

STATE OF WASHINGTON  
DEPARTMENT OF HEALTH  
BOARD OF NATUROPATHY

In the Matter of

No. M2013-1272

**JOHN A. CATANZARO**  
Credential No. NATU.NT.00000769

**STATEMENT OF CHARGES**

Respondent

The Executive Director of the Board of Naturopathy (Board), on designation by the Board, makes the allegations below, which are supported by the evidence contained in case no. 2012-1472.

**1. ALLEGED FACTS**

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

1.2 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.

1.3 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.

1.4 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.

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ORIGINAL

1.5 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.

1.6 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.

1.7 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.

1.8 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.

1.9 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.

## 2. ALLEGED VIOLATIONS

2.1 Based on the Alleged Facts, 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 which provide in part:

**RCW 18.130.180 Unprofessional conduct.** The following conduct, acts, or conditions constitute unprofessional conduct for any license holder under the jurisdiction of this chapter:

(1) The commission of any act involving moral turpitude, dishonesty, or corruption relating to the practice of the person's profession, whether the act constitutes a crime or not. If the act constitutes a crime, conviction in a criminal proceeding is not a condition precedent to disciplinary action. Upon such a conviction, however, the judgment and sentence is conclusive evidence at the ensuing disciplinary hearing of the guilt of the license holder of the crime described in the indictment or information, and of the person's violation of the statute on which it is based. For the purposes of this section, conviction includes all instances in which a plea of guilty or nolo contendere is the basis for the conviction and all proceedings in which the sentence has been deferred or suspended. Nothing in this section abrogates rights guaranteed under chapter 9.96A RCW;

...

(4) Incompetence, negligence, or malpractice which results in injury to a patient or which creates an unreasonable risk that a patient may be harmed. The use of a nontraditional treatment by itself shall not constitute unprofessional conduct, provided that it does not result in injury to a patient or create an unreasonable risk that a patient may be harmed;

...

(7) Violation of any state or federal statute or administrative rule regulating the profession in question, including any statute or rule defining or establishing standards of patient care or professional conduct or practice;

...

(13) Misrepresentation or fraud in any aspect of the conduct of the business or profession;

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**21 CFR § 312.20 Requirement for an IND.**

(a) A sponsor shall submit an IND to FDA if the sponsor intends to conduct a clinical investigation with an investigational new drug that is subject to § 312.2(a).

(b) A sponsor shall not begin a clinical investigation subject to § 312.2(a) until the investigation is subject to an IND which is in effect in accordance with § 312.40.

(c) A sponsor shall submit a separate IND for any clinical investigation involving an exception from informed consent under § 50.24 of this chapter. Such a clinical investigation is not permitted to proceed without the prior written authorization from FDA. FDA shall provide a written determination 30 days after FDA receives the IND or earlier.

**21 C.F.R. § 312.40 General requirements for use of an investigational new drug in a clinical investigation.**

...

(b) An IND goes into effect:

(1) Thirty days after FDA receives the IND, unless FDA notifies the sponsor that the investigations described in the IND are subject to a clinical hold under § 312.42; or

(2) On earlier notification by FDA that the clinical investigations in the IND may begin. FDA will notify the sponsor in writing of the date it receives the IND.

...

(d) An investigator may not administer an investigational new drug to human subjects until the IND goes into effect under paragraph (b) of this section.

**21 C.F.R. § 312.80 Purpose.**

The purpose of this section is to establish procedures designed to expedite the development, evaluation, and marketing of new therapies intended to treat persons with life-threatening and severely-debilitating illnesses, especially where no satisfactory alternative therapy exists. As stated § 314.105(c) of this chapter, while the statutory standards of safety and effectiveness apply to all drugs, the many kinds of drugs that are subject to them, and the wide range of uses for those drugs, demand flexibility in applying the standards. The Food and Drug Administration (FDA) has determined that it is appropriate to exercise the broadest flexibility in applying the statutory standards, while preserving appropriate guarantees for safety and effectiveness. These procedures reflect the recognition that physicians and patients are generally willing to accept greater risks or side effects from products that treat life-threatening and severely-debilitating illnesses, than they would accept from products that treat less serious illnesses. These procedures also reflect the recognition

that the benefits of the drug need to be evaluated in light of the severity of the disease being treated. The procedure outlined in this section should be interpreted consistent with that purpose.

**21 C.F.R. § 56.103 Circumstances in which IRB review is required.**

(a) Except as provided in §§ 56.104 and 56.105, any clinical investigation which must meet the requirements for prior submission (as required in parts 312, 812, and 813) to the Food and Drug Administration shall not be initiated unless that investigation has been reviewed and approved by, and remains subject to continuing review by, an IRB meeting the requirements of this part.

(b) Except as provided in §§ 56.104 and 56.105, the Food and Drug Administration may decide not to consider in support of an application for a research or marketing permit any data or information that has been derived from a clinical investigation that has not been approved by, and that was not subject to initial and continuing review by, an IRB meeting the requirements of this part. The determination that a clinical investigation may not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any other applicable regulations to submit the results of the investigation to the Food and Drug Administration.

(c) Compliance with these regulations will in no way render inapplicable pertinent Federal, State, or local laws or regulations.

**45 C.F.R. § 46.116 General requirements for informed consent.**

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's

participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth

above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) Public benefit of service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

**45 C.F.R. § 46.117 Documentation of informed consent.**

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by § 46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or



(2) A short form written consent document stating that the elements of informed consent required by § 46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

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

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**3. NOTICE TO RESPONDENT**

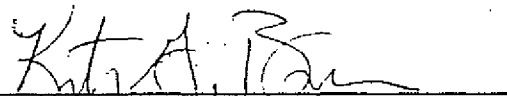
The charges in this document affect the public health, safety and welfare. The Executive Director of the Board directs that a notice be issued and served on Respondent as provided by law, giving Respondent the opportunity to defend against these charges. If Respondent fails to defend against these charges, Respondent shall be subject to discipline pursuant to RCW 18.130.180 and the imposition of sanctions under RCW 18.130.160.

DATED: January 24, 2014

STATE OF WASHINGTON  
DEPARTMENT OF HEALTH  
BOARD OF NATUROPATHY

*for*   
CHRIS HUMBERSON  
EXECUTIVE DIRECTOR

ROBERT W. FERGUSON  
ATTORNEY GENERAL

  
KRISTIN G. BREWER, WSBA #38494  
ASSISTANT ATTORNEY GENERAL

**CONFIDENTIAL SCHEDULE**

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 A:



Patient B:

