STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

RE: Janet Vondran, MD
Master Case No.: M2011-843
Document: Statement of Charges

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
MEDICAL QUALITY ASSURANCE COMMISSION

In the Matter of the License to Practice as a Physician and Surgeon of **JANET VONDRAN, MD** License No. MD00033182 Respondent	**No. M2011-843** **STATEMENT OF CHARGES**

The Disciplinary Manager of the Medical Quality Assurance Commission (Commission) is authorized to make the allegations below, which are supported by the evidence contained in file number 2009-140487. The patients referred to in this Statement of Charges are identified in the attached Confidential Schedule.

1. ALLEGED FACTS

1.1 On September 15, 1995, the state of Washington issued Respondent a license to practice as a physician and surgeon. Respondent is Board certified in Psychiatry with a Geriatric Psychiatry sub-specialty certificate. Respondent's license is currently active.

1.2 Between approximately November 2006 and January 2008, Respondent treated adult patients with Norditropin, a brand name for injectable somatropin, a human growth hormone (growth hormone) classified as a Schedule III controlled substance. During a time frame that included December 2009, Respondent advertised hormone replenishment as an anti-aging therapy to consumers via internet. In her response to inquiry by the Commission, Respondent endorsed the use of growth hormone as an anti-aging therapy. Federal and State law specifically bans the use of growth hormone as an "anti-aging" therapy or as an anabolic agent for sports. Its only legitimate use in adults is treatment of adult growth hormone deficiency, Acquired Immune Deficiency Syndrome (AIDS) wasting and short bowel syndrome. The use of growth hormone is particularly contra-indicated in patients with an active malignancy because it may accelerate the growth of cancer cells. The use of growth hormone may be causative or contributory to carpal tunnel syndrome.

1.3 The standard of care for diagnosing adult growth hormone deficiency requires:

1.3.1 The physician must have a high index of suspicion that the patient has growth hormone deficiency. Consideration for growth hormone deficiency in adults is indicated in patients with pituitary or brain disease, tumors or irradiation; patients who have suffered traumatic brain injury; patients with AIDS wasting syndrome or rare patients with short bowel syndrome. In addition, adults who had childhood onset growth hormone deficiency should be considered for continued growth hormone therapy as adults.

1.3.2 The diagnosis of growth hormone deficiency must be achieved by obtaining an insulin-like growth factor (IGF-1) level and then performing the provocative (or stimulation) test. The stimulation test is required unless the patient has deficiencies in at least three other hormone levels or the patient has a history of childhood growth hormone deficiency. A simple measurement of IGF-1 level is not sufficient to make the diagnosis, except in patients also diagnosed with panhypopituitarism.

1.3.3 If growth hormone deficiency is determine by this standard, then the physician must look for the underlying cause.

1.4 Respondent prescribed growth hormone for Patient A, a fifty-five-year old adult, from approximately November 2006 until March 2009. This prescribing began on the basis of a single low serum IGF-1 level test result. There is no notation that Patient A had a condition that would indicate a work-up for growth hormone deficiency. Respondent failed to conduct growth hormone stimulation testing for Patient A and failed to conduct sufficient regular monitoring of Patient A's hormonal. Respondent warned Patient A of risks associated with low growth hormone, but did not advise of the standard of care for prescribing human growth hormone nor of the risks of human growth hormone supplementation. Human growth hormone supplementation can cause or exacerbate carpal tunnel syndrome. Patient A developed bilateral carpal tunnel syndrome requiring surgery on both wrists in Aprll 2008, while still taking growth hormone. There is no indication Respondent made any connection between the human growth hormone therapy and the development of carpal tunnel syndrome. When symptoms of carpal tunnel syndrome occur while a patient is taking growth hormone

therapy, the dose of growth hormone should be decreased or the drug discontinued. Respondent did not discontinue growth hormone therapy for Patient A until March 18, 2009. Respondent's initiation and maintenance of growth hormone therapy for Patient A was below the standard of care and created an unreasonable risk of harm to Patient A.

1.5 Respondent treated Patient B, a forty-nine-year old adult, from approximately August 20, 2007 to November 2007. Patient B described a history of removal of a cancerous legion on her nose, but Respondent did not document the date of this surgery. There was no notation that Patient B had any condition that would indicate a work-up for growth hormone deficiency. Respondent initiated growth hormone therapy for Patient B on September 14, 2007 after a single low serum IGF-1 level was obtained. Respondent did not document informing Patient B of the risks of growth hormone therapy, which include stimulation of the growth of cancer cells. Respondent did not document Patient B's informed consent to HGH therapy. Respondent discontinued the growth hormone therapy on January 9, 2008 after the IGF-1 level rose. Respondent's initiation and maintenance of growth hormone therapy for Patient B was below the standard of care and created an unreasonable risk of harm to Patient B.

1.6 Respondent began treating Patient C, a sixty-year old adult, approximately September 26, 2007. Respondent did not document any history of pituitary or brain disease in Patient C. Patient C disclosed a history of removal of a malignant melanoma, but Respondent did not document whether this was cured or when the surgery was performed. Respondent began prescribing a growth hormone for patient C on October 5, 2007 after a single low serum IGF-1 level was obtained. Respondent's initiation of a growth hormone regime for Patient C was below the standard of care and created an unreasonable risk of harm to Patient C. Respondent documented that she advised Patient C that her low growth hormone production may be associated with premature aging, chronic illness, heart disease and/or insulin resistance, poor memory and low stamina. Respondent did not document telling Patient C of the risks of growth hormone therapy, which include stimulation of the growth of cancer cells. Respondent did not document Patient C's informed consent to growth hormone therapy. Respondent's initiation and maintenance of growth hormone treatment for Patient C was below the standard of care and created an unreasonable risk of harm to Patient C.

1.7 Respondent's record keeping for Patients A, B, C is inadequate. For each of these patients, Respondent failed to establish a basis for a diagnosis to justify prescribing and maintaining a growth hormone regime. Respondent failed to document appropriate monitoring of the patients receiving growth hormone. Respondent failed to document informed consent by these patients for the growth hormone treatment she provided.

2. ALLEGED VIOLATIONS

2.1 Based on the Alleged Facts, Respondent has committed unprofessional conduct in violation of RCW 18.130.180 (4), (7); RCW 69.41.320, WAC 246-919-610, and 21 U.S.C.A. § 333 (e) which provide:

> **RCW 18.130.180 Unprofessional conduct.** The following conduct, acts, or conditions constitute unprofessional conduct for any license holder or applicant under the jurisdiction of this chapter:
>
> . . .
>
> (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;
>
> . . .
>
> **RCW 69.41.320 Practitioners — Restricted use — Medical records.** (1)(a) A practitioner shall not prescribe, administer, or dispense steroids, as defined in RCW 69.41.300, or any form of autotransfusion for the purpose of manipulating hormones to increase muscle mass, strength, or weight, or for the purpose of enhancing athletic ability, without a medical necessity to do so.
>
> (b) A person violating this subsection is guilty of a gross misdemeanor and is subject to disciplinary action under RCW 18.130.180.
>
> (2) A practitioner shall complete and maintain patient medical records which accurately reflect the prescribing,

administering, or dispensing of any substance or drug described in this section or any form of autotransfusion. Patient medical records shall indicate the diagnosis and purpose for which the substance, drug, or autotransfusion is prescribed, administered, or dispensed and any additional information upon which the diagnosis is based.

WAC 246-919-610 Use of drugs or autotransfusion to enhance athletic ability. (1) A physician shall not prescribe, administer or dispense anabolic steroids, growth hormones, testosterone or its analogs, human chorionic gonadotropin (HCG), other hormones, or any form of autotransfusion for the purpose of enhancing athletic ability.

(2) A physician shall complete and maintain patient medical records which accurately reflect the prescribing, administering or dispensing of any substance or drug described in this rule or any form of autotransfusion. Patient medical records shall indicate the diagnosis and purpose for which the substance, drug or autotransfusion is prescribed, administered or dispensed and any additional information upon which the diagnosis is based.

(3) A violation of any provision of this rule shall constitute grounds for disciplinary action under RCW 18.130.180(7). A violation of subsection (1) of this section shall also constitute grounds for disciplinary action under RCW 18.130.180(6).

21 U.S.C.A. § 333 (e) Prohibited distribution of human growth hormone (1) Except as provided in paragraph (2), whoever knowingly distributes, or possesses with intent to distribute, human growth hormone for any use in humans other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Health and Human Services under section 355 of this title and pursuant to the order of a physician, is guilty of an offense punishable by not more than 5 years in prison, such fines as are authorized by Title 18, or both.
(2) Whoever commits any offense set forth in paragraph (1) and such offense involves an individual under 18 years of age is punishable by not more than 10 years imprisonment, such fines as are authorized by Title 18, or both.
(3) Any conviction for a violation of paragraphs (1) and (2) of this subsection shall be considered a felony violation of the Controlled Substances Act [21 U.S.C.A. § 801 et seq.] for the purposes of forfeiture under section 413 of such Act [21 U.S.C.A. § 853].

(4) As used in this subsection the term "human growth hormone" means somatrem, somatropin, or an analogue of either of them.
(5) The Drug Enforcement Administration is authorized to investigate offenses punishable by this subsection

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

3. NOTICE TO RESPONDENT

The charges in this document affect the public health, safety and welfare. The Disciplinary Manager of the Commission 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 and the imposition of sanctions under Chapter 18.130 RCW.

DATED: March 13, 2012.

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

DANI NEWMAN
DISCIPLINARY MANAGER

KRISTIN 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 below. RCW 42.56.240(1)

Patient A

Patient B

Patient C

[redacted]

STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

RE: Janet E. Vondran, MD
Master Case No.: M2011-843
Document: Agreed Order

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STATE OF WASHINGTON
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MEDICAL QUALITY ASSURANCE COMMISSION

In the Matter of the License to Practice as a Physician and Surgeon of: **JANET E. VONDRAN, MD** License No. MD00033182 Respondent	No. M2011-843 **STIPULATED FINDINGS OF FACT, CONCLUSIONS OF LAW AND AGREED ORDER**

The Medical Quality Assurance Commission (Commission), through Teresa Landreau, Department of Health Staff Attorney, and Respondent, represented by counsel, if any, stipulate and agree to the following.

1. PROCEDURAL STIPULATIONS

1.1 On March 13, 2012, the Commission issued a Statement of Charges against Respondent.

1.2 In the Statement of Charges, the Commission alleges that Respondent violated RCW 18.130.180 (4), (7); RCW 69.41.320, WAC 246-919-610, and 21 U.S.C.A. § 333 (e).

1.3 The Commission is prepared to proceed to a hearing on the allegations in the Statement of Charges.

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

1.5 The Commission has the authority to impose sanctions pursuant to RCW 18.130.160 if the allegations are proven at a hearing.

1.6 The parties agree to resolve this matter by means of this Stipulated Findings of Fact, Conclusions of Law and Agreed Order (Agreed Order).

1.7 Respondent waives the opportunity for a hearing on the Statement of Charges if the Commission accepts this Agreed Order.

1.8 This Agreed Order is not binding unless it is accepted and signed by the Commission.

1.9 If the Commission accepts this Agreed Order, it will be reported to the Health Integrity and Protection Databank (HIPDB)(45 CFR Part 61), the Federation of State

Medical Boards' Physician Data Center and elsewhere as required by law. HIPDB will report this Agreed Order to the National Practitioner Data Bank (45 CFR Part 60).

1.10 This Agreed Order is a public document. It will be placed on the Department of Health's website, disseminated via the Commission's electronic mailing list, and disseminated according to the Uniform Disciplinary Act (Chapter 18.130 RCW). It may be disclosed to the public upon request pursuant to the Public Records Act (Chapter 42.56 RCW). It will remain part of Respondent's file according to the state's records retention law and cannot be expunged.

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

2. FINDINGS OF FACT

Respondent acknowledges that evidence is sufficient to justify the following findings of fact, which the Commission hereby makes.

2.1 On September 15, 1995, the state of Washington issued Respondent a license to practice as a physician and surgeon. Respondent is Board certified in Psychiatry with a Geriatric Psychiatry sub-specialty certificate. Respondent's license is currently active.

2.2 Between approximately November 2006 and January 2008, Respondent treated adult patients with Norditropin, a brand name for injectable somatropin, a human growth hormone (growth hormone) classified as a Schedule III controlled substance. Respondent advertised hormone replenishment as an anti-aging therapy to consumers via internet. In her response to inquiry by the Commission, Respondent endorsed the use of growth hormone as an anti-aging therapy. Federal and State law specifically bans the use of growth hormone as an "anti-aging" therapy or as an anabolic agent for sports. Its only legitimate use in adults is treatment of adult growth hormone deficiency, Acquired Immune Deficiency Syndrome (AIDS) wasting and short bowel syndrome. The use of growth hormone is particularly contra-indicated in patients with an active malignancy because it may accelerate the growth of cancer cells. The use of growth hormone may be causative or contributory to carpal tunnel syndrome.

2.3 The standard of care for diagnosing adult growth hormone deficiency requires:

2.3.1 The physician must have a high index of suspicion that the patient has growth hormone deficiency. Consideration for growth hormone deficiency in adults is indicated in patients with pituitary or brain disease, tumors or irradiation; patients who have suffered traumatic brain injury; patients with AIDS wasting syndrome or rare patients with short bowel syndrome. In addition, adults who had childhood onset growth hormone deficiency should be considered for continued growth hormone therapy as adults.

2.3.2 The diagnosis of growth hormone deficiency must be achieved by obtaining an insulin-like growth factor (IGF-1) level and then performing the provocative (or stimulation) test. The stimulation test is required unless the patient has deficiencies in at least three other hormone levels or the patient has a history of childhood growth hormone deficiency. A simple measurement of IGF-1 level is not sufficient to make the diagnosis, except in patients also diagnosed with panhypopituitarism. .

2.3.3 If growth hormone deficiency is determine by this standard, then the physician must look for the underlying cause.

2.4 Respondent prescribed growth hormone for adult Patients A, B, and C beginning approximately November 2006. This prescribing began on the basis of a single low serum IGF-1 level test result for each patient. These patients had no condition that would indicate a work-up for growth hormone deficiency. Respondent failed to conduct growth hormone stimulation testing for these patients and failed to conduct sufficient regular monitoring of their hormonal levels. Respondent warned of risks associated with low growth hormone, but did not advise of the standard of care for prescribing human growth hormone nor of the risks of human growth hormone supplementation. Patient A developed bilateral carpal tunnel syndrome while still taking growth hormone. There is no indication Respondent made any connection between the human growth hormone therapy and the development of carpal tunnel syndrome. When symptoms of carpal tunnel syndrome occur while a patient is taking growth hormone

therapy, the dose of growth hormone should be decreased or the drug discontinued. Respondent did not discontinue growth hormone therapy for Patient A, and the patient required surgery on both wrists. Respondent continued the growth hormone therapy for another eleven months after Patient A's carpal tunnel corrective surgery. Patient B described a history of removal of a cancerous lesion on her nose, but Respondent did not record when. Patient C disclosed a history of removal of a malignant melanoma, but Respondent did not document whether this was cured or when the surgery was performed.

2.5 Respondent's record keeping for Patients A, B, C is inadequate. For each of these patients, Respondent failed to establish a basis for a diagnosis to justify prescribing and maintaining a growth hormone regime. Respondent failed to document appropriate monitoring of the patients receiving growth hormone. Respondent failed to document informed consent by these patients for the growth hormone treatment she provided.

3. CONCLUSIONS OF LAW

The Commission and Respondent agree to the entry of the following Conclusions of Law.

3.1 The Commission 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 (4), (7); RCW 69.41.320, WAC 246-919-610, and 21 U.S.C.A. § 333 (e).

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

4. AGREED ORDER

Based on the Findings of Fact and Conclusions of Law, Respondent agrees to entry of the following Agreed Order.

4.1 **Probation.** The Commission places Respondent's license on PROBATION for at least two (2) years from the effective date of this Agreed Order.

4.2 **Restrictions.** Respondent shall not advertise hormone supplementation treatment. Respondent shall not provide human growth hormone treatment to patients. Any patient to be considered for any hormone replacement treatment must be referred by Respondent to a board certified endocrinologist or the patient's primary care physician for consultation and treatment.

4.3 **Practice Reviews.** In order to monitor compliance with this Agreed Order, Respondent will submit to semi-annual practice reviews at Respondent's medical practice location(s). The representative will review patient records, interview Respondent and interview Respondent's associates and staff. The representative will contact Respondent to give advance notice before each practice review.

4.4 **Fine.** Respondent will pay a fine to the Commission in the amount of three thousand dollars ($3,000.00). Respondent will pay the fine within ninety (90) days of the effective date of this Agreed Order. The fine will 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, Medical Quality Assurance Commission, at P.O. Box 1099, Olympia, Washington 98507-1099.

4.5 **Compliance appearances.** Respondent shall appear before the Commission on an annual basis and present proof of full compliance with this Agreed Order. Respondent shall continue to appear annually unless otherwise instructed in writing by the Commission or its representative.

4.6 **Obey laws.** Respondent shall obey all federal, state and local laws and all administrative rules governing the practice of the profession in Washington.

4.7 **Termination.** Respondent may file a petition for termination of probation after eighteen (18) months if Respondent has been in full compliance during that period with satisfactory practice review results. Respondent shall appear in person at a hearing on the petition. At the hearing, the Department may present evidence in opposition to be considered by the Commission. After considering the petition and the evidence presented, the Commission will have sole discretion to grant or deny Respondent's petition.

4.8 **Responsibility for costs of compliance.** Respondent is responsible for all costs she may incur in the course of complying with this Agreed Order.

4.9 **Consequences of Violation.** If Respondent violates any provision of this Agreed Order in any respect, the Commission may initiate further action against Respondent's license.

4.10 **Updated Address.** Respondent shall inform the Program and the Adjudicative Clerk Office, in writing, of changes in Respondent's residential and/or business address within thirty (30) days of the change.

4.11 **Effective Date.** 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. COMPLIANCE WITH SANCTION RULES

5.1 The Commission applies WAC 246-16-800, *et seq.*, to determine appropriate sanctions. Tier B of the "Practice Below Standard of Care" schedule, WAC 246-16-810, applies to cases where substandard practices result in moderate patient harm or risk of moderate or severe patient harm. The use of human growth hormone therapy is strictly limited to specified conditions because of significant attendant risk. Although Patients A, B and C each had a single low IGF-1 level lab result, Respondent's use of growth hormone supplementation without completing stimulation testing for these patients risked moderate to severe harm because each of these patients had a contra-indication such as carpal tunnel syndrome or a history of cancer. The evidence is not clear and convincing that any patient suffered permanent, severe injury as a result of Respondent's conduct. Rather, there was an unjustified risk of moderate to severe harm. Schedule B therefore applies.

5.2 Tier B requires the imposition of sanctions ranging from two years of oversight to five years of oversight, unless revocation. Under WAC 246-16-800(3)(d), the starting point for the duration of the sanctions is the middle of the range. The Commission uses aggravating and mitigating factors to move towards the maximum or minimum ends of the range.

5.3 The aggravating and mitigating factors in this case, listed below, justify imposing sanctions at the minimum end of the range. The sanctions in this case include

probation, a prohibition on Respondent's advertising or prescribing of hormone supplementation, practice reviews, compliance appearances before the Commission, a fine and other sanctions designed to protect the public.

5.4 These sanctions are appropriate within the Tier B range. Given the facts of the case, and the following mitigating factors, it is the judgment of the Commission that patient safety will be served by allowing Respondent the potential to terminate probation after eighteen months, if she has successfully completed all requirements of this Agreed Order, including satisfactory practice review results. The Commission has determined such potential deviation from the sanction schedule is consistent with patient safety in light of Respondent's reported voluntary cessation of the use of human growth hormone to treat patients after notification of the Commission's concern.

A. As a mitigating factor: Respondent fully cooperated with the investigator for the Commission.

B. As a mitigating factor: Respondent fully admitted key facts to the Commission.

C. As a mitigating factor: Respondent describes voluntary cessation of the use of human growth hormone to treat patients once notified of the Commission's concerns.

D. The Commission did not identify any aggravating factors.

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 license after a show cause hearing. If Respondent fails to comply with the terms and conditions of this order, the Commission may hold a hearing to require Respondent to show cause why the license should not be suspended. Alternatively, the Commission 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.

7. RESPONDENT'S ACCEPTANCE

I, JANET E. VONDRAN, MD, Respondent, have read, understand and agree to this Agreed Order. This Agreed Order may be presented to the Commission without my appearance. I understand that I will receive a signed copy if the Commission accepts this Agreed Order.

JANET E. VONDRAN, MD
RESPONDENT

2/8/13
DATE

DONNA MONIZ, WSBA# 12762
ATTORNEY FOR RESPONDENT

2/8/13
DATE

8. COMMISSION'S ACCEPTANCE AND ORDER

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

DATED: Feb 21, 2013.

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

Linda A Duy
PANEL CHAIR

PRESENTED BY:

TERESA LANDREAU, WSBA # 9591
DEPARTMENT OF HEALTH STAFF ATTORNEY

Feb 24, 2013
DATE