STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

RE: John A. Catanzaro
Master Case No.: M2013-1272
Document: Agreed Order

Regarding your request for information about the above-named practitioner; attached is a true and correct copy of the document on file with the State of Washington, Department of Health, Adjudicative Clerk Office. These records are considered Certified by the Department of Health.

Certain information may have been withheld pursuant to Washington state laws. While those laws require that most records be disclosed on request, they also state that certain information should not be disclosed.

The following information has been withheld:

> The identity of the complainant if the person is a consumer, health care provider, or employee, pursuant to RCW 43.70.075 (Identity of Whistleblower Protected) and/or the identity of a patient, pursuant to RCW 70.02.020 (Medical Records - Health Care Information Access and Disclosure)

If you have any questions or need additional information regarding the information that was withheld, please contact:

> Customer Service Center
> P.O. Box 47865
> Olympia, WA 98504-7865
> Phone: (360) 236-4700
> Fax: (360) 586-2171

You may appeal the decision to withhold any information by writing to the Privacy Officer, Department of Health, P.O. Box 47890, Olympia, WA 98504-7890.

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
BOARD OF NATUROPATHY

In the Matter of **JOHN A. CATANZARO** Credential No. NATU.NT.00000769 Respondent	**No. M2013-1272** **STIPULATED FINDINGS OF FACT, CONCLUSIONS OF LAW AND AGREED ORDER**

The Board of Naturopathy (Board), through Alexander Lee, Department of Health Staff Attorney, and Respondent, represented by counsel, Rodney Moody, stipulate and agree to the following:

1. PROCEDURAL STIPULATIONS

1.1 On January 29, 2014, the Board issued a Statement of Charges against Respondent.

1.2 Respondent understands that the Board is prepared to proceed to a hearing on the allegations in the Statement of Charges.

1.3 Respondent understands that if the allegations are proven at a hearing, the Board has the authority to impose sanctions pursuant to RCW 18.130.160.

1.4 Respondent has the right to defend against the allegations in the Statement of Charges by presenting evidence at a hearing.

1.5 Respondent waives the opportunity for a hearing on the Statement of Charges provided that the Board accepts this Stipulated Findings of Fact, Conclusions of Law and Agreed Order (Agreed Order).

1.6 The parties agree to resolve this matter by means of this Agreed Order.

1.7 Respondent understands that this Agreed Order is not binding unless and until it is signed by the Board and served by the Adjudicative Clerk Office.

1.8 If the Board accepts this Agreed Order, it will be reported to the National Practitioner Databank (45 CFR Part 60) and elsewhere as required by law. It is a public document and will be placed on the Department of Health's website and otherwise disseminated as required by the Public Records Act (Chap. 42.56 RCW) and the Uniform Disciplinary Act. RCW 18.130.110.

1.9 If the Board rejects this Agreed Order, Respondent waives any objection to the participation at hearing of any Board members who heard the Agreed Order presentation.

2. FINDINGS OF FACT

Respondent and the Board stipulate to the following facts:

2.1 On September 10, 1996, the state of Washington issued Respondent a credential to practice as a naturopathic physician. Respondent's credential is currently summarily suspended.

2.2 Respondent is the "medical director" at HWIFC Cancer Research Group (Research Group) and Health and Wellness Institute of Integrative Medicine and Cancer Treatment (Cancer Institute). The Research Group was started in January of 2007 as a non-profit research entity.

2.3 The Research Group currently develops "individualized autologous peptide and whole cell based vaccine" made from the "patient's own body tissue, blood, and serum" (vaccine) in order "to assist the individual patient in their fight against their cancer." This is privately funded by "donations" made by the patient and friends of the patient to cover costs of the development of the individual patient vaccine.

2.4 On or about April 4, 2012, the Respondent stated he has not "published findings of the cancer research conducted over the last 13 years as he continues to gather data and has just began the process of sanctioning the research." The Respondent further stated that the Research Group "obtained single use IND and IRB activity on use of autologous peptide vaccine" and is moving forward to a general IND model.

2.5 The Board of Naturopathy reviewed materials submitted by the Respondent in regards to his cancer research protocol and cancer treatments for Patients A and B:

A. The Institutional Review Board (IRB) Authorization Agreement from "Piedmont Healthcare institutional Review Board" did not amount to actual IRB approval as portrayed by the Respondent. The Federal Wide Assurance number provided by Respondent was deactivated according to the Federal Office for Human Research Protections database.

B. The Respondent failed to provide adequate documentation of actual Investigational New Drug (IND) approval from the Federal Drug Administration. In addition, the Respondent did not provide any information to suggest that he is actively participating in the IND process.

C. Respondent informed the Department of Health that patients are given informed consent and complete disclosure. However, the records for Patients A and B contain no informed consent documentation. The Respondent did not meet the standard of care because he did not fully inform the cancer patients who participate in the "research" about the actual research status of the vaccine. These vulnerable cancer patients are led to believe that the vaccine is effective based on patient testimonials but Respondent has not compiled actual research to demonstrate efficacy.

D. The Respondent failed to meet the standard of care because the documentation contained in the patient records is inadequate:

1. The records do not demonstrate thorough clinical exams visit to visit.
2. Patient A's vital information was cut and pasted into multiple visits and subsequent progress notes.
3. The charting lacks findings on the tumor, region of interest, scan report data, and blood test results to objectively document whether the treatment is effective.
4. There is not adequate informed consent regarding the Respondent's cancer vaccine.
5. Respondent did not maintain separate research charting for each patient.

2.6 The Respondent was asked to provide further information on the laboratory utilized to produce the vaccine for cancer patients, to provide additional information related to any IRB and IND research approval, and to provide research data related to the effectiveness of the vaccine.

2.7 In response, on or about October 4, 2013, the Respondent admitted that because he "...is not involved in a project which seeks premarket approval from the FDA, his practice has not developed a data base which gathers the type of data that would be required of a drug or device manufacture...." This was not consistent with his statement provided on April 4, 2012, where he indicated that he was "in the process of moving forward to a general IND model. In addition, on or about April 5, 2012, Respondent submitted that he "currently has an IND number for this protocol with pending IRB approval." The Respondent has not been able to provide any valid evidence of IRB approval.

2.8 The Respondent further admitted that the vaccine is not produced in a laboratory environment and that he personally makes each vaccine. He was unable to verify quality assurance or quality control data about the products injected into patients. The Respondent did not provide any further documentation regarding IRB and IND oversight on the vaccine's use on humans. Respondent did not provide verification that his manufacturing protocol meets "good laboratory practice" or any documentation regarding certification of his lab.

2.9 Respondent's injection of patients with cancer who are at higher risk for infection and death with a biological drug (vaccine), without assurance that the biological drug was manufactured in accordance with federally required standards/protocol, did not meet the standard of care. Unless data is collected on adverse impacts and this data is reported, there is no way to demonstrate any level of safety. Because this data does not exist, Respondent's research protocol is unsafe for patients. In addition, Respondent's failure to collect research data in the course of conducting research on human subjects is unethical and lowers the standing of the profession.

3. CONCLUSIONS OF LAW

The Board and Respondent agree to the entry of the following Conclusions of Law:

3.1 The Board has jurisdiction over Respondent and over the subject matter of this proceeding.

3.2 Respondent has committed unprofessional conduct in violation of RCW 18.130.180(1), (4), (7), (13), and 21 CFR 312.20, 21 CFR 312.40(b) and (d), 21 CFR 312.80, 21 CFR 56.103, 45 CFR 46.116 and 45 CFR 46.117.

3.3 The above violations provide grounds for imposing sanctions under RCW 18.130.160.

4. COMPLIANCE WITH SANCTION RULES

4.1 The disciplining authority applies WAC 246-16-800, *et seq.*, to determine appropriate sanctions. WAC 246-16-800(2)(c) requires the disciplining authority to impose terms based on a specific sanction schedule unless "the schedule does not adequately address the facts in a case."

4.2 The sanction schedules stated in rule do not address the conduct in this case. RCW 18.130.390 and WAC 246-16-800(2)(d) require the disciplining authority to use its judgment to determine appropriate sanctions when the sanction schedules do not address the conduct in question. Here, the disciplining authority determined that a period of suspension and additional conditions upon reinstatement appropriately addresses Respondent's professional misconduct.

5. AGREED ORDER

Based on the Findings of Fact and Conclusions of Law, the Board and Respondent agree to entry of the following Agreed Order:

5.1 Respondent's credential to practice as a naturopathic physician in the state of Washington is **SUSPENDED** for at least one (1) year commencing on January 29, 2014. Respondent may not petition for reinstatement of credential until at least January 29, 2015.

5.2 Prior to petitioning for reinstatement, Respondent shall complete a minimum of seven (7) hours of continuing education, pre-approved by the Commission, in the area of ethics. Respondent shall provide the Board with proof of completion of such continuing education within thirty (30) days of such completion. These seven (7) hours of continuing education shall be in addition to mandatory continuing education hours that may be required for credential renewal.

5.3 Respondent shall take and pass the Board's jurisprudence examination prior to petitioning for reinstatement.

5.4 Respondent shall pay a fine to the Board in the amount of five thousand dollars ($5,000.00), which must be received by the Board prior to petitioning for

reinstatement. The fine shall be paid by certified or cashier's check or money order, made payable to the Department of Health and mailed to the Department of Health, Board of Naturopathy, at PO Box 1099, Olympia, WA 98507-1099. Credit or Debit cards can also be used for payment at the front counter of the Department of Health building at 111 Israel Road SE, Tumwater, WA 98501, during regular business hours.

5.5 If and when Respondent petitions for reinstatement, the disciplining authority may place terms and conditions on Respondent's credential as deems necessary to protect the health and safety of the public. These conditions are to include:

A. Respondent's credential to practice as a naturopathic physician in the state of Washington shall be placed on **PROBATION** for at least eight (8) years. Respondent's credential is **RESTRICTED** as follows:

B. Respondent, and all physicians employed by or working at the Health and Wellness Institute (H&W), and/or any other business entity under Respondent's control, shall confine their practice to the scope of practice for naturopathic physicians as defined by RCW 18.36A.040. Respondent is the owner operator of H&W. Neither Respondent nor any naturopathic physician in his employment and/or association at H&W will engage in cancer research and/or treatment requiring the issuance of an Investigational New Drug (IND) approval or Institutional Review Board (IRB) approval and/or the administration of autologous cancer vaccines during the period of Respondent's probation. ***Respondent is permitted to treat cancer patients during his probationary period only so long as all treatment provided is within the scope of naturopathic practice and adheres to all regulatory requirements. Respondent must collaborate with a medical doctor and/or osteopathic physician in treating a cancer patient. Collaboration requires proactive communication within a team based structure in order to treat the patient. This collaboration must be evidenced clearly by the patient charting/records.***

C. In addition to any other inspections it may make, the Department of Health and/or Board may audit records and review Respondent's

practice at his place of employment on an unannounced basis for the duration of the probation period, in order to ensure compliance with the practice restriction, terms of this agreed order, and all regulatory laws relevant to the profession. These audits shall also review records to ensure appropriate patient billing.

5.6 Respondent is responsible for all costs of complying with this Agreed Order.

5.7 Respondent shall obey all federal, state and local laws and all administrative rules governing the practice of the profession in Washington. Respondent shall only prescribe controlled substances permitted by WAC 246-836-210, which are testosterone and codeine.

5.8 The Board was informed of certain additional patients (*see* Attachment A) who have paid monies to HWIFC Cancer Research Group (HWIFC), a cancer research 501(c)(3) nonprofit corporation, for the autologous vaccine but did not actually receive the vaccine, and/or did not receive a refund of monies paid for the vaccine. Respondent is the Medical Director for HWIFC. Within twelve (12) months from the effective date of this agreed order, Respondent shall refund all monies paid for each vaccine to the designated patients below (or their personal representative) unless the patient or their personal representative declines the refund in writing. These additional patients and monies owed are listed in Attachment A and referenced below:

Patient C: $17,750.
Patient D: $6,250.00
Patient E: $30,000.00
Patient F: $23,500.00
Patient G:$12,500.00
Patient H: $25,000.00
Patient I: $25,500.00
Patient J: $25,500.00
Patient K: $12,750.00
Patient L: $2,000.00

Within thirty (30) days of the effective date of this Agreed Order, Respondent shall provide a copy of this Agreed order to each of the patients identified in

Attachment A. Respondent shall provide the Board a full accounting of all patient refunds within twelve (12) months from the effective date of this Agreed Order.

5.9 The effective date of this Agreed Order is the date the Adjudicative Clerk Office places the signed Agreed Order into the U.S. mail. If required, Respondent shall not submit any fees or compliance documents until after the effective date of this Agreed Order.

5.10 Respondent further agrees that he does hereby release and forever discharge the State of Washington and its officers, agents, employees, agencies and departments from any and all existing claims, damages and causes of action of any nature whatsoever that could be alleged based upon the occurrences or events described in his claim for damages previously filed by claimant against the State of Washington and the Washington State Department of Health under DRM # 30370039.

6. FAILURE TO COMPLY

Protection of the public requires practice under the terms and conditions imposed in this order. Failure to comply with the terms and conditions of this order may result in suspension of the credential after a show cause hearing. If Respondent fails to comply with the terms and conditions of this order, the Board may hold a hearing to require Respondent to show cause why the credential should not be suspended. Alternatively, the Board may bring additional charges of unprofessional conduct under RCW 18.130.180(9). In either case, Respondent will be afforded notice and an opportunity for a hearing on the issue of non-compliance.

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7. ACCEPTANCE

I, JOHN A. CATANZARO, have read, understand and agree to this Agreed Order. This Agreed Order may be presented to the Board without my appearance. I understand that I will receive a signed copy if the Board accepts this Agreed Order.

JOHN A. CATANZARO
RESPONDENT

10·30·14
DATE

RODNEY MOODY, WSBA #17416
ATTORNEY FOR RESPONDENT

10/30/14
DATE

8. ORDER

The Board accepts and enters this Stipulated Findings of Fact, Conclusions of Law and Agreed Order.

DATED: October 31, 2014

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
BOARD OF NATUROPATHY

PANEL CHAIR

PRESENTED BY:

ALEXANDER H. LEE, WSBA #35824
DEPARTMENT OF HEALTH STAFF ATTORNEY

October 31, 2014
DATE

ATTACHMENT A

CONFIDENTIAL SCHEDULE TO INCLUDE ADDITIONAL PATIENTS FOR PAYMENT

This information is confidential and is NOT to be released without the consent of the individual or individuals named herein. RCW 42.56.240(1).

Patient C: [redacted]

Patient D:

Patient E:

Patient F:

Patient G:

Patient H:

Patient I:

Patient J:

Patient K:

Patient L: