

IN THE COURT OF APPEALS OF OHIO
TENTH APPELLATE DISTRICT

State of Ohio ex rel. Bax Global, Inc. :
Relator, :
v. : No. 06AP-135
The Industrial Commission of Ohio and : (REGULAR CALENDAR)
Diana J. Brenneman, :
Respondents. :
:

D E C I S I O N

Rendered on February 20, 2007

Watkins, Bates & Carey, Kimberly S. Kondalski, and Jessica R. Hamner, for relator.

Marc Dann, Attorney General, and Andrew J. Alatis, for respondent Industrial Commission of Ohio.

Koder & Strauss, and Robert D. Strauss, for respondent Diana J. Brenneman.

IN MANDAMUS

BROWN, J.

{¶1} Relator, Bax Global, Inc., has filed an original action requesting that this court issue a writ of mandamus ordering respondent, Industrial Commission of Ohio ("commission"), to vacate its order authorizing the disc replacement surgery and pre-

surgical MRI performed on claimant, Diana J. Brenneman, and to order the commission to deny such treatment.

{¶2} This matter was referred to a magistrate of this court pursuant to Civ.R. 53(C) and Loc.R. 12(M) of the Tenth District Court of Appeals. On September 29, 2006, the magistrate issued a decision, including findings of fact and conclusions of law, recommending that this court deny relator's request for a writ of mandamus. (Attached as Appendix A.) No objections have been filed to that decision.

{¶3} Based upon an examination of the magistrate's decision and an independent review of the evidence, and, finding no error of law or other defect on the face of the magistrate's decision, this court adopts the magistrate's decision as our own, including the findings of fact and conclusions of law contained therein. In accordance with the magistrate's recommendation, relator's request for a writ of mandamus is hereby denied.

Writ denied.

SADLER, P.J., and FRENCH, J., concur.

APPENDIX A

IN THE COURT OF APPEALS OF OHIO

TENTH APPELLATE DISTRICT

State of Ohio ex rel. Bax Global, Inc.	:	
Relator,	:	
v.	:	No. 06AP-135
The Industrial Commission of Ohio and Diana J. Brenneman,	:	(REGULAR CALENDAR)
Respondents.	:	

MAGISTRATE'S DECISION

Rendered on September 29, 2006

*Watkins, Bates & Carey, Kimberly S. Kondalski and
Jessica R. Hamner, for relator.*

*Jim Petro, Attorney General, and Andrew J. Alatis, for
respondent Industrial Commission of Ohio.*

*Koder & Strauss, and Robert D. Strauss, for respondent
Diana J. Brenneman.*

IN MANDAMUS

{¶4} Relator, Bax Global, Inc., has filed this original action requesting that this court issue a writ of mandamus ordering respondent Industrial Commission of Ohio

("commission") to vacate its order which authorized the disc replacement surgery performed on Diana J. Brenneman ("claimant") and the pre-surgical MRI and ordering the commission to deny that treatment based upon *State ex rel. Miller v. Indus. Comm.* (1994), 71 Ohio St.3d 229.

Findings of Fact:

{¶5} 1. Claimant sustained a work-related injury on September 4, 2002, and her claim has been allowed for the following conditions: "SPRAIN LUMBAR REGION: AGGRAVATION OF PRE-EXISTING LUMBAR DEGENERATIVE DISCS AT L3-L4, L4-L5; ANNULAR TEARS AT L3-4, L4-L5."

{¶6} 2. Claimant pursued conservative treatment, including epidural steroids, which were not helpful. Claimant also underwent chiropractic treatments, which gave her some relief but did not return her to her normal functional capacities, including work. Claimant also underwent IDET (intradiskal eletrothermal treatments). Conservative treatments did not provide claimant relief and her condition continued to deteriorate.

{¶7} 3. Claimant was seen on several occasions by Daniel J. Sullivan, M.D. In his December 17, 2003 report, Dr. Sullivan noted the following impression/plan:

At this point the study that I would be most interested in seeing would be the diskogram and hopefully L3-4 and L4-5 were the levels chosen. I have not had seen much in the way of positive results from IDET. In fact, I have never seen it work. If the patient had a positive diskogram at L3-4 and the IDET was done at that and the L4-5 level was negative on discography I would advise this patient to wait until the release of the artificial disc on the market. I would expect that to be sometime within the next 12 months. If on the other hand, if the patient was positive at both levels I do not believe even the European literature supports placement of two contiguous artificial discs in the lumbar spine, therefore, if the

surgical route were the way to go I would likely recommend two level ALIF.

Dr. Sullivan concluded that report as follows:

I have asked the patient to think long and hard, however, about the surgical option. She is quite young and there is not that much pathology on the MRI scan. The last thing she needs is an operation that doesn't work. I believe if many of the local providers saw her they would offer her a PLIF with two level posterior segmental fixation in the form of screws and rods L3 to L5. If she has that operation she will be nostalgic for the pain she has now.

{¶8} 4. Dr. Sullivan issued another report dated December 19, 2003, where he noted as follows:

I have outlined the options with this patient at some length. They are essentially three. Number one, do nothing; she has already gone through all non-operative measures as well as IDET with a poor result. It makes no sense to recreate the wheel, go back to physical therapy, chiropractic and the like. The end is going to be pretty much the way she is now. Number two, interbody fusion at L3-4; the diskogram is positive at this level and negative as regards provocation at L4-5. The likely result of such a surgical procedure, if done correctly and via the anterior route, would be that she would have significant reduction in her present pain. The problem with proceeding in that regard is that she does not have an entirely normal disc at L4-5. It is likely that over time she will run into problems at that level. How long that would take is difficult to predict. It would be years rather than months, however. Number three, await the FDA release of the artificial disc. This should happen some time in a year or so. The advantage of doing an artificial disc in this patient is that the studies show that salvage post failed IDET is quite high and one would maintain motion at L3-4 thus sparing the L4-5 disc for a longer period of time.

It is my recommendation that this lady proceed to functional capacity evaluation for the purposes of disposition presently. I would counsel her to wait for the release of the artificial disc rather than proceeding to fusion at this time.

{¶9} 5. Claimant was also examined by Patrick W. McCormick, M.D., who issued a report dated April 2, 2003. Dr. McCormick recommended that claimant pursue additional IDET treatment and opined that performing a lumbar microdiscectomy under these circumstances would have a high failure rate. In his December 22, 2004 report, Dr. McCormick specifically noted that the subsequent IDET treatments which he had recommended had limited effectiveness and that claimant's symptoms continued. Because of claimant's conditions, the fact that he believed any surgery would have a high failure rate, and because the use of an artificial disc had only been approved for use at the L4-L5 and L5-S1 level, Dr. McCormick opined that claimant was not a candidate for the artificial disc based upon the fact that the disc involved was at L3-4.

{¶10} 6. Claimant was reevaluated by S.S. Purewal, M.D. In his June 9, 2004 report, Dr. Purewal noted that the February 2003 diskogram showed bulging and protrusion of the disc at L3-4 and L4-5 and that symptoms were reproduced at the L3-4 level. Dr. Purewal noted that he had reviewed Dr. Sullivan's reports and he concluded as follows:

For the allowed conditions under this claim, Ms. Brenneman has reached maximum medical improvement. For the additionally requested conditions, she has also reached maximum medical improvement pending further treatment in the future when the artificial disc might be released for general use.

There is evidence to support the medical necessity of additional treatment in the form of pain medications prescribed by Dr. Bassett. On the other hand, it is my opinion that chiropractic manipulative treatments are not likely to be of any benefit. She will need to use the pain medication as needed for an indefinite period.

I agree with the recommendation made by Dr. Sullivan that once that artificial disc is released for general use, this claimant would be a candidate for artificial disc replacement at the L3-4 level. If, however, the L4-5 level is also symptomatic, she would need two-level lumbar spine fusion at L3-4 and L4-5.

{¶11} 7. After reviewing additional medical evidence, including the reports of Dr. McCormick, Dr. Purewal issued an addendum to his June 9, 2004 report. Dr. Purewal noted that Dr. McCormick had opined that, in his opinion, claimant would not qualify for surgery involving an artificial disc because the disc involved is at L3-4. In conclusion, Dr. Purewal noted that claimant remains at maximum medical improvement ("MMI") for the allowed conditions in her claim and that there had been no change in her status since his previous evaluation on June 9, 2004.

{¶12} 8. Craig J. Ross, D.O., was asked to review claimant's medical records and render an opinion regarding her request for Charite artificial disc replacement. Dr. Ross agreed with Dr. McCormick's opinion that claimant was not a surgical candidate for lumbar fusion surgery. With regard to artificial disc replacement surgery, Dr. Ross opined that it was neither reasonable nor necessary as follows:

Although the Charite artificial dis[c] was approved for marketing by the FDA on 10/26/04, no long term studies evaluating the Charite dis[c] has been completed or published, and so the long term safety, efficacy and device longevity remain unknown. For this reason, it is the position of Liberty Mutual that these devices should still be considered investigational, and requests for coverage are carefully compared against patient selection criteria published by the manufacturer and approved by the FDA. The Charite artificial dis[c] is approved by the FDA for the treatment of degenerative dis[c] disease at one level only, at L4-5 or L5-S1. Ms. Brenneman has degenerative dis[c] disease at two levels, L3-4 and L4-5, and so does not meet the FDA approved patient selection criteria for the Charite disc.

Furthermore, the use of the Charite artificial dis[c] for replacement at the L3-4 level is clearly outside of the FDA approval, and so in my opinion and within a reasonable degree of medical certainty this request is clearly experimental and investigational, and therefore not reasonable or necessary.

{¶13} 9. Claimant filed motions requesting the authorization of surgery and a preoperative MRI. Claimant's motions were supported by the medical reports of Drs. Sullivan and Purewal.

{¶14} 10. The motions were heard before a district hearing officer ("DHO") on April 28, 2005. The DHO granted claimant's request for lumbar fusion surgery but denied her request for disc replacement surgery for the following reasons:

The District Hearing Officer finds that the FDA has approved the disc replacement surgery, but only for certain areas of the neck and only for the L4-5/L5-S1 level of the lumbar spine. The injured worker's counsel argues that the doctor can use his discretion as to what level to operate on. The employer argues that they cannot operate on any other level besides those approved by the FDA. The District Hearing Officer is not an expert on FDA Regulations, therefore, without some evidence as to the scope of the FDA approval, the District Hearing Officer must use caution in granting any benefit to remain in compliance with the FDA Regulations. There is no evidence as to FDA interpretation or scope of physician authority upon FDA approval. As a result, the District Hearing Officer must DENY the request for surgery of disc replacement at the L3-4 level, because it does not appear that level has been an approved level by the FDA.

{¶15} 11. Claimant appealed and the matter was heard before a staff hearing officer ("SHO") on June 10, 2005. The SHO modified the prior DHO order. Specifically, the SHO authorized the preoperative MRI and authorized the disc replacement surgery or fusion, whichever Dr. Sullivan ultimately finds appropriate. The SHO provided the following rationale for that decision:

The injured worker's attending orthopedic specialist, Daniel J. Sullivan, M.D., is requesting authorization for a Charite artificial replacement spinal disc surgical implant procedure.

The U.S. Food and Drug Administration approved the aforesaid artificial disc on 10/26/2004, for the L4-5 and L5-S1 levels. The employer argued that, since the injured worker's disc was also damaged at the L3-4 level, the implantation of the aforesaid artificial disc was not approved by the Food and Drug Administration and, therefore, not medically reasonable nor necessary. Said argument was not found to be persuasive, as use of the aforesaid medical device at one (1) level higher than that officially approved by the Food and Drug and [sic] Administration merely constitutes an "off-label use". It is well established that the U.S. Food and Drug Administration neither regulates the practice of medication nor restricts uses of those of the "official" approval, but merely approves or disapproves the use and marketing of medical devices and drugs. The Ohio State Medical Association has taken the position that "off-label use" is neither "experimental" nor "investigational". The off-label use of a medical device is merely a matter of medical judgment and, as such, subjects a physician to professional liability for exercising professional medical judgment, but off-label use of a medical device is not barred by the U.S. Food and Drug Administration.

Therefore, this Staff Hearing Officer finds that the requested medical procedure is reasonable and necessary for the allowed conditions in this claim, which resulted from the recognized industrial injury of 9/4/2002.

Therefore, it is the order of this Staff Hearing Officer that authorization is hereby GRANTED for a pre-operative MRI-scan of the lumbar spine, with and without contrast, as well as for the Charite artificial disc replacement surgery, by Daniel J. Sullivan, M.D., or an anterior lumbar interbody fusion, whichever is deemed more appropriate at the time of surgery by Daniel J. Sullivan, M.D., subject to the rules of the Bureau of Workers' Compensation and the Industrial Commission of Ohio.

This order is based upon the 2/24/2005 C-9 Physician's Request for Medical Services completed by Daniel J. Sullivan, M.D., the 6/9/2004 narrative report from S.S. Purewal, M.D., and the injured worker's testimony at hearing on 6/10/2005.

{¶16} 12. On August 2, 2005, Dr. Sullivan performed the surgery on claimant utilizing the Charite artificial disc.

{¶17} 13. Dr. Sullivan issued another report, dated August 11, 2005, in response to Dr. Ross's report. Dr. Sullivan disagreed with Dr. Ross's report, specifically noting that the FDA does not control the practice of medicine, that the use of both medications and devices "off label" by medical providers is routine and predate any peer review process and noted that there had been thousands of these procedures performed in Europe over the last 15 years. Further, Dr. Sullivan concluded by noting that claimant's August 2, 2005 surgery was successful and that claimant was doing well.

{¶18} 14. Based upon relator's further appeal, the matter was heard before the commission on October 18, 2005. The commission affirmed the prior SHO order and provided additional reasoning as follows:

The Commission finds that by way of her 03/11/2005 motion, the injured worker sought approval of Dr. Sullivan's C-9 dated 02/24/2005, requesting authorization of a pre-operative MRI of the lumbar spine, as well as either a disc replacement surgery at the L3-4 level with a Charite replacement disc, or in the alternative, a lumbar interbody fusion surgery with bone graft and devices, whichever he deemed appropriate at the time of surgery. The Commission further finds that the injured worker underwent surgery on 08/02/2005 and that based on Dr. Sullivan's resulting operative report of the same date, along with his 08/11/2005 narrative report, Dr. Sullivan selected as the appropriate surgical option the Charite disc replacement at the L3-4 level, rather than the fusion. Accordingly, the Commission finds that the treatment authorization requests at issue presently are the pre-operative MRI and the disc replacement surgery.

The Commission grants Dr. Sullivan's requests for the pre-operative MRI and the disc replacement surgery in their entirety. The Commission relies on Dr. Sullivan's C-9 dated 02/24/2005, along with his narrative reports of 12/17/2003,

12/19/2003, and 08/11/2005, to find that the treatment at issue was necessary, appropriate, and medically reasonable for the allowed conditions of the claim. The Commission finds that Dr. Sullivan's narratives were persuasive in their explanation both of the injured worker's need for and the propriety of the disc replacement surgery procedure. In addition, the Commission relies on the 06/09/2004 report of Dr. Purewal, an orthopedist who examined the injured worker at the request of the employer, who also indicated that the injured worker was a candidate for disc replacement surgery at the L3-4 level. Based on the cited medical evidence, the Commission grants the request to authorize the pre-operative MRI as well as the disc replacement surgery performed on 08/02/2005.

{¶19} 15. Thereafter, relator filed the instant mandamus action in this court.

Conclusions of Law:

{¶20} The Supreme Court of Ohio has set forth three requirements which must be met in establishing a right to a writ of mandamus: (1) that relator has a clear legal right to the relief prayed for; (2) that respondent is under a clear legal duty to perform the act requested; and (3) that relator has no plain and adequate remedy in the ordinary course of the law. *State ex rel. Berger v. McMonagle* (1983), 6 Ohio St.3d 28.

{¶21} In order for this court to issue a writ of mandamus as a remedy from a determination of the commission, relator must show a clear legal right to the relief sought and that the commission has a clear legal duty to provide such relief. *State ex rel. Pressley v. Indus. Comm.* (1967), 11 Ohio St.2d 141. A clear legal right to a writ of mandamus exists where the relator shows that the commission abused its discretion by entering an order which is not supported by any evidence in the record. *State ex rel. Elliott v. Indus. Comm.* (1986), 26 Ohio St.3d 76. On the other hand, where the record contains some evidence to support the commission's findings, there has been no abuse

of discretion and mandamus is not appropriate. *State ex rel. Lewis v. Diamond Foundry Co.* (1987), 29 Ohio St.3d 56. Furthermore, questions of credibility and the weight to be given evidence are clearly within the discretion of the commission as fact finder. *State ex rel. Teece v. Indus. Comm.* (1981), 68 Ohio St.2d 165.

{¶22} In this mandamus action, relator raises one issue: relator contends that the commission abused its discretion when it authorized the artificial disc replacement surgery as medically necessary and reasonably related to the injury in spite of the lack of FDA approval at L3-4. Stated another way, relator contends that the commission abuses its discretion when it relies on a treating physician's opinion that the surgery contemplated is reasonable and necessary and the best option available where neither the FDA nor the Bureau of Workers' Compensation ("BWC") have approved the procedure at L3-4. For the reasons that follow, this magistrate finds that relator has not demonstrated that the commission abused its discretion in this case.

{¶23} Pursuant to Ohio Adm.Code 4123-7-10(D), a self-insured employer is required to pay for medical services chosen by an injured worker upon approval by the commission of the costs. The applicable standard for authorizing medical treatment is set forth in *State ex rel. Miller*, supra. There is a three-prong test for the authorization of medical services: (1) are the medical services "reasonably related to the industrial injury, that is the allowed conditions"? (2) are the services "reasonably necessary for treatment of the industrial injury"? and (3) is "the cost of such service * * * medically reasonable"? *Id.* at 232.

{¶24} In the present case, all of the doctors agree that continued conservative treatment will be ineffective. Further, all of the doctors agree that claimant's condition

continues to deteriorate. Dr. Sullivan recommended use of the Charite artificial disc at L3-4 in spite of the fact that, as of October 2004, the FDA had only approved its use at L4-5 and L5-S1. Dr. Sullivan gave reasons for this opinion: (1) fusion at L3-4 will ultimately cause greater problems at L4-5 requiring further surgical intervention; (2) two level posterior segmental fixation would lead to an increase in pain; (3) the artificial disc at L4-5 and L4-S1 was utilized in Europe several years before the FDA approved that use here in America; (4) doctors are utilizing the artificial disc at L3-4 in Europe currently; (5) by necessity, doctors perform procedures prior to peer review; (6) this is an acceptable "off-label" use; and (7) this is claimant's best option.

{¶25} In the present case, the commission determined that the artificial disc replacement surgery was necessary, appropriate, and medically reasonable for claimant's allowed conditions. The commission relied upon the following evidence: (1) the December 17, 2003 report of Dr. Sullivan; (2) the December 19, 2003 report of Dr. Sullivan; (3) the June 9, 2004 report of Dr. Purewal; (4) the injured worker's testimony before the SHO; (5) the February 24, 2005 C-9 request by Dr. Sullivan; and (6) the August 11, 2005 report of Dr. Sullivan. Relator challenges the above-cited evidence relied upon by the commission and asserts that none of it constitutes "some evidence" upon which the commission could properly rely. As more fully explained below, the magistrate finds that relator's arguments are not well-taken.

{¶26} With regard to the challenge to Dr. Sullivan's December 17 and 19, 2003 reports, relator stresses that Dr. Sullivan was prospectively looking forward to the release of an artificial disc in the future as a possible treatment option. Specifically, relator emphasizes the following sentences from those reports: "I would advise this patient to

wait until the release of the artificial disc on the market. I would expect that to be sometime within the next 12 months."

{¶27} It is undisputed that, as of the date of these two reports, the FDA had not yet approved the use of an artificial spinal disc for treating pain associated with degenerative disc disease. It was not until October 26, 2004, that the FDA approved the Charite artificial disc for use in patients with degenerative disc disease at one level in the lumbar spine (from L4-S1) and who have had no relief from low back pain after at least six months of non-surgical treatment. Furthermore, the BWC issued a position paper in February 2005, following approval by the FDA, authorizing the procedure at the L4-L5 or L5-S1 levels only.

{¶28} Upon reviewing Dr. Sullivan's 2003 reports, the magistrate concludes that Dr. Sullivan did indeed opine that, in his opinion, claimant's best course of treatment was for her to proceed with the Charite disc replacement surgery. Dr. Sullivan noted that claimant's prior treatment had been unsuccessful, that her condition continued to worsen, and that the procedure was related to the industrial injury and reasonably necessary for claimant's treatment. Further, Dr. Sullivan specifically opined that other surgical options available to claimant should not be pursued. While it is true that Dr. Sullivan stated that claimant should proceed with the Charite artificial disc replacement as soon as the FDA approved it, he clearly was advocating that claimant have the procedure performed and, in fact, Dr. Sullivan performed the procedure himself. Upon review of these reports in their entirety, the magistrate finds that those reports do constitute some evidence upon which the commission could rely.

{¶29} Furthermore, as noted above, it was Dr. Sullivan who performed the Charite artificial disc replacement surgery on claimant. In his August 11, 2005 report, Dr. Sullivan specifically noted that the FDA does not control the practice of medicine, that the use of devices "off label" by medical providers is routine, and that use "off label" would necessarily predate any peer review process. As stated previously, Dr. Sullivan was advocating the use of the Charite artificial disc and obviously was in favor of utilizing it prior to FDA approval. Again, review of all three of Dr. Sullivan's reports, as well as his C-9, leads to the conclusion that Dr. Sullivan was advocating the use of the Charite artificial disc as soon as possible and those reports do constitute some evidence upon which the commission could and did rely.

{¶30} Relator also challenges the June 9, 2004 report of Dr. Purewal and argues that it does not constitute some evidence upon which the commission could rely. This magistrate disagrees. In that report, Dr. Purewal reviewed the reports by Dr. Sullivan and noted that claimant had reached MMI pending further treatment in the future when the artificial disc is released for general use. Again, upon his review of the reports of Dr. Sullivan, Dr. Purewal was in agreement that claimant should have the Charite disc replacement surgery. Later, in his March 2, 2005 addendum, Dr. Purewal noted that Dr. McCormick had stated that claimant would not qualify for the use of the Charite artificial disc based upon the fact that the disc involved was at L3-4. He concluded by stating that he was still of the opinion that claimant was at MMI, that there had been no changes in her status since his previous evaluation of June 9, 2004, and indicated that, based upon Dr. McCormick's assessment, continuing with pain medication was the only option.

{¶31} Relator's challenge to the report of Dr. Purewal is that he, like Dr. Sullivan, looked prospectively forward to the release of the Charite artificial disc by the FDA for general use, as a reason to remove it from evidentiary consideration. He clearly agreed with Dr. Sullivan that the surgery was a good option for claimant to pursue. Although he did later note that, according to Dr. McCormick, claimant would not be a candidate for the procedure, this does not automatically remove his report from consideration.

{¶32} Dr. Sullivan opined that, in his opinion, the use of the artificial disc at L3-4 is easier than at L4-5 and that it was currently being performed in Europe. Further, he stated that performing a fusion at L3-4 instead of utilizing the replacement disc would increase the pain and damage at L4-5. As such, based upon a review of all of Dr. Sullivan's reports and the reports of Dr. Purewal, and reading them in conjunction with the other evidence in the record and in context, the magistrate concludes that these reports do constitute some evidence upon which the commission could and did rely.

{¶33} Relator points out that, other than the reports of Dr. Sullivan, all of the evidence indicated that use of the artificial disc at L3-4 was not appropriate. Relator argues that the commission cannot authorize a procedure which has not been approved by the FDA and has not been subjected to peer review. This magistrate disagrees.

{¶34} Relator's argument that the use at L3-4 is experimental and, as such, should be denied is contradicted by Dr. Sullivan's statements that it is currently being done in Europe and that is an easier procedure than that already approved. Also, the use of the disc itself is not experimental. It is currently accepted practice to use it at L4-5 and L5-S1. In *State ex rel. Sugardale Foods, Inc. v. Indus. Comm.* (2000), 90 Ohio St.3d 383, the Supreme Court of Ohio stated that FDA and BWC approval are merely guidelines and

that it is up to the commission to decide the issue. Here, the commission found Dr. Sullivan's reports to be persuasive. The magistrate finds that this did not constitute an abuse of discretion in this particular case.

{¶35} Relator also points out that both Drs. Ross and McCormick opined that claimant should not have the Charite artificial disc replacement surgery performed. However, questions of credibility and the weight to be given evidence are clearly within the discretion of the commission as fact-finder, *Teece*, supra and it is immaterial whether other evidence, even if greater in quality and/or quantity, supports a decision contrary to the commission's period. *State ex rel. Pass v. C.S.T. Extraction Co.* (1996), 74 Ohio St.3d 373. Because this magistrate finds that the evidence relied upon by the commission constitutes some evidence, it is immaterial that Drs. Ross and McCormick held different opinions.

{¶36} Lastly, relator contends that the commission's analysis was inadequate and does not satisfy the requirements of *Noll*. Specifically, relator points out that, while the commission identified certain reports as persuasive, the commission did not explain why those reports were persuasive. This magistrate disagrees.

{¶37} Specifically, the commission determined that the use contemplated by Dr. Sullivan was an appropriate "off label" use. Further, the commission reiterated that the FDA neither regulates the practice of medicine nor restricts uses to those which have been officially approved. Further, the commission specifically indicated that it found Dr. Sullivan's narrative to be persuasive in explaining both claimant's need for and the propriety of the disc replacement surgery procedure. Looking back at those reports, the commission adopted Dr. Sullivan's rationale. The magistrate concludes that the

