

# WISCONSIN DEPARTMENT OF REGULATION & LICENSING



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STATE OF WISCONSIN  
BEFORE THE CHIROPRACTIC EXAMINING BOARD

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IN THE MATTER OF THE DISCIPLINARY :  
PROCEEDINGS AGAINST :  
: FINAL DECISION AND ORDER  
RENEE NODORFT, D.C., :  
RESPONDENT. : **ORDER 0000729**

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[Division of Enforcement Case No. 08 CHI 027]

The parties to this action for the purposes of Wis. Stat. § 227.53 are:

Renee Nodorft, D.C.  
5004 N. Northwood Trace  
Janesville, WI 53545

Division of Enforcement  
Department of Regulation and Licensing  
1400 East Washington Avenue  
P.O. Box 8935  
Madison, WI 53708-8935

Wisconsin Chiropractic Examining Board  
Department of Regulation and Licensing  
1400 East Washington Avenue  
P.O. Box 8935  
Madison, WI 53708-8935

PROCEDURAL HISTORY

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final decision of this matter, subject to the approval of the Chiropractic Examining Board. The Board has reviewed this Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following:

FINDINGS OF FACT

1. Renee Nodorft, D.C., Respondent, date of birth September 28, 1978, is licensed by the Wisconsin Chiropractic Examining Board to practice chiropractic in the state of Wisconsin, pursuant to license number 12-4115, which was first granted on February 10, 2005.
2. Respondent's last address reported to the Department of Regulation and Licensing is 5004 N. Northwood Trace, Janesville, Wisconsin 53545.
3. At all times relevant to this matter, Respondent practiced chiropractic at Clinical Chiropractic of Whitewater, S.C.

4. In spring of 2008, Respondent published 1,500 fliers in Whitewater Register Newspaper which advertised spinal decompression services with an 86% success rate for treatment of sciatica, bulging discs, herniated discs and degenerative disc disease.

5. In February of 2008, Respondent's website, Clinicalchiropractic.com contained an advertisement which stated:

[W]e have developed an extensive and comprehensive treatment plan utilizing the **"State of the Art" care using the revolutionary FDA cleared Spinal Decompression Technology** ... clinical studies have **REVEALED AN AMAZING SUCCESS RATE IN MORE THAN 80% OF PATIENTS** with treatment of lumbar disc related problems.

6. Statistical success rates for spinal decompression treatment have not been sufficiently substantiated by reliable, peer-reviewed, published scientific studies to provide a representative likelihood of successful treatment.

7. Respondent uses the 3DactiveTrac manufactured by the Saunders Group to provide spinal decompression treatment.

8. The Saunders Group, as the manufacturer of a medical device, was required to register it with the Food and Drug Administration ("FDA"). The FDA classifies medical devices by the level of danger posed to the consumer. The FDA denies market approval, grants market approval or grants market clearance.

9. "Market approval" represents that the FDA has determined that the device is safe and effective for its intended purpose. Formal clinical and laboratory studies are required to prove that the device is safe and effective.

10. "Market clearance" represents only that the FDA has determined that the device is "substantially equivalent" to a similar device cleared by the FDA prior to the 1976 Medical Device Amendments to the Federal Food, Drug and Cosmetic Act. Premarket clearance lacks assurances of the safety and efficacy of the device which are required by the FDA's premarket approval process.

11. The 3DactiveTrac has not received market approval by the FDA. It received market clearance from the FDA on August 31, 2000 because a substantially equivalent device existed prior to May 28, 1976.

12. The FDA has not determined that the 3DactiveTrac is safe and effective for spinal decompression treatment. Through its market clearance and classification processes, the FDA has classified the 3DactiveTrac as a Class II device which poses a moderate level of risk to the user.

### CONCLUSIONS OF LAW

1. The Wisconsin Chiropractic Examining Board has jurisdiction over this matter pursuant to Wis. Stat. § 446.03 and authority to enter into this stipulated resolution of this matter pursuant to Wis. Stat. § 227.44(5).
2. Respondent, by conduct described above, published advertising which contained a misrepresentation of fact, in violation of Wis. Admin. Code § CHI 6.02(15)(a).
3. Respondent, by conduct described above, published advertising which was likely to create unjustified expectations of favorable results, in violation of Wis. Admin. Code § CHI 6.02(15)(c).
4. Respondent, by conduct described above, published advertising which contained representations that in reasonable probability would cause an ordinarily prudent person to misunderstand or be deceived, in violation of Wis. Admin. Code § CHI 6.02(15)(e).

### ORDER

NOW, THEREFORE, IT IS HEREBY ORDERED:

1. Respondent, Renee Nodorft, D.C., is hereby REPRIMANDED for the conduct set out above.
2. Respondent shall provide all patients, with whom the 3DactiveTrac or other similar device is used, a written disclosure which shall be preapproved by the Board's designee, and which includes the following statement:

The [device name] is a vertebral decompression device which has been cleared for marketing by the FDA for temporary relief of pain. The [device name] has not been approved by the FDA. The FDA has never tested the efficacy or safety of the [device name], nor is there any scientific basis for a representative likelihood of successful treatment by this device or a similar device.

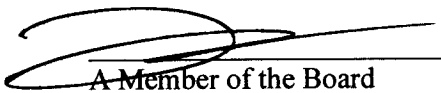
3. The license of the Respondent is hereby LIMITED as follows:
  - a. Respondent shall, within 90 days of the date of this Order, schedule and successfully complete and pass a one hour essay examination on Wisconsin Chiropractic Regulations at the Department coordinated with the prosecuting attorney assigned to this case.
  - b. Upon successful completion and passing of the Wisconsin Chiropractic Regulation Exam and payment of costs, the Limitations shall be removed from Respondent's license and Respondent will be granted a full, unrestricted license.
4. Respondent shall pay the Department's COSTS of this matter in the amount of TWO HUNDRED FIFTY DOLLARS (\$250.00).
5. Payment of the COSTS shall be submitted within thirty days from the date of the order payment shall be made payable to the Wisconsin Department of Regulation and Licensing and sent to the Department Monitor at the address referenced in paragraph 6 below.

6. Payment of costs shall be mailed, faxed or delivered by the Respondent to the Department Monitor at this address:

Department Monitor  
Division of Enforcement  
Department of Regulation and Licensing  
P.O. Box 8935, Madison, WI 53708-8935  
Telephone (608) 267-3817, Fax (608) 266-2264

7. Violation of any of the terms of this Order may be construed as conduct imperiling public health, safety and welfare and may result in a summary suspension of Respondent's license to practice in the state of Wisconsin. The Board in its discretion may in the alternative impose additional conditions and limitations or other additional discipline for a violation of any of the terms of this Order. In the event Respondent fails to comply with payment of costs, and passing of the exam, Respondent's license to practice in the state of Wisconsin may, in the discretion of the Board or its designee, be SUSPENDED, without further notice or hearing, until Respondent has complied with all the terms and conditions of this Order.

Wisconsin Chiropractic Examining Board

By:   
A Member of the Board

3/17/11  
Date