Pleas, Susan

TREATMENT

Proper and necessary medical and surgical services (RCW 51.36.010)

Spinal column stimulator

Although implantation of spinal column stimulator is "controversial" treatment per medical aid rules, such treatment may be authorized if the treatment is rehabilitative and reflective of accepted standards of good practice, thereby satisfying the requirements that it be "medically necessary" treatment within the meaning of WAC 296-20-01002 and "proper and necessary medical and surgical services" within the meaning of RCW 51.36.010.In re Susan Pleas, BIIA Dec., 96 7931 (1998) [dissent] [Editor's Note: The Board's holding explicitly followed in Murray v Dep't of Labor & Indus., 192 Wn.2d 488 (2018).]

Scroll down for order.

BEFORE THE BOARD OF INDUSTRIAL INSURANCE APPEALS STATE OF WASHINGTON

IN RE:	SUSAN M. PLEAS) DOCKET NO. 96 7931

CLAIM NO. J-746527) DECISION AND ORDER

APPEARANCES:

Claimant, Susan M. Pleas, by Law Office of William D. Hochberg, per William D. Hochberg

Employer, Advanced Technology Labs, None

Department of Labor and Industries, by The Office of the Attorney General, per Beverly Norwood Goetz, Assistant

The claimant, Susan M. Pleas, filed an appeal with the Board of Industrial Insurance Appeals on September 25, 1996, from an order of the Department of Labor and Industries dated August 14, 1996. The order affirmed a prior order dated June 3, 1996, that denied authorization and payment for a spinal cord stimulator. **REVERSED AND REMANDED.**

DECISION

Pursuant to RCW 51.52.104 and RCW 51.52.106, this matter is before the Board for review and decision on a timely Petition for Review filed by the Department of Labor and Industries to a Proposed Decision and Order issued on December 31, 1997, in which the order of the Department dated August 14, 1996, was reversed and remanded to the Department with direction to issue an order authorizing payment for the claimant's spinal cord stimulation treatment.

The Board has reviewed the evidentiary rulings in the record of proceedings and finds that no prejudicial error was committed, and the rulings are affirmed.

Upon thorough review, we feel that the disposition of this appeal by our industrial appeals judge was correct. However, we have granted review in order to provide an analytical framework for determining what constitutes "proper and necessary medical and surgical services" to which

injured workers are entitled pursuant to RCW 51.36.010. Such a framework is important to aid in uniformity in analysis of the facts and the applicable law.

The issue in this appeal is whether in this case a specific treatment service, referred to at various times as a spinal column stimulator, epidural spinal column stimulator or a dorsal column stimulator (and hereinafter referred to by the acronym SCS), is "proper and necessary" medical service within the meaning of RCW 51.36.010. This is the fourth time we have been called upon to determine whether, and under what circumstances, the Department should authorize a spinal column stimulator. The past Decision and Orders, none of which have been classified by us as a "Significant Decision," are *In re Larry Morefield*, Dckt. No. 90 5663 (May 5, 1992); *In re Jerry Albaugh*, Dckt. No. 91 1481 (November 12, 1992); and *In re Kim O. Machado*, Dckt. No. 94 1240 (August 2, 1995). The first two of these decisions affirmed the Department's denial of authorization of the SCS implant, while the last one reversed the Department and ordered that the treatment be provided. The result in each of these decisions was heavily dependent on the facts presented at hearing. This is true in this appeal as well.

SCS is a "treatment of last resort" for patients with intractable neuropathic pain in the extremities. It is used in cases of intractable pain and hypersensitivity caused by injured nerve roots in the spine or peripheral nerves to modify or block nerve activity that the brain interprets as pain. The Department refuses to authorize SCS implants in all cases, basing its decision on a recommendation from its Medical Advisory Industrial Insurance Committee (MAIIC). Dr. Gary Franklin, the Department's medical director and a neurologist, and Dr. John Loeser, the neurosurgeon member of the MAIIC, testified that there is insufficient medical literature, meeting appropriate scientific standards, to show that SCS is effective or that it leads to functional improvement of patients. Dr. Franklin believes that SCS is palliative treatment only and does not

meet the accepted standards of good practice of neurosurgery and pain management. Dr. John Oakley, the claimant's attending neurosurgeon, and Mr. Starkenbaum, a biomedical engineer for a company that makes SCS units, testified that SCS is approved by the U.S. Food and Drug Administration and that the Department of Labor and Industries is virtually alone among insuring entities in its refusal to authorize its usage in appropriate cases.

Ms. Pleas is a 55-year-old woman who, as a proximate result of an industrial injury of May 29, 1986, sustained Failed Back Surgery Syndrome (FBSS) that manifests itself through severe, continuous and intractable leg pain that is neuropathic in nature. No treatment modality, including surgery, physical therapy, chiropractic manipulation, acupuncture, naturopathic treatment, various medications, including anti-depressants, and a pain clinic, helped curtail or alleviate her neuropathic leg pain. Ms. Pleas attempted to start a fabric business, designing garments with a computer that she operated while reclining in a chaise lounge at her home. However, she found that she could work in this way only one-half to two hours per day and many days not at all. Dr. Oakley, her attending neurosurgeon, testified that Ms. Pleas was totally unable to perform all work due to her back condition. Her mental state was deteriorating.

Dr. Oakley suggested to Ms. Pleas that implantation of a SCS might provide her with pain relief. Before implanting the device, Dr. Oakley used a screening protocol to determine if she was a good candidate for this treatment. As part of the protocol, Dr. Oakley had the claimant examined by Dr. Ray Baker, an anesthesiologist and specialist in pain management, who implants SCS devices as part of his practice. Dr. Baker concluded that SCS was indicated in her situation. On February 29, 1996, Dr. Oakley surgically implanted the device, on a temporary basis, to see if and to what extent Ms. Pleas actually obtained pain relief. Ms. Pleas noted immediate, dramatic and continuous relief of her leg pain. On March 18, 1996, Dr. Oakley performed the procedure necessary to make the implant permanent. In the year since the implant has become permanent,

Ms. Pleas has not needed to see Dr. Oakley (she has seen his nurse four or five times to make sure she was receiving the optimal stimulation from the unit) and no longer takes pain medication. She will require a minor surgical procedure every 3.2 years in order to replace the internal battery powering the SCS unit. Ms. Pleas now works at home at least two hours per day and plays golf four or five times per week, walking the course.

Decisions of the Department either to authorize or deny authorization of a treatment service are reviewed de novo, by a preponderance of the evidence, inasmuch as neither RCW 51.36.010 nor WAC 296-20-01002 categorize treatment authorization decisions as within the "sole discretion" of the director of the Department. *Morefield*.

Appeals from denial of treatment authorization usually are tried before us as if the issue was one of classification of the proposed treatment within a dichotomy as either "curative" treatment to be authorized or "palliative" treatment to be denied. This sort of analysis is an oversimplification and has no legal basis in the statutes, regulations or case law. *In re Terri Tollie*, Dckt No. 85 3932 (December 17, 1987). The term "curative" is contained within the definition of "medically necessary" found in WAC 296-20-01002, but that regulation also indicates that treatment provided for diagnosis and rehabilitative treatment may also be medically necessary. The word "palliative" does not appear in industrial insurance statutes and is found in the regulations promulgated thereunder only three times. In WAC 296-20-03001(13) it appears in the context of provision of long-term prescription of medication. WAC 296-20-03003(8) refers to a "rule prohibiting palliative treatment," but no such rule appears anywhere in Chapters 296-20, 296-21, or 296-23, WAC. In WAC 296-23-260(1)(b) doctors performing medical examinations for the Department are required to state whether proposed treatment is curative or palliative. None of these regulations is applicable

here. Maintenance or supportive care, [see, e.g., WAC 296-20-03002(4) and WAC 296-23-190(3)(h)] generally is not authorized, but it still is erroneous to decide authorization of treatment questions merely by determining which descriptive term best applies.

Statutory guidance on this issue is scanty and very general. RCW 51.36.010 establishes an injured worker's entitlement to "proper and necessary medical and surgical services" as well as to "proper and necessary hospital care and services." These phrases are not defined. RCW 51.36.015 includes chiropractic care and evaluation as a service available to injured workers under RCW 51.36.010. Additionally, RCW 51.36.020 authorizes a few specific types of treatment, equipment and treatment-related appliances, but SCS is not one of these.

The phrase "proper and necessary medical and surgical services" is not defined within Title 51, RCW. The duration of treatment is discussed within RCW 51.36.010, but only in generalities. The Legislature gave the director of the Department the authority to make rules that include determinations about the types of treatment to be provided to injured workers to enable him to properly administer the provision of medical and surgical services to injured workers. RCW 51.04.030(1); RCW 51.04.020(4). These determinations must take into consideration the remedial nature of the Industrial Insurance Act. RCW 51.04.010.

The "Medical Aid Rules," Chapter 296-20, WAC, do not contain a definition of "proper and necessary medical and surgical services." But a definition of "medically necessary" is contained within WAC 296-20-01002. That regulation states, in part:

Medically necessary: Those health services are medically necessary which, in the opinion of the director or his or her designee, are:

- (a) Proper and necessary for the diagnosis and curative or rehabilitative treatment of an accepted condition; and
- (b) Reflective of accepted standards of good practice within the scope of the provider's license or certification; and
- (c) Not delivered primarily for the convenience of the claimant, the claimant's attending doctor, or any other provider; and

(d) Provided at the least cost and in the least intensive setting of care consistent with the other provisions of this definition.

In no case shall services which are inappropriate to the accepted condition or which present hazards in excess of the expected medical benefits be considered medically necessary. Services which are controversial, obsolete, experimental, or investigational are presumed not to be medically necessary, and shall be authorized only as provided in WAC 296-20-03002(6).

The vast majority of treatment authorization decisions require an individualized analysis to ascertain if the proposed treatment is medically necessary. However, WAC 296-20-01002 is not the only regulation that may be applicable when conducting such an analysis. The Department has promulgated other, more specific regulations that may apply concurrently or in its stead. Some specific treatment modalities and services are the subject of specific regulations found within Chapters 296-20, 296-21 and 296-23, WAC. One such specific regulation, WAC 296-23-175, applies to the provision of SCS treatment. Many common kinds of treatment require prior authorization before being provided to the injured worker. WAC 296-20-03001.

A case-by-case analysis is not necessary when certain types of treatment are proposed. WAC 296-20-030 lists certain treatments that the Department has determined to be proper and necessary in all cases so that they are authorized even without prior application. WAC 296-20-03002 (1)-(5) lists treatments that the Department has determined never to be proper and necessary in any case and, therefore, never will authorize.

The Department contends that SCS cannot be authorized in any case, including this one, because it is "maintenance care" within the meaning of WAC 296-20-03002(4) and, because based on the recommendation of the MAIIC, it has a policy that SCS is never to be authorized. However, in Ms. Pleas' case the SCS treatment was not mere maintenance care inasmuch as it was intended to increase her physical functioning and end her total disability status by enabling her to return to work, an outcome that appears very close to being achieved. The recommendation of the MAIIC

does not permit the Department to prohibit all authorizations of SCS treatment. That committee is advisory only. Furthermore, when Department policy conflicts with a validly promulgated regulation, the policy is not given effect. See, e.g., *In re State Roofing & Insulation Inc.*, BIIA Dec., 89 1770 (1991), and *In re Howard Sells*, Dckt. No. 95 4334 (December 20, 1996).

Authorization of SCS treatment must be determined on a case-by-case basis. WAC 296-23-165 and WAC 296-23-175, regarding miscellaneous services and appliances in general and stimulators in particular, do not contain an absolute prohibition of such treatment services, but instead set requirements for its authorization on a case-by-case basis. WAC 296-23-165(1) and (3) reiterate the requirement that provision of a stimulator must be medically necessary for it to be authorized. Thus, this specific regulation requires SCS treatment to meet the WAC 296-20-01002 definition of "medically necessary."

The Department argues that pursuant to WAC 296-20-01002, SCS treatment must be presumed **not** to be medically necessary because it is controversial and/or experimental. While we do not believe SCS to be experimental, we agree that it is "controversial" within the meaning of WAC 296-20-01002. SCS treatment has been available for over 20 years. The three surgical experts who testified all use it as treatment in selected cases of failed back surgery syndrome (FBSS), the condition from which Ms. Pleas suffers. It only is used when virtually all other possible treatments have been tried and failed. The FDA has approved the device. Most entities providing medical insurance authorize it in appropriate cases. On the other hand, Dr. Franklin and Dr. Loeser testified that the medical literature has not proven SCS to be efficacious or cost effective, the methodology of other studies has been poor, and the results often are only anecdotal. However, the value of Dr. Loeser's study itself is questionable since it is no more than a survey of earlier studies and did not attempt to give weight to more recent studies that more likely reflect positive results from the better technology that Dr. Loeser admits exists currently.

The evidence discussed above shows that while SCS is not experimental, it is controversial. Since SCS is controversial it must be presumed not to be medically necessary. Nonetheless, it still can be authorized as provided by WAC 296-20-03002(6). Since such treatment can be approved in certain cases, it follows that the presumption that it is not medically necessary can be rebutted. This regulation requires the Department to use a case-by-case analysis based on the definition of medically necessary found in WAC 296-20-01002.

In examining this individual case, we believe that Ms. Pleas has shown that the permanent implant of the SCS was rehabilitative treatment and thus medically necessary within the meaning of WAC 296-20-01002 and "proper and necessary medical and surgical services" within the meaning of RCW 51.36.020. "Rehabilitative" and "rehabilitation" are not defined in the statutes or regulations. Webster's II New College Dictionary 934 (1995) defines "rehabilitate" as: "to restore to good health or useful life, as through education or therapy." Thus, treatment that improves functioning, even if it does not improve the underlying pathology, is rehabilitative. Drs. Loeser and Franklin testified that rehabilitation had three components. Return to work was the primary measure of rehabilitation, but others include improved physical functioning and pain relief. However, we have held that mere pain relief is not enough to prove that treatment is improving functioning. In re Calvin Leslie, Dckt. No. 93 1261 (May 2, 1994). While the literature reviewed by Dr. Loeser included individual case histories where SCS resulted in markedly improved functioning and even return to work by injured workers due to the relief of pain, his study and Exhibit No. 2 show that the only finding that can be made about the efficacy of SCS is that approximately 50 percent of the patients receiving the implant will have pain relief of 50 percent or greater. This is a very subjective finding and does not itself justify authorization of SCS. Dr. Oakley believes that soon to be published studies will more clearly show the rehabilitative effects of SCS. But until those studies are published, Dr. Loeser's survey of the literature remains unrebutted.

Notwithstanding the above observations, Ms. Pleas has proven that the implantation of a SCS unit has been rehabilitative treatment in her case. As of the date of her testimony, Ms. Pleas' SCS unit had functioned for 18 months without complication. She experienced a marked decrease in pain and an increase in functioning. The rehabilitative effect of the treatment can be verified by the decrease in prescriptions sought, decrease in the use and cost of medical services, and the increase in the claimant's activity level and ability to work. Adding time spent golfing to the amount of time she works each day, it is likely that she has become physically capable of performing gainful employment. In this case, the presumption that SCS is not proper and necessary medical treatment has been rebutted.

Dr. Franklin pointed out that the evidence that SCS had a rehabilitative effect in this case originated after the treatment had been provided. Authorization of treatment is not dependent on a good result from that treatment in any one particular case. Nor should treatment authorization be delayed until after the treatment has been provided and proven to be effective. Such a delay harms the Department as well as the injured worker. Nonetheless, in situations where the treatment has been provided prior to it being authorized, the Board has held that a determination that surgical treatment was medically proper and necessary may be based on "20-20 hindsight" provided from findings of the surgery itself. *In re Zbiegniew Krawiec*, BIIA Dec., 90 2281 (1991) and *In re Rebecca Armack*, Dckt. No. 68,368 (October 21, 1985).

The Department also contends that SCS treatment is not medically necessary treatment because it is not reflective of accepted standards of good practice. WAC 296-20-01002(b) requires treatment to be reflective of the standard of good practice within the scope of the provider's license or certification. In this case, the scope of the provider's license in question is that of neurosurgery and surgical pain management. Dr. Franklin, the Department's medical director, has concluded

that because the MAIIC, which advises the Department on medical matters, (see WAC 296-20-01001) has recommended that SCS treatment not be authorized, that necessarily means that such treatment does not meet the accepted standard of good practice.

Dr. Franklin's conclusion is erroneous. The testimony of Dr. Loeser, the neurosurgeon member of MAIIC, makes it clear that the committee's rejection of SCS was due to an inability to prove to its satisfaction that such treatment is rehabilitative and cost effective. Dr. Loeser, Dr. Oakley, and Dr. Baker, who perform surgical procedures in these fields, **all** provide SCS implants to their patients who meet their screening criteria. Dr. Franklin, on the other hand, is not a surgeon and treats patients only irregularly. His opinion about what constitutes the standards of good practice of neurosurgery and pain management is entitled to less weight.

The Board, in *Morefield* and *Albaugh*, concluded that implantation of SCS was not reflective of accepted standards of good practice based on Dr. Franklin's interpretation of the MAIIC advisory opinion. In this case, evidence from the neurosurgeon member of the committee was presented, which rebutted Dr. Franklin's views. Because more complete information from a first-hand source was available in this case, the Board can distinguish those two non-leading decisions and reject their holdings under the facts of this case.

The Department contends that SCS should not be authorized because it is not cost effective. However, information from one of the latest studies (Exhibit No. 2) indicates otherwise. In Ms. Pleas' case, it has clearly been cost effective. Her consumption of medication and medical services has dropped to almost nothing, there have been no complications, and she has improved from likely permanent and total disability status to a person whose activity levels are consistent with some amount of gainful employment. The Department maintains that future costs of maintenance of the SCS unit and battery replacement may prove that this form of treatment may yet prove not to be cost effective in this case. The evidence in the record, especially Exhibit No. 2, suggests that

this is a possibility; however, to say that it will occur in this case is mere speculation that cannot justify denial of authorization of this treatment.

Of course, the Department must consider factors related to future costs when determining if proposed treatment is medically necessary. RCW 51.04.030; WAC 296-20-01002(d). Department is justifiably concerned about the costs of SCS treatment, especially since authorization of such treatment, while initially cost effective, might prove not to be cost effective due to future implant revisions, battery changes, etc. There is no way to accurately forecast future need for treatment in any one individual case. Ms. Pleas may need the stimulator the rest of her life, it may cease to be effective some time in the future, or she may be able to function without the SCS unit at some time in the future. Because of the uncertainties in the treatment of individual cases, the Department routinely reserves claim costs in vast numbers of cases in order to protect the solvency of the medical aid and other funds to which it is entrusted. This decision does not prevent the Department from continuing to use those practices. Rules are in place that the Department can use to manage the continued care that may be necessary due to the SCS unit. See WAC 296-23-175 and WAC 296-20-1102. Dr. Oakley testified that a second type of SCS unit, one that does not require an internal battery, is available. The Department may mandate the use of that type of unit if it proves itself to be less costly and/or a less invasive form of treatment than the unit Ms. Pleas currently uses.

The Department argues that even if permanent implantation of a SCS meets the definition of "medically necessary," it should not be responsible for payment for that treatment service since the implantation took place without prior authorization as required by WAC 296-20-03002(6) and WAC 296-20-1102(3), as well as without prior medical consultation as required by WAC 296-20-045. The implant took place prior to the authorization required by WAC 296-20-03002(6). Moreover, even though Dr. Baker's examination of the claimant may have been consistent with the

WAC 296-20-03002(6) and WAC 296-20-045 requirement of a consultation prior to treatment, it did not meet all of the requirements of WAC 296-20-045 or WAC 296-20-051. However, the failure to comply with these regulations prior to receiving the treatment does not necessarily mean that the authorization of the SCS implant must be denied in this case. In regard to the lack of prior authorization for treatment, the Court of Appeals held, in *Boise Cascade Corp. v. Huizar*, 76 Wn. App. 676, 686 (1994):

if a claimant can establish that he or she notified L&I or the self-insured of the need for medical treatment and supplied information pertinent to a determination of whether the treatment was causally connected to the industrial injury, neither L&I nor the self-insured can use its lack of prior authorization as a basis for denying payment for services later found to be medically necessary and causally connected to the industrial injury. To conclude otherwise would be contrary to the express purpose and intent of the Industrial Insurance Act.

In this case, Ms. Pleas met the requirements listed in *Huizar*. Dr. Oakley could not remember if he sought authorization on behalf of Ms. Pleas for SCS treatment from the Department. However, it is clear that he did seek such authorization inasmuch as he testified that he obtained alternative coverage from another source once the Department denied his authorization request. SCS treatment was intended to treat the residuals of the claimant's low back condition, and the intractable leg pain therefrom, which the Department had already accepted under this claim. Finally, the claimant's dramatic post-implant improvement and the testimony of Dr. Oakley provide sufficient proof that SCS was medically necessary treatment for a condition proximately related to the industrial injury.

Prior to the *Huizar* case, we held in *Krawiec* and *Armack* that failure to follow the regulations requiring prior authorization of treatment and a second medical opinion did not prohibit authorization of treatment if, once the treatment was provided, it proved itself to be rehabilitative in some verifiable fashion. In this case, as stated earlier, there is no doubt that the SCS implant has proven to be rehabilitative for Ms. Pleas.

In summary, authorization of SCS treatment must be determined by the Department on a case-by-case basis. In this case, Ms. Pleas has proven that SCS treatment is rehabilitative and reflective of the accepted standards of good practice within the scope of her provider's license. Therefore, in her case, SCS is "medically necessary" treatment within the meaning of WAC 296-20-01002 and also "proper and necessary medical and surgical services" within the meaning of RCW 51.36.010. The Department order dated August 14, 1996, must be reversed and the Department directed to authorize and pay for SCS treatment in this individual case.

FINDINGS OF FACT

- 1. On May 29, 1986, while in the course of her employment as a secretary for Advanced Technology Laboratories, the claimant, Susan M. Pleas, caught her foot in a pallet and fell, striking her back on a desk, for which she required medical and surgical treatment. On June 4, 1986, the claimant filed an application for benefits with the Department of Labor and Industries. The claim was allowed and benefits were paid. On June 3, 1996, the Department issued an order denying authorization or payment for a spinal cord stimulator. The claimant filed a timely request for reconsideration with the Department. On August 14, 1996, the Department issued an order affirming its June 3, 1996 order. On September 25, 1996, the claimant filed a Notice of Appeal with the Board of Industrial Insurance Appeals. On November 13, 1996, this Board issued an order granting the claimant's appeal, assigning it Docket No. 96 7931, and directing that further proceedings be held.
- 2. As a proximate result of the May 26, 1986 industrial injury and surgical treatment therefor, the claimant sustained failed back surgery syndrome, which manifested itself primarily through severe, continuous, and intractable leg pain that was neuropathic in origin. No treatment modality, including surgery, physical therapy, chiropractic manipulation, acupuncture, naturopathic treatment, various medications, including anti-depressants, and a pain clinic, helped curtail or alleviate her neuropathic leg pain. As of February 29, 1996, the claimant was unable to perform any form of reasonably continuous gainful employment.
- 3. As of February 29, 1996, the claimant was a good candidate for implantation of a spinal column stimulator. On that date, a temporary stimulation unit was implanted and attached to an external pulse generator. The implant provided immediate, dramatic, and continuous relief of the claimant's neuropathic leg pain. On March 18, 1996, the stimulator implant was made permanent. Since that time, the claimant has experienced marked relief of leg pain, her physical functioning and

- ability to tolerate activity have improved significantly, and she is able to engage in activity consistent with sedentary employment.
- 4. Implantation of a spinal column stimulator in carefully screened cases of failed back surgery syndrome, such as this one, is rehabilitative in nature. Such treatment is controversial, but is not obsolete, experimental, or investigational. Implantation of a spinal column stimulator is within the standards of good practice of neurosurgery and pain management.
- 5. As of February 29, 1996, the claimant's attending neurosurgeon had requested, but not obtained, authorization from the Department of Labor and Industries to implant a spinal column stimulator in the claimant as treatment for her failed back surgery syndrome proximately caused by the May 29, 1986 industrial injury and surgical treatment therefor. As part of the screening protocol prior to implanting the spinal column stimulator in the claimant, her attending neurosurgeon had her evaluated by a medical doctor who specialized in anesthesiology and pain management.

CONCLUSIONS OF LAW

- 1. The Board of Industrial Insurance Appeals has jurisdiction over the subject matter and the parties to this appeal.
- 2. In this case, implantation of a spinal column stimulator was "medically necessary" within the meaning of WAC 296-20-01002 and also "proper and necessary medical and surgical services" within the meaning of RCW 51.36.010.
- 3. In this case, failure to comply with the prior authorization requirements of WAC 296-20-03002(6) and WAC 296-20-1102(3) and with all of the WAC 296-20-03002(6) and WAC 296-20-045 requirements for consultation prior to treatment do not relieve the Department from the responsibility to authorize and pay for implantation of a spinal column stimulator.
- 4. The order of the Department of Labor and Industries dated August 14, 1996, that affirmed an order dated June 3, 1996, that denied authorization and payment for a spinal column stimulator, is incorrect and is reversed. This claim is remanded to the Department with

direction to authorize and pay for the implantation of the claimant's spinal column stimulator.

It is so ORDERED.

Dated this 31st day of August, 1998.

BOARD OF INDUSTRIAL INSU	RANCE APPEALS
THOMAS E. EGAN	Chairperson
FRANK E. FENNERTY, JR.	Member

DISSENT

I dissent. While I am glad Ms. Pleas has relief from her pain as a result of her SCS implant, I must disagree with the majority's opinion that she has met her burden of proof by showing that the SCS implant was medically necessary because of its rehabilitative effect for her. Rather, her burden of proof must be to first show that the Department's denial of authorization of SCS procedures for industrially injured workers is incorrect. She has not met this burden. This record, as the majority notes, makes it clear that the SCS implantation procedure is still significantly controversial within the medical community, and therefore presumed not to be medically necessary under WAC 296-20-01002.

The Department has broad supervisory authority granted by the Legislature to determine types of treatment provided to injured workers through the workers' compensation system. To accomplish this, the Department relies on the Washington State Medical Association (WSMA) committee to specifically advise them on acceptable community standards of treatment for the industrial insurance system. Medical policy coverage decisions are based on available data about clinical outcomes and proven efficacy of treatments. Dr. Franklin explained in his testimony that Dr. Oakley and Dr. Loeser were asked to participate on the WSMA subcommittee formed to look at SCS coverage because of their experience performing SCS implants. After being presented with Dr. Oakley's data and Dr. Loeser's review of available research, the committee unanimously voted

to advise the Department not to cover SCS implants as an acceptable standard of care. The majority accords Dr. Franklin's opinion less weight due to the fact that he is not a surgeon. In fact, Dr. Franklin's training in epidemiology is far more critical to the evidence of whether methodologically sound scientific evidence exists to support the effectiveness of SCS. Dr. Franklin's opinion that current studies do not support SCS as an accepted standard of good practice is persuasive. It is not rebutted by the anecdotal opinions of the surgeons who have performed the procedure, the fact that the appliance has FDA approval, or the fact that other insurance programs may pay for the procedure. The expert medical testimony in this record is in agreement that existing research is weak and does not shed light on which individuals are likely to benefit, predictable clinical outcomes, or even the appropriate length of time necessary to ascertain whether a positive outcome has been realized. Dr. Franklin's and Dr. Loeser's testimony clearly show that SCS remains a controversial procedure.

The majority applies the "20-20 hindsight" holdings of *Krawiec* and *Armack* to determine the SCS implant was medically necessary based on testimony the implant resulted in functional improvement for Ms. Pleas. In fact, this case is distinguishable from both *Krawiec* and *Armack* which involved medical procedures routinely accepted by the medical community without controversy, and noncompliance of the treating physicians with Department preauthorization regulations. In contrast, this case involves a controversial medical procedure that is not accepted by the Department as a matter of policy, even if the physician complies with preauthorization

requirements. As such, the majority's opinion that the Department must perform a retrospective case-by-case assessment and decide coverage based on the worker's response to the treatment is legally incorrect. It is unreasonable to require the Department to conduct a retrospective analysis of each case on which a controversial procedure has been denied and to pay for treatment based on the treatment result. As a matter of public policy, entitlement to industrial insurance benefits should not be decided on the basis of the worker's response to a particular form of treatment. To do so will encourage physicians and patients to proceed in hopes of achieving results sufficient for coverage, and opens up virtually all unauthorized treatments for later consideration and litigation. Further, this would undermine the Department's authority and statutory role in supervising treatment for injured workers "with the intent that it be in all cases efficient and up to the recognized standard of modern surgery." RCW 51.04.020(4)

The Department order dated August 14, 1996, denying authorization of Ms. Pleas' March 18, 1996 surgery is correct and should be affirmed.

Dated this 31st day of August, 1998.

JUDITH E. SCHURKE Member

BOARD OF INDUSTRIAL INSURANCE APPEALS

In re: SUSAN M. PLEAS

Claim No. J-746527 Docket No. 96 7931

DISSENT