

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA
Winston-Salem Division**

Civil Action 1:07CV363

DANNY WAYNE GRAYSON,

Plaintiff,

**minSURG CORPORATION,
ORTHOPEDIC DEVELOPMENT
CORPORATION and JAMES
DOULGERIS,**

Defendants.

**COMPLAINT
(JURY TRIAL DEMANDED)**

NOW COMES the plaintiff, complaining of the defendants, and alleges and says:

I. PARTIES AND JURISDICTION

1. Plaintiff is a citizen and resident of Clemmons, North Carolina, which address is located in the Middle District of North Carolina, Winston-Salem Division. Defendant minSURG Corporation employed plaintiff on November 1, 2006 as a Vice-President of TruFUSE® Sales of the company reporting to James Doulgeris.

2. Defendant minSURG Corporation is a Florida corporation, having been incorporated in March of 2004, with its head office located in Clearwater, Florida. Defendant minSURG Corporation is a subsidiary corporation of defendant ORTHOPEDIC DEVELOPMENT CORPORATION (herein "ODC") which is a Florida Corporation, having been incorporated in October of 2003, also with its principal office located in Clearwater, Florida.

3. Defendant JAMES DOULGERIS, (herein "DOULGERIS") is a citizen and resident of Florida and recruited plaintiff for his employment position as a Vice-

President of Sales, TruFUSE®. Defendant **DOULGERIS's** titles are that of President, CEO and a Director of **ODC** and President of minSurg Corporation.

4. Jurisdiction is founded upon 28 USC §1332, complete diversity, in that the plaintiff is a resident of the State of North Carolina and all defendants are residents of the State of Florida.

II. FACTUAL ALLEGATIONS

A. Plaintiff's employment to market TruFUSE® Technology

5. Prior to employing plaintiff, defendant DOULGERIS told plaintiff he needed plaintiff's sales experience and connections in the orthopedic surgical product field to help make TruFUSE® a successful product. DOULGERIS told plaintiff minSURG/ODC wanted a marketing plan for TruFUSE® which would maximize sales in the shortest time period so as to make the company a targeted takeover candidate. Therefore, plaintiff's compensation had two components: (1) cash compensation in the form of salary, commission and expense reimbursement and (2) stock options in minSURG Corporation.

6. Prior to employing plaintiff defendant, DOULGERIS told plaintiff the following in order to induce plaintiff's employment:

- that TruFUSE® had been used in over 200 cases to date and enjoyed a nearly 100% success rate, all of which had been performed safely, delivering good to excellent outcomes without exception at half the cost of alternatives;
- that there had never been a revision or failure;
- that two more training sessions for 70 additional surgeons, one at an American Association of Orthopedic Surgeons (AAOS) sponsored cadaver lab and the second at a Johns Hopkins affiliated lab, would be completed by November 20, 2006;
- that TruFUSE® was being used in over two dozen cases per week with volume increasing exponentially;

- that minSURG had a Scientific Advisory Board composed of prominent physicians, healthcare professionals and business executives;
- that ODC is managed by experienced health care executives and governed by a strong and diverse Board of Directors;
- that a cost and outcome study is being conducted by BayCare Health Services, a 9 hospital group in Tampa Bay, Florida and a long term outcome study is being performed internally by minSURG in cooperation with minSURG's participating surgeons. Results of both would be provided periodically.
- that the TruFUSE® solution would be used to fuse spinal facets to limit patients' pain caused by persistent and disabling back pain experienced by large segments of the population, by using donated human bone as a structural element to stop the joints from moving and eventually heal the joints together, rather than using metal screws to forcibly hold them together with the principal benefits of TruFUSE® compared to pedicle screw based methods including: (1) orthobiologic advantage, (2) comparable stability, (3) technical simplicity, (4) lower cost and (5) shorter recovery time;
- that the use of TruFUSE® Facet Fusion Allograft in some spine surgical procedures, allows for the surgeon and health care facility to change the code of procedure to a posterior spine fusion (CPT 22612 and DRG 498), which nearly doubles the surgeon's reimbursement and nearly triples the facility's reimbursement;
- that TruFUSE® had excellent outcomes;
- that TruFUSE® is the ONLY orthobiologic solution for facet fusion;
- that TruFUSE® offered technical simplicity;
- that DOULGERIS stated in an email to plaintiff, "I don't mess with people's lives. A commitment has to be solid and honest." (e-mail to plaintiff on October 18, 2006.

7. Because of defendant DOULGERIS's representations, plaintiff accepted the position of Vice President of TruFUSE® Sales having the duties and functions over

North American Sales, which included developing and managing the distributor network to ensure continuity of company sales goals.

8. Plaintiff's compensation included a monthly base salary of \$16,667, commissions in accordance with a schedule of commission percentages and based on sales revenue, which are payable on the 15th of the following month, in accordance with the company's commission schedule, year-end bonus, stock options, vacation leave of 15 calendar days per calendar year, expense reimbursement and health insurance.

B. Plaintiffs empirical evidence and experience with TruFUSE® after beginning employment.

9. Plaintiff, still living in Clemmons, North Carolina, began employment on November 1, 2006 in accordance with the contract of employment, attached hereto and incorporated herein by reference as Exhibit A.

10. Shortly after beginning employment, plaintiff learned of graft tolerance issues and overall graft design problems that could lead to a post-operative problem with the TruFUSE® procedure resulting in graft pullout. Plaintiff also learned that:

- No clinical study or company data existed to support DOULGERIS's claim of "nearly a 100% success rate";
- No clinical study or company data existed to support DOULGERIS's claim of TruFUSE® being used on over 200 surgical patients from March through September of 2006 without any known complications;
- No clinical study or company data existed to support DOULGERIS's claim that TruFUSE® is the ONLY orthobiologic solution for facet fusion;
- No clinical study or company data existed to support DOULGERIS's claim of "short term results indicate that hospital length of stay is reduced by half and recovery/rehabilitation times are reduced significantly as well;"

- No clinical study or company data existed to support DOULGERIS’s claim of TruFUSE® being an excellent alternative to bone growth stimulators for posterior fusion;
- No clinical study or company data existed to support DOULGERIS’s claims of “this initial stability remains intact until the joint has healed together;”
- No clinical study or company data existed to support DOULGERIS’s claim of patients who undergo TruFUSE® surgery are “fully recovered in three months or less;”
- No clinical study or company data existed to support DOULGERIS’s claim of TruFUSE® surgery “providing immediate pain relief;”
- No clinical study or company data existed to support DOULGERIS’s claim of “patients report significant pain relief while still in the recovery room;”
- No clinical study or company data existed to support DOULGERIS’s claim of TruFUSE® surgery providing “enhanced patient satisfaction via shorter hospital stays and reduced recovery and rehabilitation time;”
- No clinical study or company data existed to support DOULGERIS’s claim that TruFUSE® has already shown that it shortens historical average length of stay by half, reduces the need for additional bone graft supplements and lessens utilization of instrumentation required to achieve a secure fusion, as well as decreasing the need for adjuncts like bone stimulators;
- No clinical study or company data existed to support Doulgeris’s claim of that “TruFUSE® surgery is the Truest solution for back pain;”
- No clinical study or company data existed to support DOULGERIS’s claim of “Patients - prospect of immediate pain relief and likely permanent pain relief from a minimally invasive outpatient surgery where the patients can go back to work or normal activities in a few weeks and be fully recovered in a few months;”
- No company data existed to support DOULGERIS’s claim that a cost and outcome study was being conducted at BayCare Health Services, a 9 hospital group in Tampa Bay, Florida or that a long term outcome study was being performed internally in cooperation with participating surgeons;

- No company data existed to support DOULGERIS's claim of 70 additional trained surgeons by November 20, 2006, nor was TruFUSE® being used in two dozen cases per week as DOULGERIS claimed;
- No company Good Manufacturing Practices program existed, or exists to the date of the filing of this complaint, as required by the Food and Drug Administration (FDA) prior to the sales and marketing of TruFUSE®;
- DOULGERIS falsely claimed a "Case Study" of a 45 year old male patient, where there was less than 12 days post-operative patient follow-up;
- DOULGERIS falsely claimed medical reviews of inflated case numbers;
- DOULGERIS falsely claimed numbers of participating active and certified surgeons;
- DOULGERIS falsely claimed "this is the only spinal fusion that can be done on an outpatient basis;"
- DOULGERIS falsely claimed TruFUSE® offers a solution to individuals for whom medicine provides little relief, but do not yet qualify for a fusion surgery;
- DOULGERIS falsely claimed that an arrangement had been made for Bernard Guiot, M.D. to come on board fulltime for training as soon as March 15, 2007;
- DOULGERIS falsely claimed clinical data regarding the percentage rates of graft pullout and pseudoarthrosis;
- DOULGERIS falsely claimed that if TruFUSE® has a 50% pullout rate and a 25% return of symptom, ODC and minSURG will still thrive in their market spot with TruFUSE®;
- DOULGERIS falsely claimed that the "angle of attack with TruFUSE® is almost straight down;"
- DOULGERIS falsely claimed that, "As such, TruFUSE® provides a surgical solution where there was none before;"
- DOULGERIS falsely claimed that minSURG has been collecting increasing evidence that spinal segments fused with TruFUSE remain immobilized even in

- the absence of one or both dowels because primary arthrodesis occurs around the compaction tunnel and not into the dowel.”;
- DOULGERIS falsely claimed accuracy of data and information contained in marketing and training material and online website content, approving it for distribution to surgeons;
 - DOULGERIS false claimed that a multi-center study was underway for a prospective comparison of single level PSF or circumferential fusion compared to the TruFUSE® technique;
 - DOULGERIS falsely claimed that minSURG has been collecting increasing evidence that spinal segments fused with TruFUSE® remain immobilized even in absence of one or both dowels because primary arthrodesis occurs around the compaction tunnel and not into the dowel;
 - DOULGERIS falsely claimed that “we require surgeons to be trained and qualified to use TruFUSE®;”
 - DOULGERIS falsely claimed that he hired a qualified Director of Professional Education to design, implement and direct the TruFUSE® Training program;
 - DOULGERIS falsely stated his credentials, education and experience in the medical device industry;
 - DOULGERIS falsely claimed and claims “TruFUSE® is proving to be a popular option with a large surgeon population;”
 - DOULGERIS falsely claimed key surgeons and industry financial leaders have “endorsed” or “blessed” TruFUSE®;
 - Surgeons, hospitals and distributors were and are provided marketing materials and online website content by ODC that focus on reimbursement, by stating:
 - “Simple billing -- reimbursement coding is the same as traditional posterior fusion. Typically, code 22612 is used for lumbar spinal fusion and code 22614 is used for spinal fusion and extra segment augmentation” (Reference: www.trufuse.com, Surgeons, Surgeon Benefits);
 - “Good for Patients, Good for Business” (Reference www.trufuse.com, Distributors;

- “Less time in the OR, less physically demanding cases, less stress because of the less risk during the surgery, less hospital rounding time, and less follow-up visits, all for the same reimbursement as metal based alternative” (Reference: Frequently Asked Questions, dated 6/1/2006)
- “Medicare and virtually all private insurance carriers cover lumbar fusion.” (Reference: Frequently Asked Questions, dated 6/1/2006);
- “The implant record holders are:” (Reference: Presentation by Peter Sontag, Chairman of the Board of ODC, at the LifeLink Foundation Board of Governor’s Meeting on April 19, 2007 in Tampa, FL)

11. Plaintiff became concerned the claims set forth in the preceding paragraph should be corrected; the claims violated plaintiff’s personal sense of ethics and his concern for patient care. Over the past 10 years, plaintiff has distinguished himself as a credible marketing representative of orthopedic surgical devices which performed as represented in the hands of capable and competent neurosurgeons or orthopedic surgeons. Plaintiff became concerned DOULGERIS’s false claims could or would be considered marketing to “induce” surgeons to use the product, not only for its claimed efficacy, but because it increases reimbursement for both surgeons and health care facilities from Medicare and health insurers. Although there was a minimal risk of injury to the patient if TruFUSE® failed, should the product fail, the patient would most likely experience a recurrence of symptoms requiring future surgery. Plaintiff came to realize approximately 40 to 50% of the patients who had the TruFUSE® procedure were also covered by Medicare. Plaintiff came to realize that defendants’ claim of data to substantiate their claims in a majority of cases did not exist. In other words, Medicare and other health insurers are rendering payment for something the procedure is not delivering, namely a fusion. Defendants do not have any substantial data or clinical study to support their claims. Defendants knew or reasonably should have known there were problems with the TruFUSE® product.

12. Plaintiff has approached DOULGERIS on numerous occasions about plaintiff's concerns regarding the TruFUSE® procedure and product design, but was ignored or told the concerns would be addressed, yet DOULGERIS failed to act upon those concerns. Plaintiff has also approached DOULGERIS on numerous occasions to specifically point out the liability to the company that could result from DOULGERIS's claims as to percentage of graft pullouts, percentage of **pseudoarthrosis**, percentage of success rates, number of cases and indications of TruFUSE® without a clinical study or significant verifiable data to support those claims.

FIRST CLAIM FOR RELIEF
(Fraudulent Inducement to Contract)
(Against all Defendants)

13. Plaintiff incorporates paragraphs 1 through 12 as if more fully set forth herein.

14. Defendants, prior to November 1, 2006, were aware that the plaintiff had worked for many years in the orthopedic surgical product field and that, during those years of hard work and experience, he had established a sterling and unimpeachable reputation for competence, honesty and ethical probity.

15. Prior to and during the formation of the employment agreement between plaintiff and defendant minSURG Corporation, defendants made a series of false and/or materially-misleading statements and representations of present and past fact about the alleged TruFuse® "solution" and about the qualifications and educational background of defendant DOULGERIS in an effort to induce plaintiff to execute the employment agreement with Defendant minSURG Corporation so that the Defendants could benefit from and "trade upon" the reputation and the contacts of plaintiff in the orthopedic surgical product field. These false and materially-misleading statements of present and past fact related to and included, *inter alia*, the existence of various surgical studies, company data, case studies, medical reviews, the FDA-required Good Manufacturing Practices program and the educational

qualifications and professional experience of defendant DOULGERIS as described above in Paragraphs 7 and 10 of the plaintiff's complaint.

16. These statements and representations of present and past fact made by defendants were false and/or materially-misleading when made and defendants knew or reasonably should have known that these statements and representations were false and/or materially-misleading when made.

17. Plaintiff relied upon the false and/or materially-misleading statements and representations of present and past fact made by defendants and plaintiff's reliance upon these statements and representations was reasonable. But for the false and/or materially-misleading material factual statements and representations made by defendants, Plaintiff would not have entered into an employment agreement with defendant minSURG Corporation. The defendants' pre-contract formation false and/or materially-misleading statements and representations of present and past fact undermined plaintiff's ability to make an informed decision as to whether to enter into the employment agreement.

18. Plaintiff has suffered damages proximately related to the series of false and/or materially-misleading statements and representations made by defendants in an amount to be established at the trial of this matter, said amount which plaintiff states to be in excess of \$75,000.00, excluding interest and costs.

SECOND CLAIM FOR RELIEF

(Breach of Contract)

(Against minSURG Corporation)

19. Plaintiff incorporates paragraphs 1 through 12 as if more fully set forth herein.

20. An agreement existed between plaintiff and defendant minSURG Corporation with respect to the amounts due and owing to Plaintiff from defendant minSURG Corporation.

21. The employment agreement provided that salaries and commissions due to Plaintiff were to be paid on a regular, determined schedule.

22. As of the date of the filing of this complaint, defendant minSURG Corporation has breached its agreement with plaintiff in that defendant minSURG Corporation has willfully failed and refused to pay over to plaintiff the following sums which are justly due and owing to plaintiff: (1) plaintiff's salary from May 1 to May 15 in the amount of \$8,333.50; (2) plaintiff's commissions for sales during the month of April of 2007 in the amount of \$12,312.50 and (3) plaintiff's reimbursable expenses in an amount in excess of \$10,000.00. Plaintiff is also entitled to 30 days salary, in the amount of \$16,667.00, plus commissions, from the date of separation, and in accordance with the employment agreement. Upon information and belief, defendants have communicated to third parties that plaintiff has been terminated from his employment.

23. Plaintiff has performed all of his duties and obligation under the employment agreement between plaintiff and defendant minSURG Corporation or stands ready, willing and able to perform all of his remaining duties and obligations under said employment agreement.

24. Plaintiff has suffered damages due to the breach of the agreement by defendant minSURG Corporation in the amount of at least \$30,646.00.

THIRD CLAIM FOR RELIEF

(Supplemental State Law Claim)

(Against Defendant minSURG)

25. Plaintiff incorporates paragraphs 1 through 12 as if more fully set forth herein.

26. Plaintiff brings this supplemental claim pursuant to 28 U.S.C. § 1367(a).

27. Defendant minSURG Corporation is an “employer” and plaintiff is an “employee” within the meaning of those terms as defined in N.C.G.S. § 95-25.2 of The North Carolina “Wage and Hour Act,” N.C.G.S. 95-25.1, *et seq.*

28. Defendant minSURG Corporation was obligated pursuant to N.C.G.S. § 95-25.6 to pay plaintiff the wages, commissions and expenses on his regularly-scheduled payday, which defendant minSURG Corporation has failed and refused to do.

29. As of the date of the filing of this complaint, defendant minSURG Corporation owes plaintiff the sum of \$47,313.00 in wages, commissions and expenses pursuant to the applicable provisions of The North Carolina Wage and Hour Act.

30. In addition, pursuant to N.C.G.S. § 95-25.22(a1) and (d), defendant minSURG Corporation is liable to plaintiff for liquidated damages in the amount of \$47,313.00, costs and fees of this action, plus reasonable attorney’s fees.

WHEREFORE, plaintiff prays the Court for the following relief:

1. For compensatory damages in excess of \$835,000.00;
2. For exemplary damages in the discretion of the jury, in accord with applicable law;
3. For costs and fees and the plaintiff’s reasonable attorney’s fees;
4. For trial by jury as to all matters so triable; and

5. For such other and further relief as to the court seems just and proper.

This the 7th day of May, 2007.

/s/ Randolph M. James NC Bar # 10,000
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