second set of interrogatories, Dr. Leak stated that he had had been without malpractice insurance coverage from August 2003 through March 2004. Dr. Leak further indicated that he had notified his patients of his lapse in malpractice insurance coverage, stating: "Notices that Pain Control Consultants and it's Physicians did not have malpractice coverage were posted on an 8x11 notice at the registration window at eye level where all patients register and in the waiting room with the Ohio 1800 complaint line." (St. Ex. 41)

Third Set of Interrogatories

299. Sometime after returning the Board's second set of interrogatories, Dr. Leak received the Board's Third Set of Interrogatories Directed to William David Leak, M.D. Dr. Leak provided written responses to those interrogatories as instructed and signed the document on

July 13, 2005. The Board received the completed, signed document the following day. (St. Ex. 42)

One of the questions in the third set of interrogatories asked:

2. During the time period August 2003 to March 2004, in which [Dr. Leak] was without malpractice insurance coverage, did Dr. Leak or anyone at his direction provide individually to each and every patient to whom Dr. Leak provided nonemergency professional services a written notice of Dr. Leak's lack of malpractice insurance on its own page with an acknowledgment receipt of the notice?

(St. Ex. 42)

In response, Dr. Leak answered: "No. Notices were posted conspicuously on bulletin boards, in waiting room areas and public areas of the building." (St. Ex. 42)

300. Dr. Leak testified that he had been unaware of the statute that specifies the method for notifying patients of the lack of malpractice insurance coverage, Section 4731.143, Ohio Revised Code. Dr. Leak testified that his malpractice insurance had lapsed some time before he discovered that it had lapsed. Dr. Leak further testified that, after he learned of the lapse in coverage, the insurance agent told him that he needed to notify his patients of his lack of coverage, but did not provide any details about how to do it. Dr. Leak further testified, "We did the best we could do based on what the agent told us we could do." (Tr. at 470-471)

Additional Information

Testimony of Dr. Boswell Concerning Dr. Leak

301. Dr. Boswell testified that he has a very good opinion of Dr. Leak's knowledge base and clinical skills in interventional pain medicine. (Tr. at 50)

Dr. Boswell testified that he has been on lectures with Dr. Leak and has shared a podium with him. Dr. Boswell further testified that he had been an editor of a textbook in which Dr. Leak had written a chapter. (Tr. at 34-36)

Testimony of Dr. Boswell Concerning Approaches to Pain Medicine: Neurology vs. Anesthesiology

302. Dr. Boswell testified that he believes that there is a difference in philosophy between the ways that neurology and anesthesiology look at pain medicine. Dr. Boswell further testified:

The neurology approach is more medication and less intervention. Anesthesiology has always been more interventional in the sense of doing nerve blocks and stimulators and pumps, things like that. Things that Leak was doing that I wanted my fellows to observe or learn about back in 1996. That's why I had the original affiliation with Leak.

(Tr. at 43-44)

Dr. Boswell agreed that physicians who are in different specialties see the work of others through their own viewpoint rather than those within the same specialty. Dr. Boswell testified: “[I]t’s a difference in philosophy. Probably a difference in knowledge base as well. I mean, [anesthesiology and neurology are] just different specialties.” Dr. Boswell noted that, when he had worked at CWRU, he and Dr. Chelimsky had had interdisciplinary meetings, discussed patients and worked together. Dr. Boswell further testified that they did not always agree on approaches but that they had a collegial relationship and formulated good plans for the patients that they co-managed. Moreover, Dr. Boswell testified that both he and Dr. Chelimsky were within the standard of care even though they viewed patients differently and had differences of opinion concerning treatment. (Tr. at 44-45)

Testimony of Dr. Boswell Concerning the Use of EDX Studies in Interventional Pain Management

303. Dr. Boswell testified that the subspecialty of pain medicine is a relatively young subspecialty. Dr. Boswell further testified:

[T]he specialty’s constantly changing. And there are numerous areas of controversy and uncertainty about the value of the diagnostic tests, what the results mean, the appropriate treatment options, the interventional procedures, and so forth. We’re not sure.

It’s all evidence-based and some of the evidence is not very strong. The best evidence we have for pain medicine treatments right now would be considered a level two evidence with some randomized control trials.

(Tr. at 55-56)

Dr. Boswell testified that, under such circumstances, a clinician uses the diagnostic techniques that he or she believes to be of value. (Tr. at 57-58)

Testimony of Dr. Griffin

304. Dr. Griffin offered the following opinion concerning Dr. Leak:

[Dr. Leak is] brilliant. Doesn’t always run the clinic the way I would. He’s amazing with his hands and has the ability to correctly adjust in O.R. I’ve seen him invent new procedures on the spot to counter a problem that the patient had anatomically. It was—every time you work with the guy is a learning experience.

(Tr. at 3077)

Dr. Hoogendoorn's use of Knowledge Gained in Fellowship

305. Dr. Hoogendoorn testified that he is board-certified by the American Academy of Pain Management, and explained how he has used the knowledge gained during the fellowship. Dr. Hoogendoorn stated:

I sit on their education advisory committee. Since then I've applied it to the foot and ankle. I've written—I'm published. I've written textbook chapters on pain management for major podiatry texts. I lecture for a spinal cord stimulator company to podiatrists so they understand how this can build—not build but help their patient population and what to look for. I've lectured for drug companies that are used for chronic pain from the podiatrist's perspective. I've made the most of what could possibly be made from that educational experience, and I have a constant referral source for chronic painful conditions of the foot and ankle only.

(Tr. at 2519-2520)

306. Dr. Hoogendoorn testified that, since completing his fellowship, he has developed a “niche practice” treating chronic podiatric pain. Dr. Hoogendoorn further testified that it is a referral-based practice from other physicians, allopaths, osteopaths, and podiatrists. (Tr. at 2528-2529)

FINDINGS OF FACT

1. From in or about November 1998 to in or about November 2001, in the routine course of his practice, William David Leak, M.D., undertook the treatment of Patients 1 through 24 as identified on a confidential Patient Key. In treating Patients 1 through 24, Dr. Leak inappropriately utilized testing and/or failed to provide treatment in accordance with the minimal standards of care. Examples of such conduct include, but are not limited to, the following:
 - (a) Dr. Leak failed to refer or timely refer and/or document the referral or timely referral of Patients 1-4, 9, 11-13, 16-21, and 23 for psychological consultation. Dr. Chelimsky testified convincingly that, with chronic pain patients, the standard of care requires that a referral for a psychological consultation be made within three months of the patient presenting to the practice, and that the referral be documented in the medical record.

The evidence was insufficient to support this finding with regard to Patients 14, 15, and 24. A document in the medical record for Patient 14 shows a date for the timely referral of Patient 14 to behavioral medicine; a note in the medical record for Patient 15 indicates that he had had an appointment with a psychiatrist within three months following his first visit, which obviates the need for a referral; and, the

discharge summary for Patient 24's first visit indicates that Patient 24 had been referred to a psychologist.

- (b) Dr. Leak should have but failed to refer Patients 20 and 23 to an addiction medicine specialist and/or obtain toxicology screens despite signs of drug abuse and/or diversion.
- (c) Dr. Leak performed unnecessary testing including somatosensory evoked potentials [SSEP], nerve conduction studies and/or "selective tissue conductance" [STC] studies [collectively, EDX studies] on Patients 1, 2, 4-6, 15-17 and 23.

Further, Dr. Leak performed unnecessary testing including somatosensory evoked potentials and/or "selective tissue conductance" studies [again, collectively, EDX studies] on Patients 7-9, 11-14, 18-20 and 22.

In addition, Dr. Leak improperly performed and/or caused to be improperly performed somatosensory evoked potentials testing. For example, Dr. Chelimsly convincingly opined that the latencies purportedly observed for Patient 1 differ by far more than could be true clinically.

The evidence supports a finding that the EDX testing performed on the above patients was unnecessary.

- First, SSEP testing is no longer considered by most physicians to be useful for diagnosing radiculopathy, although some physicians continue to use it for that purpose based on old literature. Further, SSEP *cannot* be used to diagnose radiculopathy in the thoracic spine. Many of Dr. Leak's patients had had SSEP studies of the thoracic spine.

Further, when Dr. Leak performed SSEP, he performed it on either most of the cervical roots (C4-C8), several of the thoracic roots (T2, T4, T6, T8, and T12), and/or or most of the lumbar roots (L2-L5 and S1). There was no tailoring of the tests to the area relevant to the patient complaint. Further, Dr. Leak tested nerve roots for which no normative values have been established regarding SSEP testing.

Dr. Leak presented evidence that SSEPs (along with NCSs and STCs) were not used to diagnose patients but were instead used to confirm patients' subjective complaints of pain. That purpose was called into question by Dr. Chelimsly, who testified convincingly that some patients who exhibit no physical problems may truly suffer from pain, and others who exhibit many physical problems have no pain. Accordingly, the testing was unnecessary because it could not reliably demonstrate that a patient's complaint of pain was legitimate.

- The evidence supports a finding that the nerve conduction studies performed were unnecessary. Dr. Katirji and Dr. Chelimsly testified convincingly that Dr. Leak's patients who suffered from radicular pain should have had needle EMG performed as well as nerve conduction studies, and that nerve conduction studies were, by

themselves, without value. The other patients suffered from joint pain or back pain and did not require nerve conduction studies at all.

In addition, Dr. Leak always tested the same nerves, bilaterally. If a cervical SSEP was performed, he also performed nerve conduction studies of the median and ulnar nerves, both motor and sensory. If a lumbar SSEP was performed, there would also be sensory nerve conduction studies of the sural nerves, and motor nerve conduction studies of the peroneal and tibial nerves. (No nerve conduction studies were performed in conjunction with thoracic SSEPs.) Further, nerve conduction studies were not restricted to the areas relevant to the patient's complaint, or to the side where the patient complained of pain. Moreover, the same nerves were tested in each patient. Dr. Katirji noted that the human body contains more nerves than the ulnar, median, sural, peroneal, and tibial nerves, and questioned why other nerves were never tested. He concluded that no thought seemed to have been given to the tests that were ordered and performed; Dr. Leak and Dr. Griffin essentially were following the same diagnostic plan no matter the patient's presenting complaint.

- The evidence shows that STC studies had no value as they were used by Dr. Leak. Dr. Jay testified that STCs are appropriate for monitoring the progress of diabetic neuropathy; however, none of the STCs performed by Dr. Leak on these patients appear to have been used for that purpose. Further, the evidence is clear that STCs are absolutely worthless for the pre- and post-injection tests Dr. Leak was doing—Dr. Jay, an expert for the Respondents, testified that they are useful for that purpose *only for autonomic blocks*. None of the relevant injections were autonomic blocks. Moreover, the results of the pre- and post-injection blocks appeared to be random and there was no distinguishable pattern; some blocks seemed to “fix” some levels while other blocks seemed to cause further pathology. Dr. Chelimsky testified persuasively the results made no sense.

In addition, Dr. Chelimsky testified convincingly that STC testing is unproven technology and that the mere non-experimental use of STC studies is below the minimal standard of care. However, because there is evidence that Dr. Boswell, whose repute is not in question,³⁶ has used STC, this finding carries little weight.

³⁶ With regard to the weight that should be accorded Dr. Boswell's testimony, counsel for both the State and Dr. Leak each spoke very highly of Dr. Boswell. During the course of arguing in favor of an objection, Mr. Clifford stated:

Are we using Dr. Boswell's medical knowledge, which is vast and I don't dispute that? * * * [Dr. Boswell was brought to discuss other matters], not his knowledge, which I don't dispute as being vast, in pain medicine.

(Tr. at 50)

To which Mr. Graff, Dr. Leak's counsel, responded:

We have available to us, thankfully from the State, one of the very top pain interventionists in the country, from one of the number one programs in the world. * * * (Tr. at 50-51)

Nevertheless, the evidence supports a finding that STC studies as used by Dr. Leak for the above-referenced patients were unnecessary.

Furthermore, the Respondents argued that Dr. Katirji and Dr. Chelimsky are not similar practitioners to Dr. Leak because both Dr. Katirji and Dr. Chelimsky are neurologists whereas Dr. Leak is an anesthesiologist. However, as it concerns EDX testing, the specialty with the greatest level of expertise is neurology. If Dr. Leak elects to do his own EDX studies, he is treading in the province of neurology and is held to the standard of a neurologist. Dr. Leak cannot persuasively argue that that standard does not apply to him simply because he is an anesthesiologist. Accordingly, the Respondents' argument is rejected.

- (d) The evidence is insufficient to support a finding that, “[d]espite test results reflecting abnormal findings related to the purported area of involvement, the left L5 nerve root, [Dr. Leak] failed to limit treatment to the left L5 nerve root of Patient 20 and, in fact, [Dr. Leak] performed blocks on all of Patient 20’s lumbar nerve roots.” Although Dr. Leak performed blocks on L2 through S1, he did not perform blocks on “all of Patient 20’s lumbar nerve roots.”
- (e) Even if the EDX studies on Patients 1, 2, 4-9, 11-23 had been necessary, Dr. Leak inappropriately failed to perform, recommend, and/or document the performance or recommendation of needle EMG examinations as was appropriate.
- (f) Dr. Leak failed to identify and/or document an appropriate indication for the use of the EDX studies on Patients 1, 2, 4, 5, 7-9, 11-23.
- (g) Dr. Leak failed to properly document an appropriate comment on purported abnormal EDX study results for Patients 1, 5-9, 11-14, 17-19, 21 and 22. Although the test reports always included an interpretation of the results, there was nothing in the medical records for those patients that integrated the abnormal results with the care of the patient. Dr. Leak argued that the abnormal results simply confirmed the diagnosis. If that were the case, there should have been a statement to that effect in the medical record. As it is, a reasonable interpretation of the medical records as kept by Dr. Leak would be that the abnormal results were ignored.
- (h) Dr. Leak failed to change and/or document a change in treatment or management of Patients 1, 5-9, 11-14, 17-19, 21 and 22 based on the abnormal results of EDX studies.
- (i) Dr. Leak failed to form and/or document the formation of an individualized clinical impression for Patients 1-10 and 12-24. Nothing in these medical records cohesively connects patient complaints, histories, physical examinations, and test results with the physician’s impressions, diagnoses, and plan for the care of the patients. For example, each medical record contains a one or two page list of diagnoses; however, it is impossible to tell how Dr. Leak determined the diagnoses without reviewing hundreds of pages of records of testing, nurses notes, discharge summaries, procedure notes, et cetera, that have little documented interconnection with each other.

- (j) Dr. Leak inappropriately threatened to withhold prescriptions from Patients 5 and 12 unless they gave consent to perform diagnostic and/or invasive procedures.
- (k) Dr. Leak failed to provide critical individualization of treatment, and instead inappropriately engaged in a “cook-book” approach to pain management treatment.
- (l) Dr. Leak engaged in and/or supervised the excessive use of invasive techniques and blocks, including: chemoneurolytic and other injections and/or radiofrequency lesioning; and/or spinal decompression; and/or discography or provocative discography; and/or thoracic decompression; and/or root ganglion injections in Patients 2-5, 7-9, 11, 12, 14, 15, 17, and 20-22.

Nevertheless, the evidence is insufficient to support this finding with regard to Patient 18. Although Patient 18 had a number of procedures performed, Dr. Leak performed only a single procedure on Patient 18—decompression adhesiolysis at L5-S1 on the left side. All other procedures were performed by a different physician, Dr. Ranieri, who apparently had been a fellow and then an attending physician at PCC. Dr. Ranieri’s relationship to PCC at the time of the procedures in question was never established.

The Respondents argued that Dr. Chelimsky should not be considered a similar practitioner to Dr. Leak with regard to interventional pain medicine because Dr. Chelimsky is a neurologist and Dr. Leak is an anesthesiologist. Further, the Respondents obtained testimony from Dr. Boswell that the two fields approach pain medicine with different philosophies. Therefore, the Respondents argue, Dr. Chelimsky cannot opine on the standard of care that applies to Dr. Leak. However, although this argument initially seems to have merit, it is not persuasive for the reasons discussed below.

- First, regardless of the educational background of the physician, the three certifying boards that provide subspecialty certification in pain medicine use the same examination to certify pain medicine physicians. This signifies that the field of pain medicine has a single standard of care regardless of the educational background of the individual practitioner.
- In addition, it is evident from Dr. Griffin’s situation that a physician need not have a background in any particular field—or in either neurology, anesthesiology, or physical medicine and rehabilitation—to obtain subspecialty certification in pain medicine. Dr. Griffin never completed a residency and spent the majority of his medical career practicing emergency medicine; however, he holds subspecialty certification in pain medicine through the American Board of Physical Medicine and Rehabilitation, an ABMS-member board, after having completed Dr. Leak’s fellowship and passing the examination. If one were to accept the Respondents’ argument that each specialty has its own standard with regard to pain medicine,

then it would likely be impossible to determine what standard should apply to Dr. Griffin. From a public policy standpoint, that is unacceptable.

- Furthermore, Dr. Leak trained physicians in his own fellowship whose educational backgrounds were diverse. As evidenced by Dr. Griffin's and Dr. Hoogendoorn's participation in the fellowship, he did not restrict his fellowship to physicians who were trained in anesthesiology. If one were to accept the Respondents' argument, it would mean that Dr. Leak could not opine on the standard of care that applied to his own fellows, which is nonsensical.

Accordingly, the evidence is sufficient to find that Dr. Chelimsky is competent to provide an opinion concerning the standard of care that applies to the pain medicine practice of Dr. Leak.

Finally, the Respondents' defense of "fanning the needle" is not supported by the medical records and is therefore unconvincing. The majority of procedure notes that describe a large number of trigger point or chemoneurolytic injections being made—in some cases as many as 40 in one sitting—clearly indicate that each of the injections involved a separate needle entry.

- (m) The evidence is insufficient to support a finding that Dr. Leak inappropriately performed and/or inappropriately ordered invasive techniques, including, but not limited to, discography in the L5-S1 area, three-stage injection and SI joint injections, a three-stage decompression, as well as a spinal cord stimulator screen and implant, and an intralink port placed presumably for some type of drug delivery system, within a three-month period of time on Patient 18, a morbidly obese patient who was a high risk candidate for general anesthesia.

As stated in Findings of Fact 1(1), above, Dr. Leak performed only one procedure on Patient 18. The other procedures were performed by Thomas Ranieri, M.D., whose name appeared on Pain Control Consultants, Inc., letterhead, and who Dr. Leak testified was an attending at Pain Control Consultants, Inc. Therefore, there is no substantial evidence that Dr. Leak ordered that the other procedures be performed.

- (n) The evidence is sufficient to support a finding that Dr. Leak inappropriately used, and/or supervised a podiatrist to engage in the use of, destructive modalities of treatment such as chemolytic agents indiscriminately on nerves and muscles on Patients 7 and 17. This allegation is interpreted to refer only to the appropriateness of the injections and not to Dr. Leak's allowing Dr. Hoogendoorn to practice beyond the scope of podiatric medicine.

Dr. Leak testified that, Sarapin, the chemoneurolytic agent administered to Patients 7 and 17, is a nondestructive agent and similar to an anesthetic. However, Dr. Griffin testified that the purpose of Sarapin is to destroy nerve tissue. Dr. Bressi was not asked to address this issue. Accordingly, Dr. Leak's position that Sarapin is a

nondestructive agent is rejected. Nevertheless, the evidence that Sarapin is a *mild* destructive agent is uncontroverted.

Dr. Chelimsky provided testimony that chemoneurolytic injections should be made to nerve tissue, not muscle tissue. Dr. Leak testified that Sarapin can be injected into muscle tissue with the hope that it will neutralize nerve fiber within the muscle. Dr. Chelimsky regarded that technique as unproven. Dr. Bressi was not asked to address the issue. Based on Dr. Chelimsky's testimony, as well as Dr. Griffin's testimony that Sarapin is a destructive agent, albeit a mild one, Dr. Leak's position is rejected. Therefore, the injections performed under Dr. Leak's supervision on Patients 7 and 17 were inappropriate. Furthermore, although two of the procedure notes identify the procedures as injections into the "dorsal cutaneous innervation" of the muscles involved, the descriptions of the procedures state that the injections were made into muscle tissue.

No evidence was presented that Dr. Leak used, and/or supervised Dr. Hoogendoorn in the use of, destructive modalities of treatment such as chemoneurolytic agents in the treatment of Patient 5.

- (o) The evidence supports a finding that Dr. Leak inappropriately targeted and treated nine roots in a single radio-frequency procedure on Patient 20.
 - (p) The evidence is insufficient to support a finding that Dr. Leak inappropriately targeted and treated twelve roots in a single radio-frequency procedure on Patient 4. Rather, the evidence shows that there were two separate procedures in the nerve roots were treated.
2. The evidence is insufficient to support a finding that, during the period in or about August 2000 through in or about November 2001, Dr. Leak aided and abetted Kyle Elliott Hoogendoorn, D.P.M., in the unlawful practice of medicine and surgery by permitting and/or supervising Dr. Hoogendoorn in:
- (a) administering chemoneurolytic and other injections into the splenius capitis, levator scapulae, trapezius, superior trapezius, cervical erector spinae, thoracic erector spinae, lumbar erector spinae, latissimus dorsi, paraspinal, and/or rhomboid muscles, and/or the interspinous ligament, and/or greater trochanter, and/or gluteal area, and/or zygapophyseal joint of Patients 1-5, 7-9, 11, 14, 17, 20-22;
 - (b) prescribing, for the treatment of non-podiatric conditions, controlled and noncontrolled medications, including, but not limited to, Nicotrol, Wellbutrin, Neurontin, Propranolol, Vioxx, Zyprexa, Ultram, Oxycontin, Clonazepam, Duragesic, Depakote, Senokot, Trazadone, hydrocodone, methadone, Transderm Scop, Celebrex, Zanaflex, Catapres, Zithromax, propoxyphene, Diflucan, oxazepam and/or methylphenidate to Patients 2, 7, 11-14, 18, 20, 21, 23 and 24.

2. The Respondents presented evidence that, during the period in question, Dr. Hoogendoorn had been engaged in a pain medicine fellowship run by Dr. Leak. In his written reports and testimony, Dr. Chelimsky had expressed concern with regard to Dr. Hoogendoorn's activities in the fellowship, and opined that Dr. Hoogendoorn had practiced beyond the scope of podiatric medicine. However, Dr. Chelimsky later acknowledged during the hearing that he had had insufficient information upon which to render a fully accurate opinion with regard to the structure of the fellowship. Accordingly, Dr. Chelimsky's opinion with regard to the fellowship program is accorded less weight. Note that this applies only to his opinion concerning the scope of practice issue, and not to his opinion concerning minimal standard of care issues.

Although the wisdom of a podiatrist engaging in such a fellowship may be questionable, the evidence shows that it is more likely than not that the fellowship at PCC was a legitimate fellowship. Moreover, the Respondents presented convincing evidence that, in January 2002, Dr. Leak's fellowship program received approval as a podiatric fellowship by the Council for Podiatric Medical Education [CPME]. In addition, unrefuted testimony indicates that there was no change in the structure or content of the fellowship after CPME approval was granted. Furthermore, unrefuted testimony indicates that ten physicians, including Dr. Griffin, who completed the fellowship, obtained subspecialty certification in pain medicine through an ABMS-approved board. The evidence also shows that, during residency training, and under the supervision of allopathic or osteopathic physicians, podiatrists venture into areas that would be beyond their scope of practice outside of the training program. Testimony from one witness suggests that this may occur in podiatric fellowships as well. Finally, it is clear from the evidence that Dr. Leak, Dr. Griffin, and Dr. Hoogendoorn believed that the fellowship program was legitimate.

Accordingly, the evidence is insufficient to support a finding that Dr. Leak aided and abetted Dr. Hoogendoorn in the unlawful practice of medicine and surgery.

3. Despite the lapse of his malpractice insurance coverage during the period in or about August 2003 to in or about March 2004, Dr. Leak failed to:
 - (a) provide written notice of his lack of malpractice insurance coverage [malpractice notice] to every patient seeing him for nonemergency professional services which provided a space for the patient to acknowledge receipt of the malpractice notice; and/or
 - (b) obtain from every patient seeing him for nonemergency professional services the patients' signatures acknowledging receipt of the malpractice notice; and/or
 - (c) maintain a signed written malpractice notice in the patient chart for every patient who saw him for nonemergency professional services.

CONCLUSIONS OF LAW

1. The conduct of William David Leak, M.D., as set forth in Findings of Fact 1, constitutes “[a] departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established,” as that clause is used in Section 4731.22(B)(6), Ohio Revised Code.
2. The conduct of Dr. Leak as set forth in Findings of Fact 3, constitutes a “failure to provide notice to, and receive acknowledgment of the notice from, a patient when required by Section 4731.143 of the Revised Code³⁷ prior to providing nonemergency professional services, or failure to maintain that notice in the patient’s file,” as that clause is used in Section 4731.22(B)(30), Ohio Revised Code.
3. As set forth in Findings of Fact 2, the evidence is insufficient to support a conclusion that the conduct of Dr. Leak constitutes “[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 2923.03, Ohio Revised Code, Complicity, to wit: Section 4731.41, Ohio Revised Code, Practice of medicine or surgery without certificate. Pursuant to Section 4731.99(A), Ohio Revised Code, violation of Section 4731.41, Ohio Revised Code, constitutes a felony offense. Nevertheless, because the unusual nature of Dr. Hoogendoorn’s fellowship presented a case of first impression for the Board, the Board was substantially justified in pursuing this allegation.

* * * * *

The evidence clearly shows that Dr. Leak’s treatment of Patients 1 through 24 fell below the minimal standard of care. His violations include subjecting his patients to unnecessary tests—in some cases to an extraordinary number of unnecessary tests—without documenting the necessity for those tests and seemingly without heed to abnormal results when abnormal results were obtained. Further, Dr. Leak subjected patients to an excessive number of invasive procedures, including chemoneurolytic injections into muscle tissue. Moreover, his practice withheld prescriptions from two patients until they gave consent to have diagnostic or invasive procedures performed, and the procedures were unnecessary. Finally, he failed to follow the statutory requirements for notifying patients of his lapse of medical malpractice insurance. Such conduct, taken together, merits the severest sanction.

The effective date of the Proposed Order is delayed for 30 days to permit his patients to find new physicians without interrupting their care.

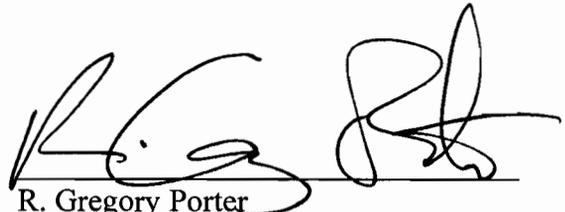
³⁷ As in effect from April 10, 2001, through December 29, 2004.

PROPOSED ORDER

It is hereby ORDERED that:

The certificate of William David Leak, M.D., to practice medicine and surgery in the State of Ohio shall be PERMANENTLY REVOKED.

This Order shall become effective thirty days from the date of mailing of notification of approval by the Board. In the thirty day interim, Dr. Leak shall not undertake the care of any patient not already under his care.



R. Gregory Porter
Hearing Examiner

State Medical Board of Ohio

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EXCERPT FROM THE DRAFT MINUTES OF AUGUST 13, 2008

REPORTS AND RECOMMENDATIONS AND PROPOSED FINDINGS AND PROPOSED ORDERS

Dr. Varyani announced that the Board would now consider the Proposed Findings and Proposed Orders appearing on its agenda. He asked whether each member of the Board had received, read and considered the hearing record; the findings of fact, conclusions and proposed orders; and any objections filed in the matters of: Shelly Bade, M.D.; Eugene Allan Brewer, M.D.; William David Leak, M.D.; Brian Frederic Griffin, M.D.; Kyle Elliott Hoogendoorn, D.P.M.; Parisa Khatibi, M.D.; and William W. Nucklos, M.D.; and the Proposed Findings and Proposed Orders in the matters of John A. Halpin, M.D., and Frank Murray Strasek, D.P.M. A roll call was taken:

ROLL CALL:

Mr. Albert	- aye
Dr. Egner	- aye
Dr. Talmage	- aye
Dr. Suppan	- aye
Dr. Madia	- aye
Mr. Browning	- aye
Mr. Hairston	- aye
Dr. Stephens	- aye
Dr. Mahajan	- aye
Dr. Steinbergh	- aye
Dr. Varyani	- aye

Dr. Varyani 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:

Mr. Albert	- aye
Dr. Egner	- aye
Dr. Talmage	- aye
Dr. Suppan	- aye
Dr. Madia	- aye
Mr. Browning	- aye
Mr. Hairston	- aye

Dr. Stephens - aye
Dr. Mahajan - aye
Dr. Steinbergh - aye
Dr. Varyani - aye

Dr. Varyani noted that, in accordance with the provision in Section 4731.22(F)(2), 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. They may, however, participate in the matter of Dr. Khatibi, as that case is not disciplinary in nature and concerns only the doctors' qualifications for licensure. In the matters before the Board today, Dr. Talmage served as Secretary and Mr. Albert served as Supervising Member.

The original Proposed Findings and Proposed Orders shall be maintained in the exhibits section of this Journal.

WILLIAM DAVID LEAK, M.D.

.....
DR. STEINBERGH MOVED TO APPROVE AND CONFIRM MR. PORTER'S FINDINGS OF FACT, CONCLUSIONS OF LAW, AND PROPOSED ORDER IN THE MATTER OF WILLIAM DAVID LEAK, M.D. MR. BROWNING SECONDED THE MOTION.

.....
Prior to the vote being taken, Dr. Madia advised that he has an acquaintance with Dr. Leak and would, therefore, abstain from voting on this case.

A vote was taken on Dr. Steinbergh's motion to approve and confirm:

ROLL CALL:

Mr. Albert	- abstain
Dr. Egner	- aye
Dr. Talmage	- abstain
Dr. Suppan	- aye
Dr. Madia	- abstain
Mr. Browning	- aye
Mr. Hairston	- nay
Dr. Amato	- aye
Dr. Stephens	- nay
Dr. Mahajan	- aye

EXCERPT FROM THE DRAFT MINUTES OF AUGUST 13, 2008
IN THE MATTER OF WILLIAM DAVID LEAK, M.D.

Dr. Steinbergh - aye
Dr. Varyani - aye

The motion carried.



State Medical Board of Ohio

77 S. High St., 17th Floor • Columbus, OH 43215-6127 • (614) 466-3934 • Website: www.med.ohio.gov

August 9, 2006

William David Leak, M.D.
1680 Watermark Drive
Suite 100A
Columbus, OH 43215

Dear Doctor Leak:

In accordance with Chapter 119., Ohio Revised Code, you are hereby notified that the State Medical Board of Ohio [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) From in or about November 1998 to in or about November 2001, in the routine course of your practice, you undertook the treatment of Patients 1-24 as identified on the attached Patient Key (key confidential to be withheld from public disclosure). In treating Patients 1 - 24, you inappropriately utilized testing and/or failed to provide treatment in accordance with the minimal standards of care. Examples of such conduct include, but are not limited to, the following:
 - (a) You failed to refer or timely refer and/or document the referral or timely referral of Patients 1-4, 9, 11-21, 23 and 24 for psychological consultation.
 - (b) You failed to refer Patients 20 and 23 to an addiction medicine specialist and/or obtain toxicology screens despite signs of drug abuse and/or diversion.
 - (c) You performed unnecessary testing including somatosensory evoked potentials, nerve conduction studies and/or "selective tissue conductance" studies [collectively, EDX studies] on Patients 1, 2, 4-6, 15-17 and 23. Further, you performed unnecessary testing including somatosensory evoked potentials and/or "selective tissue conductance" studies on Patients 7-9, 11-14, 18-20 and 22. Further, you improperly performed and/or caused to be improperly performed somatosensory evoked potentials testing. For example, the latencies purportedly observed for Patient 1 differ by far more than could be true clinically.

Mailed 8-10-06

- (d) Despite test results reflecting abnormal findings related to the purported area of involvement, the left L5 nerve root, you failed to limit treatment to the left L5 nerve root of Patient 20 and, in fact, you performed blocks on all of Patient 20's lumbar nerve roots.
- (e) Assuming, *arguendo*, that EDX studies on Patients 1, 2, 4-9, 11-23 were necessary, you failed to perform or recommend and/or document the performance or recommendation of a needle EMG examination.
- (f) You failed to identify and/or document an appropriate indication for the use of the EDX studies on Patients 1, 2, 4, 5, 7-9, 11-23.
- (g) You failed to properly document an appropriate comment on purported abnormal EDX study results for Patients 1, 5-9, 11-14, 17-19, 21 and 22.
- (h) You failed to change and/or document a change in treatment or management of Patients 1, 5-9, 11-14, 17-19, 21 and 22 based on the abnormal results of EDX studies.
- (i) You failed to form and/or document the formation of an individualized clinical impression for Patients 1-10 and 12-24.
- (j) You inappropriately threatened to withhold prescriptions from Patients 5 and 12 unless they gave consent to perform diagnostic and/or invasive procedures.
- (k) You failed to provide critical individualization of treatment, and instead inappropriately engaged in a "cook-book" approach to pain management treatment.
- (l) You engaged in and/or supervised the excessive use of invasive techniques and blocks, including: chemoneurolytic and other injections and/or radiofrequency lesioning; and/or spinal decompression; and/or discography or provocative discography; and/or thoracic decompression; and/or root ganglion injections in Patients 2-5, 7-9, 11, 12, 14, 15, 17, 18 and 20-22.
- (m) You inappropriately performed and/or inappropriately ordered invasive techniques, including, but not limited to, discography in the L5-S1 area, three-stage injection and SI joint injections, a three-stage decompression, as well as a spinal cord stimulator screen and implant, and an intralink port placed presumably for some type of drug delivery system, within a three-month period of time on Patient 18, a morbidly obese patient who was a high risk candidate for general anesthesia.

- (n) You inappropriately used, and/or supervised a podiatrist to engage in the use of, destructive modalities of treatment such as chemolytic agents indiscriminately on nerves and muscles on Patients 5, 7 and 17.
 - (o) You inappropriately targeted and treated twelve roots in a single radio-frequency procedure on Patient 4 and nine roots in a single radio-frequency procedure on Patient 20.
- (2) During the period in or about August 2000 through in or about November 2001, you aided and abetted Kyle Elliott Hoogendoorn, D.P.M., in the unlawful practice of medicine and surgery by permitting and/or supervising Dr. Hoogendoorn in:
- (a) administering chemoneurolytic and other injections into the splenius capitis, levator scapulae, trapezius, superior trapezius, cervical erector spinae, thoracic erector spinae, lumbar erector spinae, latissimus dorsi, paraspinal, and/or rhomboid muscles, and/or the interspinous ligament, and/or greater trochanter, and/or gluteal area, and/or zygapophyseal joint of Patients 1-5, 7-9, 11, 14, 17, 20-22;
 - (b) prescribing for the treatment of non-podiatric conditions controlled and noncontrolled medications, including, but not limited to, Nicotrol, Wellbutrin, Neurontin, Propranolol, Vioxx, Zyprexa, Ultram, Oxycontin, Clonazepam, Duragesic, Depakote, Senokot, Trazadone, hydrocodone, methadone, Transderm Scop, Celebrex, Zanaflex, Catapres, Zithromax, propoxyphene, Diflucan, oxazepam and/or methylphenidate to Patients 2, 7, 11-14, 18, 20, 21, 23 and 24.
- (3) Further, despite the lapse of your malpractice insurance coverage during the period in or about August 2003 to in or about March 2004, you failed to:
- (a) provide written notice of your lack of malpractice insurance coverage [malpractice notice] to every patient seeing you for nonemergency professional services which provided a space for the patient to acknowledge receipt of the malpractice notice; and/or
 - (b) obtain from every patient seeing you for nonemergency professional services the patients' signatures acknowledging receipt of the malpractice notice; and/or
 - (c) maintain a signed written malpractice notice in the patient chart for every patient who saw you for nonemergency professional services.

Your acts, conduct, and/or omissions as alleged in paragraph (1) above, individually and/or collectively, constitute "[a] departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual

injury to a patient is established,” as that clause is used in Section 4731.22(B)(6), Ohio Revised Code.

Further, your acts, conduct, and/or omissions as alleged in paragraph (2) 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 2923.03, Ohio Revised Code, Complicity, to wit: Section 4731.41, Ohio Revised Code, Practice of medicine or surgery without certificate. Pursuant to Section 4731.99(A), Ohio Revised Code, violation of Section 4731.41, Ohio Revised Code, constitutes a felony offense.

Further, your acts, conduct, and/or omissions as alleged in paragraph (3) above, individually and/or collectively, constitute a “failure to provide notice to, and receive acknowledgment of the notice from, a patient when required by section 4731.143 of the Revised Code prior to providing nonemergency professional services, or failure to maintain that notice in the patient’s file,” as that clause is used in Section 4731.22(B)(30), Ohio Revised Code.

Pursuant to Chapter 119., Ohio Revised Code, you are hereby advised that you are entitled to a hearing in this matter. 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.”

William David Leak, M.D.

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Copies of the applicable sections are enclosed for your information.

Very truly yours,

A handwritten signature in black ink that reads "Lance A. Talmage M.D." with a stylized flourish at the end.

Lance A. Talmage, M.D.
Secretary

LAT/blt
Enclosures

CERTIFIED MAIL # 7004 2510 0006 9801 7480
RETURN RECEIPT REQUESTED

cc: Keith W. Schneider, Esq.
250 Civic Center Drive
Suite 200
Columbus, OH 43215

CERTIFIED MAIL # 7004 2510 0006 9801 7473
RETURN RECEIPT REQUESTED