IN THE CIRCUIT COURT OF THE STATE OF OREGON

FOR THE COUNTY OF WASHINGTON

STATE OF OREGON, acting by and through the OREGON MEDICAL BOARD, Plaintiff, v. PAUL NORMAN THOMAS, Defendant.	Case No. 21CV30201 COMPLAINT (Judicial Enforcement of Subpoena – ORS 677.270) CLAIM NOT SUBJECT TO MANDATORY ARBITRATION Plaintiff not required to pay filing fees in advance – exempt per ORS 20.140

Plaintiff State of Oregon, acting by and through the Oregon Medical Board ("OMB"), alleges the following facts for its complaint against Defendant Paul Norman Thomas.

GENERAL ALLEGATIONS

1.

Plaintiff OMB is a state licensing board with authority under ORS chapter 677 to license, regulate, and discipline medical doctors, doctors of osteopathic medicine, podiatric physicians, physician assistants and acupuncturists in Oregon.

2.

Defendant Thomas obtained a license to practice as a medical doctor in Oregon from Plaintiff in 1988. He has practiced pediatric medicine and is the president and owner of non-party Integrative Pediatrics Inc., a pediatric medical clinic located in Washington County.

///

DEPARTMENT OF JUSTICE
1162 Court Street NE
Salem, OR 97301-4096
PHONE: (503) 934-4400

3.

Pursuant to its authority under ORS 677.320, OMB has initiated an investigation into whether Defendant engaged in unethical conduct or otherwise violated standards of conduct for licensees in connection with studies on the impact of an alternative vaccination schedule for measles, mumps and rubella (MMR) and other vaccines on patients seen at his pediatric practice.

4.

To further its investigation, OMB used its authority under ORS 677.320(2) and (3) to serve Defendant with an administrative Subpoena Duces Tecum dated August 21, 2020 (the "Subpoena"). The Subpoena required Defendant to produce specified categories of documents and information related to his studies by September 21, 2020. A true copy of the Subpoena is attached as Exhibit 1 and incorporated into this Complaint by reference.

5.

As detailed below, Defendant has resisted the Subpoena and has to date not provided information that Plaintiff needs for its investigation. Plaintiff brings this action pursuant to ORS 677.270 to compel Defendant's compliance with the Subpoena.

Information at Issue

6.

The Subpoena seeks information related to medical studies involving Defendant's patients. The studies purport to present health-related and immunity level outcomes in patients who previously received care through Defendant at Integrative Pediatrics, including patients who received MMR vaccines or other vaccines according to alternative schedules differing from public health authority recommendations.

7.

One of Defendant's studies is titled, "Can Integrative Medicine Approaches and a Selective Vaccine Schedule Impact the Health and Rates of Autism in a General Pediatric Population?" ("Study 1"). The study describes a population of approximately 161 Integrative

DEPARTMENT OF JUSTICE
1162 Court Street NE
Salem, OR 97301-4096
PHONE: (503) 934-4400

Pediatrics patients who received the MMR vaccine after the age of 3, which is later than public health authority recommendations.

8.

Defendant also presented results of Study 1 on his patients in a book he co-authored called *The Vaccine-Friendly Plan: Dr. Paul's Safe and Effective Approach to Immunity and Health-From Pregnancy Through Your Child's Teen Years*. In Appendix E to the book, Defendant said that he studied autism and autism spectrum disorder rates in 2,230 patients seen at his clinic. He divided the patients into three groups: 1) 1,098 patients who had received "Dr. Paul's Vaccine-Friendly Plan," which included skipping or delaying recommended vaccines; 2) 238 patients who received no vaccines: and 3) 894 patients who were largely vaccinated according to Centers for Disease Control guidelines.

9.

Defendant conducted another study titled, "An Approach to Get MMR Immunity in a Population of Vaccine Fearful Patients" ("Study 2"). Study 2 purported to examine the MMR immunity rates of 484 Integrative Pediatrics patients depending on whether they received the MMR vaccine before or after the age of 3. On information and belief, Study 2 has not been published.

10.

The Subpoena requires that Defendant produce specific information related to each study, including:

a) With respect to the Study 1, the Subpoena requires that Defendant provide the names and dates of birth for the approximately 161 patients subject who received an MMR vaccine after the age of 3 years old;

b) With respect to Study 1, the Subpoena requires Defendant to provide the names and dates of birth for the 1,098 patients who were vaccinated according to the Dr. Paul's Vaccine-Friendly Plan;

DEPARTMENT OF JUSTICE
1162 Court Street NE
Salem, OR 97301-4096
PHONE: (503) 934-4400

c) The names and dates of birth for patients in Defendant's studies who were given only a single dose of the MMR vaccine and had titers drawn to test for the level of antibodies in their blood, along with the corresponding titer information; and

d) With respect to Study 2, a summary report, including a description of the research methods and the process used for obtaining informed consent, and production of copies of all forms used to obtain informed consent.

The Subpoena gave a deadline of September 21, 2020 for Defendant to produce the information.

11.

Defendant has failed to comply with the Subpoena. Defendant provided OMB with spreadsheets identifying MMR vaccine dosage information, titer data, notes, and other information for patients involved in Study 1. Defendant, however, did not provide the names and dates of birth for the patients included in the studies, as required by the Subpoena. Plaintiff needs the patient information for purposes of its investigation into whether Defendant complied with applicable ethical and professional standards in connection with the studies or in administering vaccines according to the vaccination schedules described. Defendant did not provide any documents related to Study 2 or a summary report as required.

12.

Defendant has resisted providing patient-identifying information for Study 1 on the merit-less grounds that he is prohibited from disclosing the information by regulations pertaining to institutional review boards, which are organizations designated under Food and Drug Administration regulations to oversee clinical trials to protect the rights and welfare of human subjects. Defendant submitted Study 1 for advance approval by the Western Institutional Review Board (now part of the WCG IRB) and received a waiver under *former* 45 C.F.R. § 46.101(b)(4) of certain regulations pertaining to studies under 45 C.F.R. part 46, with the waiver conditioned, on among things, his not identifying the patients in the studies.

DEPARTMENT OF JUSTICE
1162 Court Street NE
Salem, OR 97301-4096
PHONE: (503) 934-4400

13.

The waiver of 45 C.F.R. part 46 regulations granted to Defendant under *former* 45 C.F.R. § 46.101(b)(4) does not prevent Plaintiff from exercising its lawful authority to obtain the patient-identifying information for purposes of its investigation into Defendant's conduct. The regulation does not expressly or impliedly limit the ability of health oversight agencies like OMB to obtain patient-identifying information for purposes of lawful investigations and regulation of the practice of medicine.

14.

Indeed, separate regulations promulgated under the Health Insurance Portability and Accountability Act (HIPAA), expressly authorize Plaintiff to receive the patient-identifying information demanded in the Subpoena. Under 45 C.F.R. § 164.512(d), a provider such as Defendant (deemed a "covered entity" under HIPAA) may provide individually identifiable health information to a health oversight agency for oversight activities authorized by law, including civil or administrative investigations and licensure and disciplinary proceedings.

15.

Plaintiff included with its Subpoena a statement of its authority under 45 C.F.R. § 164.512(d) to receive the patient-identifying information for purposes of its investigation. Plaintiff seeks the information only for its internal purposes related to the investigation and not to publicly disclose any patient identities. Under ORS 676.165(5), information obtained in the course of an investigation is exempt from public disclosure. Moreover, Plaintiff's statement directs Defendant under 45 C.F.R. § 528(a)(2)(i) to suspend through August 21, 2023 any right of the patients under HIPAA to receive an accounting of information provided to Plaintiff in response to the Subpoena, as such disclosures to the subject patients could compromise the investigation.

DEPARTMENT OF JUSTICE
1162 Court Street NE
Salem, OR 97301-4096
PHONE: (503) 934-4400

16.

In addition to resisting providing any patient-specific information for Study 1, Defendant has not provided any documents or information related to Study 2. Defendant has disclaimed any knowledge of Study 2. However, Defendant conducted the study and prepared a written summary, which states that the study was also submitted to the Western Institutional Review Board for a determination that it was exempt from the IRB requirements.

For its CLAIM FOR RELIEF (Judicial Enforcement of Subpoena – ORS 677.270), Plaintiff alleges:

17.

Re-alleges paragraphs 1-16.

18.

Plaintiff duly issued and served the Subpoena on Defendant pursuant to its authority under ORS 677.320(2) and (3).

19.

Defendant has failed to provide the documents and information required under the Subpoena.

20.

Pursuant to ORS 677.270, Plaintiff is entitled to one or more remedies from this Court compelling Defendant's compliance with the Subpoena, including through the imposition of remedies for contempt.

PRAYER FOR RELIEF

Wherefore, Plaintiff prays for an order or judgment against Defendant compelling him to comply with the Subpoena by producing all responsive documents and information, imposing remedial sanctions if Defendant does not comply, awarding Plaintiff its costs and disbursements and awarding such further and other relief that the court deems just and equitable.

DEPARTMENT OF JUSTICE
1162 Court Street NE
Salem, OR 97301-4096
PHONE: (503) 934-4400

DATED this 27th day of July, 2021.

ELLEN F. ROSENBLUM
Attorney General

/s/ Daniel J. Rice

Daniel J. Rice #084536
Assistant Attorney General
Oregon Department of Justice
1162 Court Street NE
Salem, OR 97310
Telephone: (503) 947-4400
Fax: (503) 373-7067
Daniel.rice@doj.state.or.us
Trial Attorney for Plaintiff

DEPARTMENT OF JUSTICE
1162 Court Street NE
Salem, OR 97301-4096
PHONE: (503) 934-4400

BEFORE THE
OREGON MEDICAL BOARD
STATE OF OREGON

In the Matter of: 19-0714 Oregon Medical Board	)	SUBPOENA DUCES TECUM

TO: Paul Norman Thomas, MD
Integrative Pediatrics,
11790 SW Barnes Road Ste 140
Portland, OR 97225

IN THE NAME OF THE STATE OF OREGON: You are directed, pursuant to ORS Chapter 677, to appear at the Medical Board, on September 21, 2020, at the hour of 10:00 a.m., at the **Oregon Medical Board, 1500 SW 1st Avenue, #620, Portland, Oregon 97201**, to bring with you the following:

1. As noted in the allegation summary in the accompanying letter, another study conducted by the Licensee has been added titled "An Approach to get MMR Immunity in a Population of Vaccine Fearful Parents."
    a. A summary report on this matter, explaining in sufficient detail your response to the allegation. To include, but not limited too; your research method, your process for Informed Consent, and provide copies of the forms used.

2. As previously requested in the Notice of Investigation dated 07/23/2020, please address the following requests;
    a. Please provide the following requests in an Excel spreadsheet if possible;
        i. Names and DOB's of the patients in your study of response to MMR who were vaccinated after the age of three (n= approx. 161).
        ii. Names and DOB's of the patients in your later study (Appendix E in your book,) who were vaccinated after the age of three (Group One, n= 1098).
        iii. List of names and DOB's of patients who received a single dose of MMR and had subsequent titers drawn; include the titer results.

3. Provide any and all correspondence the Licensee had with journals seeking to publish either of his studies.

4. You are also requested to provide a summary response to the allegation that you have willfully violated Oregon Revised Statutes by refusing to provide information that was lawfully requested in the Board's request of July 23, 2020.

The documents to be produced are relevant to the Board's investigation involving a licensee. This subpoena is issued pursuant to ORS 677.320 (2) and (3).

In the alternative, you may deliver or mail the documents to the person serving this subpoena by the date and time specified above, in which event you need not appear at the Oregon Medical Boards office in response to this subpoena. The Board is not responsible for any payment for costs associated with the copying or delivery of subpoenaed records pursuant to ORS 677.320 (2) and (3).

Witness fee of $5.00 and mileage fee of eight cents per mile will be tendered with this subpoena if the above alternative is not accepted as an option.

NOTE: ORS 183.440 and ORS 677.265(10) provide, in applicable cases, that the Circuit Court of any County shall compel obedience to subpoenas issued and served, and to punish disobedience or any refusal to testify, or to answer any lawful inquiry.

DATED this August 21, 2020

OREGON MEDICAL BOARD

By: _____

Nicole Krishnaswami, JD
Executive Director

Jason Boemmels
Investigator
971-673-2686

AUTHORITY TO REVIEW, USE, OR DISCLOSE INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION AS A HEALTH OVERSIGHT AGENCY

TO: Paul Norman Thomas, MD
REGARDING: **Oregon Medical Board Investigation #19-0714**

The **Oregon Medical Board** is responsible for exercising general supervision over the practice of medicine and podiatry in the State of Oregon. Pursuant to ORS 677.320, the Board is authorized to compel the production of documents and testimony, inspect records, and obtain information for the purpose of protecting the public from the practice of medicine by unauthorized or unqualified persons, unprofessional conduct, and other violations of the Medical Practice Act.

Consistent with 45 CFR Sec. 164.512(d), the Board and/or representatives identified below are authorized to review, use, or disclose individually identifiable health information as a Health Oversight Agency for oversight activities authorized by law, including audits; civil, administrative or criminal investigations; inspections; licensure or disciplinary actions; civil; administrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight of individuals or entities subject to government regulation to determine compliance with program standards. The information requested constitutes the minimum necessary information for the health oversight purpose, function, or activity described above. This statement provides the authority for the Board of Medical Examiners' staff and/or representatives identified below to review, use, or disclose this information, pursuant to 45 CFR Sec. 164.512(f) and 164.514(h)(2).

(If the space below is checked, then the law requires you to observe the following statutory requirement.)*

_X___ Notice of Confidential Investigation: The Board requires that you temporarily suspend an individual's right to receive an accounting of disclosures made to the Board as a Health Oversight Agency. Revealing the protected health information that has been disclosed to the Board would be reasonably likely to impede the Board's investigation. This right to disclosure should be suspended from the date of receipt of this notice until August 21, 2023. As a covered entity, you must comply with this request, 45 CFR Sec. 164.528(a)(2)(i).

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) provides that individuals generally have a right to receive an accounting of disclosure of protected health information made by the covered entity. A covered entity, however, **must temporarily suspend giving an individual an accounting of disclosures to health oversight agencies or law enforcement officials when such agency or official provides the covered entity with an oral or written statement that such an accounting would impede the agency's activities, 45 CFR 164.528(a)(2)(i). It should also be noted that investigatory information obtained by the Board in the course of conducting an investigation that includes review of medical records constitutes information that is exempt from public disclosure pursuant to ORS 676.165(5) and ORS 676.175(1).*

Name: _____ Date: August 21, 2020
Jason Boemmels, Investigator
Oregon Medical Board