IN THE SUPREME COURT, STATE OF WYOMING

2018 WY 99

APRIL TERM, A.D. 2018

August 22, 2018

IN THE MATTER OF THE WORKER'S COMPENSATION CLAIM OF: LINDA J. HARBORTH, Appellant (Petitioner), v. STATE OF WYOMING, ex rel., DEPARTMENT OF WORKFORCE SERVICES, WORKERS' COMPENSATION DIVISION, Appellee (Respondent).	S-18-0003

Appeal from the District Court of Campbell County
The Honorable Michael N. Deegan, Judge

Representing Appellant:

C. John Cotton, Cotton Law Offices, P.C., Gillette, Wyoming.

Representing Appellee:

Peter K. Michael, Wyoming Attorney General; Daniel E. White, Deputy Attorney General; J.C. DeMers, Senior Assistant Attorney General; Michael J. Finn, Senior Assistant Attorney General; Kelly D. Mullen*, Assistant Attorney General. Argument by Ms. Mullen.

** An Entry of Appearance was filed on May 3, 2018.*

Before DAVIS, C.J., and BURKE†, FOX, KAUTZ, and BOOMGAARDEN, JJ.

† Chief Justice at time of oral argument.

FOX, Justice.

[¶1] Linda J. Harborth underwent artificial disc replacement to treat her work-related back injury. The Department of Workforce Services, Workers' Compensation Division, (the Division) denied benefits for the surgery because the artificial disc and the surgical procedure had not been approved by the U.S. Food and Drug Administration (FDA), and Ms. Harborth had not produced sufficient objective medical support for their use. After a contested case hearing, the Medical Commission upheld the Division's decision, determining that the procedure was both an "off-label" use of medical services and "alternative medicine" for which benefits were not authorized. The district court affirmed the Medical Commission's decision, and we also affirm.

ISSUES

[¶2] We rephrase the issues as follows:

1. Did the Medical Commission erroneously determine that Ms. Harborth's non-FDA-approved medical procedure was an "off-label" use of medical services?

2 Did substantial evidence support the Medical Commission's determination that Ms. Harborth's non-FDA-approved medical procedure was "alternative medicine" for which Ms. Harborth did not provide adequate support?

3. Was the Medical Commission's decision arbitrary and capricious?

FACTS

[¶3] In 2006, Ms. Harborth suffered a compensable injury to the thoracic and lumbar regions of her spine while working as a driller at the Caballo Mine for the Powder River Coal Company. For a few years, Ms. Harborth was able to continue working while treating her injury with physical therapy, chiropractic manipulation, and various medications, but the treatments ultimately proved ineffective. In 2009, Robert J. Benz, M.D., performed a hemilaminotomy and discectomy at L5-S1. Despite the surgery, the pain returned. Ms. Harborth again attempted conservative treatment with limited success. In 2014, Nathan Simpson, M.D., observed severe disc narrowing at T12-L1 and L4-S1 and recommended a laminectomy.

[¶4] Ms. Harborth sought a second opinion from Sharad Rajpal, M.D., of Boulder, Colorado. Dr. Rajpal noted degeneration at the L4-5 level, "no disc with complete loss of disc height and bilateral lateral recess and foraminal stenosis" at L5-S1, and progressive degeneration at T12-L1. Dr. Rajpal recommended a foraminotomy at L4-5 and transforaminal lumbar interbody fusions (TLIF's) at both L5-S1 and T12-L1. Ms. Harborth testified that Dr. Rajpal's surgery would cost approximately $400,000.

[¶5] The Division requested two peer reviews of Dr. Rajpal's proposed surgery. First, Robert A. Narotsky, M.D., wrote:

> It is being recommended that [Ms. Harborth] undergo an L5-S1 TLIF, T12-L1 TLIF and right L4-5 laminotomy and foraminotomy to treat her current symptoms. This is not unreasonable, however, I question the need for decompression at L4-5. Additionally, I would consider obtaining a scoliosis series and assessing overall sagittal alignment given her accentuated lumbar lordosis. Lastly, I am concerned that she has significant degenerative changes at T10-11 and T11-12 that could be contributing to her thoracolumbar pain and should be investigated further prior to surgery.

Second, Judson H. Cook, M.D., opined that Dr. Rajpal's proposed fusion of L5-S1 was reasonable, but "it might be more reasonable to proceed with L4-5 fusion versus simple decompression given her primary issue as axial low back pain."[1] Dr. Cook stated that the fusion at T12-L1 was medically reasonable, but he declined to recommend preauthorization because he believed that the degeneration at that level was not caused by the initial compensable injury.

[¶6] The Division eventually preauthorized Dr. Rajpal's proposed surgery in October 2014. In the meantime, however, Ms. Harborth had become apprehensive about undergoing the procedure:

> [Ms. Harborth:] . . . Basically I wanted to know, since all of this was being told to me, what was my quality of life going to be in a year, five years or ten years? And [Dr. Rajpal] just told me not to think about it, we would just think about today and surgery. And, to me, that was hard to accept.
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> Q. [Ms. Harborth's counsel:] Did you do some work to find out what the downstream consequences were of fusions?
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> A. Yes, I did. As well as working at the mine, seeing other people who had fusions, overall most of them did not do well, and I was online as I was looking at all of this, it said the

[1] Dr. Cook's initial peer review of Dr. Rajpal's proposed surgery was neither provided to the Medical Commission nor contained in the record. We cite to Dr. Cook's subsequent peer review which incorporated his prior analysis of Dr. Rajpal's proposed surgery.

> fusion -- as well as it was backed up by the doctors, is that the fusion is not your first treatment, it's the very last treatment you do because it can lead to more problems since all of it is hinged together, it doesn't move, that you have extra wear and tear on the joints around it, so in time, you could end up having a lot more fusions.
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> Q. What was your understanding of your ability to return to work . . . [if] you elected to go ahead with the fusions?
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> A. [Dr. Rajpal] didn't recommend that I return to work, and I was told by a person here at the Wyoming Workforce or work office that people undergoing this type of procedure do not return to work. And at [Dr. Rajpal's] office they were telling me that I would have to learn to dress differently, they would show me how because I would not be very movable, with my hip especially.

[¶7] While investigating spinal fusions online, Ms. Harborth had come across Karsten Ritter-Lang, M.D., a German orthopedic surgeon with the Enande spinal center in Bremen, Germany, who performed artificial disc replacement surgery using the "M6" artificial disc. The Enande website promoted the procedure as superior to fusion, because "the M6 prosthesis . . . can biomechanically mimic the natural disc" and "a large percentage of patients can lead a completely normal life." Ms. Harborth contacted several former patients of Dr. Ritter-Lang via the Enande website, who "highly recommended" Dr. Ritter-Lang's disc replacement procedure. Ms. Harborth submitted her medical records to Dr. Ritter-Lang and, upon his review, he found a "clear medical indication for surgical intervention" and recommended a fusion at T12-L1, implantation of the M6 artificial disc at L4-5, and a fusion at L5-S1. Dr. Ritter-Lang would perform the surgery in Germany for approximately $61,000. However, even though the M6 device was approved for use in all European Union (EU) countries, Australia, South Africa, Russia, Brazil, and Mexico, it was not approved by the FDA. Likewise, the FDA had not approved the placement of an FDA-approved device adjacent to a fusion.

[¶8] Hoping to preserve her mobility and continue working, Ms. Harborth elected to have surgery with Dr. Ritter-Lang. Although the Division approved Dr. Ritter-Lang as Ms. Harborth's new health care provider, it stated: "This is not a pre approval of the bills. All bills will be reviewed for reasonable and necessary medical care and the relatedness to the original injury." Accordingly, the Division requested Dr. Narotsky and Dr. Cook to update their opinions to include an assessment of the surgical procedure recommended by Dr. Ritter-Lang. Dr. Narotsky wrote:

> Dr. Rajpal has recommended that [Ms. Harborth] undergo an L5-S1 TLIF, T12-L1 TLIF and right L4-5 laminotomy and foraminotomy to treat her current symptoms. Dr. Ritter-Lang has recommended an L5-S1 anterior-posterior fusion, T12-L1 posterior cemented fusion and L4-5 disc arthroplasty. Neither approach is unreasonable, however, I question the need for any surgery at L4-5 at this time whether it be decompression alone or disc arthroplasty.

Dr. Narotsky repeated his recommendation that Ms. Harborth obtain a scoliosis series to assess overall sagittal alignment, and to rule out T10-11 and T11-12 as possible pain generators. Dr. Narotsky concluded: "Although I think both approaches are reasonable Dr. Rajpal's proposal would certainly be less invasive. Arthroplasty could still be done at L4-5 in the future if it became necessary."

[¶9] Dr. Cook listed three concerns with Dr. Ritter-Lang's approach. First, "one of the general contraindications to a total disk arthroplasty is symptomatic facet arthropathy and it is documented that the patient had positive responses to L4-5 facet blocks and therefore a disk replacement at this level would maintain motion at the painful L4-5 facet joints." Second, Dr. Cook stated, "[t]o my knowledge, there has been no United States FDA approval of the M6-L disk replacement system."[2] Third, disc replacements approved by the FDA "are not indicated to be placed adjacent to a fused segment of the lumbar spine." For these reasons, Dr. Cook recommended against authorizing Dr. Ritter-Lang's surgery.

[¶10] While the Division was seeking peer reviews, Ms. Harborth was in "excruciating" pain. Thus, she did not wait for the Division to preauthorize Dr. Ritter-Lang's surgery. Paying out of her own pocket,[3] Ms. Harborth travelled to Germany and underwent surgery with Dr. Ritter-Lang. On January 8, 2015, Dr. Ritter-Lang performed a fusion at T12-L1 and implanted the M6 prothesis at L4-5. During surgery, however, Dr. Ritter-Lang discovered that the condition of the L5-S1 segment was better than he had expected; thus, he also placed an M6 prosthesis at L5-S1. By implanting M6 discs at the adjacent levels of L4-5 and L5-S1, Dr. Ritter-Lang avoided the FDA's nonapproval of, and Dr. Cook's concern with, performing arthroplasty adjacent to a previous fusion. However, the implantation of artificial discs at adjacent levels of the lumbar spine also lacked FDA approval.

[2] The "M6-L" appears to be the M6 model designed for use in the lumbar region.

[3] Ms. Harborth's insurance company eventually paid for the surgery, less the cost of the non-FDA-approved M6 artificial discs. The Wyoming Miners Association covered her co-payments and Ms. Harborth paid her own travel expenses.

[¶11] In February 2015, the Division denied compensation for the surgery, finding that it was not reasonable and necessary medical treatment.[4] The Division noted that both the M6 disc and the surgical procedure lacked FDA approval. Under Wyo. Dep't of Workforce Services, Rules, Regulations & Fee Schedules, Workers' Comp. Div., ch. 10 (2018) (Division Rules), the Division determined the procedure to be "alternative medicine," "experimental care," and "off-label use" of medical services. Ms. Harborth timely requested a hearing on the Division's denial of compensation.

[¶12] Meanwhile, Ms. Harborth's surgery appeared to be a success. In June 2015, Ms. Harborth was released to work with no restrictions. She returned to her previous duties of running heavy equipment and drilling. She was no longer taking pain medication. She testified that the surgery allowed her to "do things that I have not been able to do in years."

[¶13] Ten months later, in April 2016, the Medical Commission held a contested case hearing. Dr. Ritter-Lang did not testify at the hearing. Instead, he was deposed by written interrogatories, in which he provided short responses to 12 questions. Ms. Harborth also submitted a printout of a few webpages from Dr. Ritter-Lang's company's website. Ms. Harborth testified about the injury, her treatment history, the basis of her decision to undergo surgery with Dr. Ritter-Lang, and the surgery's apparent success. Colleen Gibson, a former patient of and current "international case manager" for Dr. Ritter-Lang, testified that Dr. Ritter-Lang successfully performed two artificial disc replacement surgeries on her back. As an international case manager, she had observed patients who experienced positive results. However, Ms. Gibson would not attest to the overall efficacy of Dr. Ritter-Lang's M6 disc implantations.

[¶14] The Medical Commission affirmed the Division's denial of compensation, concluding that Ms. Harborth failed to prove by a preponderance of the evidence that Dr. Ritter-Lang's surgery was reasonable and necessary. The Medical Commission determined that the M6 disc and its placement at adjacent levels of the lumbar spine was noncompensable both as "off-label" use of medical services and "alternative medicine" under Chapter 10 of the Division Rules. The district court affirmed the Medical Commission's decision. Ms. Harborth timely perfected this appeal.

STANDARD OF REVIEW

[¶15] When an appeal is taken from a district court's review of an administrative agency's decision, we examine the case as if it came directly from the agency, giving no deference to the district court's decision. *Morris v. State ex rel. Dep't of Workforce Servs., Workers' Comp. Div.*, 2017 WY 119, ¶ 23, 403 P.3d 980, 986 (Wyo. 2017) (citing *Guerrero v. State ex rel. Dep't of Workforce Servs., Workers' Comp. Div.*, 2015 WY 88, ¶ 11, 352 P.3d 262, 265 (Wyo. 2015)). Wyo. Stat. Ann. § 16-3-114(c) (LexisNexis 2017) establishes the scope of our review:

[4] The Division clarified at the contested case hearing that it would cover the fusion at T12-L1 because it had already preauthorized this portion of the procedure as part of Dr. Rajpal's proposed surgery.

> (c) To the extent necessary to make a decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. In making the following determinations, the court shall review the whole record or those parts of it cited by a party and due account shall be taken of the rule of prejudicial error. The reviewing court shall:
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> . . . .
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> (ii) Hold unlawful and set aside agency action, findings and conclusions found to be:
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> (A) Arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law;
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> (B) Contrary to constitutional right, power, privilege or immunity;
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> (C) In excess of statutory jurisdiction, authority or limitations or lacking statutory right;
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> (D) Without observance of procedure required by law; or
>
> (E) Unsupported by substantial evidence in a case reviewed on the record of an agency hearing provided by statute.

[¶16] A worker's compensation claimant has the burden of proving every essential element of her claims by a preponderance of the evidence. *E.g.*, *Morris*, 2017 WY 119, ¶ 25, 403 P.3d at 986. Where, as here, the hearing examiner determines that the claimant failed to meet her burden of proof, "we will decide whether there is substantial evidence to support the agency's decision to reject the evidence offered by the [claimant] by considering whether that conclusion was contrary to the overwhelming weight of the evidence in the record as a whole." *Id.* (quoting *Dale v. S & S Builders, LLC*, 2008 WY 84, ¶ 22, 188 P.3d 554, 561 (Wyo. 2008)).

> If the agency's decision is supported by substantial evidence, we cannot properly substitute our judgment for that of the agency and must uphold the findings on appeal. Substantial evidence is relevant evidence which a reasonable mind might accept in support of the agency's conclusions. It is more than a scintilla of evidence.

Walton v. State ex rel. Wyo. Workers' Safety & Comp. Div., 2007 WY 46, ¶ 9, 153 P.3d 932, 935-36 (Wyo. 2007) (citations omitted). We review an agency's conclusions of law de novo and will affirm only if the agency's conclusions are in accordance with the law. *Morris*, 2017 WY 119, ¶ 25, 403 P.3d at 987.

DISCUSSION

[¶17] The Division is charged with authorizing "reasonable and necessary" medical and hospital care for an employee's work-related injury, and with establishing rules to guide such authorization. Wyo. Stat. Ann. § 27-14-401 (LexisNexis 2017); Wyo. Stat. Ann. § 27-14-102(a)(xii) (LexisNexis Supp. 2018); Division Rules, ch. 7, § 3(a)(i); Wyo. Stat. Ann. § 27-14-601(e) and (o) (LexisNexis 2017). The challenge in the ever-changing landscape of medical treatment and technology is to maintain the balance between authorizing reasonable care and obtaining objective and verifiable evidence of a procedure or device's efficacy. *See, e.g., Figari v. Travelers Indem. Co. of Connecticut*, No. 03-12-00664-CV, 2014 WL 7466768, at *2 (Tex. App. Dec. 16, 2014) (state workers' compensation code requires "evidence based medical evidence" to support a finding that medical services are "reasonably required"); *Krohn v. Home-Owners Ins. Co.*, 802 N.W.2d 281, 290-91, 293 (Mich. 2011) (in the context of private insurance, the determination of whether a medical procedure is "reasonably necessary" under state statute must be based on objective and verifiable medical evidence). To achieve that balance, the Division Rules recognize optional approaches to verifying that a procedure or device lacking FDA approval is reasonable and necessary. Chapter 10 of the Division Rules guides the evaluation of "miscellaneous medical protocols." For "off-label use of medical services," the health care provider must submit a comprehensive review of the medical literature supporting the off-label use, including "at least two (2) reliable prospective, randomized, placebo-controlled, double-blind trial[s]." Division Rules, ch. 10, § 19. If the device or procedure is deemed "alternative medicine," its reasonable necessity may be demonstrated by "sufficient documentation for safety or effectiveness against specific conditions," and "a valid scientific base." *Id.*, ch. 10, § 3.

[¶18] The Medical Commission determined that Dr. Ritter-Lang's placement of M6 artificial discs at adjacent levels of the lumbar spine was not reasonable and necessary. It reasoned that the FDA had not approved the M6 device or the procedure of implanting artificial discs at adjacent levels;[5] and, in the absence of FDA approval, Ms. Harborth had failed to meet her burden of providing a valid basis for concluding that the surgery could be approved as either an "off-label use of medical services," or "alternative medicine." We examine each of these determinations.

[5] The State argues that "The FDA is the leading authorizer of medical techniques and devices in the United States and ***its rejection*** demonstrates that the proposed device had not met certain safety or effectiveness standards for approval." (Emphasis added.) But the record contains no evidence that the FDA has reviewed, let alone rejected, the M6 device or the procedure of implanting M6 discs at adjacent levels of the lumbar spine. There is no evidence that an application for FDA approval has ever been made.

I. Did the Medical Commission erroneously determine that Ms. Harborth's non-FDA-approved medical procedure was an "off-label" use of medical services?

[¶19] "Off-label use of medical services" is defined as: "Medications, treatments, procedures or other medical services used for other than the approved Food and Drug Administration (FDA) indications." Division Rules, ch. 10, § 19.

> These services should be medically necessary, i.e., have a reasonable expectation of cure or significant relief of a condition consistent with any applicable treatment parameter (Rules and Regulations Chapter 1, Section 3, Subsection (ag)). The Health Care Provider must document in the medical record the off-label use is medically necessary, and will submit to the Division a comprehensive review of the medical literature. This review will include at least two (2) reliable prospective, randomized, placebo-controlled, double-blind trial[s]. The Division will consider the quality of the evidence and determine medical necessity.

Id. The Medical Commission found that Dr. Ritter-Lang's placement of the M6 disc at adjacent levels of the lumbar spine was an "off-label" use of medical services which could be found medically necessary only if supported by a comprehensive review of the medical literature including two reliable, prospective, randomized, placebo-controlled, double-blind trials.

[¶20] The Medical Commission determined that Ms. Harborth did not provide adequate alternative support. Although we agree that she failed to provide ***any*** literature (other than the website promotional material), we find that the implantation of the M6 artificial disc at adjacent levels of the spine is not an "off-label" use of the M6 device. As one court has explained,

> [o]nce the FDA has cleared a device for introduction into the stream of commerce, physicians may use the device in any manner they determine to be best for the patient, regardless of whether the FDA has approved the device for this usage. This practice by physicians is known as 'off-label' usage.

Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 197 (4th Cir. 2001). Chapter 10, § 19 of the Division Rules defines an "off-label" medical service as one that deviates from a use that has been approved by the FDA: "[m]edications, treatments, procedures or other medical services used for other than ***the*** approved Food and Drug Administration (FDA) indications." (Emphasis added.) "We interpret agency rules utilizing the same standards

we use when interpreting statutes." *Worker's Comp. Claim of Stallman v. State ex rel. Wyo. Workers' Safety & Comp. Div.*, 2012 WY 147, ¶ 16, 288 P.3d 707, 713 (Wyo. 2012) (citation omitted). "When a statute is sufficiently clear and unambiguous, we give effect to the plain and ordinary meaning of the words . . . ." *Matter of Hall*, 2018 WY 35, ¶ 13, 414 P.3d 622, 627 (Wyo. 2018) (citation omitted). Under Chapter 10, § 19 of the Division Rules, the plain definition of "off-label" use does not encompass the surgical implantation of an M6 artificial disc adjacent levels. The M6 artificial disc is not approved for any use by the FDA. Thus, there is no "label" from which a medical provider may deviate.

II. Did substantial evidence support the Medical Commission's determination that Ms. Harborth's non-FDA-approved medical procedure was "alternative medicine" for which Ms. Harborth did not provide adequate alternative support?

[¶21] The Medical Commission also relied on Division Rules, ch. 10, § 3, which provides:

> Except as provided in Section 10 of this Chapter, the Division will not authorize or pay for any alternative medicine treatments, defined as any medical practice or intervention that lacks sufficient documentation for safety or effectiveness against specific conditions, or lacks a valid scientific base.

The Medical Commission determined the procedure to be "alternative medicine" under Chapter 10, § 3, finding that the record lacked sufficient documentation for the safety or effectiveness of the M6 disc or its placement at adjacent levels.

[¶22] We examine the entire record to determine whether the Medical Commission's conclusion was contrary to the overwhelming weight of the evidence. *Morris*, 2017 WY 119, ¶ 25, 403 P.3d at 986; *see also Worker's Comp. Claim of Rodgers v. State ex rel. Wyo. Workers' Safety & Comp. Div.*, 2006 WY 65, ¶ 18, 135 P.3d 568, 575 (Wyo. 2006). In support of its findings, the Medical Commission received undisputed evidence that neither the M6 disc nor its placement at adjacent levels had FDA approval. The Medical Commission also received two medical opinions disfavoring Dr. Ritter-Lang's proposed surgery. Dr. Narotsky stated that neither Dr. Rajpal's nor Dr. Ritter-Lang's approach was unreasonable, but he found that Dr. Ritter-Lang's proposed disc replacement at L4-5 was not yet necessary (arthroplasty could be done "in the future ***if it became necessary***" (emphasis added)) and thus favored Dr. Rajpal's "less invasive" procedure. Dr. Cook was concerned with the absence of FDA approval, as well as the potential for symptomatic facet arthropathy. Thus, he would not recommend authorization of arthroplasty at L4-5 "without further information."

[¶23] Ms. Harborth, who carried the burden to provide further information documenting the safety and effectiveness of Dr. Ritter-Lang's procedure, presented the following evidence to the Medical Commission.

A. Testimony of Ms. Harborth

[¶24] Ms. Harborth testified that she contacted former patients of Dr. Ritter-Lang who were pleased with the results of their surgeries:

> He had links [on the website] that would -- from previous patients that over the years that he had done from the United States, and I did call a number of those people, talked with them personally on what their experiences were, and they highly, highly recommended him, including one lady who is a rancher from Austin, Texas, and she has three [M6 devices] in her back. And she was telling me that she doesn't even take aspirin for pain meds. She is doing exceptionally well.

B. Testimony of Colleen Gibson

[¶25] Colleen Gibson, Dr. Ritter-Lang's case manager and former patient, testified that Dr. Ritter-Lang implanted "Maverick" discs (a predecessor to the M6 disc) in her lumbar spine at L4-5 and L5-S1. According to Ms. Gibson, the surgery "gave me my life back. I am able to work. I am able to do all of the things I love to do." Ms. Gibson testified that Dr. Ritter-Lang's subsequent implantation of two M6 discs in her cervical spine was "even a better experience."

[¶26] Ms. Gibson also testified that, as a case manager, she acted as a liaison between potential patients and Dr. Ritter-Lang, helping to gather medical information, book surgery, and arrange travel and accommodations. After surgery, she followed up with patients at regular intervals: immediately after returning home, 12 weeks after surgery, 6 months after surgery, and 24 months after surgery. She had worked with "well over a thousand" patients of Dr. Ritter-Lang.

> Q. [Ms. Harboth's Counsel:] . . . [D]o you have an estimate as to the percentage of those who have achieved a positive outcome?
>
> A. [Ms. Gibson:] I don't have a percentage, no.
>
> Q. . . . [D]o you have an estimate as to the ratio of those with a positive -- a very positive outcome?
>
> A. I have seen a lot of excellent results. I have seen many, many patients that were able to return to work. I have seen patients who are able to return to all of their sports

activities. And I have had patients tell me that before surgery, they had a feeling of hopelessness, depression, unable to work, unable to pay for their homes, and following surgery, they were given their lives back. And they have all told me that they couldn't be happier and that they would tell everybody they know about what they went through and their experience with Dr. Ritter[-Lang].

On cross-examination, the Division asked Ms. Gibson about complication rates:

> Q. . . . We sent some written interrogatories to Dr. Ritter[-]Lang. One of the questions to him was about complication rates with the M-6 artificial disk replacement, and he said that the range could -- and the studies were like somewhere between zero to 30 percent as far as complication rates. Is that consistent with what you have seen since you have been working for [Dr. Ritter-Lang], I mean?
>
> A. Like I said, I have seen excellent results with Dr. Ritter[-]Lang. I cannot comment on any percentages because I don't have that information.
>
> Q. Okay. That is a better question left for Dr. Ritter[-]Lang, I assume?
>
> A. Yes, it is.
>
> Q. Okay. Have you seen bad results, though, in some cases?
>
> A. I have seen excellent results. Of course, not every surgery can be a hundred percent perfect, and it's that way with any surgery.
>
> Q. Okay. Well, you told us about the excellent results. I guess my question is just have you seen cases that -- well, that did not come out the way that they had hoped and even came out poorly?
>
> A. I would rather Dr. Ritter[-]Lang comment on that as I am not qualified to comment on that.

C. Printout of the Enande Website

[¶27] Ms. Harborth submitted a printout of some portions of the Enande website. The website described Dr. Ritter-Lang as

> one of the most respected speakers worldwide at symposiums about orthopedic surgery and neurosurgery regarding treatment using artificial intervertebral discs. His participation in the ongoing development of intervertebral disc prosthetics technology, prototypes, and implants, provides great benefits to the patients he treats. Patients come from all over the world to use the services of Dr. Ritter-Lang and his highly qualified team. Dr. Ritter-Lang is among an elite group of the most experienced Disc Replacement surgeons in the world, and has dedicated his career to the sub-specialty of Disc Replacement.

The website provided Dr. Ritter-Lang's curriculum vitae, indicating approximately 20 years of experience as an orthopedic specialist. It stated that Dr. Ritter-Lang had "performed almost 7,000 surgeries, of which 4,798 were spinal column reconstructions and has done over 3,500 Disc Replacement procedures using a wide range of implants both cervical and lumbar."

[¶28] As to the safety and effectiveness of artificial disc replacement using the M6 prosthesis, the website stated:

> Our team is currently looking back on over 3,500 patients with more than 5600 implants, including more than 2,700 patients with 4,200 implants in the lumbar spine and over 800 patients with over 1380 implants in the cervical spine. The complication rate is about 1.4%, wherein a majority of the complications can either be managed without additional revision surgery or are negligible.

D. Dr. Ritter-Lang's Deposition by Written Interrogatories

[¶29] Dr. Ritter-Lang testified via written deposition, providing brief responses to 12 interrogatories jointly propounded by the parties. Dr. Ritter-Lang stated that the information in the Enande website was accurate; that the M6-L disc and its placement at adjacent levels had been approved in all European Union (EU) countries, Australia, South Africa, Russia, Brazil, and Mexico; and that the complication rates for other health care providers' implantation of the M6-L disc "lie between 0 and 30%." Finally, Dr. Ritter-Lang agreed that Ms. Harborth's surgery was successful and confirmed that he did not anticipate future complications.

[¶30] Our examination of the Medical Commission's decision is confined by our standard of review, which "turns not on whether we agree with the outcome, but on whether the agency could reasonably conclude as it did, based on all the evidence before it." *Morris*, 2017 WY 119, ¶ 25, 403 P.3d at 987 (citation omitted); *see also Hildebrant v. State ex rel., Dep't of Workforce Servs., Workers' Safety & Comp. Div.*, 2015 WY 41, ¶ 12, 345 P.3d 875, 879 (Wyo. 2015) ("Whether we might reach the same result or not, we will not reweigh the evidence, but instead defer to the [agency's] decision if it is based upon relevant evidence that a reasonable mind might accept."). Considering the evidence before it, the Medical Commission could reasonably conclude that Dr. Ritter-Lang's surgery was "alternative medicine" and that Ms. Harborth failed to produce sufficient documentation for its safety and effectiveness.

[¶31] The testimony of Ms. Harborth and Ms. Gibson did little to document the safety and effectiveness of the M6 disc replacement at adjacent levels of the lumbar spine. Ms. Harborth merely reported having conversations with a "number" of unnamed former patients who "highly, highly recommended" Dr. Ritter-Lang, including "a rancher from Austin, Texas," who enjoyed outstanding results. The patients were contacted via links on the Enande website and presumably selected by Enande to provide testimonials for the company. Ms. Gibson had personally followed up with thousands of patients after surgery; yet, she was unable to offer any observation as to the overall success rate of their surgeries. She described with specificity only the results of her own surgery, which did not involve implanting M6 discs in her lumbar spine. The testimony of both witnesses was too vague and too subjective to satisfy the requirement for objective and verifiable evidence.

[¶32] We also view the information on the Enande website with caution, as the website is a marketing tool directed at potential customers for Dr. Ritter-Lang. It is not unreasonable to question the reliability of information contained in promotional materials and seek corroboration from objective sources. *See, e.g., Birch v. State ex rel. Wyo. Workers' Safety & Comp. Div.*, 2014 WY 31, ¶ 4, 319 P.3d 901, 904 (Wyo. 2014) (discounting "promotional materials generated by the treatment provider and the manufacturer of the device . . . , both of which not surprisingly extolled the treatment benefits of [the device]"). Objective evidence that would substantiate the claims of Enande and Dr. Ritter-Lang may have been available. The Enande website stated that the M6 disc "has been thoroughly investigated biomechanically" and "studies published internationally in recent years have shown that artificial disc replacement is superior to fusion or conservative treatment." When asked about the complication rate of other providers' implantation of M6 discs, Dr. Ritter-Lang stated that "[t]he complication rates ***in studies*** lie between 0 and 30%" (emphasis added).[6] Indeed, a device and a procedure approved by all EU countries,

[6] The Medical Commission found it unclear whether the complication rate between 0 and 30% referred to all brands of artificial discs or only the M6 disc. The Medical Commission's finding was incorrect. The parties had propounded the following interrogatory to Dr. Ritter-Lang: "Is your experience of a

Australia, South Africa, Russia, Brazil, and Mexico very likely has documentation of its safety and effectiveness which may overcome the lack of FDA approval. But it was Ms. Harborth's burden to introduce it into the record, and none can be found.

[¶33] Dr. Ritter-Lang's testimony by written interrogatories barely expanded on the information contained in the Enande website. He listed the countries that have approved the M6 device and its placement at adjacent levels. His remaining responses were cursory. Six of his 12 answers were either "yes" or "no." Other than listing the countries that have approved the M6 device, his longest answer was 15 words. Dr. Ritter-Lang supplied a complication rate of 0 to 30% for the implantation of M6-L discs by other medical providers. Although his response clearly referred to the implantation of M6-L devices, *see supra* n.6, it was not unreasonable for the Medical Commission to seek clarification of such a wide-ranging figure, whether by reviewing the studies in which this figure was published or by questioning Dr. Ritter-Lang. As the Medical Commission stated, "[u]nfortunately, Dr. Ritter-Lang did not testify in this case and his representative, Colleen Gibson, declined to answer questions concerning complication rates for surgeries performed by Dr. Ritter-Lang." The Medical Commission is "given wide latitude to . . . ascribe the relevant weight given to the evidence presented[,] including medical evidence and opinion." *Hildebrant*, 2015 WY 41, ¶ 13, 345 P.3d at 879 (citations and internal quotation marks omitted). It was not unreasonable for the Medical Commission to find Dr. Ritter-Lang's sparse offering unsatisfactory.[7]

[¶34] Ms. Harborth urges us to consider the success of her surgery as documentation of its safety and effectiveness. Under the unusual circumstances of this case, in which Ms.

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complication rate of approximately 1.4% similar to the complication rates for other health care providers, generally, for the M6L? If not, what are the general complications for other health care providers?" Dr. Ritter-Lang answered: "The complication rates in studies lie between 0 and 30%." The interrogatory plainly queried Dr. Ritter-Lang on complication rates for other providers' use of the M6-L disc. The Medical Commission's contrary conclusion formed one basis of its determination that Dr. Ritter-Lang's procedure was "alternative medicine." However, we examine the entire record to determine whether there is substantial evidence to support an agency's findings. *Rodgers*, 2006 WY 65, ¶ 18, 135 P.3d at 575.

[7] Ms. Harborth argues that

> the Medical Commission stated that it "(did) not question Dr. Ritter-Lang's medical judgment to implant an artificial disc." It cannot be both ways. Dr. Ritter-Lang cannot have exercised appropriate "medical judgment" in performing the surgery and implanting the M6 at adjacent levels, and at the same time have the surgery not be "medically reasonable and necessary."

Contrary to Ms. Harborth's assertion, the Medical Commission did not state that Dr. Ritter-Lang "exercised appropriate medical judgment in performing the surgery and implanting the M6 at adjacent levels." It merely stated that it did not question his judgment to implant ***an*** artificial disc, but "nothing in the record presented demonstrates why the non-FDA approved device was necessary."

Harborth proceeded with surgery before the Division completed its preauthorization evaluation, it may be tempting to weigh the actual outcome of surgery into the determination of compensability. Because Ms. Harborth underwent surgery costing $340,000 less than Dr. Rajpal's procedure and returned to her previous work duties with no restrictions and no pain medication, the evidence of her outcome is especially compelling. However, even if our standard of review allowed us to reweigh the evidence, it would be unreasonable to view the outcome of a medical procedure as a factor that trumps all others. We keep in mind that the Division's Rules do not award compensation for medical treatments only if they are "successful" (assuming arguendo that the "success" of a medical treatment can always be measured); instead, in order to receive medical benefits, a claimant must show that his treatment is "reasonable and necessary." A patient might fail to respond to reasonable and necessary medical treatment; and, likewise, a patient may benefit from elective, "unnecessary" medical treatment.

[¶35] Similarly, Chapter 10, § 3 of the Division Rules demands sufficient documentation for safety or effectiveness "against specific conditions," which indicates the need to show evidence of a treatment's efficacy in treating the claimant's ***condition***—evidence that is necessarily objective. A claimant's successful surgery is only a single instance of success, and is not a substitute for objective and verifiable medical data demonstrating the procedure's overall record for safety and effectiveness. Where, as here, the record contains very sparse objective, verifiable evidence that Dr. Ritter-Lang's procedure was generally safe and effective against the specific condition of disc degeneration at adjacent levels of the lumbar spine, the success of Ms. Harborth's surgery (or the success of any other individual's surgery) does not shift the overwhelming weight of the evidence in her favor.

[¶36] We hold that FDA approval of a medical device or treatment is not required to establish that it is reasonable and necessary; but, under Chapter 10, § 3 of the Division Rules, the Division may require a claimant requesting a non-FDA-approved medical device or treatment to produce reliable documentation of its safety and effectiveness against her specific medical condition.[8] A claimant need not produce, as Ms. Harborth suggests, a "complete summary of every scrap of medical literature that has been printed . . . ." Applying our standard of review, however, we find in the record substantial evidence to support the Medical Commission's determination that, in the absence of FDA approval, Ms. Harborth did not satisfy her burden to document the safety and effectiveness of placing the M6 disc at adjacent levels in the lumbar spine. Having found substantial evidence to support its decision, we will not substitute our judgment for that of the Medical Commission.

[8] We distinguish a device or treatment that has no FDA approval from one that has FDA approval, yet is used "off-label." Chapter 10, § 19 of the Division Rules provides separate guidelines for authorization of off-label uses. *See supra* ¶ 19.

III. Was the Medical Commission's decision arbitrary and capricious?

[¶37] We also apply the arbitrary and capricious standard as a "safety net" to catch agency action, "which prejudices a party's substantial rights or which may be contrary to the other review standards under the Administrative Procedure Act, yet is not easily categorized or fit to any one particular standard." *McIntosh v. State ex rel. Wyo. Workers' Safety & Comp. Div.*, 2013 WY 135, ¶ 31, 311 P.3d 608, 616 (Wyo. 2013) (citations omitted). Examples of arbitrary and capricious actions include making inconsistent or incomplete findings of facts or conclusions of law, failing to admit testimony or other evidence that was clearly admissible, or violating a party's right of due process. *Id.*; *Rodgers*, 2006 WY 65, ¶ 19, 135 P.3d at 575.

[¶38] In her brief, Ms. Harborth concludes each of her arguments by asserting that the Medical Commission's decision was "contrary to the overwhelming weight of the evidence, contrary to its own findings, contrary to law, arbitrary and capricious, and should be reversed," but only makes one specific allegation that the Medical Commission acted arbitrarily and capriciously in determining Dr. Ritter-Lang's procedure to be "alternative medicine." Ms. Harborth stated that it was "just as arbitrary and capricious for the Medical Commission to admit documents and testimony into evidence and then arbitrarily ignore them, as it [was] to refuse admission in the first place." Ms. Harborth merely requests us to reweigh the evidence, a task we will not undertake. *Hildebrant*, 2015 WY 41, ¶ 12, 345 P.3d at 879. The Medical Commission accepted into the record all the evidence offered by the parties. The Medical Commission considered the testimony of Ms. Harborth and Ms. Gibson, the information from the Enande website, the opinion of Dr. Ritter-Lang, as well as the successful outcome of Ms. Harborth's surgery. We conclude that the Medical Commission's decision was not arbitrary or capricious.

CONCLUSION

[¶39] Implantation of non-FDA-approved artificial discs at adjacent levels of the lumbar spine was not an "off-label" use of medical services. However, substantial evidence supported the Medical Commission's determination that Ms. Harborth failed to provide sufficient documentation of the procedure's safety and effectiveness, thus rendering it "alternative medicine" for which benefits were properly denied. The Medical Commission's decision was not arbitrary and capricious. Affirmed.