**STATE OF ALASKA**

**DEPARTMENT OF COMMERCE, COMMUNITY AND ECONOMIC DEVELOPMENT**

**DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING**

**BEFORE THE STATE MEDICAL BOARD**

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| In the Matter of: | ) | |
| | ) | |
| DAVID ODOM, M.D. | ) | OAH Case No. 12-0111-MED |
| | ) | Agency No. 2800-09-012 |

## DECISION ON REMAND

This is a disciplinary matter case before the Alaska State Medical Board ("Board") on remand from the Superior Court for the State of Alaska, Third Judicial District at Anchorage. The court vacated the Board's decision in this case and remanded the case to the Board "for further proceedings, consistent with the Order on Appeal."[1] The court has directed the Board to reconsider its decision, considering Dr. Odom's proposal for action,[2] a filing not previously considered by the Board in its earlier decision due to its untimely filing. Upon reconsideration, the Board affirms its prior decision.

The Board has now considered the proposal for action filed by Dr. Odom in this matter as directed by the court. After carefully reviewing the proposal for action, the Board finds the arguments advanced in Dr. Odom's proposal for action to be unavailing.

As indicated by the court, "[t]he factual findings of the Board remain undisturbed."[3] And while as the court points out, "[t]his does not mean that the Board is bound by its findings,"[4] the Board has decided not to re-open the evidence in this case as is its prerogative. The Board and in accordance with AS 44.64.060(e)(3), rejects the proposed decision issued by the Office of Administrative Hearings,[5] and instead, readopts the Division of Corporations, Business and

[1] *Odom vs. State*, Case No. 3AN-14-08082 CI, (*Order On Appeal*, August 19, 2015), pg. 18.
[2] *ITMO: David Odom, M.D.*, OAH No. 12-0111-Med (*Respondent's Opposition to Division's Proposal for Action*, May 23, 2014).
[3] *Odom vs. State, Order On Appeal*, at 18.
[4] *Id.* fn. 42.
[5] *ITMO: David Odom, M.D.*, OAH No. 12-0111-Med (*Proposed Decision*, April 18, 2014).

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Professional Licensing's proposal for action.[1] Ultimately and as espoused by the court, "[s]ubstantial evidence supports the Board's factual and disciplinary findings"[2] in this case.

After reconsideration of the facts of the case, including consideration of Dr. Odom's late-filed proposal for action, the Board reaffirms its prior decision to revoke Dr. Odom's license.

This Order takes effect immediately upon approval by the Board.

DATED this 17 day of September, 2015 at Anchorage, Alaska.

ALASKA STATE MEDICAL BOARD

By: [redacted]
David A. Miller, M.D., FACS
Board President

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[1] *ITMO: David Odom, M.D.*, OAH No. 12-0111-Med (*Division's Proposal for Action to the State Medical Board*, May 9, 2014), a copy of which is appended hereto.
[2] *Odom vs. State, Order On Appeal*, at 1.

**STATE OF ALASKA**
**BEFORE THE ALASKA OFFICE OF ADMINISTRATIVE HEARINGS ON REFERRAL FROM THE STATE MEDICAL BOARD**

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|---|---|
| In the matter of: | |
| David Odom, M.D., | OAH No. 12-0111-MED |
| Respondent | Agency No. 2800-09-012 |



## DIVISION'S PROPOSAL FOR ACTION TO THE STATE MEDICAL BOARD

The Division of Corporations, Business and Professional Licensing ("Division"), by and through the Attorney General's office, and pursuant to AS 44.64.060(e), hereby provides the State Medical Board ("Board") with its proposal for action. As discussed in more detail below, Division contends that it was below the standard of care for Dr. Odom to 1) prescribe phentermine to a patient with known cardiomyopathy, when such use was contraindicated in the medical literature, and 2) prescribe four times the recommended dosage of thyroid hormone to the same the patient for her supposed hypothyroidism, when her thyroid levels were in fact normal. Such actions put Dr. Odom's patient at an increased risk for sudden death. Therefore, the Division proposes that the Board reverse the findings of the Administrative Law Judge ("ALJ") and find that Dr. Odom's conduct was incompetent, unprofessional, and below the standard of care.

### I. Introduction

Following a hearing on October 3-5, 2012, in Fairbanks, the ALJ assigned to the case issued a proposed decision on April 18, 2014. The ALJ found that, despite the

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testimony of the Division's expert in endocrinology and internal medicine, Dr. Patrick Nolan, as well as the warning contained in the Drug Information Handbook (a drug treatise relied on by Dr. Nolan), and multiple contraindications in the product literature, Dr. Odom's prescription of phentermine to a patient with known cardiomyopathy was not below the standard of care. Similarly, despite the testimony of Dr. Nolan, the medical literature that he relied on, and the product information, the ALJ found that Dr. Odom's prescribing of four times the recommended dosage of thyroid hormone to a patient with normal thyroid levels was not below the standard of care.

If this decision were adopted by the Board, it would signal to the Alaska medical community that contraindications and dosage limits can be freely ignored, even with controlled substances.

The Board has the necessary expertise to decide this case based on the evidence, even without the aid of expert testimony. *Matter of Nathanson*, Case Nos. 2800-97-5, *et al* (Board Decision, March 25, 2002) at page 37; *Matter of Van Houten*, Case Nos. 2802-99-005 *et al* (Board Decision, November 12, 2002) at page 24; *Matter of Kohler*, OAH No. 10-0635-MED (Board Decision, July 28, 2011) at page 41. Courts recognize that medicine is a complex subject and the Board is a competent body equipped with the necessary knowledge to determine all licensing actions. *Id*; *Storrs v. State Medical Board*, 664 P.2d 547, 554 (Alaska 1983); *Taylor v. Johnston*, 985 P.2d 460, 465 (Alaska 1999).

Therefore, the Division recommends that, based on AS 44.64.060(e)(5), the Board reject the application of the ALJ's interpretation of AS 08.64.326(a)(9) (licensee

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has engaged in unprofessional conduct), 12 AAC 40.967 (defining unprofessional conduct to mean any act or omission by a licensee that does not conform to the generally accepted standards of practice for the profession for which the licensee is authorized to practice), AS 08.64.326(a)(8)(A) (professional incompetence gross negligence, or repeated negligent conduct) and 12 AAC 40.970 (defining professional incompetence to mean lacking sufficient knowledge, skills or professional judgment in that field of practice in which the physician engages, to a degree likely to endanger the health of his patient), and find, based on the evidence contained in the proposed decision (including the product literature), and the Board's own medical expertise, that it was below the standard of practice, unprofessional, and incompetent for Dr. Odom to prescribe phentermine to a patient with known cardiomyopathy and to prescribe four times the recommended dosage of thyroid hormone.

That amendment to the decision can be made at page 20, paragraph D, of the proposed decision. If the Board would like an assistant attorney general to assist it in considering such a change in the proposed decision, it can do so by contacting Deputy Attorney General Nancy Gordon at 269-5100.

If the Board does reject the ALJ's proposed interpretation of the above statute and regulations, and find that Dr. Odom violated the above statutes and regulations, then it should impose sanctions for those violations. Imposing a suspension on Dr. Odom's license would be consistent with prior Board decisions involving inappropriate prescribing by physicians. For example, in *Matter of Van Houten*, *supra*, the Board affirmed the summary suspension of a physician's license, finding that the physician

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violated AS 08.64.320(a)(8)(A) in part because the he lacked good judgment in prescribing controlled substances. Decision at page 30.

In a later case, the Board found that a physician's failure to meet professional standards for prescribing controlled substances was a serious violation of AS 08.64.326(a)(8)(A). *Matter of Gerlay*, OAH No. 05-0321-MED (Board Decision, July 24, 2008) at page 24 (physician's license revoked). In that case, the Board found that the physician's prescription practices were not inadvertent or negligent, but rather were intentional and deliberate. *Id.*

Thus, a suspension of Dr. Odom's license would be justified herein, as he also lacked good judgment in prescribing phentermine (a controlled substance) and thyroid hormone, his prescription practices were intentional and deliberate, and he will continue to practice in the same manner if not deterred. *Wendte v. State, Board of Real Estate Appraisers*, 70 P.3d 1089, 1094 (Alaska 2003) (suspension of a professional license can legitimately serve to deter conduct). Alternately, the Board could impose a fine, reprimand, probation, education, and permanent restriction on respondent's practice, including a prohibition against prescribing phentermine and thyroid hormone to patients.

Any such imposition of sanctions could be made in the proposed decision at page 19, paragraph B.

Alternatively, the Board could return the case to the ALJ to consider the evidence described below (including the product literature for both drugs, the Drug Information Handbook, Dr. Nolan's report and testimony, and the Board's prior *Bartling* decision)

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and make additional findings regarding whether Dr. Odom's prescribing of phentermine and thyroid hormone violated AS 08.64.326(a)(8)(A), 12 AAC 40.970, AS 08.64.326(a)(9), and 12 AAC 40.967 and, if so, what sanctions should be imposed. AS 44.64.060(e)(2) (Board may return the case to the ALJ to take additional evidence or make additional findings).

That amendment to the decision can be made at page 19, paragraph A of the proposed decision.

**II. It was unprofessional, incompetent, and below the standard of care for Dr. Odom to prescribe phentermine to a patient with known cardiomyopathy.**

In response to the Division's question as to whether Dr. Odom provided "appropriate medical care to this patient", Dr. Patrick Nolan, the Division's expert, stated in his report that he did not think the patient "should have received the medicines that she received", which included phentermine. Proposed Decision at pages 12-13, note 110. Clearly, if prescribing phentermine was not "appropriate medical care", then, in Dr. Nolan's opinion, it did not meet the standard of care. However, the ALJ concluded that Dr. Nolan's report did not state that it was below the standard of care to prescribe phentermine. *Id.*

The ALJ did acknowledge that Dr. Nolan testified that Dr. Odom's prescription of phentermine was below the standard of care because 1) phentermine can cause arrhythmia, 2) the use of phentermine created risks for a variety of cardiac diseases and the patient's cardiologist should have been consulted, and 3) he had consulted with several cardiologists as part of his review of this case and he believed that none of them

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would have prescribed phentermine for this patient, given her history of cardiomyopathy. Proposed Decision at page 13.

In addition, although not noted in the decision, Dr. Nolan testified that he also reviewed and relied on a drug treatise called *The Drug Information Handbook - A Comprehensive Resource For All Clinicians And Healthcare Professionals*, endorsed by the American Pharmacists Association. That treatise (described in the decision only as a reference book) included what Dr. Nolan described as a "severe warning", which stated that physicians should "avoid stimulants [e.g., phentermine] in patients with ... cardiomyopathy ..." Proposed Decision at page 12.

Actually, the entire quote from that treatise (which was admitted into the record) shows that Dr. Odom's prescribing of phentermine put his patient at an increased risk for sudden death: "Avoid stimulants [e.g. phentermine] in patients with known serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, or other serious cardiac problems that could *increase the risk of sudden death that these conditions alone carry*." Division's Exhibit 23 at page 1342 (emphasis added)

Finally, Dr. Nolan also relied on the product literature, which also contained multiple contraindications regarding the prescribing of phentermine to patients with heart disease or cardiovascular disease, which he believed included cardiomyopathy. As the ALJ acknowledged, phentermine is a controlled substance that stimulates the central nervous system and is chemically related to amphetamine. Proposed Decision at page 5. According to the product literature, it elevates blood pressure and can have adverse effects on the cardiovascular system, such as palpitations (pounding or racing

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heartbeat), tachycardia (rapid heartbeat), increased blood pressure and, with overdosage, arrhythmia (abnormal heart beat rhythm). Proposed Decision at pages 5-6, 12. The product literature also states that it is contraindicated for patients with cardiovascular disease, advanced arteriosclerosis and moderate to severe hypertension. *Id* at page 6, note 53 ("You should not take phentermine … if you have … a history of heart disease" or "severe or uncontrolled high blood pressure").

It has always been the Division's position that the above product literature, including the contraindications, supported Dr. Nolan's testimony and the treatise he relied on, not that it alone established the standard of care. However, because the ALJ determined that, since the Division did not "prove" that the product literature alone established the standard of care, he chose to completely ignore that evidence. Proposed Decision at pages 10-12. However, ignoring a product warning would be contrary to the Board's most recent decision on the subject, where the warning was very much considered a part of the standard of care.

In *Matter of Bartling*, OAH No. 12-0221-MED (Board Decision, July 19, 2013), the Board considered the Division's claim that prescribing a Duragesic patch to a patient when she was not opioid tolerant was contrary to FDA warnings and demonstrated professional incompetence or gross negligence. Decision at pages 9-10. A boxed warning for the patch stated that it should only be prescribed for patients who were already receiving opioid therapy and who were opioid tolerant. *Id* at page 9. The warning went on to define opioid tolerant patients. *Id*. The experts were in dispute as to whether the patient was opioid tolerant. *Id* at pages 9-10. The ALJ and the Board

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ultimately came to the conclusion that the patient was opioid tolerant, and therefore the prescribing of the Duragesic patch medically appropriate. *Id* at page 10.

In short, in *Bartling*, the Board considered the above warning, in light of the expert's testimony, whereas in the present case, the ALJ did not even consider the contraindications and warnings in deciding whether Dr. Odom's conduct was medically appropriate. Proposed Decision at page 12 ("it is … not necessary to determine whether the contraindication stated on the label was intended to apply to cardiomyopathy").

In fact, Dr. Nolan was adamant that the contraindication in the product literature applied to this case because cardiomyopathy (a heart muscle disease) is in fact a cardiovascular disease, an opinion which the courts also agree with. *See Mayor and City Council of Baltimore v. Schwing*, 717 A.2d 919, 933 (Md. Ct. Ap. 1998) ("cardiovascular disease … is not a singular malady, but rather encompasses four principal diseases … as well as a significant number and variety of other ailments, including … cardiomyopathy") (relying on the American Heart Association, 1998 Heart and Stroke Statistical Update and the LSO International Classification of Diseases, prepared by the National Centers for Disease Control and Prevention). *See* Proposed Decision at page 12, note 104.

Dr. Nolan also testified that when a drug use is contraindicated, it means that a physician should not prescribe it, an opinion which is also shared by the courts. *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 815 (5th Cir 1992) (when a use is contraindicated, the manufacturer and the FDA have already balanced the costs and benefits of the drug and determined that, under the stated conditions, the risks of using

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the product always outweigh the benefits; therefore, absent exceptional circumstances, a physician should not prescribe a product when its use is contraindicated).

Moreover, the courts have uniformly relied on the above contraindication in the product literature and found that physicians have breached the standard of care when they have prescribed phentermine to patients with cardiovascular disease. For example, in a case where a physician issued 180,000 prescriptions over the internet without physically examining any of the persons receiving the prescriptions, including prescriptions for phentermine, a Washington physician testified at a disciplinary hearing that weight loss drugs such as phentermine were inappropriate for patients who have liver failure, hypertension, hypothyroidism, hypolipidemia, sleep apnea or cardiovascular disease. *Ancier v. State, Department of Health,* 166 P.3d. 829, 834 (Wash. Ct. App 2007). The expert also testified that phentermine could precipitate angina or heart attacks in patients predisposed to cardiovascular disease and was known to cause chemical dependence. *Id.*

The Medical Quality Assurance Commission was persuaded by and agreed with the above expert's testimony and issued a decision revoking the physician's license. *Id* at 835. The court affirmed, relying in part on the above expert testimony. *Id* at 836.

Similarly, in a malpractice case, a jury awarded $7 million in damages in part because a patient with coronary artery disease had been prescribed phentermine, which the court determined was contraindicated for patients with cardiovascular disease. *Fletcher v. Pennsylvania Property & Casualty Guaranty Assoc.*, 27 A.3d 299 (Pa. Cmwlth. Ct. 2001). Finally, in another malpractice case, an internal medicine expert

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testified that the physician being sued should not have prescribed phentermine to a patient with left ventricular dysfunction because phentermine was contraindicated for individuals with cardiac disease. *Zac v. Riffel*, 115 P.3d 165, 170 (Kan. Ct. App. 2005) (case remanded for a new trial).

The ALJ justified ignoring the product literature because he found that it only represented a manufacturer's risk assessment, rather than the judgment of a medical board or licensing authority as to the safety of a particular use. Proposed Decision at page 11. However, as discussed above, contraindications regarding phentermine are also contained in the Drug Information Handbook, which is not from the manufacturer. And, as discussed above, contraindications or warnings have been considered by the Board and by the courts in determining the standard of care. Paradoxically, the ALJ himself relied primarily on the product literature in the second half of the decision to decide (incorrectly, as discussed below) that the dosage of thyroid hormone was not below the standard of care. Proposed Decision at page 15 ("the manufacturer's literature does not suggest that the eventual prescription level of 180mg per day was below the standard of care").

The ALJ does not explain why the product literature was relevant to the standard of care with regard to thyroid hormone but was not relevant to the standard of care with regard to phentermine.

Finally, the ALJ gave credence to Dr. Nolan's claim that there were no "studies" to support the claim that phentermine may have harmful effects on a patient with cardiomyopathy. Proposed Decision at page 14 (Division did not admit into evidence

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studies of phentermine). However, it would hardly be ethical to study the increased risk of sudden death that phentermine would have on persons with cardiomyopathy. The only way that such a study could "prove" the Division's case was if most of the participants died in the process.

In short, there was no justification for Dr. Odom to prescribe phentermine to the patient at issue, as he knew that she had heart disease, in the form of cardiomyopathy. It was not, as argued at hearing, a permissible "off label" use of the drug. Proposed Decision at page 11. Rather, every day that Dr. Odom's patient took phentermine, she was at an increased risk for sudden death. Whether or not he caused her death, the Board should find his conduct demonstrated a lack of sufficient knowledge, skills or professional judgment which clearly endangered her health, as well as a failure to conform to the generally accepted standards of practice for his profession, in violation of AS 08.64.326(a)(8)(A), 12 AAC 40.970, AS 08.64.326(a)(9), and 12 AAC 40.967.

**III. It was unprofessional, incompetent, and below the standard of care for Dr. Odom to prescribe four times the recommended dosage of thyroid hormone and to combine thyroid hormone and phentermine in the same patient.**

For patients with hypothyroidism (where the thyroid gland produces inadequate quantities of thyroid hormones), the product literature for Armour Thyroid (a thyroid hormone) stated that the usual starting dose was 30mg, with increments of 15mg every 2-3 weeks. Proposed Decision at page 7. Dr. Odom ignored that limitation and initially prescribed Armour Thyroid in a dosage of 120mg per day, four times the recommended dosage. Proposed Decision at pages 4, 15. The ALJ found that this initial prescription was in excess of the standard starting dosage as stated on the label. *Id.* at page 15. With

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increments of 15mg every 2-3 weeks, Dr. Odom's patient should have been taking 60mg by the 5th week. However, by the 5th week, Dr. Odom had increased the dosage to 240mg per day, again, four times the recommended dosage for someone in their 5th week. *Id.*

There was abundant evidence in the record as to the dangers of larger doses of thyroid hormone. For example, the product literature for Armour Thyroid stated that "larger doses may produce serious or even life-threatening manifestations of toxicity, particularly when given in association with sympathomimetic amines such as those used for their anorectic effects." Proposed Decision at page 7. Dr. Nolan testified that "sympathomimetic amines" meant phentermine; thus, not only was there a danger in higher dosages, but that the danger was magnified because the thyroid hormone was being combined with phentermine.

This means that, once again, Dr. Odom was needlessly putting his patient at an increased risk of sudden death. This time, the large doses of thyroid hormone he was prescribing put her at risk for life threatening manifestations of toxicity, and that risk was even greater because she was already taking phentermine. And, this increased risk of death was totally unnecessary because the patient's thyroid levels were actually in the normal range. Proposed Decision at page 6.

The product literature also stated that thyroid hormones should be given with great caution in a number of circumstances where the integrity of the cardiovascular system, particularly the coronary arteries, is suspected. Proposed Decision at page 7.

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Thus, Dr. Odom should have been extra cautious with a patient with cardiomyopathy, rather than providing such large doses.

Finally, the product literature warned that providing excessive amounts of thyroid hormone could be harmful, and could actually induce hyperthyroidism (where there is too much thyroid) or a hypermetabolic state (an abnormally increased rate of metabolism). *Id.*

Dr. Odom's patient did in fact suffer some of these serious side effects. At hearing, Dr. Nolan testified that, in his experience, patients receiving 240mg per day of thyroid hormone would typically show low levels of TSH, indicating that they were receiving too much of the hormone. Proposed Decision at page 16. In other words, the patient was demonstrating hyperthyroidism or thyroid toxicity. Additionally the patient reported "jitteriness" while taking 240mg per day and so the hormone dosage was eventually reduced to 180mg per day, only three times the recommended dosage. Proposed Decision at pages 4-5, 15. This jitteriness was a symptom of the patient's hypermetabolic state caused by the excessive dosage - that was the reason why the dosage was reduced.

Unlike his finding with phentermine, where he found that the product literature did not establish the standard of care and could therefore be ignored, the ALJ herein relied on the product literature to conclude that "Dr. Odom's prescriptions were within the recommended range", and therefore were not below the standard of care. Proposed Decision at page 16. The ALJ makes this finding despite his contradictory finding that Dr. Odom's initial prescription "was in excess of the standard starting dosage as stated

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on the label." *Id* at page 15. The ALJ apparently relied on the product literature which suggested that even a daily dosage of 180mg could, in some circumstances, be appropriate. Proposed Decision at page 7 ("Failure to respond to doses of 180mg suggests lack of compliance or malabsorption"). He then concluded that "the manufacturer's literature does not suggest that the eventual prescription level of 180mg per day was below the standard of care." Proposed Decision at page 15.

What the ALJ leaves out is that Dr. Odom's patient did not "eventually" reach the prescription level of 180mg per day; rather, she received too much thyroid hormone too soon. As discussed above, the product literature stated that for hypothyroidism, the usual starting dose was 30mg, with increments of only 15mg every 2 to 3 weeks. Proposed Decision at page 7. Thus, after 5 weeks, the patient should have only been receiving, at most, 60mg, rather than the 240mg she was receiving. At the rate of 15mg every 2 weeks, it would have taken her at least an additional 16 weeks to get up to the reduced level of 180mg. So, by any measure of calculation, Dr. Odom's dosage was grossly excessive.

The ALJ also contends that Dr. Nolan was not so much concerned about the specific dosage of thyroid hormone as he was with the diagnosis of hypothyroidism itself. Proposed Decision at page 16. And, since the Division did not allege that Dr. Odom misdiagnosed hypothyroidism, his testimony could be ignored. *Id.*

But the ALJ omits the fact that Dr. Nolan's initial report stated that Dr. Odom's patient was provided with an "excessive dosage of thyroid hormone." *Id.* at page 8. Although not mentioned in the decision, Dr. Nolan's report concluded that "even if she

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did need thyroid hormone, she received too much thyroid (4 grains of Armour Thyroid daily)." R. 131. Since a grain is 60mg (Proposed Decision at page 15, note 136), Dr. Nolan specifically found in his report (which he also testified to at hearing) that Dr. Odom's dosage of 240mg per day was "too much." While Dr. Nolan questioned Dr. Odom's diagnosis of hypothyroidism (since the patient's thyroid levels were in the normal range), he found that it was the dosage, not the diagnosis, that put the patient at risk for death. R. 131 (report finding that "excess thyroid" (along with phentermine) could have contributed to the patient's death).

Finally, the ALJ justifies his conclusion by claiming that the quantities prescribed were not harmful to the patient's health. Proposed Decision at page 16. Besides ignoring the above evidence, the ALJ also ignores the fact that there is no requirement that the Division prove that Dr. Odom's conduct caused any harm to the patient. *See Halter v. Dept. of Comm. & Econ. Dev., Med. Bd.*, 990 P.2d. 1035 (Alaska 1999) (physician disciplined for professional incompetence and repeated negligent conduct even though there was no actual harm to any patient). The issue (at least with regard to incompetence) is whether Dr. Odom's conduct was likely to endanger the health of his patient. 12 AAC 40.970.

Thus, Dr. Nolan's testimony, plus the above medical literature, supports the Division's claim that Dr. Odom's patient received excess thyroid hormone. In a similar case, an appellate court affirmed a decision of the Minnestoa State Board of Medical Examiners, which disciplined a physician for prescribing two times the recommended maximum dosage of a benzodiazepine (i.e., Restoril) found in the Physician's Desk

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Reference. *Kollmorgen v. State Board of Medical Examiners*, 416 N.W.2d 485, 488 (Minn. Ct. App. 1987). Again, the Board should find that Dr. Odom's conduct demonstrated a lack of sufficient knowledge, skills or professional judgment which clearly endangered the patient's health, as well as a failure to conform to the generally accepted standards of practice for his profession, in violation of AS 08.64.326(a)(8)(A), 12 AAC 40.970, AS 08.64.326(a)(9), and 12 AAC 40.967.

Dated this 9th day of May, 2014, at Anchorage, Alaska.

MICHAEL C. GERAGHTY
ATTORNEY GENERAL

By: [redacted]
Robert C. Auth
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**BEFORE THE ALASKA OFFICE OF ADMINISTRATIVE HEARINGS**
**ON REFERRAL BY THE ALASKA STATE MEDICAL BOARD**

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| | ) | |
| DAVID ODOM, M.D. | ) | OAH No. 12-0111-MED |
| | ) | Agency No. 2800-09-012 |

**[*REJECTED PROPOSED*]**
**DECISION**

## I. Introduction

The Division of Corporations, Business and Professional Licensing (Division) issued an accusation requesting the imposition of a disciplinary sanction by the Alaska State Medical Board (Board) on Dr. David Odom. Dr. Odom is a bariatric physician. The accusation alleged that Dr. Odom's treatment of a single patient, S.Q., warranted imposition of a sanction because he: (1) failed to conduct an adequate examination; (2) prescribed phentermine notwithstanding a diagnosis of cardiomyopathy; and (3) provided excess thyroid hormone with phentermine as treatment for weight loss.

Dr. Odom requested a hearing, and the matter was referred to the Office of Administrative Hearings. The assigned administrative law judge conducted a hearing and heard expert testimony on behalf of the Division by Dr. Patrick Nolan, an endocrinologist, and on behalf of Dr. Odom by Dr. David Bryman, a bariatric physician, and Dr. Neal Rouzier, who practices emergency medicine.

The Division did not prove that Dr. Odom's examination was below the standard of care. The evidence is undisputed that the use of phentermine is contraindicated by label for patients with cardiovascular disease. However, the Division did not prove that to prescribe phentermine to S.Q. was below the standard of care. Moreover, the Division did not prove that Dr. Odom prescribed thyroid hormone as a weight loss treatment, or that the dosages he prescribed were excessive and fell below the standard of care.

Because the Division did not prove that Dr. Odom engaged in repeated negligent conduct or gross negligence, or that he is professionally incompetent, the Division's request to impose sanctions is denied.

## II. Facts

Dr. David Odom graduated from the Baylor College of Medicine in 1970.[1] He was a resident in anesthesiology at the University of Southern California Medical Center.[2] Dr. Odom practices medicine in Fairbanks as Fairbanks Life Enhancement, Inc.[3] His practice consists of anti-aging, natural hormone replacement therapy, and weight loss treatment.[4] Dr. Odom is certified by the American Board of Medical Specialties in anesthesiology and by the American Board of Anti-Aging and Regenerative Medicine.[5]

Dr. Odom was first licensed as a physician in Alaska in 1974.[6] He is also admitted to practice in six other states.[7] Dr. Odom has never had disciplinary action taken against any of his licenses.[8] He was the subject of an investigation by the Division on behalf of the Board in Alaska in the 1990's, which did not result in Board discipline.[9]

The patient whose treatment is the subject of this disciplinary proceeding, S.Q., was diagnosed with peripartum cardiomyopathy in 2002, although she was symptom-free during 2006.[10] She did gain weight, however,[11] and she began seeing Dr. Odom on April 27, 2007, when she was 36 years old, for weight loss treatment and hormone evaluation.[12] At that time, S.Q. was 5' 7", weighed 193 pounds, and had a body mass index (BMI) of 30.2.[13] In his initial physical examination, Dr. Odom noted an irregularly irregular heartbeat, which S.Q. stated was a long-standing condition pre-dating her cardiomyopathy.[14] Dr. Odom noted that she was being followed by a cardiologist and was taking prescription medication for her cardiomyopathy.[15] S.Q. told him she had taken fenfluramine and phentermine in a combined form (fen-phen) eleven

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1 R. 6, 483.
2 Testimony of Dr. Odom.
3 *See* R. 10.
4 R. 38-39, 371.
5 R. 39.
6 R. 6, 443 (original issue date 12/19/74).
7 R. 28, 39, 371.
8 R. 389.
9 R. 416, 433 (Investigation No. 2800-94-26); R. 441 (suspension of clinical privileges at Fairbanks Memorial Hospital).
10 R. 190 ("Since I last saw her in February of 2005 she has had no cardiac symptoms.") (Dr. Krause, 11/16/2006).
11 *See* R. 190 (11/16/2006: "She has had some increase in weight that she attributes to dietary indiscretion and busy lifestyle and inability to exercise regularly."; weight 197; up 22 pounds from February, 2005).
12 R. 3, 10, 56.
13 R. 77, 217.
14 R. 217, 222.
15 *See* R. 216, 222.

years previously, with good effect.[16] Fen-phen had subsequently been taken off the market following reports of potentially fatal effects on the heart.[17] However, the Food and Drug Administration recently approved the use of phentermine, in combination with topiramate, for weight loss reduction treatment.[18]

Dr. Odom recorded an impression of thyroid deficiency, hormone imbalance, cardiomyopathy and obesity.[19] Dr. Odom started S.Q. on a weight loss program at that time.[20] The weight loss program consisted of monitoring, nutrition, hydration, cardiovascular exercise, resistance exercise, and weight loss medication and amino acid supplements.[21] As medication, Dr. Odom prescribed 15 milligrams of phentermine, twice daily, and 500 milligrams of tyrosine, three times daily.[22] Tyrosine is a simple amino acid that the body converts to epinephrine and norepinephrine; tyrosine is taken in combination with phentermine to provide sufficient epinephrine and norepinephrine for the phentermine to act.[23]

Dr. Odom provided S.Q. with an informed consent form for weight loss treatment that mentioned the appetite suppressant medications he used have labeling suggesting usage in quantities and for periods substantially less than he typically used them for.[24] The form did not mention heart disease, cardiovascular disease or cardiomyopathy as conditions rendering use of the drug contraindicated.[25] He also provided her with an informed consent form for hormone supplement therapy noting that "the medical community is generally satisfied when hormone levels are at a MINIMAL level" and that "the standard Fairbanks Life Enhancement will strive to reach is the OPTIMAL level of hormone balance." The form notes "this may cause an apparent disagreement as to diagnosis and need for treatment by other physicians involved in my care."[26]

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16 R. 222.

17 Ex. 15, p. 3 (valvular heart disease and primary pulmonary hypertension [PPH]); Ex. 17, p. 3. *See generally*, In Re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Products Liability Litigation, 582 F.3d 524 (3rd Cir. 2009).

18 Nolan #6 0:11; Bryman #7 0:16.

19 R. 217.

20 R. 58.

21 R. 61-64; R. 205.

22 R. 74, 217, 227.

23 R. 66-67.

24 R. 206.

25 R. 206.

26 R. 207.

S.Q. visited Dr. Odom's clinic weekly for three months until the end of June, and thereafter once a month.[27] During those visits she was generally assessed by Dr. Odom's assistants for her status, but she did see Dr. Odom on June 26 and September 14.[28] On all of these visits her condition was monitored by means of checks of her vital signs, weight and body mass index.[29] Her dosages of phentermine and tyrosine were kept the same.[30]

Laboratory tests on May 7, 2007, showed: TSH, 2.302; $T_4$,1.19, and $T_3$, 2.9.[31] Dr. Odom considered S.Q.'s TSH to be high, and her $T_3$ to be low, both indicative of hypothyroidism.[32] However, Dr. Odom diagnosed hypothyroidism as a clinical diagnosis, not as a laboratory diagnosis.[33] On the basis of his examination, he had found "a very strong constellation of low thyroid symptoms[,]"[34] including constipation, numbness and tingling in the hands, wakening at night, cold hands and feet, fatigue, irritability, and weight gain.[35] Other symptoms of hypothyroidism, such as fibromyalgia, muscle cramps, brittle fingernails, hair loss, diminished sweating, persistent low back pain, decline of memory and concentration, and dry skin were not noted.[36] Relying on her symptoms and the laboratory studies, beginning June 26 Dr. Odom prescribed Armour thyroid, 120 milligrams daily, to be increased to 180 milligrams after two weeks and to 240 milligrams daily after four weeks.[37] S.Q. visited Dr. Odom thereafter once a month from mid-July through mid-September.[38] On those visits, in addition to continued checks of her vital signs, weight and body mass index, staff questioned her as to such things as jitteriness or pounding heartbeat,[39] but her thyroid hormone levels were not tested again. On September 14, S.Q. reported jitteriness while taking 240 milligrams per day, and so the thyroid hormone dosage was settled at 180 milligrams per day.[40] At the time of her last visit with Dr.

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27 R. 211-213 (Ex. 5).
28 R. 220-221.
29 R. 211-213 (Ex. 5).
30 R. 225, 226.
31 R. 17.
32 *See* R. 18 (reference range for female less than 2.0); R. 50, 53.
33 R. 35, 44.
34 R. 44.
35 R. 17, 45-46, 238.
36 R. 17, 46-47.
37 R. 226.
38 R. 211-213.
39 R. 55-57, 70.
40 R. 73, 220, 225.

Odom, on September 14, S.Q. had lost 33 pounds and weighed 160 pounds; she had a body mass index of 25.1.[41]

S.Q. did not return to Dr. Odom after September 14. His last prescription, for a 30 day supply of phentermine and thyroid hormone, was issued on September 10 and was not refilled.[42] On October 25, 2007, S.Q. was seen by Dr. Krauss at the Alaska Heart Institute.[43] Dr. Krauss noted, "She has had a remarkable year and with careful adjustment of her diet, successfully lost 30 pounds…. She sees Dr. Odom…."[44] She did not report using phentermine or thyroid hormone.[45] She was treated at the Tanana Medical Clinic on November 1 and 30, 2007, and January 16, 2008.[46] S.Q. passed away on March 6, 2008, as a result of cardiac failure.[47]

Phentermine is a Schedule IVA controlled substance.[48] It is a sympathomimetic amine that stimulates the central nervous system and is chemically related to amphetamine,[49] which is a Schedule IIA controlled substance.[50] According to the manufacturer's label, phentermine is indicated "as a short-term (a few weeks) adjunct in a regimen of weight reduction based on exercise, behavioral modification and caloric restriction…for patients with an initial body mass index $\geq 30$ kg/m$^2$, or $\geq 27$ kg/m$^2$ in the presence of other risk factors (e.g., hypertension, diabetes, hyperlipidemia)."[51] According to the manufacturer's labeling, phentermine elevates blood pressure and can have adverse effects on the cardiovascular system, such as palpitations (pounding or racing heartbeat), tachycardia (rapid heartbeat), increased blood pressure and, with

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41 R. 77-78, 211-212.

42 Ex. 12, 14.

43 R. 189.

44 R. 189

45 *See* R. 189 (listing current medications).

46 R. 165-173.

47 *See* R. 249-277. The Division did not suggest that S.Q.'s demise had any relationship to Dr. Odom's treatment. Testimony at the hearing established that the medication prescribed by Dr. Odom would have long since been eliminated from her system, and she had been treated by her cardiologist on several occasions since her last visit to Dr. Odom some six months before her death.

48 AS 11.71.170(d)(2). According to the manufacturer's label, phentermine can result in dependence if abused. *See* Div. Ex. 15, pp. 1, 3; Ex. 17, pp. 1-2. Dr. Bryman testified that warning on the label is based on the structural similarity of phentermine to amphetamine, which is addictive, and that there are no studies showing that phentermine itself has addictive properties. The Division has not argued that Dr. Odom's prescription of the medication was below the standard of care based on any addictive properties the medication may have.

49 *See* Div. Ex. 13 ("Phentermine is chemically related to the amphetamines, but it does not have its addictive properties.") (Dr. Odom handout); Ex. 15, p. 2 (describing Adipex [brand name phentermine hydrochloride] as "related chemically and pharmacologically to the amphetamines."). Identical language to the latter is used in the National Institute of Health's online drug information, a compendium of manufacturer's drug labels. *See* Ex. 17, pp. 1-2, 4.

50 AS 11.71.150(e)(1).

51 Ex. 15, p. 2; Ex. 17, p. 2.

overdosage, arrhythmia (abnormal heartbeat rhythm).[52] Manufacturer's labels distributed with the medication state that it is contraindicated for patients with cardiovascular disease, advanced arteriosclerosis, and moderate to severe hypertension.[53]

Thyroid hormones enhance oxygen consumption and metabolism of carbohydrates, lipids and proteins at a cellular level.[54] Thyroid stimulating hormone (TSH), produced in the pituitary gland, stimulates the production of thyroid hormones ($T_3$ and $T_4$) by the thyroid gland.[55] $T_4$ is the primary product of the thyroid, although it produces small amounts of $T_3$ as well. However, most $T_3$ in the bloodstream is the product of conversion of $T_4$ outside of the thyroid. $T_3$ is the metabolically active thyroid hormone that works at the cellular level.[56]

TSH levels do not directly reflect thyroid hormone ($T_3$ and $T_4$) levels. Rather, the level of TSH reflects the degree to which the pituitary gland is stimulating the production of thyroid hormone (primarily, $T_4$). Thus, under normal conditions, the lower the level of TSH in the bloodstream, the higher the level of thyroid hormones. The normal range for the TSH level of a mid-life adult in the general population is around 0.4-4.2 mIU/mL.[57] The normal range of an adult in the general population for $T_3$ is 2.3-4.2 pg/mL, and for $T_4$ is 0.61-1.76 ng/dL.[58] Obese persons have different normal ranges of thyroid hormones than the general population.[59] S.Q.'s levels were within the normal ranges for the general population.[60]

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52 Ex. 15, pp. 1, 4; Ex. 17, p. 2, p. 4 (adverse reactions include "palpitation, tachycardia, elevation of blood pressure"). *See also* Div. Ex. 13 ("Increased heart rate – can occur while exercising when taking phentermine") (Dr. Odom handout); Ex. 16 (Physician's Desk Reference, online), p. 2 ("high blood pressure,… increased heart rate,…throbbing heartbeat"); Ex. 18, p. 3-4 ("pounding heartbeats or fluttering in your chest") (Drugs.com); Ex. 19 (emedicinehealth.com).

53 *See* Div. Ex. 15, p. 3. Identical language is used in the National Institute of Health's online drug information, a compendium of manufacturer's drug labels. *See* Ex. 17, p. 3 (9/7/2012), pp. 1-2 (9/6/2012). *See also* Ex. 18, p. 2 (Drugs.com) ("You should not take phentermine…if you have…a history of heart disease (coronary artery disease, hearth rhythm problems, congestive heart failure, pulmonary hypertension" or "severe or uncontrolled high blood pressure.").

54 *See* Ex. 20, p. 1; 22, p.1.

55 Nolan #6 0:27 (referring to thyroxine).

56 Nolan #6 0:32-33; R. 49 (Odom interview).

57 *See* Ex. 23, p. 1859 (age 21-54). The laboratory that tested S.Q. used a reference range of 0.35—5.500. Ex. 4, R. 239. The laboratory result is reported in micro IU (international units) per milliliter. Dr. Nolan testified that there is currently some debate as to whether the upper limit of the reference range should be reduced, and that the current literature speaks of a normal TSH level as around 3.5. Nolan #6 0:27-28, 0:50, 1:23. *See* Ex. 25, p. 3.

58 Ex. 4, R. 239. The laboratory result for $T_3$ is reported in picograms per milliliter, and for $T_4$ in nanograms per deciliter.

59 Bryman #7 1:06-08, #9 0:12.

60 *Supra*, note 31.

Armour thyroid is a natural product derived from porcine thyroid glands.[61] It contains both $T_3$ (liothyronine) and $T_4$ (levothyroxine).[62] Product labels state that it is indicated in patients with hypothyroidism and do not state that it is contraindicated for patients with cardiovascular disease or cardiomyopathy.[63] However, the manufacturer's literature includes this warning:

> Drugs with thyroid hormone activity, alone or together with other therapeutic agents, have been used for the treatment of obesity. In euthyroid [normal functioning thyroid] patients, doses within the range of daily hormonal requirements are ineffective for weight reduction. Larger doses may produce serious or even life-threatening manifestations of toxicity, particularly when given in association with sympathomimetic amines such as those used for their anorectic effects….
> The use of thyroid hormones in the therapy of obesity, alone or in combination with other drugs, is unjustified and has been shown to be ineffective.[64]

The literature includes this precaution:

> Thyroid hormones should be used with great caution in a number of circumstances where the integrity of the cardiovascular system, particularly the coronary arteries, is suspect.[65]

According to the manufacturer's literature, "[t]he dosage of thyroid hormones is determined by the indication and must in every case be individualized according to patient response and laboratory findings." For hypothyroidism, "[t]he usual starting dose is 30 mg…, with increments of 15 mg every 2 to 3 weeks. …Most patients require 60 to 120 mg/day. Failure to respond to doses of 180 mg suggests lack of compliance or malabsorption. Maintenance dosages 60 to 120 mg/day usually result in normal serum $T_4$ and $T_3$ levels."[66] Providing excessive amounts of thyroid hormone can be harmful, and may induce a hyperthyroidism or a hypermetabolic state, but can generally be treated by reducing the amount provided.[67]

## III. Analysis

The Division initiated an investigation in this matter in 2009.[68] The Division's investigator obtained S.Q.'s medical records from Dr. Odom, her cardiologist, the Tanana Valley

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61 *See* Ex. 20-22.
62 *See* Ex. 20-22.
63 *See* Ex. 20, p. 3.
64 Div. Ex. 20, p. 3; Ex. 22, p. 2.
65 Div. Ex. 20, p. 4; Ex. 23, p. 2.
66 Ex. 20, p. 8; Ex. 22, p. 4. *See also*, Ex. 21, pp. 2-3 (drugs.com).
67 *See* Ex. 20, p. 7; Ex. 22, p.4; Nolan #6 0:38.
68 R. 1.

Clinic and Fairbanks Memorial Hospital and provided them to Dr. Nolan.[69] Dr. Nolan reviewed the records and provided a written report, which is in the record.[70] Dr. Nolan's opinion was that Dr. Odom's treatment plan was not appropriate because the patient had no clinical indication for thyroid hormone, should not have been prescribed thyroid hormone or phentermine,[71] and was provided an excessive dosage of thyroid hormone.[72] He noted that the major risk factor for S.Q. was her cardiomyopathy.[73]

The investigator interviewed Dr. Odom, and a transcript of that interview is in the record.[74] Dr. Odom stated that he diagnosed hypothyroidism based on S.Q.'s clinical symptoms.[75] He indicated that he considered the thyroid levels indicated in her laboratory results sub-optimal, even if within standard reference range limits,[76] and that he prescribed thyroid hormone based on the combination of her clinical symptoms and those laboratory results.[77] He described the weight loss treatment provided to S.Q., which included among other things prescription of phentermine.[78] Dr. Odom acknowledged that physicians outside his area of practice might disagree with his approach to thyroid treatment, but stated that his treatment was consistent with his training in his area of practice.[79]

After reviewing a transcript of Dr. Odom's interview, Dr. Nolan submitted a supplement to his report. Dr. Nolan's view is that primary thyroid failure is defined by TSH levels, and he characterized Dr. Odom's approach to thyroid hormone therapy as contrary to modern endocrinology and a reversion to older therapeutic approaches.[80]

The Division and Dr. Odom were unable to reach an agreement to resolve the matter,[81] and on April 12, 2012, the Division filed an accusation for imposition of a disciplinary sanction. The accusation alleges that three aspects of Dr. Odom's treatment of S.Q. are grounds for imposition of a disciplinary sanction: (1) failing to conduct an adequate examination; (2)

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69 R. 1, 3.
70 R. 129-137.
71 R. 130.
72 R. 131, 132.
73 R. 131, 132.
74 R. 37-122.
75 R. 45-46.
76 R. 50-54.
77 R. 54 ("So I look at this triad, this high TSH, the low free $T_3$, and her symptom complex. And I say to myself let's give her a trial of thyroid.").
78 R. 60-67. *See* note 21, *supra*.
79 R. 81-85.
80 R. 126.
81 *See* R. 2.

prescribing phentermine to a patient with a diagnosis of cardiomyopathy, and (3) combining excess thyroid hormone with phentermine for weight loss.[82] Based upon those aspects of Dr. Odom's treatment, the Division asserts that a disciplinary sanction is warranted pursuant to AS 08.64.326(a)(8)(a) (professional incompetence, gross negligence, or repeated negligent conduct) and AS 08.64.326(a)(9) (unprofessional conduct).[83]

Professional incompetence means "lacking sufficient knowledge, skills, or professional judgment in that field of practice in which the physician…engages, to a degree likely to endanger the health of his…patient."[84] Unprofessional conduct means any act by a licensee that does not conform to the generally accepted standards of practice of medicine.[85] Negligent conduct is conduct that falls below the ordinary standard of care exercised by reasonable members of the profession in the physician's specialty.[86] Gross negligence is "an extreme departure from the ordinary standard of care" entailing "more than ordinary inadvertence or inattention." [87]

A. Adequacy of Examination

When interviewed by the Division's investigator, Dr. Odom was asked to describe his examination. He stated he listened to the heart and lungs and examined the neck, and "that is my basic exam."[88]

S.Q. filled out a health history[89] and a "hormone history".[90] Dr. Odom's record of his initial physical examination is in the record.[91] It contains Dr. Odom's notes based on examination of her thyroid, lungs and heart, and records her height, weight, age blood pressure, pulse, body fat and lean body mass ("LBM").[92] His patient history is recorded in physician's notes dated April 27.[93] Dr. Odom also ordered laboratory tests, the results of which are also in the record.[94] Neither the Division's Hearing Brief nor its written

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82 Accusation, ¶7.
83 *Id.*
84 12 AAC 40.970.
85 *See* 12 AAC 40.967.
86 *See* In Re Kohler, OAH No. 10-0635-MED (Board of Medicine 2011), at 15, note 48.
87 *See* In Re Kohler, OAH No. 10-0635-MED (Board of Medicine 2011), at 14, *citing* Storrs v. Lutheran Hospitals and Homes Society of America, Inc., 661 P.2d 632, 634 & n. 1 (Alaska 1983).
88 R. 43.
89 R. 216.
90 R. 238.
91 R. 217.
92 *See also* R. 211-213.
93 R. 222.
94 R. 223, 237.

Closing Argument identified any aspect of Dr. Odom's examination as inadequate. Counsel did not reference the examination during his opening statement.

Dr. Nolan's written report does not specifically state that Dr. Odom's examination was inadequate, but does note, "I could not find an adequate abdominal or neurological exam on the record."[95] At the hearing Dr. Nolan was asked if he had an opinion about the examination. He did not offer an opinion that the examination was below the standard of care, although he did offer an opinion that there should have been an abdominal examination as well as a neurological examination.[96] Dr. Bryman, testifying as an expert on behalf of Dr. Odom, did not note any deficiency in the examination or the records pertaining to it.[97]

In the absence of any expert testimony that the failure to perform an abdominal or neurological examination was below the standard of care, the Division has not established grounds for imposing a disciplinary sanction based on this allegation.

B. Prescription of Phentermine

The Division's position is that the use of phentermine was contraindicated for S.Q. and that to prescribe medication when it is contraindicated is below the standard of care. In support of its position, the Division refers to the medication label, which states that phentermine is contraindicated for patients with cardiovascular disease, and to case law that allegedly "supports the proposition that phentermine is contraindicated for patients with cardiovascular disease and therefore should not be prescribed [to them,]"[98] Dr. Odom responds that phentermine was not contraindicated for a patient with cardiomyopathy, and that even if it was, it was not below the standard of care for Dr. Odom to prescribe it.

The parties' arguments conflate two quite different issues. The first issue is whether the contraindication stated on the label establishes the standard of care. The second issue is whether Dr. Odom's decision to prescribe phentermine fell below the standard of care.

*1. The Division Did Not Prove the Label Establishes the Standard of Care*

The Food and Drug Administration requires that a drug manufacturer list as a contraindication:

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95 R. 130.

96 Nolan #6 0:25.

97 Bryman #7 0:11.

98 Closing Argument at 6, *citing* Ancier v. State, Department of Health, 166 P.3d 829, 834 (Wash. Ct. App. 2007); Fletcher v. Pennsylvania Property and Casualty Insurance Guaranty Association, 27 A.3d 299 (Pa. Cmwlth. Ct. 2011); Zac v. Riffel, 115 P.3d 165, 170 (Kan. Ct. App. 2005).

> any situations in which the drug should not be used because the risk of use (e.g. certain potentially fatal adverse reactions) clearly outweighs any possible therapeutic benefit.[99]

Thus, by definition, a contraindication stated in the manufacturer's label represents the manufacturer's judgment that the risk of use clearly outweighs any possible therapeutic benefit.

Dr. Odom asserts that a drug manufacturer, being risk averse, may list uses as contraindicated for a broader range of conditions than have actually been studied in depth. Moreover, he points out, labels reflect the data existing at the time of manufacture, which may be limited or incomplete.[100] As a result, he argues, labels may overstate or understate the actual risks of a particular use. For this reason, in his view, that a particular use is contraindicated on the label does not necessarily mean that it is always below the standard of care to use the medication in a manner that is contraindicated.[101] Dr. Bryman also testified that a contraindication stated on a label is not binding on the physician.[102]

Dr. Odom and Dr. Bryman's testimony in effect adopts the view that permissible "off-label" use of a medication, which is commonplace in medical practice,[103] may include prescription for a use that is contraindicated on the label. A contraindication stated on a label represents a manufacturer's risk assessment, rather than the judgment of a medical board or licensing authority as to the safety of a particular use. Moreover, as Dr. Odom points out, a contraindication stated on a label may be based on outdated or incomplete studies, rather than on the most recent or most rigorous clinical studies. In light of the fact that labels represent a manufacturer's judgment as of the date of approval, the Division has not shown that it is necessarily below the standard of care to prescribe a drug when, according to the manufacturer's label, its use is contraindicated and there are no exceptional circumstances to justify disregarding

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99 21 C.F.R. §201.57(c)(5).

100 Bryman #7 0:17, #9 0:38, #10 0:19.

101 Odom #15 0:24.

102 Bryman #7 0:35.

103 *See, e.g.*, Planned Parenthood v. Dewine, 696 F.3rd 490, 496 note 4 (6th Cir. 2012) ("The FDA regulates the marketing and distribution of drugs by manufacturers, not the practices of physicians in treating patients."); Weaver v. Reagan, 886 F.2d 194, 198 (8th Cir. 1989) ("FDA approved indications were not intended to limit or interfere with the practice of medicine nor to preclude physicians from using their best judgment in the interest of the patient."; "'Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling.'", *quoting* FDA Drug Bulletin 12:4 [1982]).

the contraindication. It is therefore not necessary to determine whether the contraindication stated on the label was intended to apply to cardiomyopathy.[104]

*2. Prescription of Phentermine Was Not Shown to Be Below Standard*

The accusation in this case asserts that Dr. Odom's "prescriptions of phentermine to a patient with an established diagnosis of cardiomyopathy…constituted substandard care."[105] In short, whether Dr. Odom's treatment fell below the standard of care was not entirely predicated on the fact that the manufacturer's label states that phentermine is contraindicated for patients with cardiovascular disease. Rather, it is also predicated on the allegation that it was below the standard of care to prescribe phentermine for a patient with cardiomyopathy.

The record contains substantial evidence that the prescription of phentermine entails a variety of risks to a patient's circulatory system. For example, the manufacturer's label states that among the adverse reactions that can reasonably be anticipated with phentermine are cardiac palpitation, tachycardia, and increased blood pressure,[106] and Dr. Bryman testified that phentermine can cause a slight increase the heartbeat rate. [107] The reference book that Dr. Nolan considered most reliable (Lexpro) advises, "Avoid stimulants [*e.g.*, phentermine] in patients with…cardiomyopathy…," which he described as a "severe warning."[108]

Dr. Nolan has very little clinical experience with phentermine and he did not review any studies of phentermine.[109] His written report does not state that it was below the standard of care to prescribe phentermine, rather it states that he would not himself

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104 The Division argued that the contraindication for cardiovascular disease, as stated on the label, includes cardiomyopathy. Division's Closing Argument at 6, *citing* Mayor and City Council of Baltimore v. Schwing, 717 A.2d 919, 933 (Md. Ct. App. 1998) ("cardiovascular disease…is not a singular malady, but rather encompasses four principal diseases…as well as a significant number and variety of other ailments, including…cardiomyopathy."). The court in that case relied on the World Health Organization's International Classification of Diseases (ICD). The ICD was created for statistical and data purposes that do not necessarily reflect the purposes for which drugs are labeled as contraindicated, or the studies upon which those labels are based. In any event, the most recent classification, ICD-10 classifies cardiomyopathy and cardiovascular disease as distinct forms of heart disease. *See* World Health Organization, International Statistical Classification of Diseases and Related Problems, 10th Revision (ICD-10), Chapter IX (Diseases of the Circulatory System), I42. www.who.int/classifications/icd/en (accessed October 30, 2103). S.Q.'s specific condition, peripartum cardiomyopathy, is classified as a pregnancy-related condition. *Id.*, O90.3 (cardiomyopathy in the puerperium). Dr. Odom's position is that the contraindication stated on the label did not apply to a patient with cardiomyopathy.

105 Accusation, ¶7.

106 Ex. 15, p. 4 (9/13/2012); Nolan #6 1:06.

107 Dr. Bryman testified that phentermine can increase the heartbeat by 5 beats per minute. Bryman #9 0:05. Dr. Rouzier, however, testified that phentermine does not increase the heartbeat. Rouzier #21 0:17.

108 Ex. 23, p. 1342. *See* Nolan #6 1:33-1:35; Nolan #26 0:12.

109 *See* Nolan #6 1:12.

have prescribed it,[110] and that is what he testified as well.[111] Dr. Nolan testified that phentermine can cause arrhythmia and that because use of phentermine created risks for a variety of cardiac diseases, S.Q.'s cardiologist should have been consulted.[112] He added that he had consulted with several cardiologists and he believed that none of them would have prescribed phentermine for S.Q., given her history of cardiomyopathy.[113] For these reasons, his opinion was that Dr. Odom's prescription was below the standard of care.[114]

Dr. Odom asserts that there are no studies to support the claim that phentermine may have harmful effects on a patient with cardiomyopathy, and that the initial labeling was based on studies of amphetamines, rather than studies specific to phentermine.[115] However, Dr. Odom had considered another of his patients with atrial fibrillation to be not a good candidate for phentermine, warranting a cautious approach, such that he did not prescribe it to her.[116] He testified that he would not prescribe phentermine to a patient with an "unstable" heart condition, such as recurrent chest pains.[117]

A recent clinical study submitted into the record by Dr. Odom found no evidence that phentermine caused an increase in blood pressure when used for weight treatment.[118] Dr. Bryman, who is licensed in Alaska and has been prescribing phentermine in his bariatric practice for 20 years,[119] testified that phentermine is routinely prescribed for anorectic purposes by bariatric physicians nationwide, and that in his opinion the use of phentermine is contraindicated for patients with active symptoms of cardiovascular disease and that it was within the standard of care to prescribe it to S.Q., notwithstanding her diagnosis of cardiomyopathy.[120] He testified that about 30% of the patients he treats with phentermine have some form of heart disease and many of his patients are referred to him by cardiologists, consistent with the view that obesity

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110 R. 130-131 ("I do not think she should have received the medicines that she received"; "I would not use amphetamine-like drugs, particularly in this case.")

111 Nolan #6 1:10.

112 Nolan #6 0:46, 0:54-55, 1:07, 1:15.

113 Nolan #6 0:44; Nolan Supp. 0:55.

114 Nolan #6 1:09.

115 Bryman #7 0:14-15.

116 R. 112. Dr. Odom's discussed this patient, P., in an interview with the Division's investigator before the accusation was filed. The full interview is in the record. R. 37-122.

117 Odom #14 0:24.

118 E. Hendricks, F. Greenway, E. Westman, and A. Gupta, "Blood Pressure and Heart Rate Effects, Weight Loss and Maintenance During Long-Term Phentermine Pharmacotherapy for Obesity", 19 Obesity 2351 (2011).

119 Bryman#7 0:07, #9 0:02.

120 Bryman #7 0:12, 0:34, #8 0:08.

contributes to problems with the circulatory system.[121] Dr. Bryman testified that the warnings on the phentermine manufacturer's label are based on studies of amphetamines, not on studies of phentermine, and that there are no studies showing that phentermine has adverse effects on the cardiovascular system.[122] In his opinion, based on clinical experience, the studies that lead to the label do not accurately reflect the risks of phentermine.[123] He noted that the Food and Drug Administration has recently approved the use of phentermine in combination with topiramate for weight loss treatment, based on studies showing no adverse cardiovascular effects.[124] He added that in his opinion, absent current symptoms of cardiomyopathy, the use of phentermine was not contraindicated and it was not necessary for Dr. Odom to consult with S.Q.'s cardiologist.[125] Dr. Bryman and Dr. Rouzier testified that a slight increase in heartbeat would not endanger S.Q.'s health, notwithstanding her diagnosis of cardiomyopathy.[126] Moreover, Dr. Odom's records do not show any increase in S.Q.'s heart rate or blood pressure during the time she was treated by him.[127]

The Division did not call S.Q.'s treating cardiologist, or any other cardiologist, as a witness, and it did not admit into evidence any studies of phentermine to support the allegations in the accusation. Dr. Nolan has little clinical experience with phentermine. Given Dr. Bryman's substantial clinical experience with phentermine, including the use of phentermine for patients referred by cardiologists, the Division has not shown by a preponderance of the evidence that it was below the standard of care to prescribe phentermine to S.Q. Similarly, it has not shown that to prescribe it to S.Q. was grossly incompetent or indicative of professional incompetence.

C. Prescription of Excess Thyroid Hormone As Treatment for Obesity

The accusation in this case alleges that "[e]ven if [S.Q.] did need thyroid hormones, her dose of four grains of Armour Thyroid daily was excessive."[128] It asserts that Dr. Odom's treatment was below the standard of care because of "his combination of excess thyroid hormone

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121 Bryman #7 0:16, #9 0:41, 0:50, #10 0:01.
122 Bryman #7 0:14-16, 0:43. *See also* Rouzier #21 0:18.
123 Bryman #9 0:09, 0:12, 0:16.
124 Bryman #7 0:16.
125 Bryant 0:35, 0:48. Dr. Odom testified that if S.Q. had an "unstable" heart condition, he would not have prescribed phentermine. Odom #15 0:24.
126 Bryant #9 0:06-07, 1:07; Rouzier #24 0:02-03.
127 R. 211-213.
128 Accusation, §3.

with phentermine for weight loss."[129] Read broadly, the accusation identifies two distinct reasons why Dr. Odom's treatment of S.Q. was substandard: first, he prescribed thyroid (in combination with phentermine) as treatment for weight loss; and second, he prescribed an excessive dosage of thyroid.

*1. Prescription for Weight Loss*

That it is inappropriate to prescribe thyroid for weight loss treatment was undisputed. Dr. Nolan testified that thyroid is not an appropriate treatment for obesity,[130] as did Dr. Bryman.[131] The Division introduced evidence stating that "[t]he use of thyroid hormones in the therapy of obesity, alone or combined with other drugs, is unjustified and has been shown to be ineffective."[132]

However, Dr. Odom testified that he did not prescribe thyroid for S.Q. as a treatment for weight loss, but as treatment for hypothyroidism. He provided S.Q. with separate informed consent forms, one for weight loss, and one for hormonal therapy.[133]

The preponderance of the evidence is that Dr. Odom did not prescribe thyroid as treatment for weight loss, but as treatment for what was, in his view, hypothyroidism. The Division has not shown that Dr. Odom violated the standard of care by prescribing thyroid hormone for weight loss.

*2. Excess Dosage*

Dr. Odom initially prescribed thyroid hormone, beginning June 26, in a dosage of 120 milligrams per day.[134] Over the course of five weeks, he increased the dosage to 240 milligrams per day.[135] On September 14, S.Q. reported jitteriness while taking 240 milligrams per day, and so the dosage was settled at 180 milligrams per day.[136]

Dr. Odom's initial prescription was in excess of the standard starting dosage as stated on the label. However, the manufacturer's literature does not suggest that the eventual prescription level of 180 mg per day was below the standard of care; rather, it suggests that such a dosage might be appropriate if response did not occur within the more usual range of 60-120 mg.

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129 Accusation, §7.
130 Nolan #6 0:53.
131 Bryman #9 0:34.
132 Ex. 20, p. 3.
133 *See* R. 206-207.
134 R. 226.
135 Ex. 226.
136 R. 73 (Ex. 10); R. 225 (noting one grain is 60 milligrams).

Dr. Nolan testified that in his experience, patients receiving 240 milligrams per day of thyroid hormone would typically show low levels of TSH, indicating they were receiving too much of the hormone.[137] Dr. Nolan's view was that an average person with hypothyroidism might use from 100-200 mg per day.[138] Dr. Nolan's view, in substance, was that the dosage Dr. Odom prescribed was excessive not because he started S.Q. at 60 mg per day rather than the standard 30 mg per day, or because the eventual level of 180 mg per day was excessive, but rather because S.Q. did not need any thyroid treatment at all.[139] In short, Dr. Nolan's opinion was that Dr. Odom's diagnosis of hypothyroidism was mistaken, because absent laboratory findings of sub-normal thyroid levels, a patient does not have that condition.[140] In substance, this is the view of the American Association of Clinical Endocrinologists.[141] Dr. Odom and Dr. Rouzier subscribe to an alternative view, accepted by many clinicians in their field of practice, to the effect that normal laboratory findings simply reflect the thyroid hormone levels found in the population generally, rather than the levels that will result in optimal functioning.[142] In their view, a clinical diagnosis of hypothyroidism can be sufficient to warrant prescription of thyroid hormone, even if the laboratory findings are within normal reference limits.[143]

It is not necessary to decide which of these competing views is correct, because the Division's accusation did not allege that Dr. Odom misdiagnosed hypothyroidism. Rather, it alleged that he provided excess thyroid hormone. But Dr. Odom's prescriptions were within the recommended range, and Dr. Rouzier testified that prescription of thyroid hormone in the dosages prescribed by Dr. Odom is commonplace.[144] The Division did not prove that the quantities prescribed were below the standard of care, or that they were harmful to S.Q.'s health.

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137 Nolan #6 0:57 ("It means the pituitary is sensing she's getting too much.").

138 Nolan #6 0:59-1:01.

139 Nolan #6 0:26 (nothing in lab tests suggests a need for thyroid hormone). He did note that at the level administered, he would expect perturbation of thyroid levels. Nolan #6 0:47.

140 Nolan #6 0:47-49;1:19. Dr. Nolan's supplemental written report is to the same effect. *See* R. 126.

141 Ex. 25, p. 463-464 ("Appropriate laboratory evaluation is critical to establish the diagnosis and cause of hypothyroidism in the most cost-effective way.") (American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for the Evaluation and Treatment of Hyperthyroidism and Hypothyroidism) (Endocrine Practice, Vo. 8 No. 6) (2002); Ex. 26, p. 2 ("Characteristic symptoms and physical signs…can signal hypothyroidism. However…it is critically important to perform diagnostic laboratory tests to confirm the diagnosis and to determine the cause[.]").

142 *See, e.g.*, R. 207. This is the position espoused by Dr. Rouzier, as well. *See, e.g.*, Ex. D, pp. 162-163. *See also*, Ex. 26, p. 2 ("[A] value of free T4 that is 'within normal limits' may not be appropriate for a particular individual.").

143 R. 50-51 (Odom interview) (Ex. 10). Dr. Odom's lab results assessment reflects these opinions. *See* R. 223 (bold "H" [high] for TSH; bold "L" [low] for $T_3$.

144 Rouzier #21 0:19-21, 0:28-29.

## IV. Conclusion

The Division did not establish by a preponderance of the evidence that Dr. Odom's examination was below the standard of care, that he prescribed thyroid hormone for weight loss treatment or in amounts below the standard of care, or that it was below the standard of care to prescribe phentermine to S.Q.. Accordingly, the petition to impose a disciplinary sanction is denied.

DATED April 18, 2014.

*Signed*
Andrew M. Hemenway
Administrative Law Judge

[This document has been modified to conform to the technical standards for publication.]