

# Health Technology Assessment

## Bone Growth Stimulators

### Public Comments and Responses

**August 3<sup>rd</sup>, 2009**

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## HAYES INC. RESPONSE TO PUBLIC COMMENTS

*Hayes Inc. is an independent vendor contracted to produce evidence assessment reports for the WA HTA program on behalf of The MED Project at Oregon State Health Science University. For transparency, all comments received during the comments process are included. However, comments related to program decisions, process, or other matters not pertaining to the report are acknowledged through inclusion, but are not within the scope of response for report accuracy and completeness.*

*Note on comments below: Industry comments are in italics, Hayes response in normal font below italicized font.*

### Response to Industry Comments

#### DJO

*“The draft Hayes report indicates few CMF clinical studies in peer reviewed literature upon which to appraise the safety and efficacy. As noted in the report, the research entitled, “Combined Magnetic Field Accelerate and Increase Spine Fusion” was published in the well respected Spine journal.”*

This publication was reviewed in the Hayes (2004a) systematic review and thus is evaluated as evidence from a systematic review.

*“Additional published studies describe the mechanism of action behind the CMF technology.”*

Mechanism of action is not a criterion upon which quality ratings were assigned. However, some additional minor clarification was added to the **BACKGROUND** section of this report regarding this issue.

*“The optimal range of electromagnetic frequencies for bone growth stimulation has been shown to be less than 150Hz (See Section I, Documents 5-6, “The effect of Low-Frequency Electrical Fields on Osteogenesis” and “Orthopedic Basic Science”.) CMF operates at a continuous frequency of 76.6 Hz, within the optimal range.”*

This is not a criterion that was evaluated within this rapid review assessment.

*“Additional published studies support the clinical benefit of CMF. The Hayes draft report does mention the Hanft, et.al. research on “The Role of Combined Magnetic Field Bone Growth Stimulation as an adjunct in the treatment of Neuroarthropathy/Charcot Joint”, in which CMF significantly accelerated the consolidation process of acute, phase 1, Charcot joint. Another example is the peer reviewed research from Longo, et.al.*

*demonstrates that CMF was efficacious in patients who had failed to progress to healing despite prior prolonged use of PEMF stimulation.”*

The Hanft et al. (1998) study referenced by DJO is evaluated in the Hayes (2004a) systematic review and is thus included as evidence from a systematic review. The Longo et al. (2000) article falls outside of the search parameters (2003 to present) for studies published since the systematic reviews. As a case series (n=20), it would not have significantly improved the quality of the body of evidence for noninvasive electrical stimulation and nonunion of fractures.

*“Finally, the very rigorous OL1000 pre-market approval (PMA) research clinical trial had again very strict entrance and outcome criteria, verified by an independent, blinded panel. (See Section I, Document 9, “Multicenter Nonunion Clinical Investigation of the CMF OL1000 Bone Growth Stimulator”).*

*“The rigor of the OL1000 PMA study is evidenced by the fact that the OL1000 is the only bone growth stimulator to not have efficacy results downgraded as a result of long-term follow-up studies. In addition, the Patient Registry Data, approved by the FDA, shows an overall 75.1 percent heal rate (See Section III, Document 1, “Patient Registry Data in OL1000 product brochure.)”*

The review was limited to studies published in the peer-reviewed literature. Neither of these sources meets this criterion.

*“The draft report notes that in general bone growth stimulation devices are safe and effective. Both the OL1000 and SpinaLogic devices are FDA approved Class III medical devices... FDA has determined that the OL1000 and SpinaLogic devices are **safe and effective** for their intended uses (See Section II, Documents 1-6, FDA approval letters).”*

The rapid review assessment notes the safety of all noninvasive bone growth stimulators.

*“Patient ease of use and quality of life are important factors used by the Hayes report to evaluate health technologies. There is abundant information available supporting the OL1000 and SpinaLogic as being extremely easy to use and as improving quality of life for the patient... (See Section III, Documents 4-5, Patient Manuals.”*

Convenience of use and potential for improving pain and functional outcomes are noted in the expanded **Conclusion and Discussion** section of the final draft.

*“Cost effectiveness is another factor generally reviewed in technology assessments. One of the reasons DJO Incorporated has been so successful with our bone growth stimulator is because their cost effectiveness compared to surgery.”*

The literature search did not find any economic evaluation studies pertaining to specifically to CMF devices or to noninvasive electrical stimulation devices, in general.

## **EBI, LLC (Biomet)**

*Comments that the review did not reflect the role of bone growth stimulators in clinical practice, the value of avoiding surgery, and the lack of alternative nonoperative treatments for nonunion*

Revisions have been made in several sections of the report to underscore the importance of both radiographic outcome and other clinical endpoints (reduced pain, improved function, and enhanced quality of life). In fact, the Findings section of the report now parses out radiographic outcomes and secondary outcomes such as those detailed in the preceding sentence. Avoidance of further surgery was not an outcome reflected in the key questions defined for this review. However, this goal is now acknowledged in the ***Conclusions and Discussion*** and the lack of quantitative data demonstrating this type of impact was noted. The expanded ***Discussion*** also reflects positive aspects of the technology, such as convenience and safety.

*“Upon initial review, it is noted that the assessment is flawed in its exclusion of clinical studies prior to 2003. These papers are relevant and should be included in the review. Osteogenic stimulators have been used in clinical practice for more than 30 years. Most of these devices were FDA approved and came on the market in the 1970’s and 1980’s. Clinical studies published in that period should not be excluded based simply on their date of publication.”*

*“Hayes should not have arbitrarily limited their analysis to data generated within the last few years, when a comprehensive evaluation of all relevant data is needed for effective understanding of clinical importance.”*

This report represents a *rapid review* of the state of the evidence, not a complete health technology assessment. Systematic reviews that evaluated studies published prior to 2003 were included as part of the body of the evidence. Information provided by those reviews about individual studies published prior to 2003 played a critical role in the assignment of quality ratings for each technology and indication.

*“In addition, a significant portion of clinical data from the various FDA PMA studies are not included in this assessment. This is a significant supportive body of evidence - which was generated under the FDA’s guidance for conducting clinical studies on nonunions and other indications. The PMA studies for these devices are the basis for the various determinations that osteogenic stimulators are safe and effective for their labeled indications.”*

*“Hayes should not discount and dismiss the seven FDA PMA controlled studies.”*

The review was based only on studies published in the peer-reviewed literature.

*“Long-standing national coverage policies for electronic bone growth stimulators have been in place since 1980”*

*“Most payors have periodically expanded their coverage policies for these devices based on scientific evidence that the technology contributes to improved net health outcomes.”*

*“There is a significant body of scientific evidence appropriate to this unique therapy that supports positive medical coverage policies.”*

Medical coverage policies were not included in the MED Core Source List for guidelines.

### **Smith & Nephew, Inc. (Exogen)**

*“What is the evidence of efficacy and effectiveness (accelerated healing, bone fusion, reduced pain, improved functional status) of bone stimulators (ultrasound, invasive, and non-invasive) compared to treatment without stimulators:”*

*i. Long bones*

*Data submitted to FDA as part of the Exogen nonunion Premarket Approval Application (PMA) submission and FDA approval includes delayed/nonunion in various long bones including the tibia, femur, fibula, humerus, etc.”*

The FDA PMA data do not meet inclusion criteria for this rapid review. Conclusions regarding safety and efficacy for this rapid review are derived solely from an assessment of the peer-reviewed, published medical literature.

*“The HTA Draft Report assigns a “very low” rating to these data, thus ignoring some pragmatic methodological considerations when studying nonunions. Dijkman, et al. assert that it is “generally considered unethical to conduct placebo-controlled studies on their treatment” because it would deny treatment to a patient that by definition of receiving a nonunion diagnosis will not spontaneously heal.”*

The quality of evidence for LIPUS and delayed/nonunion was considered low because of several methodological limitations in addition to the lack of placebo controls. The evidence grade must reflect the type of study designs and any other weaknesses relative to conduct of studies as well as the direction and magnitude of the results. Pragmatic and ethical considerations are taken into account when translating the evidence assessment into policy.

*“The HTA Draft Report on p. 35 states that the overall healing rates for LIPUS were good to excellent ranging from 73%-100%. Since the HTA DRAFT REPORT further cites a success rate for surgical treatment of nonunion fractures from 68%-96% (p. 15; Dijkman, et al., 2009; Gebauer, et al., 2005) the noninvasive, patient friendly option of LIPUS seems particularly attractive from a patient perspective.”*

The apparent safety and convenience of LIPUS are noted in the expanded Conclusion and Discussion section of the final draft.

*“Bones of wrist:*

*Many of the above studies include patients with fractures in bones of the wrist including the ulna, radius, and scaphoid.*

*iii. Other bones: The Exogen nonunion PMA data set includes the following bones:*

*Long bones- tibia, femur, radius, humerus*

*Short bones- metatarsal, metacarpal*

*Other bones- calcaneus, clavicle, pelvis, rib, scaphoid, ankle”*

Only evidence from the published, peer-reviewed literature was considered. Published data regarding the efficacy of LIPUS for the treatment of bones of the wrist and other bones is scarce and of low quality. Also, in the few studies that included various types of bones, outcomes were not reported separately.

*“When used to treat subgroups with comorbidities that may increase risk of fracture non-union with fresh fractures of the long bones:*

*There is an abundance of data that risk factors can impair a patient's ability to heal and lead to nonunion. One of the most widely agreed upon risk factors is smoking. Cook, et al. evaluated data from the LIPUS distal radius and tibia fracture studies to understand the impact of LIPUS on patients that smoke.*

*Additional data adapted from the Heckman dataset (below) indicates that LIPUS can help mitigate other risk factors including advanced age and fracture gap size.”*

The “additional data” from the Heckman did not appear in the published literature.

*“Gebauer, et al. showed that in a diabetic animal model, LIPUS appeared to mitigate the risk associated with diabetes.”*

Article selection criteria excluded data from animal studies.

*“The Cook data referenced above on patients that smoke includes patients with fractures of the distal radius. Additionally, Mayr, et al. (attached) evaluated LIPUS' ability to accelerate fresh fractures of the scaphoid including patients that smoke. The author found a consistent acceleration with other studies including the patients that smoke.”*

The article by Cook (1997) was included in the 2003 Hayes review; results are described in Table 1 and were taken into account as “evidence from systematic reviews” in the **FINDINGS** discussion of the LIPUS section.

The Mayr et al. (2000) article was included in the systematic review by Busse et al. (2009), but the review authors do not mention that patients were smokers. This is a deficiency of the review by Busse et al.; however, the Mayr article is small (n=28) and would not dramatically add to the already-noted evidence (see evidence for key question #3 in the LIPUS section) of a relatively greater treatment effect in patients with risk factors than in patients without risk factors.

*“What is the evidence of cost implications and cost effectiveness? While the HTA draft report addresses safety and efficacy, it does not address cost. We identified three published cost studies.”*

Cost implications and cost effectiveness were outside the scope of this rapid review. Furthermore, all three cost studies referenced in the public comments are derived from clinical abstracts/posters not yet published in any peer-reviewed scientific journal. As a result, these cost studies were not included for discussion under **ECONOMIC EVALUATIONS**.

#### *Other comments*

##### *Mechanism of Action*

##### *Key Differences*

##### *Dose*

Additional information regarding mechanism of action has been added to the **BACKGROUND** section. Detailed information regarding technical differences between the different types of bone growth stimulators falls outside of the scope of this rapid review.

*“It is important to note that the PMA nonunion FDA approval for LIPUS is not specific to any bone. The FDA approval is for nonunion of all bones exclusive of skull and vertebra.*

*FDA Approvals- In recognition of the varying clinical data and efficacy in different patient populations, the FDA has granted distinct approvals for each device.”*

FDA approval is not a factor in critical appraisal of the evidence.

##### *Price & Coding*

Details regarding price and coding information was outside the scope of this rapid review.

##### *Missing Data*

*“The HTA Draft Report posted appears to rely entirely on two sources: 1) the LIPUS Hayes report from 2003 and 2) the Busse meta-analysis from 2009. Unfortunately, there*



*was no independent analysis done, thus any errors or oversight in search criteria in the aforementioned analyses are carried through to the current tech assessment. Given the above observations, we would like to submit for consideration the following studies which appear to have been omitted. Consideration of the entire body of evidence will provide for a more complete understanding of the relevance of this technology in the orthopedic setting.”*

The comprehensiveness of the two systematic reviews and the adequacy of their analysis were taken into account in forming conclusions. Based on the inclusion criteria of studies evaluating at least 50 patients, Coughlin et al. (2008) and Gold et al. (2005) were excluded from this rapid review. Their inclusion would not have improved the overall quality of considered evidence because of their very small sample sizes and lack of controls.

Only clinical trials published in the peer-reviewed medical literature selected for review, hence clinical abstracts (Graf and Merritt; Straus et al., 1999; Schofer et al., 2009) were excluded from this rapid review.

#### *Ongoing Research & Studies*

Discussion regarding ongoing research and future studies are outside of the scope of this rapid review.

#### *Quality Ratings & Consistency*

*“Within the HTA Draft Report, the systematic studies and the primary studies are used to provide a quality rating. It is unclear from the text of the report what criteria are used to assign the quality rating. It does not appear that the GRADE approach for assigning quality of evidence and strength of recommendations has been used as was the case in the Busse paper. This ambiguity confounds the aggregation of the Busse quality ratings with those in the current HTA Draft Report thus rendering the entire report difficult to interpret.”*

The quality of selected primary studies was assessed with the aid of MED checklists, and overall bodies of evidence by outcome and indication were graded according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. The report has been revised to enhance clarity and improve interpretation of the findings.

*“The rationale for the differential data requirements for LIPUS and electrical stimulator data is not explained and clearly has the potential to skew the report in favor of one technology over another. A more complete explanation is needed to better interpret the report.”*

This rapid review was not intended to be a comparative assessment of the various BGS technologies. Inclusion criteria for each technology was identified independent of one another, and was partially based on the volume of evidence

available for each technology. The studies excluded from the LIPUS section would also not have met the 20-patient cutoff for the electrical stimulation set of evidence. Also, because they did not have control or comparison groups, they would not have improved the overall quality of evidence (details in Appendix II).

### *Statistics*

*“A common theme throughout the HTA Draft Report is the subjective assessment of clinical study size.”*

Selected studies were not judged solely or even primarily on the basis of sample size. However, quantity of data (# of studies and sample sizes) was a consideration in judging the quality of entire bodies of evidence for different outcomes.

*“The size of a clinical study cannot be judged solely on the basis of the number of patients, but must take into consideration the effect size. However, it is not statistically appropriate to criticize a study for having small numbers of patients if the effect of the treatment is statistically significant. Figure 2 shows the effect size for a number of the published studies.*

*Table 2 shows the number of patients required to reach statistical significance based on an effect size of -1.”*

Even if the study was large enough to show a statistically significant change (effect), the smaller the sample size, the less likely it is to be representative of the population of interest. In addition, appropriate sample size, power analyses, and clinically relevant effect sizes should all be determined *a priori* to determine the likelihood of finding valid conclusions from the population being evaluated.

*Criticisms of the review by Busse et al. (2009).*

Compared with the Busse review, both the first and final drafts of the report are different in these respects: less harsh view of radiographic fusion as an outcome measure for healing; improvements in pain, fracture and QOL treated as secondary rather than primary outcomes; and losses to follow-up balanced with consistency of results across studies. These differences are made more explicit in the final draft. Conclusions in both drafts are more favorable than those expressed by Busse et al.

### **Orthofix** (page numbers refer to the *initial draft* of the report, not the final version)

*Data on volume of fusion procedures and prescription of stimulators (pp. 6, 16):* Unclear source; information cannot be cited.

*Comments about positive conclusions in earlier (2004) Hayes report (p. 9):* Earlier assessments were reevaluated in light of the formal evidence grading system adopted by Hayes after 2004, other published systematic reviews, and recently published studies.

*Comments simply citing results from studies that were included in the selected reviews or selected from recent primary literature (pp. 12, 62, 66):* All study results, and the quality of the studies, were taken into account in the analysis.

*Relationship between age and bone healing (p. 12, 87):* Statement in report has been amended to read “not been expressly studied in the elderly”. Suggested reference by Lu et al. does not appear to be a study of bone growth stimulation; other references have been cited to make the point that age affects bone healing.

*Citations of studies investigating mechanism of action (pp. 16):* Not important, given the objectives of the report.

*Additional details on proper use of and features of devices (pp. 18, 20):* Not necessary, given the objectives of the report.

*Additional guidelines (p. 21):* Submitted guidelines are from payers; these were not among the guideline sources specified by the MED Project.

*Comments on AHRQ guidelines (p. 22):* One comment refers to CMS policy, which is described under Policy Context (BACKGROUND). The other comment is a critique of the AHRQ guideline conclusions; the guideline section is meant to be descriptive only.

*Mooney 1993 (p. 24, 62, 66):* Such a study could not be located in the published literature. Mooney et al. (1990) is part of the evidence provided by the 2004 Hayes review and included in Appendix VII. Positive results from this trial do not change the observation of “conflicting results” between this trial and another. Small corrections as suggested by Orthofix have been made in Table 5.

*Discussion of study by Foley et al. (2008) (p. 72, 73):* The difference of “92.6% v. 86.7%” cited by Orthofix corresponds to the “small difference” in the text. No reason given for the suggestion to “Remove the last 2 sentences of the paragraph”. Text has been corrected to read “in patients older than 50 years of age”; other phrase referring to men versus women still appears to be correct.

*Suggestion that a small body of evidence supports noninvasive electrical stimulation in failed fusion/arthrodesis (p. 81):* The existence of studies with negative results needs to be acknowledged.

*Cost data (p. 83):* Unpublished data/studies were not considered for this report. The Washington State data from HCUP are not available without purchase.

*Addition of 2004 and 2008 studies to tables from 2004 Hayes report (Appendix V) (p. 123):* These 2 studies are included in Table 6 and were discussed in the report.

*Miscellaneous:* (a) Some comments appear to have no relevance to the context in which they are placed or provide no information in addition to the text (pp. 11, 16, 26). (b) Comments provide information not appropriate to the context but which is mentioned elsewhere in the report (p. 81). (b) Changing “two studies” to “three studies” would be incorrect; context is discussion of the *primary* studies selected *in addition* to systematic reviews (p. 71). (c) Suggested correction appears to be exactly same as text (81). (d) Suggested references are preclinical studies or from textbooks (p. 87, 88).

### **PUBLIC COMMENTS**

DJO = 4 pages

EBI, LLC (Biomet) = 2 pages

Smith & Nephew, Inc. = 1 page

Orthofix = 1 page

**DJO:**

July 21, 2009

Health Technology Assessment Program  
676 Woodland Square Loop SE  
P.O. Box 42712  
Olympia, WA 98504-2712

RE: HTA Draft Report - Bone Growth Stimulator

To Whom It May Concern:

Thank you for the opportunity to submit public comment regarding the recent draft report on the safety and efficacy of bone growth stimulators. Specifically, we would like to address the preferred non-invasive electrical stimulation devices and the Combined Magnetic Field (CMF) technology.

The CMF OL1000 and SpinaLogic devices utilize state of the art CMF electromagnetic technology, which increases the specificity and potency of treatment. CMF is the only technology to employ both static and dynamic fields clinically proven to stimulate production of growth factors in osteoblasts and fracture callus in vitro and in vivo. Due to this specificity and potency of the CMF signal, a 30-minute per day treatment is all that is required. The 30 minute daily treatment seriously increases patient compliance and therefore, improved clinical outcomes.

We would like to address the criteria that are used in making an assessment of a particular technology.

**Published Studies and Clinical Benefits**

The draft Hayes report indicates few CMF clinical studies in peer reviewed literature upon which to appraise the safety and efficacy. There are, in fact, numerous published studies that support the clinical benefit of CMF technology and demonstrate efficacy utilizing evidence based medicine.

As noted in the report, the research entitled, “Combined Magnetic Field Accelerate and Increase Spine Fusion” was published in the well respected Spine journal. This was a very rigorous, prospective, double-blind, placebo-controlled, randomized study with strict entrance criteria. The research revealed that CMF increased fusion success by 21 percentage points – a 49 percent improvement in fusion (see Section I, Document 1, “Combined Magnetic Field Accelerate and Increase Spine Fusion”)

Additional published studies describe the mechanism of action behind the CMF technology. (See Section I, Documents 2-4, “The Role of Insulin-Like Growth Factors II in Magnetic Field Regulation of Bone Formation”, “Combined Magnetic Fields Increase Insulin-Like

Growth Factor II in TE85 Human Osteosarcoma Bone Cell Cultures” and “Biophysical Stimulation of Fracture Healing Mediated by IGF-II”). CMF remains the only technology with an FDA approved mechanism of action. (See Section II, Document 2 – FDA approval letter.)

The optimal range of electromagnetic frequencies for bone growth stimulation has been shown to be less than 150Hz (See Section I, Documents 5-6, “The effect of Low-Frequency Electrical Fields on Osteogenesis” and “Orthopedic Basic Science”). CMF operates at a continuous frequency of 76.6 Hz, within the optimal range.

Additional published studies support the clinical benefit of CMF. The Hayes draft report does mention the Hanft, et.al. research on “The Role of Combined Magnetic Field Bone Growth Stimulation as an adjunct in the treatment of Neuroarthropathy/Charcot Joint”, in which CMF significantly accelerated the consolidation process of acute, phase 1, Charcot joint. Patients treated with CMF were able to resume ambulation in less time, often with less joint destruction and with less residual deformity. (See Section I, Document 7, “The Role of Combined Magnetic Field Bone Growth Stimulation as an adjunct in the treatment of Neuroarthropathy/Charcot Joint”). Another example is the peer reviewed research from Longo, et.al. demonstrates that CMF was efficacious in patients who had failed to progress to healing despite prior prolonged use of PEMF stimulation. (See Section I, Document 8, “Successful treatment of Recalcitrant Nonunions with Combined Magnetic Field Stimulation”).

Finally, the very rigorous OL1000 pre-market approval (PMA) research clinical trial had again very strict entrance and outcome criteria, verified by an independent, blinded panel. Patients in this study had very difficult to heal, established non-union fractures, with the average time from injury at 29.3 months and an average of 2.5 prior surgeries. The study revealed that patients with the OL1000 had an outcome rate for these very difficult to treat fractures of 60.7 percent with an average time to heal of 6.0 months. Fractures less than two years post-injury had an outcome heal rate of 73.6 percent, outstandingly, tibia fractures healed at a rate of 75.6 percent. (See Section I, Document 9, “Multicenter Nonunion Clinical Investigation of the CMF OL1000 Bone Growth Stimulator”).

The rigor of the OL1000 PMA study is evidenced by the fact that the OL1000 is the only bone growth stimulator to not have efficacy results downgraded as a result of long-term follow-up studies. In addition, the Patient Registry Data, approved by the FDA, shows an overall 75.1 percent heal rate (See Section III, Document 1, “Patient Registry Data in OL1000 product brochure.”)

### **Safety and Effectiveness**

The draft report notes that in general bone growth stimulation devices are safe and effective. Both the OL1000 and SpinaLogic devices are FDA approved Class III medical devices. As you know, Class III is the most stringent regulatory category for devices and requires the filing of a pre-market analysis (PMA). The PMA approval process is lengthy and extremely rigorous. As stated on the FDA website, “PMA approval is based on determination by FDA

that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).” FDA has determined that the OL1000 and SpinaLogic devices are **safe and effective** for their intended uses (See Section II, Documents 1-6, FDA approval letters).

In addition, there are no known adverse events from the use of the OL1000 or SpinaLogic bone growth stimulators. There has never been a liability claim ever made for either the products, and the overall product complaint rate is less than 0.5 percent. Note the vast majority of the small numbers of complaints are related to mechanical issues, with no impact on patient safety. Also, there have not been any Medical Device Reports (MDRs), a reporting requirement of FDA, which allege any injury-related problems associated with our bone growth stimulators.

#### Patient Ease of Use and Quality of Life

Patient ease of use and quality of life are important factors used by the Hayes report to evaluate health technologies. There is abundant information available supporting the OL1000 and SpinaLogic as being extremely easy to use and as improving quality of life for the patient.

A key advantage of both products is the treatment time of only 30 minutes per day. In comparison, competitive bone growth stimulators require much longer treatment times, up to 24 hours per day. (See Section III, Documents 1-2 Product information.)

The list below, summarizing several of the features and benefits of the products, details how easy the OL1000 and SpinaLogic devices are for patients to utilize.

- The short 30 minute daily wear time minimizes any potential inconvenience to the patient.
- While wearing the device, that patient will feel no sensation and is able to ambulate for normal daily activities as the devices are ergonomically designed for comfort.
- The OL1000 and SpinaLogic are all-in-one devices, with simple one-button operation.
- Unlike other non-invasive bone growth stimulators, the treatment field for the CMF units is large and does not require precise placement over the fracture or fusion for successful healing,
- No direct skin contact is required when treating with our device.
- The built-in LCD screen displays easy-to-read information, including a 30-minute treatment countdown clock and a compliance monitor.

(See Section III, Documents 4-5, Patient Manuals”).

Our bone growth stimulators are non-invasive, and improve the patients quality of life by allowing them to heal without extensive recovery time and associated costs of surgery, and return to work sooner.

#### Cost-Effective Health Care

Cost effectiveness is another factor generally reviewed in technology assessments. One of the reasons DJO Incorporated has been so successful with our bone growth stimulator is because their cost effectiveness compared to surgery. The list price for the OL1000 is \$4900. For example, the average cost for treating a tibia non-healing fracture is over \$37,000, which includes open reduction, debridement, stabilization, fixation, intramedullary nailing and bone grafting.

A pseudoarthrosis of the lumbar spine can have a significant surgical cost impact to the payer as well. The cost associated with a revision surgery for a lumbar pseudoarthrosis can easily climb to over \$60,000 including the hospital stay. Not to mention, the “The Lumbar Spine text by Harry N. Herkowitz, International Society for Study of the Lumbar Spine” also highlights the enormous consequential impacts. He states that, “The psychological ramifications are universal and usually become more important after failed or multiple surgeries...” Additionally, “Social factors may contribute to disability and the social consequences of disability are unavoidable”. “Depression; conversion mechanism and economic, legal and work related factors can affect a patient...” The clinically proven adjunctive use of the SpinaLogic device is a cost effective non-invasive solution.

DJO Incorporated is a leading manufacturer of bone growth stimulation and a well renowned company. DJO Incorporated is a leading global provider of high-quality, orthopedic devices, with a broad range of products used for rehabilitation, pain management and physical therapy. We also develop, manufacture and distribute a broad range of surgical reconstructive implant products. DJO Incorporated is proudly accredited by the Accreditation Commission for Health Care (ACHC) in recognition of compliance with the ACHC standards for health care services (See Section IV, Document 1, ACHC certificate).

Thousands of physicians have prescribed the CMF bone growth stimulation products and thousands of patients have successfully healed their non-union fractures and spinal fusions. Since the FDA approval of the first OL1000 device in 1994 and the SpinaLogic device in 1998 the CMF technology has been proven to be a non-operative standard of care for non-union fractures and as an adjunct to lumbar spinal fusion surgery.

The clinical benefits of the FDA approved, Class III, CMF OL1000 and SpinaLogic devices are clear. We are confident that upon review of the enclosed materials you will find the CMF technology is easy to use, cost effective, safe and effective and delivers a great quality of life for your patients.

We look forward to discussing this information with you. Please contact me directly for any further comments or documentation.

Sincerely,  
Brad Niemann  
Senior Vice President  
Regeneration  
DJO Incorporated



**EBI, LLC (Biomet):**

Biomet Spine and Biomet Trauma would like to provide the following preliminary comments on the Washington State Health Care Authority's Health Care Draft Technology Assessment on Bone Growth Stimulation.

Biomet would like to emphasize that the stated intended use of the assessment is to provide research assistance. It is not intended to be used as the sole basis for determining coverage policies or defining treatment protocols or medical modalities.

This stated purpose is of particular importance, as the assessment does not clearly articulate the important role osteogenic stimulators have as a well-accepted and valuable treatment option used in every day clinician practice settings. These nonsurgical devices are a safe and effective treatment for nonunions and spinal fusions. Clinicians generally use these devices as an alternative to nonunion bone graft surgery or repeat spinal fusion without the associated complications and comorbidities. The report is unclear in its understanding of the role these devices have in a typical clinical practice setting and the value clinicians place upon them.

Additionally, Hayes does not appear to understand that while many of the clinicians only refer to positive radiographic endpoints in their studies, it is understood by any treating clinician that positive health outcomes for osteogenic stimulation is both the positive radiographic healing in addition to no subsequent surgery.

It is in this context that the assessment did not understand the important role bone growth stimulators provide, whether used as a treatment alternative to surgically repairing a nonunion or as an adjunct to spinal fusions.

Upon initial review, it is noted that the assessment is flawed in its exclusion of clinical studies prior to 2003. These papers are relevant and should be included in the review. Osteogenic stimulators have been used in clinical practice for more than 30 years. Most of these devices were FDA approved and came on the market in the 1970's and 1980's. Clinical studies published in that period should not be excluded based simply on their date of publication.

In addition, a significant portion of clinical data from the various FDA PMA studies are not included in this assessment. This is a significant supportive body of evidence - which was generated under the FDA's guidance for conducting clinical studies on nonunions and other indications. The PMA studies for these devices are the basis for the various determinations that osteogenic stimulators are safe and effective for their labeled indications.

Overall this assessment did not adequately include pre2003 data nor FDA PMA results. It also failed to provide some important insight from outside experts on the clinical value of

these devices and the rationale for their use.

The assessment is unclear on a number of key technology and clinical issues. We believe that there are some significant flaws and bias in the evaluation:

For example:

- Long-standing national coverage policies for electronic bone growth stimulators have been in place since 1980.
- Most payors have periodically expanded their coverage policies for these devices based on scientific evidence that the technology contributes to improved net health outcomes.
- There is a significant body of scientific evidence appropriate to this unique therapy that supports positive medical coverage policies.
- Hayes should not have arbitrarily limited their analysis to data generated within the last few years, when a comprehensive evaluation of all relevant data is needed for effective understanding of clinical importance.
- Hayes should not discount and dismiss the seven FDA PMA controlled studies.
- The author(s) did not clearly understand osteogenic stimulation in context of the surgical treatment alternatives for nonunions and failed fusions.
- The author(s) did not appear to be well informed from a clinical basis in that they did not understand the clinical significance of nonunions and failed fusions and the existing requirements to intervene in some appropriate matter.
- The author(s) had not been provided or did not understand the treatment algorithm for nonunions and failed spinal fusions.
- Surgical repair of nonunions and failed fusions carry with them real life complications commorbidities. In addition, a significant number of bone graft repairs need a second surgery.

The existing body of evidence and numerous peer-reviewed studies from the medical literature was not adequately reviewed nor understood in their significance to the clinical conditions being treated.

More than 600 studies have been identified in the medical literature addressing the clinical use and scientific underpinnings of electrical bone stimulation

We urge readers of the assessment to consider the full scope of evidence supporting the important role treating physicians have placed on these devices after more than more than 30 years of clinical use and positive health outcomes in their practices.

Jim Bechtold  
Senior Vice President,  
Reimbursement & Government Affairs  
Corporate Compliance Officer - Insurance Services  
EBI, LLC (doing business as Biomet Trauma and Biomet Spine)

**Smith & Nephew:**

Ms. Leah Hole-Curry, J.D.  
Director, Health Technology Assessment  
Washington Health Care Authority  
676 Woodland Square Loop  
Lacey, Washington 98503

Thank you for the opportunity to comment on the Evidence-Based Report on Bone Growth Stimulators. Smith & Nephew, Inc. is a global medical technology business, specializing in Orthopaedics, including Reconstruction, Trauma, Endoscopy, and Advanced Wound Management. Smith & Nephew Orthopaedics manufactures and markets the EXOGEN 4000+\* Bone Healing System, a non-invasive low-intensity pulsed ultrasound device that is FDA approved to heal nonunions and accelerate the time to healing for certain fresh fractures.

We support your pursuit of EBM in the orthopaedic space and are committed to advancing this field. We back up our commitment with significant funding for clinical studies and are currently enrolling patients in two large Investigational Device Exemption studies evaluating the safety and efficacy of LIPUS in new patient populations.

We commend the Washington State Health Authority for pursuing an evidenced-based approach to policy development. However, we take issue with some aspects of the draft evaluation of the evidence. Specifically, important factors and key clinical data have not been taken into account including:

- key published clinical studies with relevant outcomes;
- peer reviewed article that fully elucidates the mechanism of action of LIPUS;
- published cost-effectiveness analyses;
- difference in FDA approvals across reviewed technologies;
- the method used to characterize evidence as low, moderate, and high quality is not outlined in the report;
- finally, we found inaccuracies in reporting results of some clinical studies.

We believe that these deficiencies result in findings that do not accurately characterize the health benefits of bone growth stimulation nor the proper place of the technologies in the orthopedic surgeons' armamentarium. Please find attached, a more complete summary of our findings as they relate to the Health Technology Assessment with supporting documentation for your review. We look forward to the opportunity to discuss the contents of the attached during the public hearing scheduled for August. In the interim, please advise if you have any questions about the attached information. Thank you for your consideration and dedication to an Evidence Based Medicine approach to the category of bone stimulation technologies.

Barbara Rohan  
Vice President, Government Affairs

**Orthofix:**

July 21, 2009

Leah Hole-Curry, JD  
Health Technology Assessment Program  
HTA Draft Report – Comments  
676 Woodland Square Loop SE  
PO Box 42712  
Olympia, WA 98504

Dear Leah:

On behalf of Orthofix, I appreciate the opportunity to respond to the HTA Draft Report on Bone Growth Stimulators.

Attached you will find a copy of the original draft report to which we have added comments, concerns and questions. For ease of perusal, we have flagged our comments on the following pages: 6, 9, 11, 12, 16, 18, 20, 21, 22, 24, 26, 62, 66, 71, 72, 73, 81, 83, 87, and 88, in addition to the tables on page 123.

If you have any questions, please do not hesitate to contact me at 916.543.9404 (office), 916.765.4702 (cell) or via email at [beascott@orthofix.com](mailto:beascott@orthofix.com).

Thank you again for all your guidance and support.

Best Regards,

Bea Scott  
National Accounts Manager

**RESPONSE TO OTHER PUBLIC COMMENTS**

Patient and Citizen = 2 comments

Physician and Healthcare Professional = 17 comments

Industry and Manufacturer = 3 comments

*For transparency, all comments received during the comments process are included. However, comments related to program decisions, process, or other matters not pertaining to the report are acknowledged through inclusion, but are not within the scope of response for report accuracy and completeness.*

**PATIENT AND CITIZEN ~****Steve Davis**

Citizen

*I am e-mailing my support of the Exogen Ultrasound Bone Healing System.*

*Exogen is indicated for non-union fractures with a 86% healing rate, and is the only bone growth stimulator approved by the FDA for fresh fractures and accelerates the healing process at 38% with only a 20 minute per day regimen.*

*Please consider these facts in reviewing the Washington state DSHS and Labor and Industry medical policies in providing the best in class technology for orthopedic patients in this state!*

**Jen VanVleet**

Patient

*I am a patient that benefited from using an Exogen Bone Stimulator prescribed to me by my doctor. I broke my ankle and was in fear of loosing time off work. My doctor prescribed the Exogen as the ultrasound is the only stimulator that has proven to accelerate fresh fractures. This was extermely beneficial for me and I was able to get to work sooner. I am fortunate that my insurance recognizes the benefit of using Exogen to accelerate my fracture healing so I can get back to sooner.*

**PHYSICIAN AND HEALTHCARE PROFESSIONALS ~****Alan Woodle, MD**

Past President, Washington State Podiatric Medical Association Consultant to Pacific Northwest Ballet

*I have been in private practice as a foot/ankle specialist for 30 years and have used all the various bone stimulators for delayed/non- healing bone fractures with a very high success rate (assuming it is applied per the proper case criteria). I can highly recommend their use. My favorite unit is the Smith and Nephew Exogen Ultrasound bone*

*stimulator because of its high success rate and ease of patient use/ compliance. Feel free to contact me if you have any questions.*

**Bill Brooks, PA-C**  
Advanced Orthopaedic Institute

*I work in a busy orthopedic practice in Arlington. We have used Exogen for patients with non-unions of most all bones. Additionally, we use it for patients with high risk acute fractures. Scaphoid, metatarsal and tibia fractures are always challenging to heal. This is further complicated when patient smoke or have diabetes. We have seen great results using Exogen in both acute and non-union settings. We have been able to avoid surgery or re-surgery in many cases. The fact that patients only need to do a 20 minute daily treatments helps with compliance. I have never had much luck getting patients to where a bone stimulator for 10 hours a day.*

*We are fortunate that plans like Regence, Premera, Aetna and United healthcare cover Exogen in the acute setting. This has been of benefit to many of our patients. It seems unfortunate to me that I am unable to provide a similar acceleration in healing to my patients who are covered by DSHS or L&I. Please cover Exogen for acute fractures in patients with co morbidities which complicate healing.*

**Carlos Agüero, MD**  
Skagit Island Orthopedics

*I am an Orthopedic Physician Assistant; I have been practicing Ortho for 37 years here in MtVernon Wa. I have used many bone growth stimulators on my patients for years. I have found the Exogen stimulator most useful and effective of the group. The fact that it requires only 20 min makes compliance less of an issue. It is the only one indicated for fresh fractures.*

**David Mokhtee, M.D.**

*I wish to provide feedback for the bone stimulator review. A significant portion of my practice is L&I. I am a hand specialist in Seattle. I use Exogen on a regular basis for scaphoid non-unions. I have been happy with the healing that my patients have achieved within a few months using the Exogen for 20 minutes per day. This has been a useful tool for my practice, which has allowed me to avoid repeat surgery in patients. I have seen data that Exogen accelerates fresh fracture healing. I can see Exogen being a valuable tool for getting L&I patients back to work more quickly, by beginning treatment in the acute setting. Scaphoid fractures are perhaps the most difficult fracture in the body to heal. When a patient smokes or has diabetes the process becomes even more difficult. Exogen helps to mitigate the impact of comorbidities on the healing process. Additionally, the daily treatment time is very short. Patients are able to comply with a 20 minute treatment. My hope is that L&I would give us greater flexibility to utilize Exogen earlier in the fracture healing process to get patients back to work and reduce cost to the system.*

**David Primrose, MD**

Neurosurgeon, Virginia Mason Medical Center, Seattle

*I think patients should have the option to have a bone growth stimulator if they are at relatively high risk of fusion failure. It should be covered for redo fusions, multilevel fusions, pts on steroids. Thanks for considering it.*

**Greg Grant, MD**

*It has come to my attention that there is a decision going on in regards to government funding for bone growth stimulators and other medical devices. There are indeed limited funds in this world and people must make decisions on how best to utilize the monies supplied by tax paying citizens. I must say the only reason bone growth stimulator funding is a questionable expense is that no one making the decisions has broken a bone or treats broken bones. If such were the case the question would not be on the table.*

*As a concerned citizen of the state, and as a practicing surgeon, I want to voice my opinion that bone growth stimulators do work and the money saved by not funding them will be instead spent by paying surgeons, surgery centers, hospitals and supplies that go to healing this bone that is broken and painful. The bone is broken! If you remove the funding of bone growth stimulators, I recommend you also remove payment for all other aspects of fracture management, otherwise money will not be saved, and in fact money spent on the management of fractures will go up and in the end you will be losing money instead of saving it. Physicians do not randomly order these devices. Physicians are not reimbursed for their use, the benefit is solely for the patient. This is why government will find it difficult to run health care, the people in charge try and cut everything but themselves and their high wages, the lone drain on the system.*

*These devices are used on bones and fractures that do not heal well, or have not improved with time as expected. Bone growth stimulators assist patients with both acute and chronic fractures. If the physician feels the bone is going to heal on its own, no bone growth stimulator would be ordered, there would be no need. DSHS patients are often high risk as they have a higher incidence of tobacco use, poor nutrition and generally are in unemployed and uneducated situations in life. The injuries often involve alcohol and/or drug use meaning the injuries are often more severe. If you think bone growth stimulators are expensive, think about disability payments. Now there is a big bill.*

*Healthcare reform is coming, if this is any indicator, I fear top medical care will be obtained elsewhere. Let those who know, make the decisions. You make decisions that have repercussions on many people, listen to the many people. If you remove what makes top healthcare work, you are left with either ordinary healthcare or poor healthcare. If those people who provide top healthcare are not allowed or trusted to make top healthcare decisions, then I suppose we will be left with healthcare that was decided by someone who provides inferior healthcare or people who just make rules but never went to medical school or haven't used the medical system very much. My recommendation is*

*to spend money on making sure physicians do not take kickbacks, not on regulating how healthcare is doled out. Thank you.*

**Jeffrey Pearce, MD**

Neurological Associates of Washington

*As a practicing Neurosurgeon in Washington State I support L&I coverage for PEMF bone growth stimulators in spinal fusion patients who are at risk for or are developing a non union. My interpretation of the literature on the subject and my personal experience support their use.*

**Jefferson Cartwright, M.D.**

Advanced Orthopaedic Institute

*Dear Committee:*

*I have treated many fractures in my career. I have absolutely no doubt that Exogen is the most effective product on the market for healing non-unions and speeding up acute fracture healing. I have seen multiple studies published in JBJS which showed 38% acceleration in fresh fractures. More importantly, one study showed a 6 fold reduction in delayed or non-unions when patients were treated with Exogen compared to placebo. Though I am a surgeon, I do not want to subject my patients to primary surgeries or revisions unless absolutely necessary. The use of Exogen has helped me get patients healed and back to work more quickly than would be customary without Exogen. Maybe the most important fact about Exogen is that it requires 20 minutes a day of use. I have not had one patient tell me that Exogen is a burden to use.*

*The Exogen stimulator has also proven itself to be more effective than any electrical stimulators in my hands.*

*I treat DSHS patients as well as L&I patients, I understand that managing cost is important. However, quality patient outcomes and quicker return to work are very important as well. If you make Exogen available for non-unions at 90 days and for high risk fresh fractures with risk factors; costs will be reduced and patients will heal more quickly.*

**Jerome DaSilva, MD**

*Ultrasound bone stimulator has been a vital asset in the healing of my difficult to treat fresh fractures. Bone ultrasound prevents the negative effects of patients who smoke, have diabetes or osteoporosis and in most cases have prevented a second surgery or bone graft. With today's tough economy, the cost of the bone stimulator is justified by having patients go back to work sooner and to prevent delayed/non unions which is extremely costly to the healthcare system. I highly recommend that bone ultrasound remains an option for me to treat these patients.*



**Keleigh Nersasian, MD**

*It is my understanding that the Washington clinical reviewing the bone stimulator class of products. Exogen is currently the only ultrasonic bone stimulator that is FDA approved to accelerate fresh fractures. In my practice, this is important for certain patients who are at a higher risk for delayed/non union or at a high risk of a second surgery. Patients that have benefited from the use of Exogen are patients who smoke and have diabetes. The Exogen has proven to mitigate the negative effects that these comorbidities have on the healing process. Also, I use Exogen for patients with complex fractures. Private insurance covers these high risk patients and in my clinical opinion has saved the insurance company several thousands of dollars by applying Exogen for these type of patients.*

*I hope you review and update your guidelines to reflect at least the FDA approved guidelines as well as private insurance guidelines for Ultrasound Stimulation which is a different class than the electric stimulators.*

**Laura Topp, NP**

*Hello, I am a Nurse Practitioner in Ortho Trauma. We use Exogen bone stimulator for our acute traumatic injuries, high impact and complex tibia fractures. Our usage is in line with current clinic guidelines but I believe it would be useful to eliminate the waiting period and provide broader indications. Our patient population is increasing complex with multiple medical comorbidities, and this product is helpful to have as an adjunct to our current treatment modalities.*

**Leslie Cline, MD**

Trauma OHSU

*I understand that you are reviewing the guidelines for the bone growth stimulator class of products. I have had positive clinical experience with Exogen Ultrasound Bone stimulator in my patients who I treat acutely who are at a high risk of non unions, for ex: smokers and diabetics. I also use acutely for difficult to treat fractures such as the Pilon, Tibia, scaphoid, Jones and Femur fractures. I also use Exogen for patients who have not healed in my clinic for over 3 months and try to avoid a second surgery or bone graft. I highly encourage that you update the guidelines as I believe that Ultrasound has saved the clinic the cost of further surgery and helps to get patients back to work or their activities of daily living sooner.*

**Mark Galloway, PA-C**

*Since I began using the Exogen fracture healing system in our practice at Northwest Orthopedic Surgeons, I have seen significant increase in callus formation and healing in all patients that used the Exogen unit. The results are quite impressive, especially in those*

*patients with co-morbidities. Also, the 20 minute a day regimen helps a great deal with compliancy. In closing, I fully support the use of the Exogen fracture healing system.*

**Mary Goldmann, PA-C**  
Washington Orthopaedic Center

*I have used the bone stimulator in 1 case and thus far in a patient with several risk factors for mal/non-union and believe its helping him heal faster than he would be otherwise. I recommend adding it to the DSHS program as it could likely save money long-term as patients would require less surgery for ORIF, therefore, decreasing the costs incurred associated with surgery, post-op care, complications, etc.*

**Rex Nilson, D.P.M**

*It is our understanding that the State of Washington is conducting a review of bone stimulator products.*

*We have had good success with bone stimulators for our patients. We have especially found that the Exogen system is successful for our patients because it requires only 20 minutes a day, and patients are more compliant with the easier regimen. The indication for immediate use of Exogen, rather than the 90-day delay imposed for other kinds of bone stimulators, means that our patients can start the healing process sooner.*

*It is our hope that this review will lead to better patient access to a beneficial, successful resource to assist in fracture healing. Thank you for your consideration.*

**Thomas Burghardt, DPM, FACFAS**

*I am writing this email in support of the Exogen Bone Healing System to be approved for treatment of non union and certain new fractures by DSHS. I am a Podiatrist and see nonunion of fractures and also Jones type fractures that will progress to non-union. I have seen a benefit from using the Exogen on these patients in my practice. I have found the unit safe and effective.*

**William J. Tronvig, D.P.M**

*We have had the opportunity to use the Exogen Bone healing system in our office. It appears to be an excellent alternative to invasive surgical actions on patients that need the extra stimulation to help in bone growth rather than surgical intervention. This unit should be approved by DSHS so that our patients can choose this as an alterative treatment to surgery.*

*We have found this to be a great benefit in treating our patients with those hard to heal fractures; especially those who smoke, have diabetes or other co-morbidities. I have had noticed great success on those we have treated with the Exogen bone stimulator and have noticed a quicker healing time reducing the amount of surgical interventions needed. I*

*have found that patient compliance is high because it only takes 20 min a day apposed to 1 hour a day Physical Therapy or Surgery.*

*We believe it is a cost effective alternative that saves our patients, the Physician, as well as the insurer time and money.*

*I hope to see the Exogen approved on WA DSHS policies in the near future.*

## **INDUSTRY AND MANUFACTURER ~**

### **David Holman**

Smith & Nephew

*I work for Smith and Nephew. I speak patients every day who have fractures. Their goal is to get back to their normal activities as quickly possible. Exogen is the only stimulator that has proven to the FDA that it is effective for accellerating certain fresh fractures. I have seen many patients benefit from early treatment with Exogen. As for non-unions, Exogen is approved for non-unions of any bone except cranium and vertabrae. Most insurance plans consider a non-union to be at 90 days without healing. DSHS policy requires 6 months without healing. Please consider bringing you treatment guidelines for non-unions within the standards set by most everyone else. Medicare, Tricare, DOD, VA, Federal Employees, L&I, Regence, Premera, Aetna, United, Cigna, Uniform, Humana, First Choice, Great West etc. all consider 90 (or fewer) days to be the appropriate standard. Please allow us to help your patients in a timely fashion.*

### **Jores Grigorian**

Smith and Nephew

*In 1994 - Exogen treatment was approved by the FDA for accelerating time to healing for conservatively treated tibial diaphysis fractures and distal radius fractures. Clinical data submission included two prospective, randomized, multi-center, double blind studies.*

***There are no published studies of using electrical stimulation to heal fresh fractures of the bones prone to nonunion. Low intensity pulsed ultrasound using Exogen is the only bone-stimulating device FDA approved for use in some fractures. Several studies of the use of ultrasound in fresh fractures have been published and available for the public to read.***

*In general, studies have found the following for Exogen Bone Growth Ultrasound Stimulator by Smith Nephew (HCPC E0760):*

- *Faster time to heal in the ultrasound group versus placebo group*
- *A reduction in the number of days to heal and*
- *A reduction in the incidence of delayed unions.*

*The patients really have remarkable compliance rate with the Ultrasound Unit Exogen due to its 20 minutes a day treatment time and its highest efficacy rate of 86% or more. Physicians also prefer this unit since it is also FDA approved for acute fractures with comorbidities present. Majority of the commercial health plans recognize both non-union and fresh fracture for Exogen (Ultrasound Bone Growth Stimulator HCPC E0760).*

*There are also no known contraindications for the EXOGEN device. That being said I hope the committee truly looks at the electric and ultrasound as being two complete different products and update their respective medical policy to reflect the expanded indications/medical guidelines for Exogen (ultrasound bone growth stimulator).*

**Shirley Bevens**  
Smith & Nephew

*In my experience, the Exogen Bone Stimulator has had a positive impact in saving money for the hospital when applied to patients with high risk factors such as smoking and diabetes as well as for patients with high energy or low blood supply type fractures such as the Jones, scaphoid and Tibia. The cost savings to avoid a second surgery or bone graft or repair of a delayed nonunion is far more than the cost of the ultrasonic bone stimulator. Clinical case studies have proven time and time again that Exogen mitigates the negative effects of comorbidities such as smoking. One case, a patient started Exogen for her mildly displaced Jones fracture and was able to avoid surgery because she healed with Exogen. Many cases that we treat save an enormous amount of money for the healthcare system. Exogen is the only bone stimulator that is indicated for these type of fresh fractures and is definitely not in the same class as the electrical stimulators which are only indicated to treat non unions. I hope that you will follow at least the FDA guidelines and majority of the private payer guidelines whom have made these decisions based on clinical experience and published clinical trials.*