BEFORE THE BOARD OF INDUSTRIAL INSURANCE APPEALS
STATE OF WASHINGTON

In re: JAMES R. LEWIS Claim No.: AU-90361	**Docket No.: 16 10479** **CLAIMANT'S RESPONSE TO DEPARTMENT'S MOTION FOR SUMMARY JUDGMENT**

I. INTRODUCTION

The Department contends that Mr. Lewis cannot be authorized an OATS ankle surgery procedure recommended by multiple, unanimous treating physicians. The Department admits that it has never considered the merits of the medical propriety and necessity of OATS ankle surgery with respect to the specific medical facts in Mr. Lewis' L&I Claim. Instead, the Department contends that as a matter of law it is powerless and prohibited from authorizing OATS ankle surgery to Mr. Lewis. In addition, it maintains that Mr. Lewis cannot even be allowed to appeal the non-coverage of Oats ankle surgery to the Board or courts under currently-applicable law.

Speaking bluntly, the Department's position is both apathetic and inhumane. If sustained, the Department's position would procedurally leave Mr. Lewis to either live as a cripple, or to seek medical aid outside of the Industrial Insurance Act, as his particular industrial injury condition does not allow for him to reasonably select any other treatment option. The Department's position asks the Board to ignore longstanding Washington Supreme Court

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decisions, i.e., to interpret the Industrial Insurance Act in a way which serves its purposes and preserves appeal rights, in favor of abdicating to an expressly-hollow analysis performed in *Joy v. Dept. of Labor & Industries*, 285 P.3d 187 (2012), *review denied*, 297 P.3d 708 (2013).

Mr. Lewis maintains that the HTCC's assessment is in conflict with the Act, so is excluded by statute from having binding legal force. Mr. Lewis maintains that nothing in the law authorizing HTCC assessments prevents the Department from following its standard rules and exercising its discretion to allow Mr. Lewis' requested surgery as "experimental." Finally, Mr. Lewis argues that the HTCC assessment of 2012 denying participating agencies, including the Department, from paying for OATS ankle surgery is ***void ab initio*** as would pertain to the specific facts and circumstances of his claim.

Because the HTCC's assessment is legally void, it cannot be used to prevent the Department from authorizing Mr. Lewis his requested surgery, nor to deprive the Board of Industrial Insurance Appeals and higher courts of their rightful jurisdiction to hear this appeal. Moreover, Mr. Lewis must be granted rights of appeal as a fundamental observance of his Due Process rights with respect to his legally-perfected claim for medical benefits under the Industrial Insurance Act.

For these above-stated reasons and others set forth herein, Mr. Lewis requests that the Board deny the Department's motion for summary judgment. Mr. Lewis hereby presents triable issues of fact as to whether the 2012 HTCC assessment against OATS ankle surgery is legally valid and enforceable, let alone applicable to Mr. Lewis' specific L&I matter. Discovery and further developments, including trial, should therefore be allowed.

II. **EVIDENCE RELIED UPON**

Mr. Lewis relies upon his own Affidavit; the Affidavit of Michael E. Brage, M.D.; the Affidavit of Attorney Spencer D. Parr; the Declaration of De Ann McClung (originally submitted by the Department in support of its motion for summary judgment), including the exhibits

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attached thereto; and the Declaration of Josiah Morse (also originally submitted by the Department in support of its summary judgment motion), including the exhibits attached thereto.

III. FACTS

James R. Lewis was born on July 28, 1982 and is now 34 years of age. Mr. Lewis injured his left foot, ankle and heel (collectively "ankle") on June 12, 2014 while working in the course of employment covered by Washington's Industrial Insurance Act. As a result of his June 12, 2014 industrial injury, Mr. Lewis filed L&I Claim No. AU-90361, which the Department of Labor & Industries ("Department") duly allowed as compensable by its final and binding order dated August 21, 2014. These facts are not in dispute.

As a result of his left ankle injury in L&I Claim No. AU-90361, Mr. Lewis underwent all available and recommended modalities of conservative medical care, to include treatment with NSAIDs; opioids; rest; ice and elevation; physical therapy; and custom orthotic, but all of these measures failed to completely restore his left ankle function, as well as eliminate his pain, such that he had not yet reached maximum medical improvement as of August 3, 2016.[1] On August 3, 2016, Mr. Lewis underwent OATS left ankle surgery even while maintaining this appeal to the Department's denial of that procedure.[2] These facts are not reasonably in dispute.

According to his Attending Physician, Michael E. Brage, M.D., Mr. Lewis underwent left ankle radiographs on August 8, 2014; left ankle MRI on September 10, 2014; and left ankle CT exam on January 15, 2015.[3] He was objectively diagnosed with an osteochondral cyst (a.k.a. "lesion") involving the medial aspect of his left talar dome with bone marrow edema extending throughout the medial aspect of the left talus posteriorly. Generally, his left ankle condition, pre-surgery, is referred to as "osteochondritis dissecans." He had a "full-thickness" lesion, by which

[1] Affidavits of Michael E. Brage, M.D. and Richard R. Lewis.
[2] Affidavit of Michael E. Brage, M.D.
[3] Id.

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it is meant that he suffered damage to his left ankle joint's articular cartilage extending from the top surface of that cartilage down, through to the underlying bone and even into the bone marrow at the center of his bone. As a result of this condition, Mr. Lewis suffered consistent, reproducible pain, especially upon weight-bearing. He was medically unable to weight-bear for more than approximately three hours per day prior to his surgery, a "crippling" circumstance at his relatively young age. According to Dr. Brage, this crippling condition would also likely be permanent and progressive if not surgically repaired. Dr. Brage recommended OATS ankle surgery because the only other available surgical option would be left ankle fusion surgery, but a fusion surgery would be medically less-desirable as it would leave Mr. Lewis with comparatively reduced flexibility and range of motion in his left ankle.

The "OATS" procedure refers to an "osteochondral allograft/autograft transfer system" surgery whereby a plug of healthy articular cartilage is removed from a non weight-bearing area of a joint (i.e., "donor site") and transferred to a weight-bearing area (i.e., "recipient site") as a replacement for damaged articular cartilage at the recipient site. An allograft is a plug of bone taken from a cadaver whereas an autograft is a plug of bone taken from the same patient into whom it will be repositioned at the site of the damaged articular cartilage being treated.

The objective of the OATS procedure is to allow for greater, less painful weight bearing and joint motion than might otherwise be achieved without replacing the damaged articular cartilage at the recipient site. Erosion or traumatic damage to articular cartilage, which provides a soft lining or cushion at the end of bones, is known to cause symptomatic osteoarthritis. Once the articular cartilage is damaged, it will generally continue to deteriorate, i.e., become progressive.

As stated in the Department's summary judgment memorandum, the HTCC is a committee of the Health Technology Authority responsible to issue "assessments" as to whether or not certain technologies or treatments can be authorized for purchase by participating state

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agencies, including the Department of Labor & Industries, pursuant to Title 70.14, RCW (hereafter, the "HTCC law").

In 2012, the HTCC issued an assessment regarding the OATS procedure in both the knee and ankle. The assessment allowed participating agencies to purchase the technology with respect to the knee, but prohibited with respect to the ankle. The medical research upon which the HTCC's assessment was based was procured from a research company called "Spectrum Research, Inc." ("Spectrum").[4] The research process conducted by Spectrum was criticized during public comment, including specifically from Brian J. Cole, MD, MBA, as not having experienced clinicians involved in that process.[5]

Not a single Medical Doctor, Doctor of Osteopathy or Podiatric Surgeon was included on the Spectrum research team.[6] Dr. Paul Just, Director of Health Care Economics for Smith and Nephew's advanced surgical devices division criticized Spectrum's research during the HTCC's deliberations, saying that "[s]imply rejecting imperfect evidence" was "not a solution" for how to resolve the difficult questions then before the HTCC.[7] Dr. Just openly criticized Spectrum's research presentation, asserting that it had improperly demoted high-level evidence during its presentation.[8]

Samir Bhattacharyaa, a representative of DePuy Mitek, the sports medicine division of Johnson and Johnson, similarly questioned why there appeared to be a clear "discrepancy" between existing medical research and the materials presented by Spectrum to the HTCC, even calling certain assumptions "transparent" and of questionable validity.[9] Dr. Jack Burg, an Orthopedic Surgeon and past President of the Arthroscopy Association of North America

[4] Department's Exhibit 2, pg. 1 of 168.
[5] Department's Exhibit 3, pp. 7 and 23 of 44.
[6] Department's Exhibit 2, pg. 2 of 168.
[7] Department's Exhibit 5, pg. 84 of 152.
[8] Department's Exhibit 5, pg. 85 of 152.
[9] Department's Exhibit 5, pp. 86-87 of 152.

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testified to the HTCC that he agreed with the positions of Mr. Bhattacharyaa and Dr. Paul Just, and he urged approval of the OATS surgical technique generally.[10]

Dr. Brian Cole, Professor in the Department of Orthopedics and Anatomy and Biology at Rush University Medical Center testified before the HTCC that "incidents of [OATS] procedures, relative to others, is extraordinarily rare…[but that it was now] generally accepted that these are successful operations."[11] Dr. Cole indicated that erecting an excessively-high evidence barrier, such as in requiring a true randomized prospective study to either approve or disapprove, would be inappropriate, especially because the "real issue is, these patients have no other alternatives."[12]

Dr. Peter Mandt, an Orthopedic Surgeon and clinical expert also testified to the HTCC.[13] Dr. Mandt indicated that he had a special interest in Orthopedic Knee surgery,[14] and as well that if a person suffered a traumatic cartilage defect, or in situations involving osteochondritis dissecans, "there's not a lot of other ways to treat it. I mean, you're left with a big… you have a big hole in the knee, and you either live with that hole in the knee, you do a cartilage transplant into it, which restores normal function, or, you know, end up with an arthroplasty" (total knee replacement).[15] In Dr. Mandt's view, denial of OATS surgery would also just shift people into accepting other less desirable medical procedures that would create substitute risks and adverse outcomes.[16] Dr. Mandt called either traumatic defects or osteochondritis dissecans "fairly clear indications" for OATS surgery because "there really isn't any other way to treat that other than an allograft because there's a bone and cartilage defect there."[17]

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[10] Department's Exhibit 5, pp. 87-88 of 152.
[11] Department's Exhibit 5, pg. 89 of 152.
[12] Id.
[13] Department's Exhibit 5, pg. 104 et. seq. of 152.
[14] Department's Exhibit 5, pg. 105 of 152.
[15] Department's Exhibit 5, pg. 113 of 152.
[16] Id.
[17] Department's Exhibit 5, pg. 117 of 152.

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Andrea Skelly, a researcher without a medical doctorate presented on behalf of Spectrum. Ms. Skelly told the HTCC that in terms of OATS ankle surgery, when considering "functional outcomes," the one study Spectrum accepted failed to show worse functional outcomes as between OATS and other types of surgeries.[18] She testified that Spectrum's research instead focused mostly on the knees, not ankles.[19] Nevertheless, there were also some ankle studies considered by Spectrum with respect to "safety,"[20] which yielded results generally consistent with safety metrics demonstrated for OATS knee surgeries.[21] One comparative study found that pain and presence of a full thickness lesion would indicate that coverage was appropriate in ankles, consistent with the evidence available for knees.[22] No research presented by Spectrum indicated that osteochondritis dissecans in the ankle should or could be more effectively, safely, or cost-efficiently treated by any procedure other than OATS surgery.

The clinical expert, Dr. Mandt, then testified to the HTCC that although he doesn't personally do ankle allografts, his partner Tom Chi does, and "the history of osteochondral allografts in the ankle has been sort of one that's, you know, taken off from the positive results in the knee."[23] Dr. Mandt testified that Dr. Chi had also performed one of the larger research series available, and it was Dr. Mandt's belief that OATS (allograft) ankle surgery was "getting to be the more common way to do it."[24] No research or other data was presented to the HTCC indicating that there were any known or excessive risks, costs, or negative outcomes associated with OATS ankle surgery.

Please recall again that one comparative study indicated that "pain and presence of a full thickness lesion" would be inclusion criteria (i.e., reasons justifying performance of OATS ankle

[18] Department's Exhibit 5, pg. 121 of 152.
[19] Department's Exhibit 5, pg. 125 of 152.
[20] Department's Exhibit 5, pg. 144 of 152.
[21] Department's Exhibit 5, pg. 146 of 152; see also, Department's Exhibit 2, pg. 137 of 168.
[22] Department's Exhibit 2, pg. 81 of 168.
[23] Department's Exhibit 5, pg. 147 of 152.
[24] Department's Exhibit 5, pp. 147-148 of 152.

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surgery) "consistent with criteria described…for the knee."[25] Rates of potential complications with OATS ankle surgeries were also recognized to be within the same statistical ranges as potential complications with OATS knee surgeries.[26]

Spectrum's own conclusions indicated that "it is difficult to draw evidence-based conclusions regarding the key questions posed for this assessment" because of what Spectrum perceived as "poor quality of the evidence available."[27] This referred to both ankle and knee surgery sites. Nevertheless, Spectrum noted that "selected bell-weather payers are somewhat consistent for coverage of these procedures," even though the Centers for Medicare and Medicaid Services have not published a formal position.[28]

For one example where coverage has become an insurance industry norm, Spectrum provided information that Premera Blue Cross (Washington and Alaska) has a policy that "[g]enerally accepted criteria for the ankle include a focal defect and symptomatic significant symptoms…"[29] Public comments yielded information that "no reviewed commercial insurer" fails to cover OATS/mosaicplasty.[30] Of twenty-three (23) payors researched, six (6) had no policy, but seventeen (17) had "a positive policy as long as the criteria was satisfied."[31]

Despite the Department's motion for summary judgment lauding the HTCC as being comprised of medical "experts," it is instead comprised of such non-experts in the area of Orthopedic ankle surgery as a Chiropractor; Naturopathic Doctor; a Diabetes Specialist in Endocrinology; an Epidemiologist; and those with Family Medicine and Advanced Nursing Practice areas of medical specialization.[32] Yet, even within these and other unqualified HTCC members, it was pointed out during the HTCC's deliberations that a "quick PubMed search"

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[25] Department's Exhibit 2, pg. 12 of 168.
[26] Department's Exhibit 2, pg. 135 of 168.
[27] Department's Exhibit 2, pp. 156 – 157 of 168.
[28] Department's Exhibit 2, pg. 61 et. seq. of 168.
[29] Department's Exhibit 2, pp. 63 & 66 of 168.
[30] Department's Exhibit 3, pg. 14 of 44.
[31] Department's Exhibit 3, pg. 44 of 44 (see under "Summary" at bottom of page).
[32] Affidavit of Michael E. Brage, M.D., paragraph 15.

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returned over 30 articles on the ankle which had not [even] been presented to the members via the Spectrum presentation of available evidence.[33] An objection was voiced by one member that the HTCC was acting outside the scope of its "charge," because "our charge isn't just to look at the evidence from that kind of data" (referring to "RCTs and comparative studies with concurrent controls").[34]

The HTCC members ultimately voted three members to cover OATS ankle surgery and seven members to not cover[35], although it is also apparent that in voting against coverage at least certain members of the committee believed that an appeal to the respective state agencies affected by the resulting assessment would still be possible were the agencies to deny coverage to specific individuals with unique medical circumstances[36]. In other words, HTCC committee members didn't apparently even understand they were voting to become dictatorial tyrants whose quick rush to judgment would be used by state agencies to ration access to necessary and proper medical care on a non-appealable basis.

IV. ANALYSIS: SUMMARY JUDGMENT SHOULD BE DENIED. FULL REVIEW BY THE BOARD IS APPROPRIATE AND THE HTCC'S SPECIFIC ASSESSMENT AGAINST OATS ANKLE SURGERY SHOULD BE HELD INVALID AND THEREFORE NON-BINDING.

A. The Department's Summary Judgment Motion Overstates the Legal Force Due Even to Validly-Conducted HTCC Assessments, Which the OATS Ankle Surgery Assessment at Issue Here was Certainly Not.

RCW 70.14.120(1) states that "participating" agencies must comply with HTCC determinations **"unless"**, pursuant to subparagraph (1)(a), "the determination conflicts with an applicable federal statute or regulation, **or applicable state statute**; or pursuant to subparagraph (1)(b), "reimbursement is provided under an agency policy regarding experimental or

[33] Department's Exhibit 5, pg. 145 of 152.
[34] Department's Exhibit 5, pg. 143 of 152.
[35] Department's Exhibit 5, pg. 152.
[36] Exhibit 5, pg. 138, Comment of Michael Souter.

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investigational treatment, services under a clinical investigation approved by an institutional review board, or health technologies that have a humanitarian device exemption from the federal food and drug administration." (emphasis added).

Using the plain language of exception ("unless") stated above from within the HTCC law, the Board should hold that the HTCC law conflicts directly with RCW 51.36.010(2)(a), which has long provided that "necessary and proper" treatment will be authorized to injured workers under the Industrial Insurance Act. Where the HTCC law conflicts with another existing statute, RCW 70.14.120(1)(a) expressly provides that it is the HTCC law that is to yield, not the conflicting statute.

Thus, even though RCW 70.14.120(3) might ostensibly require that OATS ankle surgery be excluded from an analysis of whether it is "medically necessary, or proper and necessary" treatment when contemplating purchase of that procedure under a group health insurance benefit provided to employees of participating state agencies, including the Department, the fact that Mr. Lewis already enjoys a right to any causally-related medical care that is "necessary and proper" under RCW 51.36.010(2)(a) means that the HTCC law yields to the Industrial Insurance Act for purposes of adjudicating Mr. Lewis' L&I claim.

In addition, the Board should also find that even if the Department wished to generally follow the HTCC assessment's guidance with respect to injured and sick workers (as opposed to when merely purchasing insurance coverages for its own 2000+ employees), the Department still possesses the discretion to authorize OATS ankle surgery in Mr. Lewis' case as an "experimental or investigational treatment" or otherwise, according to the specific terms of RCW 70.14.120(1)(b).

In the alternative, the Board should hold that where it is apparent from the minutes of its deliberations that the HTCC members have voted to deny coverage generally, based upon the supposition that affected agencies can still hear and consider individual appeals, the Department

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is therefore allowed to hear the merits of an individual worker's appeal, or that of his/her treating physician.

The Department follows the Washington Administrative Code, effectively the Department's "policy," when evaluating claims of injured and sick workers. WAC 296-20-045(2) indicates that the Department can grant authorization for "procedures of a controversial nature or type not in common use for the specific condition" as long as there is a consultation with a qualified doctor with experience and expertise on the subject and the department has received notification of the expert's findings and recommendations. Certainly, those conditions are met within Mr. Lewis' L&I claim, and the Board should affirm that nothing within the HTCC law effectively requires the Department to abdicate its duties under its own longstanding policies (i.e., those that have been in existence before the HTCC law came into being in 2006). According to all experts who have reviewed Mr. Lewis claim, OATS ankle surgery should be authorized. Meanwhile, the HTCC law states that it does not overrule conflicting statutes (and arguably therefore corresponding WACS based on longstanding agency discretion meant to allow effective implementation of the RCWs). Thus, the Board should hold that the Department may now consider exercising its discretion to allow coverage in his case, even if the HTCC outcome is valid in part, or at least generally.

B. HTCC Assessments Remain Appealable to the Board by Statute and As a Result of Washington Supreme Court Precedent, Any Statement by a Hiccupping Appeals Court in *Joy* Notwithstanding.

RCW 70.14.120(4) states that "Nothing in chapter 307, Laws of 2006 diminishes an individual's right under existing law to appeal an action or decision of a participating agency regarding a state purchased health care program. Appeals shall be governed by state and federal law applicable to participating agency decisions." Before the particular HTCC assessment in contest in this claim, it is indisputable that Mr. Lewis could have appealed a non-authorization determination to the Board pursuant to RCW 51.52.060. His right to such an appeal even after

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the HTCC law was passed is expressly and carefully maintained, "not to be diminished" (paraphrased), even according to the plain language of RCW 70.14.120(4), meaning from within the plain text of the HTCC law itself. Moreover, the HTCC committee members did not understand the tyrannical ends to which their vote would now be stretched, contrary to this same plain language in the HTCC law. For this reason, the Board should find that it is inequitable and wrong to enforce an HTCC assessment vote that was taken based on mistaken legal conclusions expressed by HTCC members when casting their votes. In the alternative, the Board should read into the final assessment the limiting terms that were clearly considered by the HTCC voting members at the time their vote was cast. In other words, the Board could find that the OATS ankle surgery in question was properly denied blanket coverage, but that HTCC committee members did want appeal rights to remain (i.e., their votes were cast with implicit conditions that should still be recognized at law).

Even if one mistakenly believed that the Department was entirely bound to ignore the "necessary and proper" analysis which is the normal rule of RCW 51.36.010(2)(a) due to the conflicting language between the Industrial Insurance Act and what is contained within RCW 70.14.120(3), i.e., the HTCC law, such a result must still be appealable under the plain language of the very next (legally superseding) subparagraph within the HTCC law, RCW 70.14.120(4). That superseding provision states that:

> **"<u>Nothing</u> in chapter 307, Laws of 2006 diminishes an individual's right under existing law to appeal an action or decision of a participating agency regarding a state purchased health care program. Appeals shall be governed by state and federal law applicable to participating agency decisions." (emphasis added)**

Recall that our Washington Supreme Court has clearly stated that whenever any conflict is found as between statutory provisions, under the Industrial Insurance Act that conflict is always (not sometimes) to be resolved in favor of the injured worker. *Dennis v. Department of Labor & Indus.*, 109 Wn.2d 467, 471, 745 P.2d 1295 (1987) (internal citations omitted). Yet, even if there

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were no conflict as between RCW 51.36.010(2)(a) and RCW 70.14.120(3), then effect would still need to be given to the plain meaning of RCW 70.14.120(4), as quoted above, which preserves inviolate a right of Mr. Lewis to appeal in this case even under the HTCC law.

The Department cites to *Joy v. Department of Labor and Industries*, finding that an HTCC assessment precluding coverage for spinal cord stimulation is binding and unreviewable, but in order to get to that legally-absurd result, the *Joy* Court literally put on blinders and disregarded statutory plain language, as well as the higher precedential authority it should have observed from the Washington Supreme Court's decision in *Dennis*. Accordingly, the Board should agree to follow the higher Supreme Court precedent from *Dennis* while rejecting the absurdly-unaware position taken by the lesser Court of Appeals, Division 2, in *Joy*. The Board cannot follow both precedents, so should follow the higher and better-reasoned of the two.

Moreover, this case presents arguments not raised or addressed in *Joy*, regarding an HTCC technology assessment which is also distinguishable from that assessment analyzed in *Joy*. Here, Mr. Lewis challenges the HTCC's exclusion of OATS ankle surgery on grounds that said assessment was ***void ab initio***, an issue never raised or contemplated in *Joy* regarding the proposed spinal cord stimulator technology there in contest.

As the Board should certainly appreciate, any purported force of law (whether a contract term arranging murder for hire; an order of the Department issued without jurisdiction over person or subject matter; or an HTCC assessment excluding a given technology or medical procedure from coverage under the Industrial Insurance Act) which is void ab initio is no force of law at all. That which is void ab initio is not legally entitled to enforcement by the Board or courts, including even in the Court of Appeals, Division 2. Thus, although there was a different HTCC assessment affirmed in *Joy*, the facts of that case are distinguishable and cannot control the outcome of Mr. Lewis' claim if the Board, as a preliminary matter, finds the challenged HTCC assessment in Mr. Lewis' instant claim is void as a matter of law. If void, or if valid only

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with implied rights of individual appeal, the non-coverage assessment against OATS ankle surgery literally doesn't exist in the forcible sense the Department's current motion asserts. Normal appeal rights would then be indisputable.

C. Due Process of Law Requires the Ability for Injured Workers' to Maintain Appeals from HTCC Coverage Exclusion Assessments.

Before addressing why the Board should deem the HTCC's 2012 overly-broad, under-evaluated exclusion of OATS ankle surgery "void," and in order to preserve constitutional claims for further appeal, Mr. Lewis respectfully wishes to now state the obvious:

(1) The Industrial Insurance Act provides both liberty and property interests in medical care once the injured worker establishes an industrial injury.

RCW 51.36.010(2)(a) provides injured workers a statutory property interest in receiving "proper and necessary" medical treatment. RCW 51.36.010(2)(a) provides that:

> "Upon the occurrence of any injury to a worker entitled to compensation under the provisions of this title, he or she shall receive ***proper and necessary*** medical and surgical services at the hands of a physician or licensed advanced registered nurse practitioner of his or her own choice…and ***proper and necessary*** hospital care and services during the period of his or her disability from such injury." (emphasis added).

LIBERTY INTEREST

Because RCW 51.36.010(2)(a) confers a right of choice to injured workers in selecting a physician or licensed advanced registered nurse practitioner, "upon the occurrence of any injury [covered under the Industrial Insurance Act]," the injured worker has a statutory liberty interest in the medical care the Industrial Insurance Act provides, i.e., the injured worker is generally free to choose the medical provider from whom (s)he will receive recommendations for medical treatment, a choice which may even determine the exact care provided.

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Implicit in the injured worker's freedom to chose is the recognition that some medical providers are conservative and some aggressive in their medical treatment recommendations. Some are more or less capable, more or less likely to offer surgical options, including when providing the most advanced treatment options, if even offered at all. A Chiropractor will never request authorization to perform surgery, because that is not within the medical licensure allowed to Chiropractors, and yet a Chiropractor can certainly serve as an injured or sick worker's Attending Provider in an L&I claim. The Industrial Insurance Act gives the injured worker the liberty to choose among the various available providers, whose methods and competencies may certainly differ, and to decide in consultation with their chosen provider the best medical path forward toward maximum medical improvement in their individual case.

That an injured worker is statutorily provided a liberty interest of choice once their industrial injury claim is legally established is too obvious to deny from the plain wording of RCW 51.36.010(2)(a). Meanwhile, to burden that interest by withdrawing eligible providers of advanced surgical techniques (including "only viable surgical techniques"), like here by indiscriminately banning every form of OATS ankle surgery, in every situation, is to limit the injured worker's statutory liberty.

PROPERTY INTEREST

Because RCW 51.36.010(2)(a) provides that "upon the occurrence of any injury [covered under the Industrial Insurance Act]," an injured worker is entitled to receive at least that medical care which is considered "necessary and proper," the Industrial Insurance Act also provides an injured worker with a property interest in their medical care once their claim is established as valid. In order to precisely define that interest, the courts should look to the accepted definition of "necessary and proper" as taken from the Washington Administrative Code. Meanwhile, the courts cannot ignore the "necessary and proper" standard under the Industrial Insurance Act (it's right there), even if the *Joy* court negligently fantasized that bulwark of Industrial Insurance Act

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analysis out of existence (i.e., it was essentially ignored so that it couldn't then be in conflict with the HTCC law, producing an absurd and unworkable result).

Pursuant to WAC 296-20-01002, "necessary and proper" medical care is any medical care which meets the following requirements:

> (1) It is related to the diagnosis and treatment of an accepted condition;
>
> (2) It is reflective of accepted standards of good practice, within the scope of practice of the provider's license or certification;
>
> (3) It is curative or rehabilitative. Curative treatment produces permanent changes, which eliminate or lessen the clinical effects of an accepted condition. Rehabilitative treatment allows an injured or ill worker to regain functional activity in the presence of an interfering accepted condition. Curative and rehabilitative care produce long-term changes;
>
> (4) The care is not delivered primarily for the convenience of the claimant, the claimant's attending doctor, or any other provider; and
>
> (5) The care is provided at the least cost and in the least intensive setting of care consistent with the other provisions of this definition.
>
> (6) The injured worker has not yet reached maximum medical improvement.
>
> (7) The treatment must not be inappropriate to the accepted condition or present hazards in excess of the expected medical benefits.
>
> (8) Services that are controversial, obsolete, investigational or experimental are presumed not to be proper and necessary, but may only be provided with prior approval from the Department once the Director or the Director's designee has considered "factors including, but not limited to" those set forth in WAC 296-20-02850.

Mr. Lewis risks losing his chosen treating physicians if he is not able to accept their recommendations for medical care, and the OATS ankle surgery he requests literally meets all the above-listed requirements of "necessary and proper" as set forth in WAC 296-20-01002. Meanwhile, the OATS ankle procedure is not "controversial" merely because it has not been approved by the HTCC generally, because on the facts of this case, every medical expert who has examined the merits has concluded that Mr. Lewis should be provided OATS ankle surgery,

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and even the available HTCC minutes indicate there is not a single, known contrary indicator within the available medical research that would argue against authorizing the procedure in Mr. Lewis' case. OATS ankle surgery is literally the only curative procedure available to him. Thus, Mr. Lewis has demonstrated both liberty and property interests at stake in the instant conflict, as well as the medical necessity and propriety of the surgery sought by his ***treating physicians***.[37] Mr. Lewis is therefore entitled to a full hearing, not the stone wall of a summary judgment as requested by the Department's motion.

(2) Due Process Undeniably Requires a Fair Hearing.

There is no constitutional doubt or question that Due Process under the 5th and 14th Amendments to the federal constitution requires a hearing prior to denying "necessary and proper" medical care to Mr. Lewis under Washington's Industrial Insurance Act. His claim has been allowed, and "necessary and proper" care is the statutory mandate that applies. In addition, Washington's own constitutional law is prohibited from providing less protection of life, liberty and property than is available under the federal Constitution. Therefore, as the U.S. Supreme Court held in *Mathews v. Eldridge*, 424 U.S. 319, 332-33 (1976)(internal citations omitted), the following principle must now be observed:

> "Procedural due process imposes constraints on governmental decisions which deprive individuals of "liberty" or 'property' interests within the meaning of the Due Process Clause of the Fifth or Fourteenth Amendment…This Court consistently has held that some form of hearing is required before an individual is finally deprived of a property interest. The fundamental requirement of due process is the opportunity to be heard 'at a meaningful time and in a meaningful manner.'"

[37] The Board is well aware of the Washington Supreme Court's position on how to treat the opinions of Treating Physicians, but the import question remains, how can that Supreme Court position be squared with the supposed holding in ***Joy*** when looking at the specific and different facts of Mr. Lewis case? Again, the Board should follow the Supreme Court's instruction, not the thoughtless and careless "decision" in ***Joy*** (which didn't even permit a Due Process analysis).

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Because Mr. Lewis has not been allowed a fair hearing on the question of OATS ankle surgery, and because RCW 70.14.120(4) expressly provides Mr. Lewis an appeal right consistent with settled principles of Due Process, there is no real question that Mr. Lewis should be allowed to maintain his appeal on the merits to the Board, i.e., on whether or not the specific OATS ankle surgery recommended for him constitutes "necessary and proper" treatment in his established L&I claim under the Industrial Insurance Act. To the extent former Governor Gregoire may have improperly attempted to line-item veto away the rights of appeal granted by the legislature, or to the extent one napping Appeals Court found no error in that result while expressly declining to bother with the Due Process analysis screaming from that circumstance, the Board should simply stand fast and follow the highest authority known to it, which here is the case of ***Mathews*** decided before the U.S. Supreme Court.

D. HTCC Assessments Legally Must Provide Sufficient and Transparent Process, and Should Be Rejected By the Board as "Void" in L&I Matters Where This Has Not Been Done.

Pursuant to RCW 70.14.110(2)(a), an HTCC assessment "shall consider, in an open and transparent process, evidence regarding the safety, efficacy, and cost-effectiveness of the technology as set forth in the systematic Assessment conducted under RCW 70.14.100(4)." This mandate has implications under the Industrial Insurance Act. The Board should find that one of these is that an assessment position of the HTCC will not be used to deprive injured workers (as a matter of law) recommended medical care unless or until the HTCC assessment reports show the HTCC has adequately considered the specific technology (as opposed to general technology) being recommended in a particular injured worker's L&I claim. On the facts of Mr. Lewis' case, this standard has not been met. The Board should also be mindful that a principal reason for maintaining transparency is that the actions of the HTCC may need to be reviewed on appeal from time to time, in particular, to determine their sufficiency. It therefore makes no sense whatsoever to conclude that the Board and higher courts have no jurisdiction to conduct a fair

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hearing in the present matter as that is inconsistent with the very legal charter under which the HTCC may properly act.

For example, if the HTCC conducts itself in an insufficiently-transparent fashion, such as in failing to detail the specific facts justifying its conclusion against coverage for a specific technology assessed, or under specific unique circumstances, the Board should immediately proclaim a public policy of non-deference when reviewing such conclusory or overly-broad HTCC assessments. Conclusory assessments which are "insufficiently transparent" to the point they articulate "no discernable basis" for excluding coverage of otherwise contended "necessary and proper" medical care should be declared void and inapplicable as a violation of the Industrial Insurance Act. This follows from the plain meaning of RCW 70.14.120(1)(a), which provides that the HTCC law does not overrule conflicting statutes and therefore does not displace them. The Board should also find that HTCC assessments will be entitled to no legal deference whatsoever where, as here, Mr. Lewis has demonstrated that the HTCC had no rational basis to disapprove of the specific OATS ankle surgery requested by his physicians (for the specific condition of "osteochondritis dissecans"), since the HTCC reviewed no evidence contrary to authorizing that procedure and did find some evidence clearly in support. General or sweeping bans of medical care are fundamentally inconsistent with the individualized analysis required under the Industrial Insurance Act, and moreover, here the available information indicates that either the HTCC OATS ankle assessment is contrary to its "charge," as one of its members even indicated during deliberations, or at least that there is no factual basis upon which to determine that the HTCC non-coverage decision was rational under the facts and circumstances of Mr. Lewis' claim.

Before deferring to a particular HTCC assessment, the Board should be able to tell what reasoned analysis, predicated upon scientific evidence and process, caused the HTCC to issue an exclusion from coverage assessment that will ostensibly be used to deny Industrial Insurance Act

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rights. The Board should insist on this. If the Board cannot see the plain basis for a coverage of non-coverage determination, meaningful review is denied; the entire adjudicative process violates the liberal construction and purposes mandated within the Industrial Insurance Act[38], RCW 51.12.010; and the Board should not defer.

In addition, where the HTCC assessment rational is not discernable, the Department fails to properly investigate whether "necessary and proper" medical care is being provided, RCW 51.36.010(2)(a); and the Department's resulting denial is arbitrary and capricious because without sound reason exercised upon facts which should rightly be considered. This is true even if one agrees that HTCC votes (when properly cast in a transparent fashion) supplant and substitute for "necessary and proper" analysis so long as same are taken on a rational basis. Nothing in the ***Joy*** decision leads to the conclusion that the Board is constrained to approve of what is demonstrably an arbitrary and capricious, overly-broad finding by the HTCC in the current case. ***Nothing***. That's not what ***Joy*** held!

Here, the HTCC reviewed scientific evidence that OATS ankle surgery is as generally effective and safe as the HTCC-approved OATS knee surgery as long as the recipient has a full-thickness lesion in conjunction with significant pain. Mr. Lewis has demonstrated those inclusion criteria. The HTCC considered no contrary evidence to the proposition that osteochondritis dissecans virtually always requires cartilage transplantation through an OATS procedure, unless curative treatment is to be forgone or perhaps a total joint replacement is authorized, which on the facts of Mr. Lewis' case would be extreme. Accordingly, the Board should find that the HTCC "assessment" on which the Department now relies failed to properly

[38] *Dennis v. Department of Labor & Indus.*, 109 Wn.2d 467, 471, 745 P.2d 1295 (1987)(internal citations omitted) provides that "regardless of questions of fault and to the exclusion of every other remedy" the Industrial Insurance Act provides "sure and certain relief for workers, injured in their work, and their families and dependents"…[and to achieve this specific end], "the guiding principle in construing provisions of the Industrial Insurance Act is that the Act is remedial in nature and is to be liberally construed in order to achieve its purpose of providing compensation to all covered employees injured in their employment, with doubts resolved in favor of the worker."

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assess his particular factual circumstances, such that it would be improper to give binding legal effect to an unqualified "non-coverage" position.

(1) HTCC Assessments Require "Appropriate Entity" Review, But None Was Provided For OATS Ankle Surgery.

Pursuant to RCW 70.14.100(4)(a), "a systematic evidence-based assessment" of a chosen technology must be conducted by an "evidence-based practice center designated as such by the federal agency for health care research and quality, or other appropriate entity." Here, the assessment was lead by "Spectrum Research, Inc.," a research company which conspicuously included not a single Medical Doctor ("M.D.") or Doctor of Osteopathy ("D.O.") on its research staff (giving rise to the inference that the researchers may not have properly understood the medical treatment issue they were supposed to be researching). Spectrum was not designated as an "evidence-based practice center" ("EPC") by the appropriate federal agency[39] and it otherwise fails, by virtue of having no appropriate medical expertise on its research staff, to meet the plain meaning of "other appropriate entity" as contained in the authorizing statute. The Board should find that the resulting assessment was, thus, void as a matter of law because not conducted by a "qualified" entity, as the HTCC statute expressly requires.

Recall that even public comments by medical doctors indicated that it was inappropriate for Spectrum to conduct medical research without having any clinical expertise applicable for that purpose. Certainly, these facts raise a triable question of whether the HTCC assessment

[39] Contact information for all such designated EPCs is also listed at the following URL, which the Board will please judicially notice: http://www.ahrq.gov/research/findings/evidence-based-reports/centers/index.html (last accessed 9/19/16). Nowhere does the list of current EPCs designate the research company called "Spectrum" as approved by the Federal Agency for Healthcare Research and Quality ("AHRQ"). Meanwhile, all EPC research awards can be searched at the following URL, which the Board should judicially notice: http://gold.ahrq.gov/projectsearch (last accessed 9/19/16); as well as the fact that "Spectrum Research, Inc." has never been designated as an "EPC" by the AHRQ, even by virtue of any past contract awarded.

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relied upon by the Department's summary judgment motion should be entitled to enforcement as a matter of law, especially since there is also evidence that individual HTCC voting members, such as Chiropractor's and Naturopaths, were not qualified on their own. After all, why did the HTCC law require medical research be conducted by an "appropriate entity" if it were legally assumed committee members could independently and correctly form their own judgments without input from clinical and other experts? Why did the HTCC committee call a clinical expert and others to give comments and/or testify? Here, the Board may even rule as a matter of law that there having been no qualified, field-specific medical experts with clinical expertise in OATS ankle surgery involved in either the vendor research or resulting discussions of the HTCC, the HTCC determination that followed is not entitled to enforcement because it was a legally-insufficient as an "assessment" the HTCC law intended.

(2) **HTCC Assessments, Including the Exclusion for OATS Ankle Surgery, Should Be Found Void If They Expressly and/or Demonstrably Fail to Give the Greatest Weight to the Most "Valid and Reliable" Evidence Before Them.**

Here, the only scientific evidence considered by the HTCC indicated that OATS ankle surgery is substantially comparable in terms of positive outcomes as OATS knee surgery. The HTCC nevertheless issued an exclusion of coverage assessment for OATS ankle surgery while nevertheless adopting OATS knee surgery as appropriate for coverage. In doing so, the HTCC violated RCW 70.14.100(4)(d), which expressly "requires" assessments to give the "greatest weight" to the objectively "most valid and reliable" evidence. Here, the only evidence was in favor of coverage, so the HTCC abused its discretion to vote for non-coverage.

Here, the HTCC could not rationally follow the evidence in favor of OATS knee surgery, as well as expert opinions indicating that it is likely the only viable treatment option for the condition of osteochondritis dissecans generally (i.e., the condition Mr. Lewis suffers in his ankle), together with at least some high-level evidence indicating that outcomes are similar for

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OATS ankle surgery and OATS knee surgery with no statistical difference in potential risks, and then determine that OATS ankle surgery would be denied while OATS knee surgery would be covered. The evidence reviewed by the HTCC showed that, if anything, the comparative outcomes are similar regardless of whether the OATS surgery procedure is performed for the ankle joint or for the knee joint, at least as would pertain to the specific facts of Mr. Lewis' L&I claim, and that means that any assessment finding against coverage for the particular facts of Mr. Lewis' claim must be rejected by the Board as irrational (and as contrary to the HTCC's own charter), so not entitled to enforcement as a matter of law.

The HTCC also identified no particular, specifically-important or excessive risks, costs or other detriments even potentially-associated with the OATS ankle surgery before issuing a summary prohibition of state payments for that technology. No negative finding was detailed whatsoever in the HTCC's "assessment." Thus, the HTCC most likely abused whatever discretion it may have been assigned by the legislature pursuant to Chapter 70.14 RCW.[40] Certainly, no complete, nor legally-creditable review was ever conducted. As a result, the Board should simply point to this fact and then decline to rubber stamp the Department's summary judgment position.

In the particular circumstances of this claim, the Board should find that the 2012 HTCC upon which the Department now relies is "not entitled to automatic enforcement," even under *Joy*, because it is void ab initio as a matter of law. All positive evidence in Mr. Lewis' medical record, including by multiple surgeons, indicate that OATS ankle surgery should be allowed in Mr. Lewis' claim. All positive evidence presented to the HTCC indicated coverage would be

[40] We assert that there is a clearly-unconstitutional delegation of judicial authority granted to the HTCC, which is expressly not an executive branch "agency" (i.e., subject to the Administrative Procedures Act) according to RCW 70.14.090(5), but which is supposedly allowed to act tyrannically, without even a modicum of judicial review according to the express terms of RCW 70.14.120(3). Such a scheme does not comport with either Washington state constitutional or federal constitutional requirements, violates Separation of Powers doctrine, and ignores established law going all the way back to *Marbury v. Madison*, 5 U.S. 137 (1803).

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appropriate under the facts and circumstance of Mr. Lewis' industrial injury claim. No evidence whatsoever presented to the HTCC argued against coverage on any ground of efficacy, safety, comparative disadvantage, cost, market trend or otherwise. It was demonstrably arbitrary and capricious for the HTCC to blanket deny coverage for OATS ankle surgery based upon the evidence before it, and the Board should so find. A reasonable mind can so find, so summary judgment must be denied as a contest remains.

Using slightly different language, the HTCC's assessment exclusion of coverage should be found void ab initio because a violation of its jurisdictional limitations.[41] See, RCW 70.14.100(1)(c), requiring that before the HTCC may assess a technology, i.e., before the HTCC can exercise subject matter jurisdiction, there must be **"adequate evidence available to conduct [a] complete review."** That wasn't done here, and nor was that an argument in Joy. Here, expressly, there was inadequate evidence in the opinion of the majority of HTCC members to dictate non-coverage, yet instead of tabling the analysis (or voting on the side of those three members who followed the commands of the HTCC charter), the HTCC simply defaulted to prohibition under the apparent and mistaken belief that individual appeals would still be allowed to the participating state agencies, including the Department of Labor and Industries. The Board cannot turn away from this miscarriage of justice, as-applied, just because *Joy* failed to envision or expressly articulate any future possibility of HTCC errors that should be subject to non-

[41] An adjudicative order is "void ab initio," meaning void from the time of its issuance, if the adjudicative body making the order lacked either personal jurisdiction or subject matter jurisdiction. *Kingery v. Dep't of Labor & Indus.*, 132 Wash.2d 162, 170, 937 P.2d 565 (1997) (plurality). This concept must be parsed from the concept that "the power to decide includes the power to decide wrong, and an erroneous decision is as binding as one that is correct." *Marley v. Dep't of Labor & Indus.*, 125 Wash.2d 533, 543, 886 P.2d 189 (quoting *Dike v. Dike*, 75 Wash.2d 1, 8, 448 P.2d 490 (1968). Thus, if the HTCC's jurisdiction was wanting, because the HTCC should not have conducted an assessment where it admittedly had insufficient evidence to decide, then the HTCC's assessment was void ab initio. If jurisdiction was present, because the HTCC had sufficient evidence to decide, then the HTCC also had the power to decide wrongly (except for other constitutional defects raised elsewhere). Mr. Lewis respectfully submits that the HTCC lacked jurisdiction to exclude all affected Washingtonians from state medical coverages for the OATS ankle surgery because it admittedly had insufficient evidence before it, so should have declined to exercise subject matter jurisdiction pursuant to RCW 70.14.100(1)(c).

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deference by the Board. Rather, the Board should call out the new issues raised in this case, distinguish *Joy*, and then proceed to allow a ruling on the merits of Mr. Lewis' appeal.

Judicial standards have to be established. Blanket deference/deliberate ignorance of provable medical facts cannot be the siren call of "justice" for injured workers. Rather, the Board should now find that due to necessary implication of RCW 70.14.100(1)(c) (adequate evidence for complete review is precondition of assessment), when read in combination with RCW 70.14.100(4)(d) (assessment must give greatest weight to the most valid and reliable scientific evidence), the HTCC is allowed to disapprove of specific technologies based upon excess costs or risks or demonstrated absence of medical benefits in all circumstances; or it is allowed to approve technologies based upon favorable, objective and valid scientific evidence, even for very narrow applications of the technology under assessment (i.e., in situations where the technology is allowed for coverage under specified restrictions but otherwise generally disallowed). Either result, supported in fact, might constitute a "complete review" leading to a proper technology "assessment" for a specific procedure, and deference might therefore be appropriate. However, under the circumstance presented by Mr. Lewis in the instant case, that is not what happened. The Board owes no deference, and summary judgment is inappropriate.

(3) HTCC Determinations Must Consider Alternative Options or Significant Variations in Use and Must Be Based upon Adequate Evidence. This was Not Done for the HTCC's OATS Ankle Surgery Assessment.

Pursuant to RCW 70.14.100(1)(a)-(c), HTCC assessments are to be specifically concerned with "safety, efficacy, or cost-effectiveness, especially relative to existing alternatives, or significant variations in its use," and the HTCC is only authorized to take a position where "[t]here is adequate evidence available to conduct the complete review." Here, Mr. Lewis suffers osteoarthritis dissecans, and the simple truth of the matter is there is no alternative to OATS ankle surgery that would leave him as anything but a life-long cripple. The Board cannot sit by and

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condone that result while also fulfilling its obligations to faithfully interpret and enforce the Industrial Insurance Act.

V. CONCLUSION:

The Department's motion for summary judgment should be denied for the substantial reasons stated herein. Triable issue of fact remains, i.e., at least whether or not the HTCC assessment relied upon by the Department is void ab initio. If void ab initio, Mr. Lewis enjoys all appeal rights normally available under the Industrial Insurance Act, such that summary judgment cannot be granted to the Department at this time, because the Department must either then consider or concede the propriety and necessity of authorizing OATS ankle surgery in Mr. Lewis' industrial insurance claim.

RESPECTFULLY SUBMITTED THIS 10TH DAY OF NOVEMBER, 2016.

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