Prolotherapy and Paravertebral Facet Blocks
Serious Cause for Concern or Something Else?

Anthony Napoleon, Ph.D., ABMPP
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Introduction

This report is designed to provide the reader with an overview of the issues created by Blue Shield’s termination of Dr. John Doe’s standing as a member of its affiliate network. In particular, this report will review Blue Shield’s published reasons for said termination of Dr. Doe's affiliate status and the implications for his professional and personal reputation, medical practice and community standing. Moreover, this report will assess Blue Shield’s decision as it will likely affect other practitioners and professional organizations who utilize and/or promote prolotherapy, as well as paravertebral facet injections, as treatment modalities.

Blue Shield’s Action

On June 8, 2003, Blue Shield of California permanently terminated Dr. John Doe’s network participation. The stated reasons for this termination, which Blue Shield published in its National Practitioner Data Bank, were as follows:

“THE BLUE SHIELD CREDENTIALS COMMITTEE REVIEWED DR. DOE’S APPLICATION FOR CONTINUED NETWORK PARTICIPATION INCLUDING QUALITY OF CARE CONCERNS IDENTIFIED INTERNALLY BY A BLUE SHIELD MEDICAL DIRECTOR. THE QUALITY OF CARE CONCERNS WERE AS FOLLOWS:

1) DR. DOE CONTINUES TO PERFORM FACET BLOCKS WITHOUT THE USE OF FLUOROSCOPY WHICH IS IN VIOLATION OF OUR MEDICAL POLICY AND
2) HE CONTINUES TO PERFORM PROLOThERAPY EVEN THOUGH THE LITERATURE HAS FAILED TO ESTABLISH ITS EFFECTIVENESS NOR ESTABLISHES IT AS THE STANDARD OF CARE.

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DUE TO THE CONSEQUENT CONCERN FOR THE WELFARE OF BLUE SHIELD SUBSCRIBERS UNDER DR. 
DOE'S CARE, WE ARE TERMINATING HIS PARTICIPATION IN BLUE SHIELD'S NETWORK.” (REPORT 
#0000000000000000 (on JOHN DOE, pp. 2-3)

The report went on to make written note that the “Basis for Action” was NEGLIGENCE.

Facts of the Case

Blue Shield’s decision to terminate Dr. Doe's membership, as well as its conclusion that his treatment and care of its subscribers jeopardizes their welfare, was NOT based upon a single patient report, patient injury or complaint.

Blue Shield’s conclusions were, by definition, based upon its general beliefs about the identified treatment modalities, which are not specific to Dr. Doe, but are made to the class of treatment modalities allegedly utilized by Dr. Doe. Specifically, according to Blue Shield’s published report, its decisions “were identified internally by a Blue Shield medical director.” The reader’s attention is drawn to Blue Shield's reference to a single unnamed medical director.

As stated previously, the sole, unnamed medical director’s opinion, was made without benefit of a single medical complaint or patient misadventure involving Dr. Doe's utilization of either prolotherapy or paravertebral facet injection treatment modalities. Despite these facts, Blue Shield transformed a singular, internally communicated opinion, into an official “finding” of personal and professional negligence on the part of Dr. Doe. Once Blue Shield made its “findings,” it was obligated, by law, to report Dr. Doe to the California Osteopathic Medical Board; thus setting in motion a formal review of Dr. Doe’s medical practices.
Paravertebral Facet Blocks Without Fluoroscopic Guidance and the CPT®

In Blue Shield’s published statements, it asserted that Dr. Doe utilizes facet blocks without fluoroscopic guidance. Blue Shield not only failed to identify the actual facet block procedures performed by Dr. Doe, it completely ignored the distinctions made in the CPT® between facet block procedures utilized with and without fluoroscopic guidance.

The Current Procedural Terminology (CPT®) guidelines, published by the American Medical Association, categorizes paravertebral facet injections that are performed WITHOUT fluoroscopic guidance. Those are the procedures utilized by Dr. Doe, categorized under CPT® Codes 64622 and 64470.

The procedural description under CPT® Code 64622 is as follows: "Destruction by neurolytic agent, paravertebral facet joint nerve; lumbar or sacral, single level." The procedural description under CPT® Code 64470 is as follows: "Injection, anesthetic agent and/or steroid, paravertebral facet joint or facet joint nerve; cervical or thoracic, single level."

Both CPT® Codes 64622 and 64470 describe procedures that are performed, by definition, WITHOUT fluoroscopic guidance. If procedures 64622 and/or 64470 are performed using fluoroscopic guidance, then the appropriate CPT® Code is: 76005.1

Various healthcare providers across the nation, including Medicare coding protocol, recognize the CPT® guideline distinctions between paravertebral facet injections performed with and without fluoroscopic guidance. To the author's knowledge, Blue Shield has not published a rejection of the current CPT® guidelines which allow for the billing of paravertebral facet injection procedures WITHOUT fluoroscopic guidance. Quite to the contrary, Blue Shield requires that its members utilize CPT® codes when billing for patient care. This begs the question: If performing procedures 64622 and/or 64470 without fluoroscopic guidance is below the standard of care, then why would the CPT® provide coding classifications for them?

The Actual Facet Injection Procedures Utilized by Dr. Doe

As stated earlier, Blue Shield failed to specify which facet injection procedures Dr. Doe utilizes in his practice.

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In so doing, Blue Shield failed to distinguish between two very distinct facet injection procedures; namely, the paravertebral versus the intra-articular facet injection.

Dr. Doe does not now, nor has he ever, performed the more invasive intra-articular facet injection procedure in his practice. In addition to only utilizing paravertebral injection procedures 64622 and 64470, Dr. Doe utilizes injectable agents that have a very low incidence of side effects, such as Lidocaine HCL plus dextrose, and the neurolytic agent Sarapin® (see Appendix for a complete description of Sarapin,® which is injected as a single agent). Virtually all the serious side effects of Lidocaine are dose dependent and are well documented in the literature. In 25 years of use, Dr. Doe has not been confronted with a single serious side-effect related to his use of either Lidocaine HCL and Dextrose, or Sarapin.®

Dr. Doe agrees that imaging guidance is the standard of care when the needle enters the intra-articular facet spaces. Once the needle enters any of these spaces, imaging guidance directs the needle to its intended locus, while keeping the needle away from sensitive anatomical structures. Studies have shown that needle accuracy significantly increases when imaging guidance is utilized.

After 25 years of experience using paravertebral injection techniques, no serious side effects have ever occurred in Dr. Doe’s practice. This should not be surprising, because serious side effects, the result of improper needle placement, are much more likely to occur when the needle enters the intra-articular space.²

Paravertebral, or sometimes referred to as peri-articular facet blocks, have been shown to be safe and effective in relieving pain and ameliorating the underlying conditions which are associated with such pain.

According to Dr. Andrew Wagner, M.D., "[G]enerations of anesthesiologists have been successful in injecting around the joint."³

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² Serious side effects can occur in the form of allergic reactions to chemical agents, as well as complications which are secondary to infection. Neither of these complications are affected by the use of imaging technology.

³ Wagner, Andrew, M.D. Paraspinal Injections: Facet Joint and Nerve Root Blocks. emedicine.com, June 17, 2003. (Author’s note: emedicine is a professional/physician based on-line database of peer reviewed articles on a range of medical topics, often written by leading experts in their respective medical specialty).
According to Robert M. Silver, MD., paravertebral nerve block injections can be safely and effectively utilized without imaging assistance, and are as effective at relieving pain as the more invasive, intra-articular facet block:

“Physicians should strongly consider using the less invasive and difficult perifacet injections in those they would otherwise use the facet injection.”

Unintended Risks Associated with the Use of Fluoroscopic Guidance for Paravertebral Facet Blocks

Should Blue Shield require paravertebral facet blocks to be performed ONLY under fluoroscopic guidance, the risk to patients would exponentially increase. This would be true not only because of the risks associated with exposure to radiation, but because clinicians may be tempted to get as close as they can to the intra-articular space, rather than simply keeping a safe distance from it. Moreover, should imaging guidance become the standard of care for paravertebral injections, then the clinician may well conclude that he should forego the much safer, and often equally effective paravertebral injection, for the more invasive and more dangerous intra-articular injection. After all, a clinician may reason that if he must pay for the fluoroscope and its operator, why not use it for a procedure where it would be helpful?

With regard to cost issues, incorporating fluoroscopic or other imaging technology significantly increases the cost to both patients and insurance providers. In as much that the research indicates that a significant number of patients benefit from the less invasive and less costly paravertebral facet block, it seems logical that the more invasive intra-articular facet block be reserved for those patients who either did not benefit from the less invasive paravertebral procedure, or for those patients where it is clear, a priori, that the less invasive procedure would not achieve satisfactory results.

Prolotherapy

Blue Shield’s finding of “negligence,” as stated, was based upon its literature review and its assessment of what constituted the standard of care. For example, with regard to prolotherapy, Blue Shield wrote:

[T] HE LITERATURE HAS FAILED TO ESTABLISH ITS EFFECTIVENESS NOR ESTABLISHES IT AS THE STANDARD OF CARE.

Blue Shield’s published conclusion as to the effectiveness of prolotherapy is not shared by some of the most informed physicians in the United States. For example, The Florida Academy of Pain Medicine (FAPM)\(^5\) conducted an extensive literature review of the safety and efficacy of prolotherapy, also known as Reconstructive Injection Therapy (RIT).

This academy is comprised of some of the finest physicians in the country. Their findings are particularly relevant to this matter, because of the academy's thorough review and critical assessment of the literature. Their assessments were made and reviewed by physicians who are specialists in all the various treatment modalities currently available to physicians who treat the spectrum of musculoskeletal syndromes and disorders. Keep in mind that the FAPM is mostly comprised of Medical Doctors. The group summarized their findings:

"For decades, a small group of allopathic and osteopathic physicians has been practicing the methodology known as Regenerative Injection Therapy (RIT), also known as known in the past as prolotherapy.

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Pilot, retrospective, open face prospective, and double blind placebo controlled studies have clearly indicated RIT is effective in the treatment of chronic musculoskeletal pain arising from post-traumatic and degenerative changes in connective tissue such as ligaments, tendons, fascia, and intervertebral discs."^6 (See references in Bibliography "A": 4, 5, 8-10, 12, 14-17, 20-22, 26-28, 35-36, 38-69, 73-83, 88-99, 101-104, 106-111, 113-118, 120-122, 124-128, 133-135)

According to the FAPM, the indications for utilizing prolotherapy as a treatment modality include the following conditions:

• Chronic pain from ligaments or tendons secondary to sprains or strains. Pain from overuse or occupational conditions known as Repetitive Motion Disorders, i.e., neck and wrist pain in typists and computer operators, "tennis" and "golfers" elbows and chronic supraspinatus tendinosis.

• Chronic postural pain of the cervical, thoracic, lumbar and lumbosacral regions.

• Painful recurrent somatic dysfunctions secondary to ligament laxity that improves temporarily with manipulation. Painful hypermobility and subluxation at given peripheral or spinal articulation(s) or mobile segment(s) accompanied by a restricted range of motion at reciprocal segment(s).

• Thoracic and lumbar vertebral compression fractures with a wedge deformity that exert additional stress on the posterior ligamento-tendinous complex.

• Recurrent painful subluxations of ribs at the costotransverse, costovertebral and/or costosternal articulations.

• Osteoarthritis of axial and peripheral joints, spondylisis, spondyloysis and spondylolisthesis.

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• Painful cervical, thoracic, lumbar, lumbosacral and sacroiliac instability secondary to ligament laxity. (See Bibliography “A”: 1-45, 47-69, 71, 73-86, 89-93, 98-104, 106-111, 113-122, 124-128).

Based upon FAPM’s exhaustive review of the scientific literature, the academy concluded that the following syndromes and diagnostic entities, caused by ligament and tendon pathologies, have been successfully treated, as demonstrated in the literature, with Prolotherapy:
• Cervicocranial Syndrome (cervicogenic headaches, secondary to ligament sprain and laxity, atlanto-axial and atlanto-occipital joint sprains, mid cervical zygoapophyseal sprains)
• Temporomandibular Pain and Muscle Dysfunction Syndrome Barre-Lieou Syndrome
• Torticollis
• Cervical segmental dysfunctions
• Cervicobrachial Syndrome (shoulder/neck pain)
• Hyperextension/Hyperflexion injury Syndromes
• Cervical, Thoracic and Lumbar Zygopophyseal Syndromes
• Cervical, Thoracic and Lumbar Sprain/Strain Syndrome
• Costo-transverse joint pain
• Costovertebral arthrosis/dysfunction
• Slipping rib syndrome
• Sternoclavicular arthrosis and repetitive sprain
• Thoracic segmental dysfunction
• Tietze's Syndrome/costochondritis/chondrosis
• Costosternal arthrosis
• Xiphoidalgia syndrome
• Acromioclavicular sprain/arthrosis
• Shoulder hand syndrome
• Recurrent shoulder dislocations
• Scapulothoracic crepitus
• Iliocostalis Friction Syndrome
• Iliac Crest Syndrome
• Iliolumbar syndrome
• Internal lumbar disc disruption
• Interspinous pseudoarthrosis (Baastrup's Disease)
• Lumbar instability
• Lumbar ligament sprain
• Spondylolysis
• Sacroiliac joint pain
• Sacrococcygeal joint pain
• Gluteal tendinosis
• Trochanteric tendinosis
• Myofascial Pain Syndromes
• Ehlers-Danlos Syndrome
• Osgood-Schlatter disease
• Ankylosing Spondylitis (Marie-Strumpell disease)
• Failed Back Syndrome
• Fibromyalgia Syndrome
• Foot and/or ankle
• Sinus Tarsi Syndrome
• Metatarsalgia
• Chronic Ankle Sprain
• Instability, Laxity of ligaments

(See Bibliography “A”: 4, 5, 8-22, 26-32, 34-70, 74-85, 87-103, 105-115, 119-121, 123-127, 131-134).

The Academy, in conclusion, stated the following:

"Use of RIT in an ambulatory setting is an acceptable standard of care in the community."

The Literature Review of Robert G. Schwartz, M.D. and Noreen Sagedy, M.D.

An independent literature review was also conducted by Dr. Robert G. Schwartz, M.D. and Noreen Sagedy, M.D., as part of a retrospective study on the use of prolotherapy. The literature review of that study is presented here:

“...the rich supply of nerve endings in articular ligaments was first described by Lerich in 1930 and later by Gardner in 1953. Hackett described most joint pain as ligament pain. He was the first to scientifically demonstrate a method of strengthening ligaments by the injection of a proliferative solution. Inflammation was produced and a permanent increase in ligament size by 35-40% resulted. Hackett claimed a cure rate of 82% in 1600 patients with low back pain (1). At this time, proliferative therapy was known as sclerotherapy. This was because the irritants used in prolotherapy were thought to work by creation of scar tissue rather than by the development of proliferative response. Some of the irritants used in prolotherapy had been used to sclero-varicose veins as well (Bibliography "B" # 5).
A 1982 study by Liu, et al., quantified biochemically in a double-blind study the influence of injecting a proliferative solution (100ml of 5% sodium morrhuate) into rabbit medical collateral ligaments in situ. Results revealed a highly significant increase of the ligament's mass, thickness, enthesis strength, and its weight/length ratio in comparison with the saline injected controls (Bibliography "B" # 9).

A 1985 study, also using 5% sodium morrhuate, was conducted by Maynard et al. They did a series of five 100ul injections into intact rabbit patellar tendons and Achilles tendons. This study showed that not only is there an increase in the number of cells but also a wider variety of cell types, including fibroblast, neutrophils, lymphocytes, plasma cells, and unidentifiable cells in the injected tissues. An increase in water content and amino sugar content were also noted. Interestingly, a decrease in the mean collagen fibril diameter and hydroxyproline content were documented despite an overall increase in fibrin mass (Bibliography "B" #10).

In 1987, a double-blind study was done by Ongley et al. comparing 40 patients who received spinal manipulations and ligament strengthening proliferative therapy with 41 patients who received minor manipulations and 0.9% saline injections. One injection per week was done for 6 weeks. The solution used was 2.5% phenol/25% dextrose/25% glycerin/47.5% pyrogen free water (P25G). At 6 months following the end of the treatments, 35 patients in the experimental group reported greater than 50% improvement compared with only 16 in the control group. Furthermore, 15 patients in the experimental group were disability-free compared with 4 patients of the control group reporting no disability (Bibliography "B" # 3).

In a different study by R.G. Klein in 1989 histologic documentation of ligament proliferation in human subjects in response to proliferative injections was demonstrated. Biopsy specimens of posterior sacroiliac ligaments were performed pre- and post treatment in three patients with low back pain. Each patient received a series of six weekly injections using the P25G solution into the sacroiliac ligaments. The proliferative injections resulted in collagen of objectively increased diameter and was associated with decreased pain along with an objective increase in range of motion (Bibliography "B" # 4).
The current author conducted his own independent literature review. The focus of that review was upon the research methodology of the clinicians who have studied prolotherapy, with a particular emphasis upon any data that would support the conclusion that utilizing prolotherapy can jeopardize patient's welfare, thus forming the basis for Blue Shield's published statements.

The current author distinguished between the rigors of scientific "proof" related to efficacy, and the scientific data which would substantiate the conclusion that prolotherapy is dangerous, or in any way compromises patient's welfare. I extended my review of the "literature," with regard to safety, to include anecdotal or single clinical experience data or patient reports, within the last 40 years.

The current literature review found a wealth of research data related to the mechanism of action, application, proliferant chemistry and effectiveness of prolotherapy. Some of the more recent studies incorporated double-blind experimental research designs.

One recent study, for example, involved the application of prolotherapy to knee pain secondary to arthritis. The subjects in the study had suffered knee pain for an average of eight years. Imaging studies found that the subjects met the clinical criteria for the diagnosis of arthritis. One of the interesting aspects of this study is that many of the subjects had severe wear to their knee cartilage. Just to illustrate, thirty-five percent of the subject's knees had no cartilage remaining in one or more of the major compartments.

The treatment involved three injections of nine cc of 10% dextrose solution over six months. The control solution was comprised of H₂O. After six months, subjects experienced a 35% reduction of pain, a 45% improvement in swelling, a 67% improvement in knee buckling, and a 13 degree improvement in knee range of motion. The dextrose solution was superior to the control group's placebo solution injections at the (P = .015) level of significance.

A similarly designed study looked at the improvement of thumb and finger pain, along with mobility, after treatment with prolotherapy.

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8 The current author reviewed the literature cited herein, referenced in footnote and bibliographic entries.

In this controlled study thumb and finger pain, along with digit mobility improved, with significance levels reaching ($p = .027$) for pain and ($p = .003$) for flexibility in the experimental group, compared to the control group. As in the earlier study, the control group received water injections.\footnote{Reeves KD Hassanein K Randomized prospective placebo controlled double blind study of dextrose prolotherapy for osteoarthritic thumbs and finger (DIP, PIP and Trapeziometacarpal) joints: Evidence of Clinical Efficacy. Jnl Alt Compl Med 2000;6(4):311-320.}

Importantly, I was unable to find a study in the last 40 years which concluded, or even suggested, for that matter, that prolotherapy was anything other than a safe and non-heavily contraindicated procedure. The contraindications, though few in number, are intuitive and readily apparent. With regard to training, a number of professional organizations provide the interested clinician with in-depth training and peer support. Peer reviewed and credentialed qualifications supplants what has been demonstrated to be a safe and effective treatment modality. Just as an added note, according to some estimates, more than 300 physicians are utilizing prolotherapy in the United States as of the year 2002.\footnote{With regard to safety issues that extend beyond 40 years, I direct the reader to the work of Ross Hauser, M.D., who wrote an article entitled: How Safe is Prolotherapy. A copy of that article can be obtained at: www.getprolo.com/how_safe_is_prolotherapy.htm}

**Legitimate Criticisms of the Research on Prolotherapy**

The current author recognizes the need for rigorous scientific studies when it comes to establishing the efficacy of prolotherapy. Having put to rest the issues related to the safety of the treatment, and with any number of thoughtful, retrospective-clinical outcome studies having been published:

It appears clear that the short-comings of prolotherapy have more to do with research methodology, than the treatment itself.

Perhaps the most thoughtful criticisms of the research methodologies, used in studying prolotherapy, come from Medicare's National Coverage Determinations (NCD) and National Coverage Analyses (NCAs).
Medicare’s NCA file related to prolotherapy is identified as file (CAG-00045N). The final decision was rendered in the Fall of 1999. The NCA policy reads as follows:

"Dr. A. submitted a number of additional materials to support his request. The materials included some articles describing the technique and increased awareness of PROLOATHERAPY, as well as some listings of conferences and member organizations in which PROLOATHERAPY is taught and practiced. While this information supports Dr. A's contention that PROLOATHERAPY has many disciples, it does not provide HCFA with any scientific evidence on which to base a coverage decision, nor does it prove that treating low back pain with PROLOATHERAPY has evolved into the prevailing standard of care."

What is particularly important, with regard to the specifics of why this NCA was critical of the prolotherapy literature reviewed, had to do with the shortcomings of the research methodology used to study prolotherapy, to wit:

"The Ongley study fails to support the coverage of PROLOATHERAPY for a number of reasons. The authors report a subjective improvement in pain amelioration, but they fail to supply any persuasive objective criteria on which to base a coverage decision that must be grounded in scientifically valid evidence. Even the authors acknowledge in their conclusion 'future studies may be needed to analyse [sic] the relative import of each component of the overall procedure.' Since the authors chose to provide the participants with manipulation, exercises and anesthesia in addition to the proliferant and saline injections, it is difficult, if not impossible, to isolate the component of the treatment which gave the participants the reported relief.

Establishing a link between the subjective improvement in pain management and a particular regimen is problematical because the participants in the experimental group received a different preparation course with more anesthesia and a forceful manipulation as opposed to the placebo group's faux manipulation. Since the study did not treat the
proliferant injections as a single variable, there is no way to positively identify PROLOTHERAPY as the cause of the pain relief rather than the forceful manipulation. Also, because Medicare currently covers forceful manipulation and massage therapy by a qualified provider, HCFA would need evidence that the addition of another variable, such as PROLOTHERAPY, to a patient's course of treatment would provide greater benefit than that which is currently covered. Furthermore, even if the results concluded that the benefit in pain reduction could be positively attributed to PROLOTHERAPY, the sample size of 81 patients is really an insufficient number on which to base a positive national coverage decision.

The more recent study submitted by Dr. A also falls short of the requisite level of evidence needed for a national coverage decision. The Klein et al. study, *A Randomized Double-Blind Trial of Dextrose-Glycerine-Phenol Injections for Chronic, Low Back Pain*, published in 1993, fails in much the same way as the Ongley study before it. Again, the number of participants is small; therefore it would be difficult to use the results in support of a newly crafted national coverage decision.

The Klein study was comprised of 79 patients, 39 of which were placed in the proliferant group. Thirty of 39 patients in the proliferant group achieved a 50% or greater diminution in subjective pain or disability. The control group was not a true placebo because 'the patients received four of the five active interventions of the full treatment regimen and demonstrated statistically significant within-group improvements compared to baseline disability and pain scores.' Twenty-one of 40 patients in the placebo group reported a 50% or greater diminution in subjective pain and disability scores. A response of more than 50% of patients in the control group reporting improvement suggests that an actual treatment effect rather than a pure placebo response occurred. Even the authors note, '(t)he interventions shared by both treatment groups, including exercises, injection of local anesthetics, repeated needling, and manipulation may all enhance the success of the procedure, but the relative contribution of each intervention requires further study.'

The authors identify that further studies are needed to show greater improvement in treating pain with PROLOTHERAPY because 'the statistical significance was only borderline' when the experimental group was compared to the control group. Also, 'objective testing of range of motion, isometric strength, and velocity of movement showed significant
improvements in both groups following treatment, but did not favor either the proliferant or the control group. Further, 'the MRI and CT scans showed significant abnormalities in both groups, but these did not correlate with subjective complaints and were not predictive of response to treatment.' A total of 160 patients studied over the past twelve years, with only 79 of the patients receiving the proposed treatment, is not a large enough sample to support a change in the coverage policy.

The reader's attention is drawn to this particular comment in the NCA policy statement:

"More studies with larger control and experimental groups must be evaluated using regimens designed to isolate variables and correlate them to positive results. Ideally, these studies would consist of improvements in both objective and subjective measurement tools. However, substantial and statistically significant improvements in subjective pain scores could be persuasive if HCFA could attribute the patient benefit to the PROLOTHERAPY regimen. Some of the materials Dr. A provided noted that further studies on the benefits of PROLOTHERAPY are now being conducted. Should these additional studies be developed with larger sample sizes and should the results be based on objective measures that can clearly attribute the claimed benefits to the therapy under investigation, HCFA would be happy to reconsider the issue." (emphasis added)\(^\text{12}\)

\(^\text{12}\) See Medicare's NCA for PROLOTHERAPY for Chronic Low Back Pain (CAG-00045N). HCFA stands for the Health Care Financing Administration, which has been renamed The Centers for Medicare & Medicaid Services.
Medicare’s NCA identified what seasoned researchers would term "basic" methodological errors in the cited research studies on prolotherapy. Confounding variables, not effectively controlled between experimental and control groups; small sample sizes; and the failure to establish objective measures of pain, undermined the results of the identified studies Medicare reviewed. The current author draws the reader’s attention to the fact that:

prolotherapy, even when utilized with other interventions, was found to be safe, and was, at the very least, part of a treatment regimen that produced clinically significant results.\(^{13}\)

Neither Medicare, the FAPM, Drs. Schwartz or Sagedy, or the current author, found anything in the literature of the last 40 years that would suggest that the use of prolotherapy compromised patient's welfare.

**Prolotherapy as an Experimental or Investigational Treatment**

The Blue Cross Blue Shield Medical Policy Manual considers prolotherapy to be an “investigational” procedure.\(^{14}\) This position is mirrored by any number of health care providers in the United States. In France, as of May of 2001, prolotherapy was considered

\(^{13}\) I draw the reader's attention to an exception to this conclusion found in the work of E. Dechow, R. K. Davies, A. J. Carr and P. W. Thompson, in: *A randomized, double-blind, placebo-controlled trial of sclerosing injections in patients with chronic low back pain*  Rheumatology 1999; 38: 1255-1259  This study found no statistically significant differences in pain outcome measures between subjects who received sclerosing injections and those who received a placebo solution. The authors commented on their findings this way: "Many patients were not considered ideal candidates for sclerosing injections by the operator at the time of the treatment for a variety of reasons relating to technical difficulties, deconditioning, patients relying on invalidity benefit, excessive psychological stress, etc. even though they technically fulfilled the inclusion criteria. Therefore, the group of patients recruited into our study was likely to respond poorly to any single intervention in keeping with the relatively poor prognosis in the group of patients in the UK today. These factors may also account for the surprising lack of a significant placebo effect in our study compared with the Californian trials. These patients may be better suited to functional restoration or pain management programmes." The authors went on to comment on their definition of "significance:" "Finally, the power of our study was calculated to not miss a 50% difference between placebo and treatment groups with confidence. It is possible that we have missed a smaller improvement that would be clinically significant. We chose the 50% level because of the large placebo response seen in the other studies." The current author notes that this study found virtually no placebo effect whatsoever.


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“experimental” by that country’s national healthcare system evaluation committee. Canada’s national healthcare system, likewise, considers prolotherapy to be “investigational.” In the United Kingdom, the National Health Service doesn’t provide prolotherapy, presumably because it is only offered at a few treatment centers in the country. Most insurers in the United Kingdom DO pay for prolotherapy, although the major insurer BUPA, which states that it has over 3 million members as of 2003, in over 170 countries worldwide, has discontinued covering the procedure. Research into both governmental policy, as well as insurance industry coverage positions, revealed that the terms “investigational” and “experimental” were the prevailing terms used to describe prolotherapy. Operationally, these terms mean that "more studies are needed" before third party or government healthcare plans will pay for physician's use of prolotherapy. With regard to investigational or experimental procedures, insurance companies and governmental entities, alike, have a long-standing policy against paying for these types of procedures, outside of formalized research grant funding.

Both the terms investigational and experimental suggest that the data in support of prolotherapy as a treatment modality are "immature," or at an interim phase along the path of establishing scientific proof. Thus, the official position from both insurance carriers and governmental entities is that "the jury is out" with regard to prolotherapy. But by no means has a conclusion been published, by an insurer or governmental entity, to this author's knowledge, that the use of prolotherapy creates a cause for concern for patients.

As earlier reported here, and worth repeating, the official policy statement from Medicare is as follows:

"More studies with larger control and experimental groups must be evaluated using regimens designed to isolate variables and correlate them to positive results. Ideally, these studies would consist of improvements in both objective and subjective measurement tools. However, substantial and statistically significant improvements in subjective pain scores could be persuasive if HCFA could attribute the patient benefit to the PROLOTHERAPY regimen. Some of the
materials Dr. A provided noted that further studies on the benefits of PROLOTHERAPY are now being conducted. Should these additional studies be developed with larger sample sizes and should the results be based on objective measures that can clearly attribute the claimed benefits to the therapy under investigation, HCFA would be happy to reconsider the issue." (emphasis added)

Such an open-minded attitude, reflected in Medicare's active solicitation for more and better research studies, is not characteristic of Medicare's policy with any number of other so-called alternative therapies and treatments, which have been deemed to constitute nothing more than "quackery." Neither the insurance industry, nor governmental entities around the world, have been reluctant to render decisive and unequivocal decisions with regard to the "worthlessness" of any number of treatments. Such is not the case with prolotherapy.

Nowhere in the literature did I find that prolotherapy was deemed “dangerous” or absent value based upon clinical experience, thoughtful retrospective or experimental studies. What I did find, however, is that prolotherapy has not been underwritten by a requisite number of studies which incorporated rigorous research methodologies.

At the risk of making a technical analysis of the criticisms of the best of the published research studies, none of the flaws negatively impacted either the construct validity of prolotherapy, or the internal validity of the treatment. The construct validity of prolotherapy derives from the exceptionally well understood mechanisms by which proliferant solutions strengthen ligamentous tissue, and how stronger ligamentous tissue improves a host of musculoskeletally-mediated disorders and syndromes. Simply put, the constructs upon which the mechanisms of action for prolotherapy are built are logical and straightforward. The internal validity of prolotherapy derives from the exceptionally well documented nexus between injecting proliferant solutions into ligaments, then measuring their reduced laxity.

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15 See Medicare's NCA for PROLOTHERAPY for Chronic Low Back Pain (CAG-00045N).
No gap in the sequence of logic plagues the construct or internal validity measures of prolotherapy. This is a very important point that has been overlooked, perhaps because it is too technical, but it is of paramount importance.

Significant clinical improvement is the rule, not the exception, in the vast majority of the studies done on prolotherapy.

The inability to precisely attribute significant clinical improvement exclusively to an experimental variable, is profoundly different from critiquing research where there were no significant clinical improvements in the first place, regardless of the effective isolation of the experimental variable or control of confounding variables.

We should be clear that while the "gold standard" of research methodology is the double-blind experimental design, which incorporates the hypothetico-deductive model of reasoning, other thoughtful methodologies, e.g., retrospective clinical, along with independent and diverse clinical experiences, are not without value, if indeed they fall short of the current gold standard.

The hundreds of non-experimental research design results, paired with the sheer number of prolotherapy injections given yearly, over the last 40 years, has provided more than ample opportunity for the contraindications of prolotherapy to manifest and be reported. Some estimates of the number of prolotherapy injections given over the last 40 years approach multiple seven figure numbers. Finally, I found no official policy statement or position paper, from either a governmental entity or medical society, which described prolotherapy’s use as tantamount to “negligence,” or suggested that its use jeopardized patient's welfare.

Some may argue that prolotherapy's threat to patient's welfare may be more indirect, in that patients are being treated with prolotherapy in lieu of other more traditional methods. In response to that hypothetical criticism of prolotherapy, it seems crystal clear that other treatment modalities are not being under-utilized or ignored because of the use of prolotherapy.
Quite to the contrary, a significant number of patients who undergo prolotherapy have failed to achieve satisfactory clinical results after having been treated with a myriad of other, more traditional, treatment modalities. And as the clinical retrospective studies inform us, many, if not most of the patients who have been helped by prolotherapy, were first treated, unsuccessfully, with other more traditional treatment modalities.

**Clinical Experience Among Informed Patients**

I have chosen to incorporate the experiences of a few patients who have been treated using prolotherapy. In doing so I am not attempting to counterbalance the criticisms of the research methodologies we have presented thus far; nor am I suggesting that such patient experiences should constitute the foundation upon which the merits of prolotherapy rest. What I am suggesting, however, is that any number of well-educated and informed patients have attested to the effectiveness of prolotherapy in their lives. These patients include physicians trained in research design and methodology, athletes who are necessarily attuned to the inner workings of their body, and countless patients who have run the gauntlet of other treatments for their intractable pain and other recalcitrant symptoms. This includes countless patients who entered treatment with a skeptical eye.

Perhaps most notably, C. Everett Koop, MD., the former Surgeon General of the United States, had this to say about his personal experience with prolotherapy:

"When I was 40 years old, I was diagnosed in two separate neurological clinics as having intractable (incurable) pain. My comment was that I was too young to have intractable pain. It was by chance that I learned that Gustav A. Hemwall, M.D., a practitioner in the suburbs of Chicago, was an expert in Prolotherapy. When I asked him if he could cure my pain, he asked me to describe it. When I had done the best that I could, he replied, "There is no such pain. Do you mean a pain..." And then he continued to describe my pain much better than I could. When I said, "That’s it exactly," he said, "I can fix you." To make a long story short, my intractable
pain was not intractable and I was remarkably improved to the point where my pain ceased to be a problem. Much milder recurrences of that pain over the next 20 years were retreated the same way with equally beneficial results. Not many physicians are aware of Prolotherapy, and even fewer are adept at this form of treatment. One wonders why that is so. In my opinion, it is because medical folks are skeptical and Prolotherapy, unless you have tried it and proven its worth, seems to be too easy a solution to a series of complicated problems that afflict the human body and have been notoriously difficult to treat by any other method. Another reason is the simplicity of the therapy: Injecting an irritant solution, which may be something as simple as glucose, at the junction of a ligament with a bone to produce the rather dramatic therapeutic benefits that follow."

Dr. Koop went on to comment about the patients he saw who had not been helped by so-called traditional treatment modalities:

"Many of his patients were people who had been treated for years by all sorts of methods...I saw so many of them cured that I could not help but become a "believer" in Prolotherapy."

Dr. Koop had this to say about why some insurance companies do not pay for prolotherapy:

"[T] hat many insurance companies do not pay for Prolotherapy, largely because their medical advisors do not understand it, have not practiced it, and
therefore do not recommend it. Finally, Prolotherapy seems too simple a procedure for a very complicated series of musculoskeletal problems which affect huge numbers of patients. The reason why I consented to write the preface to this book is because I have been a patient who has benefited from Prolotherapy. Having been so remarkably relieved of my chronic disabling pain, I began to use it on some of my patients."

In conclusion, former Surgeon General Koop wrote:

"The reader may wonder why, in spite of what I have said and what this book contains, there are still so many skeptics about Prolotherapy. I think it has to be admitted that those in the medical profession, once they have departed from their formal training and have established themselves in practice, are not the most open to innovative and new ideas."

Dr. Koop is only one of thousands of educated patient success stories. In addition to patients who have been trained in scientific methodology, patients from all walks of life, some of them famous, have been successfully treated by prolotherapy.

What follows is the on-air transcript of an interview with actor and body builder, Lou Ferrigno, which aired on KCAL television in Los Angeles, California. Mr. Ferrigno's experience with prolotherapy are representative of patient results after treatment with prolotherapy:

**News Segment Transcript**

**KCAL INTRO:** Arthritis affects more than 20 million Americans. One of them is a very familiar face, Lou Ferrigno. His doctor, a sports medicine specialist, has come up with a very simple treatment for arthritis with great results.

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16 Dr. Koop's sentiments were made as an introduction to the book: *Prolo Your Pain Away by Dr. Ross Hauser.*
Prolotherapy and Paravertebral Facet Blocks
Serious Cause for Concern or Something Else?

Anthony Napoleon, Ph.D., ABMPP © 2003
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KCAL Ms. Diva Henry: You probably remember this big guy as the Incredible Hulk and Lou Ferrigno is still pretty incredible. But for the last several years he has been battling arthritis in one of his knees. He has had three knee operations, was on regular medication, and walked with a limp. But not any more, he recently went through what is called Prolotherapy.

Lou Ferrigno: I'm not taking any medication, I am able to train.

KCAL Ms. Diva Henry: Sports medicine doctor, Marc Darrow, M.D., J.D. treated Ferrigno's arthritis.

Marc Darrow M.D., J.D.: Prolotherapy works by an irritation of the tissue, it's a backwards type of a concept. It works by stimulating a small injury, in a sense, and then the healing takes place from the inflammation...it brings up the immune system, brings cells to the area that actually grow cartilage and collagen.

KCAL Ms. Diva Henry: And this is detailed in Dr. Darrow's book, The Collagen Revolution.

Marc Darrow M.D., J.D.: The solutions we use in Prolotherapy are typically Lidocaine, which is the kind of thing used in a dentist's injections....the main ingredient is dextrose (sugar).

KCAL Ms. Diva Henry: Prolotherapy is typically used in any kind of musculoskeletal pain and it's getting great results on arthritis patients like Lou Ferrigno.

Marc Darrow M.D., J.D.: It heals any type of joint disorder, it heals tendinitis, it heals muscles when they become strained, osteoarthritis...rheumatoid arthritis.

Lou Ferrigno: I am able to function pain free, not to think about having the pain in my knee. Because most people who have an arthritis problem need a knee replacement because the condition gets worse and worse....in my situation, I feel like I am 25 again!

KCAL Ms. Diva Henry: And he doesn't look his age, 50!

Lou Ferrigno: I still have 280 pounds of muscle and I am still training as hard as ever.17

Next is a testimonial from professional volleyball star Paul Gratton. His comments are presented here, in part, with the entire text of his statement presented in the Appendix of this report:

17 Dr. Darrow and Lou Ferrigno were featured on KCAL-TV in Los Angeles talking about Lou's success with Prolotherapy. The news segment was conducted by KCAL reporter Ms. Dilva Henry.
"In 1992 I retired for several reasons: Because the pain made it difficult for me to enjoy practicing, training, and playing volleyball, because the muscle stiffness made it increasingly difficult to execute certain movements crucial to my performance; and because the therapy and the anti-inflammatories were not helping much anymore.

Furthermore, what worried me the most was that my back problem did not only affect my performance but also my everyday life. Simple chores such as shoveling, raking, or painting were painful. It was impossible for me to stand or stay in the same position for longer than 10 minutes. Every night I had to get up once or twice and stretch my back. Basically, movement that involved bending at the waist was difficult to do and painful, even brushing my teeth or tying my shoes. However, I was hopeful that after my retirement I would start to feel better. I soon found out that it would get worse if I did not exercise and stretch daily.

Six or seven months after my retirement, I started getting Prolotherapy from Dr. Ouellette. At first I would get a treatment every second week, then once a month for a period of approximately six months. At first I did not notice much difference in my back condition. However, after the third session I noticed that some of the pain was gone or less present in my daily life. For example, I could sleep better, I could get in and out of the car easier and walking long distances or standing for an extended period of time was less painful.

By the last session, I felt that my back was 100 percent better. Dr. Ouellette and his Prolotherapy treatments had gone over and above my expectations and had done more for my back pain that I ever imagined possible. At that point I felt no more pain at all during my everyday activities. Also I did not feel pain or the need to do extra stretching before or after a physical activity. Most important, I felt no more pain during exercising, whether it was a recreational sport or playing volleyball.

That year, I got out of retirement and accepted a contract for the end of the French championship. I trained extensively in the gym playing volleyball and doubled the effort in the weight room to get back in shape. Not once did my back bother me. Also, I never felt the need to do extra training for my back. I did not need to apply heat packs before training or ice packs after training. My back had not felt this good in 15 years but, most importantly, I realized that my back problem was cured permanently. To this day, I never took another anti-inflammatory.

Needless to say that my only regret I have is that I did not get Prolotherapy treatment before then. I can honestly say that it would have helped me perform at a higher
level simply because I would have been able to train more in terms of time and effort. Needless to say that not having to deal with the pain on a daily basis would have made my life, in and outside the gym, much more enjoyable. Also, the day that I would have retired would not have been because of a sore back.

I hope that this statement can be of some help. However, if you need further information I would be happy to discuss this further with you. Please do not hesitate to contact me."

Yours sincerely,
Paul Gratton

Resistance to Change

Perhaps a more human characteristic, related to how the human personality reacts to change itself, may account for some of the resistance to prolotherapy we find among some insurers. I should note for the record that resistance to change cannot explain the severity of Blue Shield's decision with regard to Dr. Doe.

We accept and understand in science that some clinicians are extremely resistant to change. We saw a most recent example of this resistance to innovation and change when it came to the part that Helicobacter-pylori played in the development of peptic ulcers. In 1982, when first brought to the attention of traditional medicine, the H-pylori model and its primary proponents, Australian researchers Barry Marshall, M.D. and Robin Warren, M.D. were ridiculed. Like Prolotherapy as a treatment for low back pain, treating an ulcer with antibiotics and H2 agonists, was characterized as at best a waste of time and money, and at worst, negligence. The fact that patients were getting better, where other treatment modalities had failed, was of little concern to those who were resistant to changing their particular paradigm as it related to treating peptic ulcers. Even when research studies began to appear which documented Marshall and Warren's model, some in the medical community rejected the ever growing body of data which challenged their existing paradigm. It should come as no surprise that the primary criticisms of those studies focused upon their research design and the methodologies employed. Johns Hopkins has produced a white paper on Drs. Marshall and Warren's efforts to gain acceptance for their H-pylori/peptic ulcer connection. Here is an excerpt from that white paper:
"In a 1984 study published in The Lancet, Drs. Warren and Marshall found that, among 100 people undergoing endoscopy, all 13 people with duodenal (upper small intestine) ulcers and 24 of 28 people with gastric (stomach) ulcers were infected with the bacteria. Ulcers in the remaining patients were attributed to the use of nonsteroidal anti-inflammatory drugs, such as aspirin, naproxen (Aleve), and ibuprofen (Advil). Most doctors were not convinced by the findings, and often, Drs. Warren and Marshall met with extreme skepticism and even hostility. One possible reason was that the two men had not yet proven a cause-and-effect relationship between the bacterium and peptic ulcers. Animal experiments were impossible because rats, mice, and pigs were all immune to the bacteria. So, in July 1984, Dr. Marshall decided to swallow a large number of the bacteria himself to test his ideas about H. pylori. For five days, he noticed nothing. Then, he began to experience nausea and vomiting. Although these symptoms resolved on their own after 14 days, an endoscopy on the eighth day revealed that he had developed severe gastritis. Still, Dr. Marshall’s presentations at gastroenterology meetings did little to convince doctors who proceeded to treat ulcer patients with new acid-reducing drugs, specifically H2-blockers like cimetidine (Tagamet) and ranitidine (Zantac).”

The Hungarian physician Semmelweis, during the mid-nineteenth century, confronted a similar problem when he dared to postulate that hygiene had something to do

with an alarmingly high mortality rate among pregnant women at his hospital in Vienna. Semmelweis proposed that hands be washed before examining patients with a solution of chloride of lime. Using his own hygienic procedures, mortality dropped from 18 percent to only 2.5 percent. But then, as now, effectuating a positive clinical outcome isn't sufficient to create a paradigm shift among traditional, nostalgia-oriented physicians. Many physicians, among them the doctors of the Academy of Paris and even Rudolph Virchow at Berlin, regarded his work unfavorably. No one would pay for his antiseptic solution, and those who did use it, were often ridiculed. Dr. Semmelweis’ research was either ignored or ridiculed. Not until after Semmelweis' death, was he recognized as the clinical predecessor to Joseph Lister and what we now assume as a given, antiseptic procedures. The National Case Study for the Teaching of Science published the following on the subject of Dr. Semmelweis:

"Despite the dramatic reduction in the mortality rate in Semmelweis' ward, his colleagues and the greater medical community greeted his findings with hostility or dismissal. Even after presenting his work on childbed fever (more technically referred to as puerperal sepsis) to the Viennese Medical Society, Semmelweis was not able to secure the teaching post he desired, and so he returned to Hungary. There, he repeated his successful handwashing attack on childbed fever at the St. Rochus hospital in Pest. In 1860, Semmelweis finally published his principal work on the subject of puerperal sepsis but this, too, was dismissed. It is believed that the years of controversy and repeated rejection of his work by the medical community caused him to suffer a mental breakdown. Semmelweis died in 1865 in an Austrian
mental institution. Some believe that his own death was ironically caused by puerperal sepsis. “

I will say quite sincerely, and without satire, that if insurers and governmental entities had reviewed Dr. Semmelweis' studies on hygiene, they would have found his studies to be woefully inadequate, failing not only because of their small sample size, but the absence of control groups and the presence of confounding variables. One would only hope that had Medicare reviewed the work of Dr. Semmelweis, that it would have been as gracious with his work as it was with the studies on prolotherapy.

A more parsimonious explanation for insurer's and governmental entities resistance to "covering" prolotherapy, involves economics. With more and more physicians discovering the benefit of prolotherapy in their practice, the cash outlays would logically increase for insurance companies, that is, if a literal and concrete analysis were to be made. Such a view seems short-sighted at best. Therapies that work are almost always less expensive in the long run. Therapies that work are good for the patient, good for the employer, good for the economy in general and good for the insurance industry, that is, if the industry values a more long-term fiscal perspective, as opposed to a narrow focus upon next quarter's profits.

Blue Shield’s Use of Legal Terminology

Blue Shield chose to incorporate words and phrases in its published findings that have clear and well established legal meanings in the State of California, e.g., “standard of care” and “negligence,” among others. Specifically, with regard to the use of the legal term “negligence,” Blue Shield “found” Dr. Doe “negligent,” as though it had prosecuted the case in a civil court of law before a trier of fact. Notwithstanding Blue Shield’s liberal borrowing of legal terms and publishing its conclusions in a de facto “verdict,” Blue Shield failed to accurately reflect the meanings of the terms it utilized in its published conclusions.

According to legal experts, in the State of California, expert testimony is required to help prove, by a preponderance of the evidence, that the defendant physician breached the applicable standard of care. Unlike Blue Shield’s reliance upon only one of its medical directors, in a court of law, expert opinion is seldom unilateral and almost always involves the testimony of two experts. The credibility of expert witness opinions are put to the test under cross examination.

Blue Shield “found” Dr. Doe to be “negligent.” Blue Shield utilized a legal term with well established meaning when it made its official finding. According to legal experts, in the State of California, a physician’s duty to his patient is inextricably linked to any assessment of professional negligence. The following jury instruction (California BAJI 6.00, 8th. Edition) legally defines the duty a physician owes his patient. Failure to fulfill these obligations legally constitutes negligence:

"In performing professional services for a patient, a physician has the duty to have that degree of learning and skill ordinarily possessed by reputable physicians, practicing in the same or similar locality and under similar circumstances. The further duty of the physician is to use the care and skill ordinarily exercised in like cases by reputable members of the profession practicing in the same or similar locality under similar circumstances, and to use reasonable diligence and his or her best judgment in the exercise of skill and the application of learning, in an effort to accomplish the purpose for which the physician is employed. The failure to fulfill any such duty is negligence." [BAJI 6.00.1 (8th. Ed.)]

Despite Blue Shield’s liberal use of legal terminology, it did not assess the issue of negligence using anything remotely resembling the legal standard in the state of California. Clearly, by the legal standard, Dr. Doe did NOT breach his duty as a physician when he utilized prolotherapy and/or paravertebral facet injections, without imaging guidance.
In consideration of the following:

1. The literature reviews presented herein;
2. Medicare's NCA on the subject of prolotherapy;
3. The official coding guidelines found in the CPT;®
4. The medical community's standard use of paravertebral facet injections without the assistance of fluoroscopic guidance.

a logical conclusion is that:

Blue Shield's published "concern" for its member's welfare, along with its declaration of a finding of "negligence," appears to be nothing more than a single, uniquely harsh opinion, successfully transformed, then veiled, under the impenetrable cloak of an official finding.

Request for Reconsideration

Dr. Doe intends to request a reconsideration of Blue Shield's opinions as stated in its data bank. Such a reconsideration may include the following:

1. Blue Shield can withdraw its earlier "findings" and re-establish Dr. Doe's status as a full participating member in its healthcare network, or;
2. Blue Shield can retract its "personalized" defamatory conclusions with regard to Dr. Doe's professional negligence and accusations that he jeopardizes his patient's welfare by declaring, in written form, within its own network and by written correspondence to anyone or organization that has likely read Blue Shield's published statements:
   a. Blue Shield acknowledges that its findings are NOT based upon a single patient event or report of a complication or misadventure from Dr. Doe's medical practice.
   b. Blue Shield acknowledges that Dr. Doe has been in practice for 25 years and enjoys a stellar reputation in the community and the nation, as an expert on the use and application of Prolotherapy, in addition to his general practice as a family physician.
c. Blue Shield acknowledges that its previously disseminated findings were based SOLELY upon its philosophical belief that prolotherapy is not effective, and/or its failure to distinguish between the actual injection procedures utilized in Dr. Doe's practice; specifically, the distinction between paravertebral and intra-articular facet injections.

d. Blue Shield acknowledges that the facet injection procedures utilized by Dr. Doe are officially recognized within the CPT ® guidelines, published by the American Medical Association.

Of interest to this matter would be Blue Shield's answers to the following questions:

1. What is the name and what are the professional qualifications of the individual identified only as “a Blue Shield Medical Director” within Blue Shield's report?
2. What expertise does this medical director (identified in #1 above) have with regard to the use of prolotherapy and/or paravertebral facet blocks?
3. What are the names and professional qualifications of the members of the Blue Shield Credential’s Committee?
4. What expertise do these members (identified in #3 above) have with regard to the use of prolotherapy and paravertebral facet blocks?
5. By what standards, methods and factual basis, does Blue Shield define the “standard of care” made reference to in its narrative report?
6. Upon what factual basis did Blue Shield conclude that its member’s welfare were in any way compromised by Dr. Doe's care and treatment?
7. When Blue Shield made reference to “facet blocks,” was it referring to intra-articular and/or paravertebral facet blocks?
8. What “literature,” including the complete bibliography relied upon, did Blue Shield make reference to when it wrote that “the literature has failed to establish its (referring to prolotherapy) effectiveness nor establishes it as the standard of care?”
9. Who reviewed the “literature” and ultimately concluded that prolotherapy is not effective and does not meet the standard of care?
10. Upon what facts, data or patient information, did Blue Shield's single unnamed medical director develop his concerns for Dr. Doe's patient's welfare?
11. Do any members of the Blue Shield Committee, who were involved in the matter of Dr. Doe, have affiliations, allegiances or memberships in organizations or medical technology companies, that would directly or indirectly benefit from their published statements or actions, in regard to Dr. Doe?

Blue Shield's Focus Upon Prolotherapy

In the process of researching this report, the author came upon a letter written by C. Everett Koop, M.D. The letter was written nearly a quarter of a century ago, while he was still a professor of pediatric surgery at the University of Pennsylvania. As you can see from the letter, included in the Appendix of this report, a courtesy copy had been sent to Joseph Ichter, M.D., an employee of Blue Shield of Pennsylvania. In the letter, it appears as though Dr. Koop was writing on behalf of a practitioner who utilized Prolotherapy, lobbying for the proposition that Blue Shield of Pennsylvania should consider including prolotherapy as, to use Dr. Koop's words, a "charge item." It is unclear as to whether the addressee, Dr. Harold Walmer, D.O., had submitted his prolotherapy charges to Blue Shield of Pennsylvania, and had been denied payment.

More recently, at least one other prolotherapy practitioner has received correspondence from Blue Shield of California that suggests something about Blue Shield of California's attitude when it comes to those who utilize prolotherapy in their practice. In a letter dated February 6, 2003, Blue Shield of California sent an arguably disquieting letter to an osteopathic physician who utilizes prolotherapy. In that letter, found in the Appendix of this report, Blue Shield of California stated the following:

"Using improper CPT coding could be considered abusive billing. If this is being done knowingly by a provider, it could be considered fraudulent. We are bringing this matter to your attention so that you are aware of Blue Shield policies and as a way for you to review your billing practices to assure that your submitted codes accurately describe the services performed."
An objective observer might logically conclude that the recipient of this letter had submitted claims that appeared, on their face, suspicious and worthy of review. That was not the case, however. What is particularly noteworthy is the fact that Blue Shield acknowledged in its letter that a review of the doctor's recently submitted claims did NOT document that he had been inappropriately billing for prolotherapy. Moreover, no evidence of past improprieties was presented to justify the tone of the letter. This begs the question, then, as to how a physician who had been found to be submitting claims in a proper and forthright manner, would receive such a letter? The answer may be illustrative of Blue Shield's modus operandi, when it comes to the distinction between an individual practitioner, and someone who, regardless of his past behavior, is branded with a scarlet letter because he associates himself with the use of prolotherapy:

"Your claims came to our attention by way of your name listed on a website advertising Prolotherapy."

The letter concluded with a cautionary note to the recipient who, once again, had been targeted merely by associating himself with the use of prolotherapy. He was cautioned that his practice could be "flagged for prepayment review," should he ever commit the misdeeds for which he had never engaged in. Finally, I will draw the reader's attention to the handwritten notes, presumably made by the physician, that not only did he not engage in the targeted practices outlined in Blue Shield's letter, but:

"For the record, I do not do any insurance billing for prolotherapy and on my billing form I only use the code M0076."

Summary

Blue Shield's statements, as published in its NATIONAL PRACTITIONER DATA BANK: HEALTHCARE INTEGRITY AND PROTECTION DATA BANK, have brought into question Dr. Doe's personal and professional competency, clinical acumen and reputation as a health care provider. With regard to prolotherapy, the Blue Shield findings, which helped to form the basis for its "concern" for its member's welfare, represents an isolated and uniquely harsh assessment of prolotherapy.
Blue Shield's conclusions, with regard to Dr. Doe's use of paravertebral facet injections and prolotherapy, are not reflective of any objective and/or legal assessment of what legally constitutes negligence in the State of California, as well as other states in the Union. Blue Shield's findings ignore the current coding guidelines found in the CPT, which distinguish between injection procedures used with and without fluoroscopic guidance. Blue Shield not only judged prolotherapy to be without value, it made the quantum leap and characterized the use of prolotherapy as creating a cause for concern for patient’s welfare, and its use as a basis for a finding of physician negligence.

Physicians and Insurers

Ultimately, physicians and healthcare providers have mutual interests with regard to providing patients with safe and effective treatments. Blue Shield should seriously consider the comments made my Dr. C. Everett Koop, in this regard:

"[T] hat many insurance companies do not pay for Prolotherapy, largely because their medical advisors do not understand it, have not practiced it, and therefore do not recommend it." (emphasis added)

It bears repeating what Dr. Koop went on to say with regard to why some may be skeptical of prolotherapy:

"Finally, Prolotherapy seems too simple a procedure for a very complicated series of musculoskeletal problems which affect huge numbers of patients. The reason why I consented to write the preface to this book is because I have been a patient who has benefited from Prolotherapy. Having been so remarkably relieved of my chronic disabling pain, I began to use it on some of my patients." (emphasis added) (See Footnote 6)
Refusing to pay for prolotherapy because it is considered investigational, is a far cry from deeming that treatment’s use as justification for terminating a physician’s membership in its healthcare network, based upon concerns for patient’s welfare.

**Implications for Physicians Who Utilize Prolotherapy in Their Practice**

To clinicians who utilize prolotherapy, it is difficult to comprehend Blue Shield's actions. According to Dr. Koop, ignorance, and lack of familiarity with prolotherapy, explains the motivations of many insurance companies who refuse to pay for prolotherapy. But as previously addressed, Blue Shield has not only refused to pay for prolotherapy, it has terminated the membership of one of its physician members in its affiliate network because of, in part, that physician utilized prolotherapy.

Given the ever-increasing number of medical and osteopathic physicians who utilize prolotherapy, often times achieving outstanding results, paired with the continuing research on prolotherapy, one must question whether or not ignorance, alone, can explain Blue Shield's behavior.

Blue Shield of California acknowledged that a single medical director concluded, from his review of the literature, that prolotherapy was not effective nor met the standard of care criterion. Blue Shield's medical board went along with that single, unnamed medical director's opinion, and transformed it into an official declaration. Blue Shield took its review of the literature on prolotherapy and made a heretofore unheard of quantum leap criticism of the treatment. It did this when it concluded, in a published statement, that the use of prolotherapy helped to form the basis for its official finding of "negligence" and represents a threat to patient's welfare.

Dr. Doe is a recognized expert in the use of prolotherapy. His expertise, in this regard, have gained national acclaim. His patient success stories number in the thousands. His practice is well respected by physicians in his local and regional community, and across the country. He has established a referral network from both Medical and Osteopathic physicians. He enjoys a stellar reputation among a wide range of medical specializations.

With specific reference to prolotherapy, the statements of condemnation made against Dr. Doe may as well have been made against ANY physician who utilizes prolotherapy in his practice. Blue Shield's conclusions, along with its action to terminate Dr. Doe’s membership within its healthcare network, while specific to
Dr. Doe, are tantamount to a "shot over the bow" of anyone who utilizes prolotherapy as a treatment modality, including those practitioners who are studying prolotherapy in the clinical setting. Blue Shield's actions against one physician are, in effect, actions against every physician who utilizes prolotherapy and/or paravertebral facet blocks. Letters to other practitioners, whose only apparent sin is that they are associated with the use of prolotherapy, corroborate these conclusions.

The Responsibility of Prolotherapy Practitioners

Physicians who utilize prolotherapy are being forced to confront important, potentially precedent setting conclusions and actions, taken by one of the nation's largest insurers. Blue Shield of California has taken the quantum leap of equating the use of prolotherapy with jeopardizing patient’s welfare. Since Medicare's NCA on prolotherapy has invited more strident and methodologically sound research on the efficacy of prolotherapy, then perhaps now is the time for the various independent physician's organizations, which teach and promote prolotherapy, to join together and form a "research counsel." This proposed counsel would be funded by the various groups whose members perform prolotherapy. Incorporating former Medicare or insurance industry scientific review committee members, a two to five year research project should be created. The prolotherapy research project would incorporate bullet-proof scientific methodologies, large and irrefutable research samples and experimental designs, and at least two independent research ombudsmen whose sole task is to oversee the scientific validity of the research project during its progress.

The battle over the efficacy of prolotherapy has gone on too long. Its practitioners are some of the finest physicians in the country. Prolotherapy is in a state of scientific limbo, having made it into our patient's hearts and as an indispensable treatment option, but having failed to win over the most skeptical among us. Such is the nature of our current political and medical healthcare zeitgeist.

This latest escalation of the battle between healthcare providers, and physicians who utilize prolotherapy, represents a difference in kind from earlier conflicts. When Blue Shield stated that the use of prolotherapy caused such a concern for its member's welfare, that it had to terminate a physician's membership in its network, it raised the stakes for anyone who uses prolotherapy. Blue Shield's actions etched a bright white line, of
unprecedented historical significance, within all of the critiques of prolotherapy. Unless Blue Shield's actions are reversed, its edict on the subject establishes a potentially formidable precedent that represents a very real and direct threat to ANYONE who utilizes prolotherapy in their practice. As it stands now, one of prolotherapy's foremost teachers and proponents has been made an example of:

In conclusion, the words of Martin Niemoiler, written at Dachau, in 1942, come to mind. His work is entitled: *I did not speak*

"First they came for the Communists;
I did not speak because I was not a Communist.
Then they came for the Jews;
I did not speak because I was not a Jew.
Then they came to fetch the workers, members of trade unions;
I did not speak because I was not a trade unionist.
Afterwards, they came for the Catholics;
I did not say anything because I was a Protestant.
Eventually they came for me,
and there was no one left to speak"

Martin Niemöller, Pastor
Dachau, 1942.

Postscript: After this report was written, the author discovered that Blue Shield of California had submitted, as is required by law, its “findings” to the Osteopathic Medical Board of California. After an exhaustive and complete review of Blue Shield’s documentation in support of its assertions that Dr. Doe had jeopardized his patient’s welfare and had acted negligently in his role as a physician, the Board, on September 30, 2003, wrote the following:

“Dear Dr. Doe:

The Consultants Committee of the Osteopathic Medical Board of California has completed their review of the above-referenced case. (re: 805 Reporting, Blue Shield of California, Our Ref No. xx-xxxx-xxxx.

After a lengthy review of the information received, your response and all pertinent records, the consultants agreed that there is no merit to this case. The case is therefore closed in this office. Thank you for your cooperation in this matter.”

Prolotherapy and Paravertebral Facet Blocks
Serious Cause for Concern or Something Else?

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