STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

In the Matter of the License to Practice as a Physician and Surgeon of: **BRADFORD S. WEEKS, MD** License No. MD00030856 Respondent	**No. M2011-839** **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 2009-140473. The patients referred to in this Statement of Charges are identified to the best of the Commission's ability in the attached Confidential Schedule.

1. ALLEGED FACTS

1.1 On May 20, 1993, the state of Washington issued Respondent a license to practice as a physician and surgeon. Respondent's license is currently active.

1.2 During a time frame that included September 23, 2009, Respondent offered to consumers via the internet the use of human growth hormone in oral spray form as an anti-aging remedy. Respondent claimed he prescribed growth hormone to patients to correct "adult growth hormone deficiency syndrome", but this so-called "syndrome" was not consistent with abnormally deficient hormonal levels in the patients. Since 1988 Federal law specifically bans the use of growth hormone as an "anti-aging" therapy or for any use other than the treatment of a disease. Since 1990 Federal law further limited the use of growth hormone therapy to those medical conditions specifically authorized by the Secretary of Human services. Since 1989 Washington State law prohibits the use of growth hormone to manipulate hormones to increase muscle mass, strength or weight or to enhance athletic ability. The only tegitimate use of growth hormone prescriptions for adults is treatment of the disease of adult growth hormone deficiency, Acquired Immune Deficiency Syndrome (AIDS) wasting and short bowel syndrome.

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ORIGINAL

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 a 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 treated Patient A, born in 1945, during a time frame from January 3 2007 through August 8, 2010. Respondent prescribed growth hormone for patient A during this time frame, with a hiatus between September 10, 2007 and October 8, 2007. Respondent described in a form template presented to Patient A on October 8, 2007 that growth hormone would be prescribed as part of "replacement therapy of hormones which are deficient because of normal aging." Although titled "Informed Consent", this form did not adequately inform Patient A of the known risks of growth hormone therapy. Patient A did not meet diagnostic criteria for hypothalamic disease. Respondent failed to conduct growth hormone stimulation testing for Patient A and failed to document regular monitoring of Patient A's hormonal levels. Respondent's initiation of and maintenance of growth hormone therapy regimen for Patient A was below the standard of care and created a unreasonable risk of harm to Patient A. Respondent stopped prescribing growth hormone for Patient A on March 9, 2010, citing "state policy ambiguity".

1.5 Respondent treated Patient B, born in 1948, from May 3, 2006 through August 4, 2009. Respondent prescribed growth hormone for Patient B from May 22, 2006 through October 10, 2007. Respondent described in an informed consent template presented to Patient B on May 22, 2006, that growth hormone would be prescribed as part of "replacement therapy of hormones which are deficient because of normal aging." This form did not adequately inform Patient B of the known risks of growth hormone. Respondent failed to conduct growth hormone stimulation testing on patient B. Respondent failed to document regular monitoring of Patient B's hormonal levels. Patient B did not meet diagnostic criteria for hypothalamic disease. Respondent's initiation of prescribing 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. Respondent cited cost as the rationale for stopping growth hormone therapy for this patient.

1.6 Respondent treated Patient C, born in 1935, between August, 2006 and June 22, 2010. Respondent prescribed human growth hormone for Patient C beginning July 10, 2007. Respondent described in an informed consent template presented to Patient C on July 20, 2007, that growth hormone would be prescribed as part of "replacement therapy of hormones which are deficient because of normal aging." This form did not adequately inform Patient C of the known risks of growth hormone therapy. Patient C did not meet diagnostic criteria for hypothalamic disease. Magnetic Resonance Imaging (MRI) of Patient C's brain in April 2006 showed no evidence of pituitary or hypothalamic disease. Respondent failed to conduct growth hormone stimulation testing for Patient C and failed to document regular monitoring of Patient C's hormonal levels. Respondent's initiation and maintenance of a growth hormone regimen for Patient C was below the standard of care and created a unreasonable risk of harm to Patient C.

1.7 Respondent saw Patient D, born in 1963, from October 2007 through May 2009. Patient D had been taking a growth hormone product since 2006. Respondent prescribed growth hormone for Patient D without a work-up for growth hormone deficiency. Respondent provided Patient D with a written statement claiming that therapy with growth hormone did not require a diagnosis of disease, and describing the use of growth hormone as an anti-aging technique. Respondent's written consent form

signed by Patient D did not adequately explain the risks of growth hormone therapy. Respondent's initiation and maintenance of a growth hormone regime for Patient D was below the standard of care and created an unreasonable risk of harm to Patient D.

1.8 Respondent failed to provide un-redacted medical records to the Commission upon request by the investigator for the Commission mailed to Respondent on July 21, 2010 and September 16, 2010.

1.9 Respondent attempted to circumvent his responsibility as a licensed physician to cooperate with the Commission's request for patient records by preparing for patients' signature a form that purports to prohibit Respondent's release of medical records to any person or agency absent a court order and unless a warrant for the release of these records is obtained.

1.10 Respondent attempted to circumvent patient rights by having patients sign a commitment not to submit any documents or claims to any governmental agency for purposes of investigation.

1.11 Respondent attempted to circumvent patient rights by requiring patients to sign an agreement to hold Respondent harmless for any subsequent legal action related to their care, specifically referring to investigations by the Washington State Medical Quaiity Assurance Committee.

1.12 Respondent characterized his treatment of patients as "experimental", but did not obtain oversight or approval for experimentation on human subjects.

2. ALLEGED VIOLATIONS

2.1 Based on the Alleged Facts, Respondent has committed unprofessional conduct in violation of RCW 18.130.180 (4), (7), (8)(a); RCW 69.41.320 with definitions at RCW 69.41.300, WAC 246-919-610, WAC 246-919-620, 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;

(8) Failure to cooperate with the disciplining authority by: (a) Not furnishing any papers, documents, records, or other items;

. . .

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.

RCW 69.41.300 Definitions. For the purposes of RCW 69.41.300 through 69.41.350, "steroids" shall include the following: . . . (3) "Human growth hormones" means growth hormones, or a derivative, isomer, ester, or salt that act in the same manner on the human body.

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).

246-919-620 Cooperation with investigation.

(1) A licensee must comply with a request, under RCW 70.02.050, for health care records or documents from an investigator who is acting on behalf of the disciplining authority pursuant to RCW 18.130.050(2) by submitting the requested items within fourteen calendar days of receipt of the request by the licensee or the licensee's attorney, whichever is first. If the licensee fails to comply with the request within fourteen calendar days, the investigator shall contact the licensee or the licensee's attorney by letter as a reminder.

(a) Investigators may extend the time for response if the licensee requests an extension for a period not to exceed seven calendar days. Other requests for extension may be granted by the commission chair or the commission's designee.

(b) If the licensee fails to comply with the request within three business days after the receipt of the written reminder, a statement of charges shall be issued pursuant to RCW 18.130.180(8) and, if there is sufficient evidence to support additional charges, those charges may be included in the statement of charges.

. . .

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].

2.2 The above violation provides 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	Respondent refused to disclose name, believed to be [redacted] Date of Birth March 3, 1945
Patient B	Respondent refused to disclose name, Date of Birth January 23, 1948
Patient C	Respondent refused to disclose name, believed to be [redacted] Date of Birth May 25, 1935
Patient D	Respondent refused to disclose name, believed to be [redacted] Date of Birth May 20, 1963

STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

RE: Bradford S. Weeks, MD
Master Case No.: M2011-839
Document: Amended 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

FILED
APR 30 2012
Adjudicative Clerk

In the Matter of the License to Practice as a Physician and Surgeon of: **BRADFORD S. WEEKS, MD** License No. MD00030856 Respondent	**No. M2011-839** **AMENDED 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 2009-140473. The patients referred to in this Amended Statement of Charges are identified to the best of the Commission's ability in the attached Confidential Schedule.

1. ALLEGED FACTS

1.1 On May 20, 1993, the state of Washington issued Respondent a license to practice as a physician and surgeon. Respondent's license is currently active.

1.2 During a time frame that included September 23, 2009, Respondent offered to consumers via the internet the use of human growth hormone in oral spray form as an anti-aging remedy. Respondent claimed he prescribed growth hormone to patients to correct "adult growth hormone deficiency syndrome", but this so-called "syndrome" was not consistent with abnormally deficient hormonal levels in the patients. Since 1988 Federal law specifically bans the use of growth hormone as an "anti-aging" therapy or for any use other than the treatment of a disease. Since 1990 Federal law further limited the use of growth hormone therapy to those medical conditions specifically authorized by the Secretary of Human services. Since 1989 Washington State law prohibits the use of growth hormone to manipulate hormones to increase muscle mass, strength or weight or to enhance athletic ability. The only legitimate use of growth hormone prescriptions for adults is treatment of the disease of adult growth hormone deficiency, Acquired Immune Deficiency Syndrome (AIDS) wasting and short bowel syndrome.

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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 a 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 treated Patient A, born in 1945, during a time frame from January 3 2007 through August 8, 2010. Respondent prescribed growth hormone for patient A during this time frame, with a hiatus between September 10, 2007 and October 8, 2007. Respondent described in a form template presented to Patient A on October 8, 2007 that growth hormone would be prescribed as part of "replacement therapy of hormones which are deficient because of normal aging." Although titled "Informed Consent", this form did not adequately inform Patient A of the known risks of growth hormone therapy. Patient A did not meet diagnostic criteria for hypothalamic disease. Respondent failed to conduct growth hormone stimulation testing for Patient A and failed to document regular monitoring of Patient A's hormonal levels. Respondent's initiation of and maintenance of growth hormone therapy regimen for Patient A was below the standard of care and created a unreasonable risk of harm to Patient A. Respondent stopped prescribing growth hormone for Patient A on March 9, 2010, citing "state policy ambiguity".

1.5 Respondent treated Patient B, born in 1948, from May 3, 2006 through August 4, 2009. Respondent prescribed growth hormone for Patient B from May 22, 2006 through October 10, 2007. Respondent described in an informed consent template presented to Patient B on May 22, 2006, that growth hormone would be prescribed as part of "replacement therapy of hormones which are deficient because of normal aging." This form did not adequately inform Patient B of the known risks of growth hormone. Respondent failed to conduct growth hormone stimulation testing on patient B. Respondent failed to document regular monitoring of Patient B's hormonal levels. Patient B did not meet diagnostic criteria for hypothalamic disease. Respondent's initiation of prescribing 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. Respondent cited cost as the rationale for stopping growth hormone therapy for this patient.

1.6 Respondent treated Patient C, born in 1935, between August, 2006 and June 22, 2010. Respondent prescribed human growth hormone for Patient C beginning July 10, 2007. Respondent described in an informed consent template presented to Patient C on July 20, 2007, that growth hormone would be prescribed as part of "replacement therapy of hormones which are deficient because of normal aging." This form did not adequately inform Patient C of the known risks of growth hormone therapy. Patient C did not meet diagnostic criteria for hypothalamic disease. Magnetic Resonance Imaging (MRI) of Patient C's brain in April 2006 showed no evidence of pituitary or hypothalamic disease. Respondent failed to conduct growth hormone stimulation testing for Patient C and failed to document regular monitoring of Patient C's hormonal levels. Respondent's initiation and maintenance of a growth hormone regimen for Patient C was below the standard of care and created a unreasonable risk of harm to Patient C.

1.7 Respondent saw Patient D, born in 1963, from October 2007 through May 2009. Patient D had been taking a growth hormone product since 2006. Respondent prescribed growth hormone for Patient D without a work-up for growth hormone deficiency. Respondent provided Patient D with a written statement claiming that therapy with growth hormone did not require a diagnosis of disease, and describing the use of growth hormone as an anti-aging technique. Respondent's written consent form

signed by Patient D did not adequately explain the risks of growth hormone therapy. Respondent's initiation and maintenance of a growth hormone regime for Patient D was below the standard of care and created an unreasonable risk of harm to Patient D.

1.8 Respondent failed to provide un-redacted medical records to the Commission upon request by the investigator for the Commission mailed to Respondent on July 21, 2010 and September 16, 2010.

1.9 Respondent attempted to circumvent his responsibility as a licensed physician to cooperate with the Commission's request for patient records by preparing for patients' signature a form that purports to prohibit Respondent's release of medical records to any person or agency absent a court order and unless a warrant for the release of these records is obtained.

1.10 Respondent attempted to circumvent patient rights by having patients sign a commitment not to submit any documents or claims to any governmental agency for purposes of investigation.

1.11 Respondent attempted to circumvent patient rights by requiring patients to sign an agreement to hold Respondent harmless for any subsequent legal action related to their care, specifically referring to investigations by the Washington State Medical Quality Assurance Committee.

1.12 Respondent characterized his treatment of patients as "experimental", but did not obtain oversight or approval for experimentation on human subjects.

1.13 On February 28, 2008, Stipulated Findings of Fact, Conclusions of Law and Agreed Order (2008 Agreed Order) was entered *In the Matter of Bradford Weeks*, Washington Medical Quality Assurance Commission No. 07-03-A-1080MD. Paragraph 4.3 of the 2008 Agreed Order provided: "Prior to treating or prescribing medication to a patient, Respondent will physically examine and take a history of the patient adequate to establish a diagnoses and to identify underlying conditions and contra-indications to the medication recommended." This provision is a term of Respondent's five-year probation under the 2008 Agreed Order which began in February of 2008 and has remained continuously in effect.

1.14 Respondent violated paragraph 4.3 of the 2008 Agreed Order by his prescribing of human growth hormone for Patients A,B,C, and D without a physical examination and history of the patients adequate to establish a diagnosis of adult

growth hormone deficiency (or any other diagnosis justifying prescription of human growth hormone) and by his failure to identify underlying conditions and contra-indications to the medication recommended.

1.15 Respondent's conduct, described in the preceding paragraphs, violated paragraph 4.6 of the 2008 Agreed Order which states: "Respondent will obey all federal, state and local laws and all administrative rules governing the practice of the profession in Washington."

2. ALLEGED VIOLATIONS

2.1 Based on the Alleged Facts, Respondent has committed unprofessional conduct in violation of RCW 18.130.180 (4), (7), (8)(a), (9); RCW 69.41.320 with definitions at RCW 69.41.300, WAC 246-919-610, WAC 246-919-620, 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;
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> . . .
>
> (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;
>
> . . .
>
> (8) Failure to cooperate with the disciplining authority by: (a) Not furnishing any papers, documents, records, or other items;
>
> (9) Failure to comply with an order issued by the disciplining authority or a stipulation for informal disposition entered into with the disciplining authority;
>
> . . .

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.

RCW 69.41.300 Definitions. For the purposes of RCW 69.41.300 through 69.41.350, "steroids" shall include the following: . . . (3) "Human growth hormones" means growth hormones, or a derivative, isomer, ester, or salt that act in the same manner on the human body.

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).

246-919-620 Cooperation with investigation.

(1) A licensee must comply with a request, under RCW 70.02.050, for health care records or documents from an investigator who is acting on behalf of the disciplining authority pursuant to RCW 18.130.050(2) by submitting the requested items within fourteen calendar days of receipt of the request by the licensee or the licensee's attorney, whichever is first. If the licensee fails to comply with the request within fourteen calendar days, the investigator shall contact the licensee or the licensee's attorney by letter as a reminder.

(a) Investigators may extend the time for response if the licensee requests an extension for a period not to exceed seven calendar days. Other requests for extension may be granted by the commission chair or the commission's designee.

(b) If the licensee fails to comply with the request within three business days after the receipt of the written reminder, a statement of charges shall be issued pursuant to RCW 18.130.180(8) and, if there is sufficient evidence to support additional charges, those charges may be included in the statement of charges.

. . .

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].

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: April 30, 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	Respondent refused to disclose name, believed to be [redacted] Date of Birth [redacted]
Patient B	Respondent refused to disclose name, Date of Birth [redacted]
Patient C	Respondent refused to disclose name, believed to be [redacted] Date of Birth [redacted]
Patient D	Respondent refused to disclose name, believed to be [redacted] Date of Birth [redacted]

STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington 98504

RE: Bradford S. Weeks, M.D.,
Master Case No.: M2011-839
Document: Final 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: **NONE**

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:	Master Case No. M2011-839
BRADFORD S. WEEKS, M.D., Credential No. MD.MD.00030856, Respondent.	FINDINGS OF FACT, CONCLUSIONS OF LAW, AND FINAL ORDER

APPEARANCES:

Bradford S. Weeks, M.D., Respondent, by
Law Office of Robert N. Meals, per
Robert N. Meals, Attorney at Law

Department of Health Medical Program (Department), by
Office of the Attorney General, per
Kristin Brewer, Assistant Attorney General

PANEL: Leslie M. Burger, M.D., Panel Chair
Michael T. Concannon, J.D.
Theresa Elders, Public Member
Samuel Selinger, M.D.

PRESIDING OFFICER: John F. Kuntz, Review Judge

A hearing was held in this matter on January 11 and 12, 2013, regarding allegations of unprofessional conduct. SUSPENSION.

ISSUES

Did the Respondent commit unprofessional conduct as defined in RCW 18.130.180(4), (7), (8)(a), and (9); RCW 69.41.320 with definitions at RCW 69.41.300; WAC 246-919-610; WAC 246-919-620; and 21 U.S.C.A. § 333(e)?

If the Department proves unprofessional conduct, what are the appropriate sanctions under RCW 18.130.160?

SUMMARY OF PROCEEDINGS

At the hearing, the Department presented the testimony of Andrew Hoffman, M.D., expert witness.

The Respondent presented the testimony of:

1. Bradford Weeks, M.D.;
2. Diana Schwarzbein, M.D., expert witness;
3. Michael Farrell; and
4. Michael Bahn.

The Presiding Officer admitted the following Department exhibits:

Exhibit D-1: Curriculum Vitae of Dr. Andrew Hoffman;

Exhibit D-2: Advertisement printed from Respondent's webpage;

Exhibit D-3: Patient A's treatment records provided by Respondent on July 13, 2012;

Exhibit D-4: Patient B's treatment records provided by the Respondent on July 13, 2012;

Exhibit D-5: Patient C's treatment records provided by the Respondent on July 13, 2012;

Exhibit D-6: Patient D's treatment records provided by the Respondent on July 13, 2012;

Exhibit D-7: Stipulated Findings of Fact, Conclusions of Law, and Agreed Order, entered on February 28, 2008;

Exhibit D-8: "Evaluation and Treatment of Adult Growth Hormone Deficiency: An Endocrine Society Clinical Practice Guideline," *The Journal of Clinical Endocrinology & Metabolism* 96; 1587-1609, 2011;

Exhibit D-9: "Evaluation and Treatment of Adult Growth Hormone Deficiency: An Endocrine Society Clinical Practice Guideline," *The Journal of Clinical Endocrinology & Metabolism*, 91(5) 1621-1634, 2006;

Exhibit D-10: "American Association of Clinical Endocrinologist (AACE) Guidelines – Medical Guidelines for Clinical Practice for Growth Hormone Use in Growth Hormone-Deficient Adults and Transition Patients – 2009 Update";

Exhibit D-11: "Consensus Guidelines for the Diagnosis and Treatment of Adults with Growth Hormone Deficiency: Summary Statement Growth Hormone Research Society Workshop on Adult Growth Hormone Deficiency," *Journal of Clinical Endocrinology and Metabolism*, Vol. 83, No. 2, 1998;

Exhibit D-12: "Consensus Guidelines for the Diagnosis and Treatment of Adults with GH Deficiency II: a Statement of the GH Research Society in Association with the European Society for Pediatric Endocrinology, Lawson Wilkins Society, European Society of Endocrinology, Japan Endocrine Society, and Endocrine Society of Australia," European Journal of Endocrinology (2007);

Exhibit D-13: "Systematic Review: The Safety and Efficacy of Growth Hormone in the Healthy Elderly," *Annals of Internal Medicine*, 146: 104-115, 2007;

Exhibit D-14: JAMA Commentary, "New Developments in the Illegal Provision of Growth Hormone for "Anti-Aging" and Bodybuilding," June 18, 2008, Vol. 299, No. 23;

Exhibit D-15: JAMA, October 26, 2005, Vol. 294, No. 16 (reprinted);

Exhibit D-16: Section 303(e)(1) of the Food, Drug and Cosmetic Act, 21 USC 333(e)(1);

Exhibit D-17: U.S. Department of Justice, Drug Enforcement Agency, Office of Diversion Control, "Drugs and Chemicals of Concern", August 2007;

Exhibit D-18: List of FDA Approved Recombinant Human Growth Hormone (rhGH) Indications and Drug Products;

Exhibit D-19: Human Growth Hormone Coverage Criteria, Preferred Care Services, Inc.; and

Exhibit D-20: Indications and Usage for Omnitrope.

The Presiding Officer admitted the following Respondent exhibits:

Exhibit R-1: Curriculum Vitae – Bradford Weeks, M.D.;

Exhibit R-2: "American Association of Clinical Endocrinologist Medical Guidelines for Clinical Practice for Growth Hormone Use in Adults and Children" – 2003 Update Endocrine Practice, Vol. 9, No. 1, January/February 2003;

Exhibit R-3: Invited Report of a Workshop - *Consensus Guidelines for the Diagnostic and Treatment of Adults with Growth Hormone Deficiency: Summary Statement of the Growth Hormone Research Society Workshop on Adult Growth Hormone Deficiency* – 1997;

Exhibit R-4: *Consensus Guidelines for the Diagnostic and Treatment of Adults with GH Deficiency: Summary statement of the Growth Hormone Research Society Workshop on Adult Growth Hormone Deficiency – 1997;*

Exhibit R-5: *Consensus Guidelines for the Diagnostic and Treatment of Adults with GH Deficiency II: A statement of the GH Research Society in association with the European Society for Pediatric Endocrinology*, Lawson Wilkins Society, European Society of Endocrinology, Japan Endocrine Society, and Endocrine Society of Australia 2007;

Exhibit R-6: Rudman, Kutner, Rogers, Lubin, Fleming, Bain, "Impaired Growth Hormone Secretion in the Adult Population" J. Clin. Invest. Vol. 67, May 1981, p. 1361-1369;

Exhibit R-7: Special Committee on Questionable and Deceptive Health Care Practices, Federation of State Medical Boards of the United States, Inc., April 1997;

Exhibit R-8: Elsevier, *Archives of Gerontology and Geriatrics*, 48 (2009) p. 271-275 "Is consensus in anti-aging medical intervention an elusive expectation or a realistic goal?"

Exhibit R-9: Email from Thomas Perls to Kristen Brewer, dated August 14, 2009;

Exhibit R-10: Letter from Department of Health (DOH) Medical Quality Assurance Commission (MQAC) to Bradford Weeks, dated December 8, 2009;

Exhibit R-11: Letter from DOH MQAC to Bradford Weeks, dated January 21, 2010;

Exhibit R-12: Letter from DOH MQAC to Bradford Weeks, dated July 21, 2010;

Exhibit R-13: Letter from Wayne Carlson to Bradford Weeks, dated August 2, 2010;

Exhibit R-14: Letter from Ken Kagan to Wayne Carlson, dated September 3, 2010;

Exhibit R-15: Letter from Wayne Carlson to Bradford Weeks, dated September 16, 2010, with attachment of July 21, 2010 letter with Provision 1 crossed out;

Exhibit R-16: Letter from Ken Kagan to Wayne Carlson, dated September 20, 2010;

Exhibit R-17: Email from Michael Bahn to Ken Kagan, dated September 24, 2010;

Exhibit R-18: Letter from Mike Kramer to Bradford Weeks, dated February 2, 2011;

Exhibit R-19: Note from Laura Weeks regarding April 15, 2011 compliance hearing;

Exhibit R-20: 2010 Appointment Log excerpt indicating Wayne Carlson appointment, dated January 14, 2010;

Exhibit R-21: HGH Saizen Package Insert;

Exhibit R-22: Lilly Humatrope package insert;

Exhibit R-23: "Growth Hormone Treatment Reduces Abdominal Visceral Fat in Postmenopausal Women with Abdominal Obesity: A 12-Month Placebo-Controlled Trial," Journal of Clinical Endocrinology & Metabolism, March 1, 2005, Vol. 90, No. 3;

Exhibit R-24: "Legal Prophylaxis – The legal aspects of hormone replacement can be complicated and challenging," Healthy Aging 12/22/2008;

Exhibit R-25: HGH References to clinical studies published in peer review medical literature (Cranton);

Exhibit R-26: Legal Status of Growth Hormone (HGH) Replacement Therapy (Cranton);

Exhibit R-27: Excerpts from Ambrx web site regarding Ambrx and Dr. Andrew R. Hoffman;

Exhibit R-28: Taaffe, DR.; Pruitt, L.; Reim, J., Hintz, RL.; Butterfield, G.; Hoffman, AR.; Marcus, R.; *Effect of Recombinant Human Growth Hormone on the Muscle Strength Response to Resistance Exercise in Elderly Men*, The Journal of Clinical Endocrinology & Metabolism, Vol. 79, No. 5, p. 1361-1366;

Exhibit R-29: Taaffe, DR.; Jin, IH.; Vu, TH.; Hoffman, AR.; Marcus, R.; *Lack of Effect of Recombinant Human Growth Hormone (GH) on Muscle Morphology and GH-Insulin-Like Growth Factor Expression in Resistance-trained Elderly Men*, The Journal of Clinical Endocrinology & Metabolism, 1996, p. 421-425;

Exhibit R-30: Thompson, JL.; Butterfield, GE.; Hoffman, AR.; et al.; *Effects of Human Growth Hormone, Insulin-Like Growth Factor I, and Diet and Exercise on Body Composition of Obese Postmenopausal Women*, The Journal of Clinical Endocrinology & Metabolism, May 1, 1998, Vol. 83, No. 5, p. 1477-1484;

Exhibit R-31: Hoffman, AR.; Ceda, GP; *IGFs and aging: is there a rationale for hormone replacement therapy?* The Journal of Clinical Endocrinology & Metabolism 2004, p. 296-300;

Exhibit R-32: Hoffman, AR.; Kuntze, JE.; Baptista, J.; et al.; *Growth Hormone (GH) Replacement Therapy in Adult-Onset GH Deficiency: Effects on Body Composition in Men and Women in a Double-Blind, Randomized, Placebo-Controlled Trial*, The Journal of Clinical Endocrinology & Metabolism, May 2004, p. 2048-2056;

Exhibit R-33: Hoffman, AR.; Strasburger, CJ.; Zagar, A.; et al.; *Efficacy and Tolerability of an Individualized Dosing Regimen for Adult Growth Hormone Replacement Therapy in Comparison with Fixed Body Weight-based Dosing*, The Journal of Clinical Endocrinology & Metabolism, July 2004, p. 3224-3233;

Exhibit R-34: Denti, L.; Annoni, V.; Hoffman, AR.; et al.; *Insulin-Like Growth Factor 1 as a Predictor of Schemic Stroke Outcome in the Elderly*, American Journal of Medicine, Sept. 1, 2004, p. 312-317;

Exhibit R-35: Hoffman, AR., *Treatment of the adult growth hormone deficiency syndrome: Directions for future research*, 2005, Elsevier, p. 848-852;

Exhibit R-36: Attallah, H.; Friedlander, AL.; Hoffman, AR.; *Visceral obesity, impaired glucose tolerance, metabolic syndrome, and growth hormone therapy*, Elsevier, April 18, 2006, p. S62-67;

Exhibit R-37: Liu, H.; Bravata, DM.; Olkin, I.; Nayak, S.; Roberts, B.; Garber, AM.; Hoffman, AR.; *Systematic Review: The Safety and Efficacy of Growth Hormone in the Health Elderly*, Annals of Internal Medicine, January 2007, Vol. 146, No. 2, p. 104-115;

Exhibit R-38: Attalah, H.; Freidlander, AL.; Nino-Murcia, M.; Hoffman, AR.; *Effects of Growth Hormone and Pioglitazone in Viscerally Obese Adults with Impaired Glucose Tolerance: A Factorial Clinical Trial*, www.ploselinicaltrias.org, May 23007, p. 1-11;

Exhibit R-39: Hartman, ML.; Weltman, A.; Hoffman, AR.; et al.; *Growth Hormone Replacement Therapy in Adults with Growth Hormone Deficiency Improves Maximal Oxygen Consumption Independently of Dosing Regimen or Physical Activity*, The Journal of Clinical Endocrinology & Metabolism, January 2008, p. 125-130;

Exhibit R-40: White, HK.; Petrie, CD.; Hoffman, AR.; et al.; *Effects of an Oral Growth Hormone Secretagogue in Older Adults*, The Journal of Clinical Endocrinology & Metabolism, April 2009, Vol. 94(4), p. 1198-1206;

Exhibit R-41: McIntire, KL; Hoffman, AR.; *The Endocrine System and Sarcopenia: Potential Therapeutic Benefits, Current 'Aging Science*, 2011, Vol. 4, No. 3, p. 298-305;

Exhibit R-42: American Program Bureau Biography of Thomas Perls, M.D., "Centenarian Expert";

Exhibit R-43: *Growth Hormone/HGH/AntiAging and Sports* article by Thomas Perls, M.D.;

Exhibit R-44: *Scientists Retract Report on Predicting Longevity* article, New York Times, July 22, 2011;

Exhibit R-45: A4M Mission statement;

Exhibit R-46: White Paper Guidance for Physicians on Hormone Replacement Therapy – April 2007;

Exhibit R-47: The DEA Web Site on HGH – August 2009;

Exhibit R-48: *J Clin Endocrinol Metab*, 2005 Dec; 90(12):6431-40. Epub 2005 Sep 13. Efficacy of a long-acting growth hormone (GH) preparation in patients with adult GH deficiency. Hoffman_AR, Biller BM, Cook D. Baptista J. Siverman BL, Dao L, Attie KM, Fielder P. Maneatis T, Lippe B; Genentech Adult Growth Hormone Deficiency Study Group;

Exhibit R-49: Growth hormone therapy in the elderly: implications for the aging brain. Hoffman, AR, Lieberman SA, Ceda GP. Psychoneuroendocrinology. 1992 Aug; 17(4):327-33;

Exhibit R-50: Growth hormone (GH) replacement therapy in adult-onset gh deficiency: effects on body composition in men and women in a double-blind, randomized, placebo-controlled trial, Hoffman AR, Kuntze JE, Baptista J, Baum HB, Baumann GP, Biller BM, Clark RV, Cook D, Inzucchi SE, Kleinberg D, Klibanski A, Phillips LS, Ridgway EC, Robbins RJ, Schlechte J, Sharma M, Thorner MO,

Vance ML. J Clin Endocrinol Metab. 2004 May; 90(5): 2048-56. J Clin Endocrinol Metab. 2004 May: 89(5):2048-56;

Exhibit R-51: Review of Growth Hormone Therapy, Trina N. Seligman, N.D., Journal of Orthomolecular Medicine, Vol. 14, No. 4, 1999;

Exhibit R-52: The Human Growth Foundation website information, copyright 2012 (seven pages); and

Exhibit R-54: Searching the Clinical Fitness Landscape, Margaret J. Eppstein, Jeffrey D. Horbar, Jeffrey S. Buzas, and Stuart A. Kauffman.

The following exhibits were withdrawn or rejected:

Exhibit D-21: Declaration of Dr. Dragos G. Roman, dated January 10, 2013;

Exhibit R-53: AGHD Slide Presentation, a three-slide excerpts from Dr. Hoffman's presentafion and

Exhibit R-55: Appendix A: The Forsythe Protocol (undated).

CREDIBILITY FINDING

The Department's expert (Andrew Hoffman, M.D.) and the Respondent's expert (Diana Schwarzbein, M.D.) each testified regarding the issue of human growth hormone; the standard of care regarding its use, and the Respondent's specific use of human growth hormone in the treatment of Patients A, B, C, and D. The Commission finds Dr. Hoffman's testimony to be credible, based on his extensive experience as an endocrinologist, his extensive research relating to the use and effectiveness of human growth hormone, and it is supported by the totality of the evidence presented in this matter.

The Commission tinds Dr. Schwarzbein to be less credible. While she is an endocrinologist, Dr. Schwarzbein admitted during the hearing that she does not utilize human growth hormones in her work.

I. FINDINGS OF FACT

1.1 The Respondent was granted a license to practice as a physician and surgeon in the state of Washington on May 20, 1993.

Standard of Care

1.2 The standard of care for physicians in the state of Washington follows the generally-accepted principle that a physician must exercise the minimal degree of skill, care, and learning expected of a reasonably prudent practitioner.[1] In its broadest terms, the standard of care for the prescription of medications or hormones requires that the reasonably prudent physician determine whether a patient requires a medication or hormone based on the patient's condition or symptoms and following a careful examination of the patient. The careful examination of a patient includes all appropriate medical tests to determine if a medical condition (such as adult human growth deticiency) exists in that patient. The fact that a patient may request a type of treatment (for example, the prescription or administering of human growth hormone) does not control; a reasonably prudent physician only prescribes or administers a medication or hormone if the treatment of a medical condition or symptom requires it.

[1] *See generally* RCW 7.70.040.

Human Growth Hormone

1.3 "Hormones" are substances originating in an organ, gland or body part, which are conveyed through the blood to another body part, and chemically stimulating that body part to increase or decrease functional activity or to increase or decrease the secretion of another hormone. Human growth hormone is a naturally occurring substance that is secreted by the pituitary gland and is essential for body growth. The daily secretions of human growth hormone increase during childhood, peaking during adolescence, and steadily declining thereafter. "Panhypopituitarism" is defined as the defective or absent function of the entire pituitary gland. The effect of Panhypopituitarism is the total loss of the secretion of the growth hormone that regulates cell division and protein synthesis necessary for normal growth. The condition can affect both children[2] and adults. When it affects adults, it is called Adult Growth Hormone Deficiency (AGHD).

1.4 To treat a growth hormone deficiency (the absence of naturally occurring hormone in the patient and not the reduction of growth hormone levels that is a natural consequence of aging), a physician can prescribe a synthetic (recombinant) version to AGHD patients. Unlike other hormones or medications, human growth hormone is not approved for "off label" use (namely, the use of a drug to treat a condition for which it

[2] There are no allegations in the Amended Statement of Charges relating to the Respondent treating children using human growth hormone.

has not been approved by the Food and Drug Administration or FDA).[3] For example, prescribing human growth hormone for anti-aging therapy or to improve athletic performance and/or bodybuilding purposes are "off label" uses. These off label uses have not been approved by the Secretary of Health and Human Services. *See* 21 U.S.C.A. § 333(e). The only conditions for which human growth hormone can be used in adults are AGHD, short bowel syndrome, Acquired Immune Deficiency Syndrome (AIDS) wasting, and cachexia (a state of ill health, malnutrition and wasting). *See* Exhibit D-18 (List of FDA Approved Recombinant Human Growth Hormone (rhGH) Indications and Drug Products).

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

A. The physician must have a high index of suspicion that the patient has growth hormone deticiency. Consideration for growth hormone deticiency in adults is indicated in patients with: pituitary or brain disease, tumors or irradiation; 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. As stated in Paragraph 1.3 above, the natural decline of growth hormone that is experienced as a part of the aging process is not

[3] During the drug approval process, drug manufacturers present carefully accumulated data to the FDA about the safety and effectiveness of the product. Drugs are labeled for specific uses with data that describe the drug's performance during clinical trials. Drug effects that have been observed but not specifically proven (and for which no application is made) may be exploited for unproven or "off label" uses. *See* Taber's Cyclopedic Medical Dictionary, 21st Edition (2009), page 1624.

considered a growth hormone deficiency.

B. The diagnosis of growth hormone deficiency must be achieved by obtaining an insulin-like growth factor (IGF-1)[4] level and then performing a 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 (defective or absent function of the pituitary gland).

C. If the physician determines there is a growth hormone deficiency under this standard, then the physician must look for the underlying cause of the deficiency.

1.6 The standard of care also requires a physician using human growth hormones in the treatment of a patient to advise the patient of the possible side effects to the patient. Possible side effects include: carpel tunnel syndrome; if a patient has diabetes, use of the hormone can exacerbate the patient's diabetic condition; if a patient has a tumor or malignancy, human growth hormone can cause a growth of the malignancy or tumor; benign inter-cranial hypertension (or headaches); and edema (a local or generalized condition in which body tissues contain an excessive amount of tissue fluid). Because of these side effects, a prudent physician would both advise the patient of the side effects and obtain the patient's informed consent prior to instituting a

[4] IGF is a group of related peptides, synthesized by the liver as a result of human growth hormone secretion. A "peptide" is a compound containing two or more linked amino acids. See Taber's Cyclopedic Medical Dictionary, 21st Edition (2009), pages 1211 and 1738.

course of human growth hormone treatment for those conditions for which human growth hormone can be legally prescribed. The patient's treatment records should reflect that the physician advised the patient of the potential side effects prior to initiating the human growth hormone regime, as well as the patient's informed consent for the treatment.

The Respondent's Treatment of Patients A, B, C, and D

1.7 The Respondent graduated with a medical degree from the University of Vermont, College of Medicine in 1989. He subsequently performed his internship in Internal Medicine at the Dartmouth Hitchcock Medicine Center in 1989-1990, and then performed his medical residency training in psychiatry at the Dartmouth Hitchcock Medical Center in 1990-1993. The Respondent's medical philosophy and practice is one of integrative medicine. The Respondent views the integrative medicine approach as scientifically based (for example relying on information contained in the medical literature); the Respondent also relies on his own medical judgment. In so doing, the Respondent integrates traditional and nontraditional treatment modalities.[5] This includes the general replenishment of hormones for patients. The Respondent's integrative medicine approach also balances factors such as sleep, hydration, and the reduction of

[5] The Respondent stated he chose Washington State because it allowed for non-traditional medical practice. *See* RCW 18.130.180(4).

the patient's caffeine and alcohol intake, and the reduction or cessation of the patient's use of tobacco in treating his patients.

1.8 The Respondent's practice is exclusively an office-based consultation practice. *See* Exhibit D-3, page 107.[6] The Respondent was not the primary care physician for Patients A, B, C, and D. He provided a consultation or second opinion to the patient's primary care physician.

1.9 As a part of his office-based consultation practice, the Respondent provided Patients. A, B, C, and D with a document entitled General Agreement on Non-Standard Care (Agreement).[7] This highly detailed agreement addresses the Respondent's practice of replacing hormones (the replacement of hormones to address levels which are deficient because of normal aging). The Agreement advised Patients A, B, C, and D that if various hormone levels are found below optimal and desirable levels as normally found in younger adults, that replacement back to normal youthful adult levels might improve the patients health and prevent degenerative diseases associated with normal aging.[8] The Respondent's Agreement represents that a replenishment dose of one unit a day is optimal in order to minimize side-effects and

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[6] The Department's exhibits contained several page references. For ease of reference, the numbers located in the upper right hand corner will be used as the exhibit page numbers.

[7] There are several iterations of the Agreement; the Respondent's various iterations do contain the same highly detailed approach. The various Agreement documents are referred to by the relevant exhibit number

[8] *See* Exhibits D-4, page 232 and D-5, pages 254-255.

other risks. The Respondent's Agreements with Patients A, B, C, and D stated he advised the patients of the side-effects and other risks; the Respondent described the specific side-effect mentioned in the Agreements as: discomfort or infection at the injection site; and the relationship of human growth hormone and cancer or proliferation of disease. The Agreement notes that the Respondent is not making any warranties, assurances or guarantees of successful treatment.

1.10 The language of the Agreement found in the Respondent's treatment records for Patients A, B, and D clearly represents that the Respondent provides anti-aging treatment to his patients. As previously stated, human growth hormone treatment is limited to adult growth deficiency disease (that is, the absence of human growth hormone), AIDS wasting, cachexia, and short bowel syndrome. Even if Patients A, B, or D were found to have low human growth hormone levels as a result of aging, the available medical evidence does not support human growth hormone supplementation therapy of the type prescribed by the Respondent. Even if such supplementation were supported by medical evidence (which it is not), the standard of practice would require reaching hormone levels appropriate to the age of the patient and not to the level normally found in younger adults.

1.11 In addition, the Respondent prescribed the same amount of the human growth hormone for Patients A, B, C, and D, that is one unit/day. The Respondent has not provided any evidence of the efficacy of this dosage. The Respondent stated he prescribed this low dose of human growth hormone to his patients to improve the patient's overall physical health. Given the amount and number of other medications

and vitamins/supplements provided to Patients A, B, C, and D, it is unlikely that the Respondent could determine the efficacy of the human growth hormone treatment. The Respondent provides no explanation in his records why the dosage would be the same for these four patients.

1.12 The Respondent notes that Patients A, B, and D each report that they feel better as a result of the human growth hormone regime. The Respondent failed to conduct any testing or provide any medical evidence to support a finding that his use of human growth hormone contributes to the overall physical improvement of Patients A, B, or D.

Patient A

1.13 The Respondent provided treatment to Patient A from January 3, 2007 through August 8, 2010. Sixty-two year old Patient A was referred to the Respondent by his cardiologist. Patient A's cardiologist was seeing Patient A regarding chest discomfort and possible myocardial ischemia (inadequate supply of blood and oxygen to meet the metabolic demands of the heart muscle). Patient A's cardiologist eventually resolved the myocardial ischemia condition by inserting a stent (a device used to maintain open coronary blood vessels) in Patient A.[9]

1.14 Patient A was on a human growth hormone regime when the Respondent first began treating him. The Respondent chose to continue Patient A's human growth hormone regime and prescribed the hormone between September 10, 2007 and

[9] Dr. Hoffman (the Department's expert) testified that there is no medical evidence that using human growth hormone is appropriate in the treatment of cardiac conditions such as Patient A's myocardial ischemia condition.

October 8, 2007. At no time during his treatment of Patient A did the Respondent verify or determine whether Patient A had human growth hormone deficiency, AIDS, short bowel syndrome or other authorized condition for which human growth hormones are permitted. In addition to the human growth hormones, the Respondent provided Patient A with Testosterone and a variety of supplements such as Krill Oil, Magnesium and Vitamin C. Given the Testosterone, vitamins and other supplements the Respondent was prescribing for Patient A, it is unlikely that the Respondent could determine the efficacy of Patient A's human growth hormone treatment.

1.15 The Respondent requested Patient A sign the Agreement mentioned in Paragraph 1.9 above on October 8, 2007. *See* Exhibit D-3, pages 105-115. As a part of that Agreement, the Respondent indicated that he would chart a course to replenish any of the Patient's biochemical deficiencies. *See* Exhibit D-3, page 105. The Agreement indicated that the Respondent would treat people with endocrine/hormonal problems. *See* Exhibit D-3, page 106. The Agreement did not adequately inform Pafient A that if the biochemical deficiency or hormonal problem included the use of human growth hormone, that human growth hormone could only be used for the specified medical conditions mentioned in Paragraph 1.4 above.[10]

1.16 A review of Patient A's records shows that Patient A did not meet diagnostic criteria for adult growth deficiency disease. The Respondent failed to

[10] The Respondent's Agreement did, however, advise Patient A that the Respondent sometimes used medication to engage in "off label use." *See* Exhibit D-3, page 107, item 11.

perform growth hormone stimulation testing for Patient A and failed to document regular monitoring of Patient A's hormonal levels. The Respondent's initiation of and maintenance of growth hormone therapy regimen for Patient A, when he did not test or diagnose whether Patient A needed the hormone, was below the standard of care and created an unreasonable risk of harm to Patient A.[11] The Respondent's use of human growth hormone in the treatment of Patient A was an off label use.

Patient B

1.17 The Respondent treated Patient B from May 3, 2006 through August 4, 2006, following a referral from Patient B's primary care physician, Dr. Annemieke Suntrop. Patient B saw the Respondent regarding issues of fatigue, weight loss and high blood pressure. At the time of his initial visit, Patient B was on three blood pressure medications. The Respondent encouraged Patient B to reduce or eliminate the patient's smoking and drinking habits. The Respondent also encouraged Patient B to reduce his dairy intake. The Respondent diagnosed Patient B as having low testosterone levels, which the Respondent found to contribute to Patient B's fatigue and low stamina levels.

[11] The Respondent did perform IGF-1 testing on Patient A. The Respondent testified at hearing that the testing was not diagnostic in nature; rather the Respondent used the IGF-1 testing to monitor the dosage level of the human growth hormone he was providing to the patient.

1.18 As part of Patient B's treatment plan, the Respondent obtained a signed Request and Informed Consent for Hormone Replacement Therapy (Consent) from Patient B on May 22, 2006.[12] The stated purpose of the Consent was to allow:

> replacement therapy of hormones which are deficient because of normal aging. If my various hormone levels and IGF-1 (a growth hormone indicator) are measured and found to be below optimal and desirable levels as normally found in younger adults (as opposed to laboratory reference ranges which are compiled from typically unhealthy patients), I believe that replacement back to normal youthful adult levels might improve my health and prevent degenerative diseases associated with normal aging. I understand that the normal daily dosing (one unit/day) is optimal in order to minimize side-effects or other risks.

See Exhibit D-4, pages 232-233. The Respondent prescribed growth hormone for Patient B from May 22, 2006 through October 10, 2007. The Respondent's treatment records indicate that he diagnosed Patient B with adult human growth hormone deficiency syndrome. The Respondent prescribed the human growth hormone at one unit/day, five days a week. Based on the Consent form, the Respondent's replacement therapy was for the purpose of returning Patient B's human growth hormone levels to the "normal" level found in young adults. Treatment for this purpose was for anti-aging and not for adult growth hormone deficiency.

1.19 The Respondent's Consent form did not adequately inform Patient B of the known risks of taking growth hormone. Neither did the Respondent conduct growth

[12] As stated in Footnote 7 above, the Respondent had several iterations of the Agreement. The Respondent used different titles for the various iterations. In addition to the Consent form, the Respondent also had Patient B sign a document entitled "Concern about Fraud and Potential for Harm from Non-Standard Medical Care.

hormone stimulation testing on Patient B to determine whether Patient B did, in fact, suffer from adult growth hormone deficiency. The Respondent did conduct IGF-1 testing to monitor Patient B's human growth hormone levels. This monitoring was not to address adult growth hormone deficiency, but to allow the Respondent to monitor Patient B's hormone levels to address the human growth hormone replacement therapy.

1.20 The Respondent's continued prescribing of growth hormone therapy for Patient B without meeting the diagnostic criteria (stimulation testing to show that Patient B suffered from Adult Growth Hormone Deficiency) does not meet the standard of care in Washington. The use of human growth hormone without a medically appropriate reason was below the standard of care and created an unreasonable risk of harm for Patient B, specifically by unnecessarily exposing Patient B to the side effects which can occur from using human growth hormones. As prescribed by the Respondent, the use of human growth hormone in the Respondent's treatment of Pafient B is an off label use.

Patient C

1.21 The Respondent provided treatment to Patient C between August 2006 and June 22, 2010. Seventy-one year old Patient C was referred to the Respondent following a diagnosis of Guillain-Barre syndrome (a rare autoimmune illness which is marked by progressive and potentially fatal ascending paralysis with loss of motor refiexes). Patient C also reported gastrointestinal issues. Patient C had an extensive patient workup, including a neurological workup by Neurological Associates of Washington, prior to being seen and treated by the Respondent. Patient C was also

taking several medications, including Prednisone (a Corticosteroid), Doxepin (a Tricyclic antidepressant), and Lorazepam (a Benzodiazepine tranqualizer).

1.22 The Respondent obtained a signed Request and Informed Consent for Hormone Replacement Therapy (Informed Consent) from Patient C. The Informed Consent was signed by Patient C on July 10, 2007.[13] The Informed Consent stated that the Respondent would engage in the replacement of hormones which were deficient. The Respondent's Informed Consent informed Patient C of the Respondent's intention to replace the hormone levels to normal youthful adult levels by replenishment dosing at one unit/day.

1.23 The Respondent prescribed human growth hormone for Patient C beginning in July 2007, following a low IGF-1 lab test result. Exhibit D-5, page 257. The Respondent prescribed human growth hormone to Patient C to improved Patient C's bone health and to help heal Patient C's bed sores. By prescribing human growth hormone for her in this manner, the Respondent was treating Patient C for cachexia (as previously mentioned, a state of iil health, malnutrition, and wasting).[14] The Respondent's use of human growth hormone to treat Patient C was within the standard of care since, as previously mentioned, cachexia is a condition approved for human growth hormone treatment.

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[13] *See* Exhibit D-5, pages 254-255; *see also* Footnote 7.

[14] *See* Finding of Fact 1.4.

1.24 The Respondent's treatment records show that Patient C used the human growth hormone for two months but stopped using it because the patient did not like the cost or giving herself the injections. Patient C then restarted the use of the hormone without first consulting with the Respondent. On December 10, 2009, the Respondent stopped prescribing human growth hormone to Patient C when he advised the patient of his inability to prescribe the hormone because the state was determining policy on the issue.

Patient D

1.25 The Respondent saw Patient D from October 2007 through May 2009. The Respondent was treating Patient D for a number of conditions, including hypogonadism (inadequate production of sex hormones), sleep apnea, and fatigue. The Respondent treated Patient D's hypogonadism and fatigue by prescribing testosterone; he also diagnosed Patient D with adult human growth hormone deticiency syndrome. The Respondent prescribed growth hormone for Patient D without a work-up for growth hormone deticiency (that is, no stimulation testing). At no time during Patient D's treatment did the Respondent verify (perform stimulant testing) to determine whether Patient D had human growth hormone deticiency, AIDS wasting, short bowel syndrome or cachexia.

1.26 When he tirst consulted with the Respondent, Patient D was self-prescribing human growth hormone that he was purchasing from the internet without a prescription. Patient D began taking the human growth hormone in 2006. The Respondent convinced Patient D that he should not purchase the hormone from

the internet and that the Respondent would prescribe human growth hormone (Omnitrope[15]) for him. Toward that end, the Respondent obtained a signed Informed Consent from Patient D on October 6, 2007.[16] As with Patient B, the Informed Consent specifically provided that the Respondent was providing replacement therapy of hormones that were deficient because of normal aging. The Respondent's Informed Consent stated that the goal was the replacement of hormones back to the normal youthful adult levels to improve Patient D's health and to prevent degenerative diseases associated with normal aging. Because his prescribing of human growth hormone was not for adult hormone deficiency, AIDS wasting, short bowel syndrome or cachexia, the Respondent's prescription of the human growth hormone in the treatment of Patient D was an off label use and not within the standard of care.

1.27 On November 28, 2007, the Respondent initially prescribed human growth hormone to Patient D, one unit/day every five days (with two days off) for a six-month period.[17] On February 6, 2008, the Respondent prescribed an additional three-month period of human growth hormone (one unit every five days, with two days off).[18] On July 16, 2008, the Respondent prescribed a three-month period of human growth

[15] See Exhibit D-20 (Omitrope information obtained from Drugs.com).

[16] *See* Exhibit D-6, pages 509-510.

[17] Exhibit D-6, page 522.

[18] Exhibit D-6, page 525.

hormone.[19] On January 5, 2009, the Respondent prescribed the fourth and last three-month period of human growth hormone for Patient D.

1.28 The Respondent's written Consent Form signed by Patient D did not adequately explain the risks of growth hormone therapy.

Offering Human Growth Hormone via the Internet

1.29 During a time frame that included September 23, 2009, the Respondent offered to consumers via the internet, the use of human growth hormone in oral spray form as an anti-aging remedy. *See* Exhibit D-2. Since 1988, Federal law specifically bans the use of growth hormone as an "anti-aging" therapy or for any use other than the treatment of a disease. Since 1990, Federal law further limited the use of growth hormone therapy to those medical conditions specifically authorized by the Secretary of Human Services. *See* Exhibit D-16 (21 U.S.C.A. § 333(e)). Since 1989, Washington State law prohibits the use of growth hormone to manipulate hormones to increase muscle mass, strength or weight or to enhance athletic ability. As previously stated, the only legitimate use of growth hormone prescriptions for adults is treatment of the disease of adult growth hormone deficiency, AIDS wasting, cachexia, and short bowel syndrome. The Respondent's offer of human growth hormone to consumers over the internet was clearly intended for the purpose of anti-aging.

2008 Agreed Order

1.30 On February 28, 2008, the Commission and the Respondent entered into a Stipulated Findings of Fact, Conclusions of Law, and Agreed Order (2008 Agreed

[19] Exhibit D-6, page 532.

Order), *In the Matter of Bradford Weeks*, Washington Medical Quality Assurance Commission No. 07-03-A-1080MD. The basis for the 2008 Agreed Order was a resolution of charges alleging that the Respondent prescribed Xyrem (a Schedule III controlled substance) in the treatment of seven patients. The Respondent prescribed Xyrem for at least four of the patients, even though the patients did not live in the state of Washington, and he had never physically examined the patients. Without agreeing to any of the allegations, the Respondent did acknowledge that the evidence was sufficient to justify one or more of the Commission's factual findings. *See* Exhibit D-7.

1.31 Paragraph 4.3 of the 2008 Agreed Order provided: "Prior to treating or prescribing medication to a patient, Respondent will physically examine and take a history of the patient *adequate to establish a diagnoses and to identify underlying conditions and contra-indications to the medication recommended.*" (Emphasis added). This provision is a term of Respondent's five-year probation under the 2008 Agreed Order, which began in February 2008, and was still in effect as of the date of the hearing.

1.32 The Respondent violated Paragraph 4.3 of the 2008 Agreed Order by his prescribing of human growth hormone for Patients A, B, and D. Although the Respondent conducted a physical examination and obtained a medical history of the patients, as noted above, the Respondent did not use stimulation testing in conjunction with IGF 1 testing in his treatment of Patients A, B, or D, and this is necessary to establish a diagnosis of adult growth hormone deficiency (or any other diagnosis justifying the prescription of human growth hormone).

1.33 The Respondent's treatment of Patients A, B, and D also violated Paragraph 4.6 of the 2008 Agreed Order. Paragraph 4.6 states: "Respondent will obey all federal, state and local laws and all administrative rules governing the practice of the profession in Washington." To obey federal law required that the Respondent would only prescribe human growth hormone for the treatment of a disease or other recognized medical condition where such use was authorized by the Secretary of Health and Human Services under 21 U.S.C.A. § 355. His treatment of Patients A, B, and D did not do so.

Request for Production of Records

1.34 On December 8, 2009, the Commission informed the Respondent by letter that it had received a report alleging the Respondent committed unprofessional conduct. The letter advised the Respondent that the Commission would engage in a preliminary investigation and would keep the Respondent informed concerning that invesfigation. *See* Exhibit R-9. On January 21, 2010, the Respondent received a second letter from the Commission concerning the Respondent's use of human growth hormone in adults. *See* Exhibit R-10. The January 21, 2010 letter requested the Respondent provide answers regarding his prescription practice related to human growth hormone, including the criteria for use, testing to determine use, and requesting how the Respondent defined human growth hormone deficiency. Wayne Carlson, the Commission's investigator, subsequently requested the Respondent provide complete, non-redacted, single-sided copies of medical records of the last five adult patients treated with human

growth hormone by August 5, 2010. *See* Exhibit R-11. In making the request, the Commission's investigator cited RCW 70.02.050(2)(a) as the authority for the request.[20]

1.34 On September 3, 2010, the Respondent's attorney contacted the Commission to notify it that: (a) the Respondent found four patient files; and (b) the Respondent would redact the patient files to prevent any violation of the patient's right to privacy and to guard the physician-patient privilege. Exhibit R-13. The Respondent's position was that the Commission could determine the efficacy or advisability of the use of human growth hormone in adult patients using redacted copies.[21]

1.35 On September 16, 2010, the Commission again notified the Respondent by letter that he was required to provide copies of the patient records. In response to that request, the Respondent (through his attorney) notified the Commission that he last prescribed human growth hormone in November 2009.

1.36 As of April 30, 2012 (the date of the filing of the Amended Statement of Charges), the Respondent failed to provide un-redacted medical records to the Commission requested by the Commission's Investigator. At some unknown point subsequent to the April 30, 2012 Amended Statement of Charges, the Respondent provided the un-redacted medical records.

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[20] RCW 70.02.050(2)(a) states: "A health care provider shall disclose health care information about a patient without the patient's authorization if the disclosure is: (a) To federal, state, or local public health authorities, to the extent the health care provider is required by law to report health care information; when needed to determine compliance with state or federal licensure, certification or registration rules or laws; or when needed to protect the public health.

[21] Counsel for the Respondent during this 2010 time period was Kenneth Kagan. The Respondent's counsel at hearing was Robert Meals, who began his representation of the Respondent in 2012.

1.37 The Respondent Consent Agreement contains the following clause or similar language:

> At times, the state and other government agencies or lawyers may request Dr. Weeks to surrender medical records in order to assess the merits of corrective medical protocols since these typically different [sp] from the standard of care. In that event, in order to secure the [sp] my privacy and my medical records from inappropriate and "unreasonable searches and seizures" (4th amendment to the US Constitution) I specitically PROHIBIT Dr. Weeks and all employees of the Weeks Clinic for Corrective Medicine and Psychiatry from releasing any of my medical records to any person or agency absent a court order and unless and until a valid and legal warrant for the release of these records is obtained and presented to me as well as to the Weeks Clinic for Corrective Medicine and Psychiatry. To release my records without said warrant and court order would be an inappropriate, unacceptable violations of my rights as a patient.

See Exhibit D-3 (Patient A), page 114; Exhibit D-5 (Patient C), page 373; and Exhibit D-6 (Patient D), page 486.

1.38 The above clause (or variation of it) is evidence of the Respondent's attempt to circumvent his responsibility as a licensed physician to cooperate with the Commission's request for patient records. The Respondent's attempt to avoid complying with the Commission request is also an attempt to circumvent patient rights by having patients sign a commitment not to submit any documents or claims to any governmental agency for purposes of investigation.

II. CONCLUSIONS OF LAW

2.1 The Commission has jurisdiction over the Respondent and subject of this proceeding. RCW 18.130.040.

2.2 Except as otherwise required by law, the Department bears the burden of proving the allegations set forth in the Statement of Charges by a preponderance of the

evidence. WAC 246-11-520. The Washington Supreme Court has held the standard of proof in disciplinary proceedings against physicians is proof by clear and convincing evidence. *Nguyen v. Department of Health*, 144 Wn.2d 516, 534 (2001), *cert. denied*, 535 U.S. 904 (2002).

2.3 The Commission used its experience, competency, and specialized knowledge to evaluate the evidence. RCW 34.05.461(5).

2.4 The Department proved by clear and convincing evidence that the Respondent committed unprofessional conduct as defined in RCW 18.130.180(4), which states:

> 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 nontradifional 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;

2.5 The Department proved by clear and convincing evidence that the Respondent committed unprofessional conduct as defined in RCW 18.130.180(7), which states:

> 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;
>
> The federal statute in question is 21 U.S.C.A. § 333(e), which states:
>
> (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 an order of a physician, is guilty of an offense punishable by not more than 5 years in prison, such fines as authorized under 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 of imprisonment, such fines as authorized under Title 18, or both.

(3) Any conviction for a violation of paragraphs (1) or (2) of this subsection shall be considered a felony violation of the Controlled Substances Act [21 U.S.C.A. section 801 et. seq.] for the purpose of forfeiture under section 413 of such Act [21 U.S.C.A. section 853]. (Emphasis added).

2.6 The Respondent argues that his use of human growth hormone in treating Patients A, B, and D is not prohibited under 21 U.S.C.A. § 333(e) because it was used in the treatment of a disease or other recognized medical condition. This argument fails using the rules of statutory construction. "Statutes must be interpreted and construed so that all language used is given effect, with no portion rendered meaningless or superfluous." *Whatcom County v. Bellingham*, 128 Wn.2d 537, 546 (1996) (internal citations omitted). The treatment of a disease or other recognized medical condition is the first requirement set forth in 21 U.S.C.A. § 333(e)(1); the second requirement is where such use has been authorized by the Secretary of Health and Human Services. Currently, the only recognized medical conditions for which human growth hormones are permitted by the Secretary of Health and Human Services are: Acquired Immunity Deficiency Syndrome (AIDS) wasting; short bowel syndrome; cachexia; and adult human growth deficiency. The Respondent's treatment records for Patients A, B, and D clearly do not show the Respondent providing treatment for AIDS wasting, cachexia, or short bowel syndrome.

2.7 The Respondent's treatment notes for the patients do refer to Adult Human Growth Hormone Deticiency Syndrome (which the Respondent abbreviated as AHGHDS). As used by the Respondent, this describes a level of human growth hormone that is less than "normal youthful adult levels". As stated in Finding of Fact 1.4, human growth deficiency in adults actually refers to an *absence* of growth hormone. It does not refer to a *reduction* of growth hormone, which is a natural consequence of growing older. In fact, the Respondent did not perform stimulation testing of Patients A, B, or D to determine whether any of the patients suffered from an adult human growth hormone deticiency. Based on the totality of the evidence, the Respondent did not treat Patients A, B, or D for any condition permitted by the Secretary of Health and Human Services.

2.8 The Department proved by clear and convincing evidence that the Respondent committed unprofessional conduct as detined in RCW 18.130.180(7) (which incorporates RCW 69.41.320[22] and RCW 69.41.300), which states:

> (1)(a) A practitioner shall not prescribe, administer, or dispense steroids, as detined 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

[22] The Presiding Officer previously dismissed the allegations against the Respondent related to the portion of RCW 69.41.320(1)(a) that refers to "enhancing athletic ability." *See* Prehearing Order No. 6.

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.

RCW 69.41.300 states:

For the purposes of RCW 69.41.300 through 69.41.350, "steroids" shall mean growth hormones, or a derivative, isomer, ester, or salt that act in the same manner on the human body.

2.9 The Department proved by clear and convincing evidence that the Respondent committed unprofessional conduct as defined in RCW 18.130.180(7), as it incorporates WAC 246-919-610(2) and (3).[23] The relevant part states:

(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).

2.10 The Department proved by clear and convincing evidence that the Respondent committed unprofessional conduct as defined in RCW 18.130.180(8)(a),

[23] The Presiding Officer previously dismissed the allegations related to WAC 246-919-610(1). *See* Prehearing Order No. 6.

which states it is unprofessional conduct to fail to cooperate with the disciplining authority by "[n]ot furnishing any papers, documents, records or other items."

2.11 The Department proved by clear and convincing evidence that the Respondent committed unprofessional conduct as defined in RCW 18.130.180(9), which states "it is unprofessional conduct to fail to comply with an order issued by the disciplining authority."

2.12 Based on the totality of the evidence, the Commission concludes the Respondent's treatment of Patient C was within the standard of care in the state of Washington. The Commission concludes that the extensive workup and diagnosis the Respondent received regarding Patient C's medical condition, the use for which the human growth hormone was prescribed (bone growth and the treatment of wasting as a result of cachexia), and the short duration for which he prescribed human growth hormone are all within the standard of care. See Exhibit D-18. The Commission further concludes the Respondent's prescription of human growth hormone for Patient C does not constitute a violation of 21 U.S.C.A. § 333(e), given the neurological medical workup he received and the purpose for which he prescribed the human growth hormone. The allegations contained in the Statement of Charges regarding Patient C are therefore dismissed.

2.13 The Department requested a five-year suspension of the Respondent's license to practice medicine, a $5,000 fine, and any remedial measures the Commission deems appropriate. The Respondent requested the Commission dismiss all of the remaining allegations in the Amended Statement of Charges and a finding that the

Respondent did not commit any unprofessional conduct. In determining appropriate sanctions, public safety must be considered before the rehabilitation of the Respondent. RCW 18.130.160. The Respondent's conduct falls in Tier B of the Practice Below Standard of Care schedule. WAC 246-16-810. The Commission panel considered the following aggravating factors when determining the sanction in this matter: the potential for injury to be caused by the unprofessional conduct; prior disciplinary history in 2008; and the awareness that the conduct was wrong, as evidenced by the language in the Respondent's informed consent. The Commission panel considered the following mitigating factors when determining the sanction in this matter: the Respondent stopped prescribing human growth hormone to Patients A, B, and D in 2009.

III. ORDER

3.1 Suspension. The Respondent's license to practice as a physician and surgeon in the state of Washington is SUSPENDED for a period of at least three years from the date of this Order.

3.2 Fine. The Respondent shall pay a $5,000 administrative fine within six months of the effective date of the Order. The payment shall be made out to the State Treasurer and mailed to Department of Health Medical Program, P.O. Box 41009, Olympia, WA 98507-1099. The failure to pay the fine within the specified time will constitute a violation of this Order.

3.3 Modification. The Respondent may not seek modification of this order for three years from the date of this Order. Prior to seeking modification, the Respondent shall successfully complete a one-year fellowship or residency equivalency course that

is pre-approved by the Commission. The Respondent must appear in person for any modification hearing unless he is notified in writing by the Commission that the personal appearance requirement is not necessary.

3.4 Reinstatement. The Respondent may not seek reinstatement of his medical license for three years from the date of this Order. Prior to seeking reinstatement, the Respondent shall successfully complete a one-year fellowship or residency equivalent course that is pre-approved by the Commission. The Respondent must appear in person for any reinstatement hearing unless he is notified in writing by the Commission that the personal appearance requirement is not necessary.

3.5 Change of Address. The Respondent shall inform the program manager and the Adjudicative Service Unit, in writing, of changes in his residential and/or business address within 30 days of such change.

3.6 Assume Compliance Costs. The Respondent shall assume all costs of complying with all requirements, terms, and conditions of this Order.

Dated this 6 day of March, 2013.

MEDICAL QUALITY ASSURANCE COMMISSION

LESLIE M. BURGER, M.D., Panel Chair

CLERK'S SUMMARY

Charge	Action
RCW 18.130.180(4)	Violated
RCW 18.130.180(7)	Violated
RCW 18.130.180(8)(a)	Violated
RCW 18.130.180(9)	Violated
RCW 69.41.320 (with definitions at RCW 69.41.300)	Violated
WAC 246-919-610(2) and (3)	Violated
WAC 246-310-620	Violated
21 U.S.C.A. § 333(e)	Violated

NOTICE TO PARTIES

This order is subject to the reporting requirements of RCW 18.130.110, Section 1128E of the Social Security Act, and any other applicable interstate or national reporting requirements. If discipline is taken, it must be reported to the Healthcare Integrity Protection Data Bank.

Either party may file a **petition for reconsideration**. RCW 34.05.461(3); 34.05.470. The petition must be filed within ten days of service of this order with:

Adjudicative Service Unit
P.O. Box 47879
Olympia, WA 98504-7879

and a copy must be sent to:

Department of Health Medical Program
P.O. Box 47866
Olympia, WA 98504-7866

The petition must state the specific grounds for reconsideration and what relief is requested. WAC 246-11-580. The petition is denied if the Commission does not respond in writing within 20 days of the filing of the petition.

A **petition for judicial review** must be filed and served within 30 days after service of this order. RCW 34.05.542. The procedures are identified in Chapter 34.05 RCW, Part V, Judicial Review and Civil Enforcement. A petition for

reconsideration is not required before seeking judicial review. If a petition for reconsideration is filed, the above 30-day period does not start until the petition is resolved. RCW 34.05.470(3).

The order is in effect while a petition for reconsideration or review is filed. "Filing" means actual receipt of the document by the Adjudicative Service Unit. RCW 34.05.010(6). This order is "served" the day it is deposited in the United States mail. RCW 34.05.010(19).

For more information, visit our website at:
http://www.doh.wa.gov/PublicHealthandHealthcareProviders/HealthcareProfessionsandFacilities/Hearings.aspx