THE SUPREME COURT OF THE STATE OF ALASKA

DAVID M. ODOM, M.D., Appellant, v. STATE OF ALASKA, DIVISION OF CORPORATIONS, BUSINESS & PROFESSIONAL LICENSING, Appellee.	Supreme Court No. S-16151 Superior Court No. 3AN-14-08082 CI O P I N I O N No. 7220 – February 9, 2018

Appeal from the Superior Court of the State of Alaska, Third Judicial District, Anchorage, Kevin M. Saxby, Judge.

Appearances: Lee Holen, Anchorage, for Appellant. Robert C. Auth, Assistant Attorney General, Anchorage, and Jahna Lindemuth, Attorney General, Juneau, for Appellee.

Before: Stowers, Chief Justice, Winfree, Maassen, Bolger, and Carney, Justices.

MAASSEN, Justice.

I. INTRODUCTION

The state professional licensing division brought an accusation of professional misconduct against a doctor, alleging that he acted incompetently when he prescribed phentermine and thyroid hormone for one of his patients. The division sought disciplinary sanctions against the doctor. Following a hearing, an administrative law

judge issued a proposed decision concluding that the division had failed to show that the doctor's conduct fell below the standard of care in his field of practice and that no disciplinary sanctions were warranted. But the Medical Board instead adopted as its decision the proposal for action submitted by the division and revoked the doctor's medical license.

On appeal to the superior court, the case was remanded to the Board for consideration of the doctor's own late-filed proposal for action. The Board reaffirmed its decision to revoke the doctor's medical license, and the superior court affirmed that decision.

The doctor appeals to this court. Because the Medical Board's decision to revoke the doctor's medical license is not supported by substantial evidence, we reverse the superior court's affirmance of that decision.

II. FACTS AND PROCEEDINGS

David Odom is a bariatric physician[1] who has been licensed to practice in Alaska since 1974. His Fairbanks practice focused on anti-aging, weight loss treatment, and natural hormone replacement therapy. He is certified by the American Board of Medical Specialties in anesthesiology and by the American Academy of Anti-Aging and

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[1] Bariatrics is a branch of medicine that deals with the causes, prevention, and treatment of obesity. *Bariatrics*, THE SLOANE-DORLUND ANNOTATED MEDICAL-LEGAL DICTIONARY (1987).

Regenerative Medicine,[2] and he has been admitted to practice in six states besides Alaska. The disciplinary action in this case is his first.

A. Dr. Odom's Treatment Of S.Q.[3]

In April 2007 Dr. Odom began seeing S.Q. for weight loss treatment and hormone evaluation. He noted at her first appointment that she had an "irregularly irregular" heartbeat; she reported that in 2002 she had been diagnosed with peripartum cardiomyopathy, though it was currently asymptomatic. Cardiomyopathy is a disease of the heart muscle that can lead to sudden cardiac arrest and death;[4] peripartum cardiomyopathy by definition begins during the final month of pregnancy or within a few months after giving birth.[5]

Dr. Odom recorded his initial impressions: thyroid deficiency, hormone imbalance, cardiomyopathy, and obesity. S.Q. signed an informed consent form for weight loss treatment and another for hormone supplement therapy. Dr. Odom scheduled weekly appointments for S.Q. from April through June 2007, continuing monthly into September, so he could monitor her progress.

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[2] Dr. Odom is not board-certified in bariatrics, but the Medical Board does not require physicians to be board-certified in the fields in which they specialize. *See* Alaska State Medical Board, *Practicing a Specialty without being Board-Certified in that Specialty* (Jan. 24.2008), http://www.commerce.alaska.gov/web/portals/5/pub/MED_Guide_Speciality_Practice.pdf.

[3] We use the patient's initials to protect her privacy.

[4] *Cardiomyopathy*, STEDMAN'S MEDICAL DICTIONARY (28th ed. 2006).

[5] *Cardiomyopathy, peripartum*, STEDMAN'S MEDICAL DICTIONARY (28th ed. 2006); *see also Peripartum cardiomyopathy*, AMERICAN HEART ASSOCIATION. http://www.heart.org/HEARTORG/Conditions/More/Cardiomyopathy/Peripartum-Cardiomyopathy-PPCM_UCM_476261_Article.jsp. (last updated Sept. 30, 2016).

The obesity treatment plan included a prescription for phentermine, a central nervous system stimulant that suppresses appetite.[6] Dr. Odom also prescribed a natural thyroid hormone drug — Armour Thyroid[7] — for hypothyroidism.[8] He instructed S.Q. to start the thyroid drug at a dose of 120 milligrams daily, increasing to 180 milligrams after two weeks and 240 milligrams after four weeks; after that she could adjust the dosage herself based on her symptoms.

At S.Q.'s September 14, 2007 visit — her last to Dr. Odom's clinic — she was found to have lost 33 pounds, dropping below the weight considered clinically obese. She reported, however, that she had experienced jitteriness while taking a 240 milligram dose of Armour Thyroid, so Dr. Odom reduced the dose to 180 milligrams a day. S.Q. appears to have stopped taking both medications soon afterward; she last filled her phentermine and Armour Thyroid prescriptions on September 10, when she received a thirty day supply of each, and some pills were never used.

A month later S.Q. visited her cardiologist, who reported that she "has had a remarkable year and with careful adjustment of her diet, successfully lost 30 pounds." In early 2008, according to her husband, she "looked better and happier than she had in

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[6] Phentermine was once commonly prescribed in combination with fenfluramine as an appetite suppressant called fen-phen; fen-phen was withdrawn from the market following reports that connected its use with certain types of heart disease. *See In re Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prod. Liab. Litig.*, 582 F.3d 524, 529 (3d Cir. 2009). Phentermine remains an FDA-approved drug.

[7] Armour Thyroid contains two thyroid hormones, levothyroxine and liothyronine, as well as several inactive ingredients.

[8] Hypothyroidism is the "[d]iminished production of thyroid hormone, leading to clinical manifestations of thyroid insufficiency." *Hypothyroidism*, STEDMAN'S MEDICAL DICTIONARY (28th ed. 2006).

a long time." But on March 6, 2008, about six months after she had stopped seeing Dr. Odom, she suffered cardiac failure and died.

B. The Licensing Division's Investigation

In 2009 S.Q.'s husband filed a complaint with the State of Alaska Division of Corporations, Business, and Professional Licensing, suggesting a link between Dr. Odom's treatment of S.Q. and her death. The Division launched an investigation and sent S.Q.'s medical records to Dr. Patrick Nolan for review. Dr. Nolan, an endocrinologist,[9] concluded that it was inappropriate for Dr. Odom to have prescribed phentermine given S.Q.'s cardiomyopathy; that Dr. Odom had prescribed "too much thyroid" hormone; and that Dr. Odom had inappropriately prescribed thyroid hormone "for weight loss." Dr. Nolan also opined that the "excess thyroid [hormone] and phentermine could have contributed to [S.Q.'s] death."

Dr. Odom challenged these conclusions, asserting that Dr. Nolan, as an endocrinologist, had a starkly different view of weight loss and natural hormone replacement therapy than doctors who, like Dr. Odom, practice anti-aging and bariatric medicine. Dr. Nolan responded by declaring Dr. Odom's practice "dangerous" and "clearly . . . a threat to the public's well being," though his explanation was terse; he said in his supplemental report, "I simply refuse to argue with [Dr. Odom's approach to treatment] as clearly the evidence is in favor of modern endocrinology and against Dr. Odom."

In April 2012 the Division filed an accusation alleging that Dr. Odom had provided substandard care by failing "to conduct an adequate examination of S.Q.,"

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[9] Endocrinology is the "science and medical specialty concerned with the internal or hormonal secretions and their physiologic and pathologic relations." *Endocrinology*, STEDMAN'S MEDICAL DICTIONARY (28th ed. 2006).

prescribing "phentermine to a patient with an established diagnosis of cardiomyopathy," and prescribing "excess thyroid hormone" in combination with phentermine "for weight loss." The Division did *not* contend that Dr. Odom's treatment caused S.Q.'s death; in this appeal the Division, through its attorney at oral argument, agreed "absolutely" that there was no causal connection.[10]

C. The Administrative Proceedings

An administrative law judge (ALJ) held an evidentiary hearing on the Division's accusation over four days in October and November 2012. The Division presented the testimony of S.Q.'s husband, her mother, the Division investigator, and Dr. Nolan, who testified as an expert. Dr. Odom testified on his own behalf and also presented the expert testimony of Dr. David Bryman, a bariatric physician, and Dr. Neal Rouzier, an emergency medicine, family practice, and anti-aging physician.

The ALJ issued a proposed decision in April 2014. He concluded that the Division had failed to prove "that Dr. Odom's examination was below the standard of care"; had failed to prove "that to prescribe phentermine to S.Q. was below the standard of care"; and had failed to 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." The ALJ therefore concluded that no disciplinary sanction was warranted.

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[10] According to the administrative law judge, "[t]estimony at the hearing established that the medication prescribed by Dr. Odom would have long since been eliminated from [S.Q.'s] 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." The Board did not modify this finding, and the Division does not challenge it.

D. The Parties' Proposals For Action And The Medical Board's Decision

As permitted by AS 44.64.060(e),[11] the Division submitted a proposal for action in May 2014 that disputed the ALJ's findings and recommended that the Medical Board impose disciplinary sanctions. The Division argued that Dr. Odom's practice fell below the standard of care when he prescribed phentermine to a patient with cardiomyopathy and when he prescribed "four times the recommended dosage" of thyroid hormone to S.Q. for "supposed hypothyroidism, when her thyroid levels were in fact normal." The Division asserted that its proposed conclusions, though contrary to those of the ALJ, could be reached "based on the evidence contained in the [ALJ's] proposed decision (including the product literature), and the Board's own medical expertise."

The Medical Board was scheduled to meet to decide Dr. Odom's case in June 2014, and it received the ALJ's proposed decision and the Division's proposal for action beforehand. A problem with the mail prevented Dr. Odom from filing his own proposal for action, and though he tardily filed an opposition to the Division's proposal, the Medical Board did not review it.

At its June meeting the Medical Board discussed Dr. Odom's case in executive session; the members then voted unanimously, on the record, to "reject the

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[11] "[W]ithin 30 days after the proposed decision is served, a party may file with the agency a proposal for action . . . [recommending that the agency] do one or more of the following: (1) adopt the proposed decision as the final agency decision; (2) return the case to the administrative law judge to take additional evidence or make additional findings . . . ; (3) exercise its discretion by revising the proposed . . . sanction . . . and adopt the proposed decision as revised; (4) in writing, reject, modify, or amend a factual finding in the proposed decision . . . ; [or] (5) in writing, reject, modify, or amend an interpretation or application in the proposed decision of a statute or regulation directly governing the agency's actions . . . ." AS 44.64.060(e).

proposed decision by the ALJ and, instead, adopt the Division's Proposal for Action" as its final agency decision. As a sanction, the Medical Board ordered "the revocation of Dr. David Odom's Alaska medical license."

E. Dr. Odom's Appeal To The Superior Court And Remand

Dr. Odom appealed the Medical Board's decision to the superior court. The court held that substantial evidence supported the Board's factual and disciplinary findings, but it found a violation of Dr. Odom's due process rights in the Board's failure to consider his late-filed opposition to the Division's proposal for action; the superior court therefore vacated the Board's decision and remanded the matter to the Board for reconsideration.

At a special meeting, the Medical Board "decided not to re-open the evidence in this case as is its prerogative," and it reaffirmed its decision to revoke Dr. Odom's license. In November 2015 the superior court issued an order affirming the Board's decision.

Dr. Odom appealed to this court.

III. STANDARDS OF REVIEW

When a superior court acts as an intermediate court of appeals reviewing an administrative or agency decision, we independently review the merits of the administrative decision,[12] giving no deference to the superior court's decision.[13] We review the agency's factual findings to determine whether they are supported by

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[12] *Jurgens v. City of North Pole*, 153 P.3d 321, 325 (Alaska 2007).

[13] *State, Dep't of Revenue v. Merriouns*, 894 P.2d 623, 625 (Alaska 1995) (citing *Handley v. State, Dep't of Revenue*, 838 P.2d 1231, 1233 (Alaska 1992)).

substantial evidence.[14] Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion."[15] "The substantial evidence test is highly deferential, but we still review the entire record to ensure that the evidence *detracting* from the agency's decision is not *dramatically* disproportionate to the evidence supporting it such that we cannot 'conscientiously' find the evidence supporting the decision to be 'substantial.' "[16] The substantial evidence standard "reflects the prudence of deferring to a state professional board's special competence in recognizing violations of professional standards."[17] "But we will not uphold the imposition of reputationally and economically damaging professional sanctions based

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[14] *Jurgens*, 153 P.3d at 325 (citing *Lindhag v. State, Dep't of Nat. Res*., 123 P.3d 948, 952 (Alaska 2005); *Fields v. Kodiak City Council*, 628 P.2d 927, 932 (Alaska 1981)).

[15] *Storrs v. State Med. Bd.*, 664 P.2d 547, 554 (Alaska 1983) (citing *Keiner v. City of Anchorage*, 378 P.2d 406, 411 (Alaska 1963)).

[16] *Shea v. State, Dep't of Admin., Div. of Ret. & Benefits*, 267 P.3d 624, 634 n.40 (Alaska 2011) (emphasis in original). "[A] court may [not] displace the Board's choice between two fairly conflicting views, even though the court would justifiably have made a different choice had the matter been before it de novo. But under the substantial evidence test, a reviewing court is not barred from setting aside a Board decision when it cannot conscientiously find that the evidence supporting that decision is substantial, when viewed in the light that the record in its entirety furnishes, including the body of evidence opposed to the Board's view." *Id.* (quoting *Universal Camera Corp. v. Nat'l Labor Relations Bd.*, 340 U.S. 474, 488 (1951)).

[17] *State, Dep't of Commerce, Cmty. & Econ. Dev., Div. of Corps., Bus. & Prof'l Licensing v. Wold*, 278 P.3d 266, 273 (Alaska 2012).

on evidence that would not permit a reasonable mind to reach the conclusion in question."[18]

"We review questions of law, including the appropriate standard of proof, using our independent judgment."[19] We review the agency's selection of a particular disciplinary sanction for abuse of discretion.[20]

IV. DISCUSSION

Alaska Statute 08.64.326(a)(8)(A) authorizes the Medical Board to sanction a doctor if the Board finds after a hearing that the doctor "has demonstrated professional incompetence."[21] "Professional incompetence" is defined by regulation to mean "lacking sufficient knowledge, skills, or professional judgment in that field of practice in which the physician . . . concerned engages, to a degree likely to endanger the health of his or

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[18] *Id.* (citing *Wendte v. State, Bd. of Real Estate Appraisers*, 70 P.3d 1089, 1091 (Alaska 2003)).

[19] *Jurgens*, 153 P.3d at 325-26 (citing *Romulus v. Anchorage Sch. Dist.*, 910 P.2d 610, 615 n.3, 618-19 (Alaska 1996)).

[20] *See* AS 08.64.331(a) (identifying sanctions that the Medical Board "may" impose under various circumstances); AS 44.62.570(b) (identifying judicial inquiry on appeal as limited to the questions of jurisdiction, "whether there was a fair hearing," and "whether there was a prejudicial abuse of discretion"); *see also, e.g.*, *Colo. Real Estate Comm'n v. Hanegan*, 947 P.2d 933, 936 (Colo. 1997) (en banc) ("The imposition of sanctions is a discretionary function which, if within the statutory authority of an agency, must not be overturned unless that discretion is abused."); *Wasfi v. Dep't of Pub. Health*, 761 A.2d 257, 267 (Conn. App. 2000) ("If the penalty meted out is within the limits prescribed by law, the matter lies within the exercise of the [agency's] discretion and cannot be successfully challenged unless the discretion has been abused." (alteration in original) (quoting *Gibson v. Conn. Med. Examining Bd.*, 104 A.2d 890, 895 (Conn. 1954))).

[21] *See also* AS 08.64.101(3).

her patients."[22] Sanctions for professional incompetence may range from a letter of reprimand or required education to revocation of a medical license.[23] The Administrative Procedure Act provides that "if an accusation has been filed under AS 44.62.360" (to determine whether a license "should be revoked, suspended, limited, or conditioned"), the accusing authority "has the burden of proof by a preponderance of the evidence" unless "applicable law" requires otherwise. We assume for purposes of this discussion that the preponderance of the evidence standard applies.[24]

Dr. Odom challenges the Medical Board's decision to revoke his license as lacking substantial evidence in support of it. His argument targets the Board's two underlying findings: (1) that prescribing phentermine to S.Q. was below the standard of care because of her cardiomyopathy, and (2) that prescribing thyroid hormone to S.Q. was below the standard of care because the dosage prescribed was excessive and it should not have been given in combination with phentermine. We agree that the Board's decision lacks sufficient support in the evidence.

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[22] 12 Alaska Administrative Code (AAC) 40.970 (2017).

[23] AS 08.64.331(a).

[24] Our opinion, when first published, applied a clear and convincing evidence standard, citing the due process analysis of *Nguyen v. State, Dep't of Health Med. Quality Assurance Comm'n*, 29 P.3d 689, 696 (Wash. 2001). On the Division's petition for rehearing we conclude that this case does not require us to decide whether a standard higher than preponderance of the evidence is constitutionally mandated in professional licensing proceedings.

A. The Medical Board's Decision Does Not Support License Revocation.

We begin by explaining why the Medical Board's decisional document does not support its conclusion regardless of how we view the evidence of Dr. Odom's treatment of S.Q. We note parenthetically that the Medical Board's adoption of the Division's proposal as its final decision was clearly not what the Division had anticipated; the Division had proposed that the Board amend the ALJ's decision in some particulars, and the only sanctions it discussed were a license suspension or alternatively "a fine, reprimand, probation, education, and permanent restriction on respondent's practice, including a prohibition against prescribing phentermine and thyroid hormone to patients."

The Board's procedure was also irregular. The law requires that the Board support the revocation of a medical license with a written decision and "a brief and concise statement of the grounds and reasons for the action."[25] The decisional document of any administrative body, "done carefully and in good faith, serves several salutary purposes," such as "facilitat[ing] judicial review by demonstrating those factors which were considered" and "tend[ing] to ensure careful and reasoned administrative deliberation."[26] An ALJ's proposed decision is usually in a form that will serve these purposes, if it is adopted by the Board.[27] And AS 44.64.060(e) sets out other options if

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[25] AS 08.64.340; *see also Peninsula Mktg. Ass'n v. State*, 817 P.2d 917, 922 (Alaska 1991) (observing that "agency decisions, in exercise of their adjudicative powers, must be accompanied by written findings and a decisional document" (quoting *Messerli v. Dep't of Nat. Res., State of Alaska*, 768 P.2d 1112, 1118 (Alaska 1989))).

[26] *Se. Alaska Conservation Council, Inc. v. State*, 665 P.2d 544, 549 (Alaska 1983), *superseded by statute on other grounds*, Ch. 86, § 1, SLA 2009.

[27] *See, e.g.*, *In re Bartling*, OAH No. 12-0221-MED at 13 (July 19, 2013) (continued...)

the Board declines to adopt the ALJ's proposed decision, including returning the case to the ALJ for further proceedings, changing the ALJ's recommended disposition, and rejecting, modifying, or amending the ALJ's factual findings ("by specifying the affected finding and identifying the testimony and other evidence relied on by the agency for the rejection, modification, or amendment of the finding").[28] The Medical Board's "non-adoption options" do not expressly contemplate accepting one party's proposal for action as the Board's decision, as the Board did here; that may work sometimes, but on the other hand the proposal for action may well be, as it was here, a piece of party advocacy rather than an ostensibly impartial decisional document that clearly sets out the Board's rationale and helps facilitate judicial review.

The document that became the Board's final decision in this matter thus contains no findings of its own but asserts that its conclusion can be reached "based on the evidence contained in the [ALJ's] proposed decision (including the product literature), and the Board's own medical expertise." But the document also suggests specific amendments to the ALJ's decision and invites the Board to enlist the assistance of the attorney general's office in making revisions. While a member of the public who has both the Division's proposal for action and the ALJ's recommended decision in hand could thus — perhaps — stitch together a single decisional document with a coherent narrative,

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[27](...continued)
(adopting proposed decision); *In re Ilardi*, OAH No. 10-0114-MED at 10 (Oct. 28, 2010) (same).

[28] The Medical Board could also prepare its own decision, as in *In re Emery*, OAH No. 07-0169-MED (Jan. 30, 2009). *See also State, Div. of Corps., Bus. & Prof'l Licensing, Alaska Bd. of Nursing v. Platt*, 169 P.3d 595, 598 (Alaska 2007) (reviewing Board of Nursing decision adopting hearing officer's findings of fact and conclusions of law but adding its own different analysis).

it is not at all clear that the document's factual findings would lead to its conclusion. And the Board's decision on remand, after considering Dr. Odom's late-filed proposal for action, adds no explanation other than the conclusory statement that its earlier decision, as embodied in the Division's proposal for action, was supported by substantial evidence.

Most importantly, the document that became the Board's final decision expressly states that "[i]mposing *a suspension* on Dr. Odom's license would be consistent with prior Board decisions involving inappropriate prescribing by physicians" (emphasis added) and supports this statement with a discussion of relevant legal authorities. The Board, however, revoked Dr. Odom's license instead, based not on any written explanation but presumably on its discussion in executive session. By statute, the Medical Board must be "consistent in the application of disciplinary sanctions," and "[a] significant departure from earlier decisions of the board involving similar situations must be explained in findings of fact or orders made by the board."[29] In professional incompetence cases, the Medical Board has generally "directed its efforts to imposing appropriate limits on [the doctor's] practice or to seeking to upgrade [the doctor's] performance."[30] This approach is reflected in the Division's proposal in this case that the Board, to be consistent with its precedent, impose a suspension or consider lighter sanctions as alternatives.

License revocations, in contrast, are more likely to follow revocations in other states or convictions for crimes such as fraud, felony drug offenses, or sex

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[29] AS 08.64.331(f).

[30] *In re Kohler*, OAH No. 10-0635-MED at 51-52 (June 7, 2011) (identifying the specific area in which a doctor was incompetent and restricting him from practicing in the area of his incompetence).

offenses.[31] We have also affirmed a license revocation based on "a pattern of inadequacy,"[32] but this case involves only Dr. Odom's treatment of S.Q.; the Division did not allege or pursue a claim that Dr. Odom acted incompetently in any cases besides this one. And given the Division's further concession that Dr. Odom's treatment of S.Q. had no causal connection to her death, there is no reason apparent in the Board's decisional document why S.Q.'s case alone would warrant a sanction that is inconsistent with the Board's precedent.

We conclude that the Board's final decision fails to comply with its statutory duty to "be consistent in the application of disciplinary sanctions" or explain the inconsistency,[33] and it therefore does not support the sanction imposed.

B. The Medical Board's Conclusion That Dr. Odom's Prescription Of Phentermine To S.Q. Was Below The Standard Of Care In His Field Of Practice Is Not Supported By Substantial Evidence.

The Medical Board's decisional document is legally insufficient not only with regard to its choice of sanction, but also in its conclusion that Dr. Odom acted incompetently. One of the reasons the Board gave for adopting the Division's position was that it was "unprofessional, incompetent, and below the standard of care for Dr. Odom to prescribe phentermine to a patient with known cardiomyopathy." This

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[31] ALASKA MEDICAL BOARD, SUMMARY OF BOARD ACTIONS - 1997 TO PRESENT (Feb. 9, 2017), https://www.commerce.alaska.gov/web/portals/5/pub/MED_1997_to_2017_Board_Action_Summary.pdf.

[32] *Storrs v. State Med. Bd.*, 664 P.2d 547, 555-56 (Alaska 1983) (finding a "pattern of inadequacy" based on five cases over five years in which a doctor demonstrated an inability to foresee common complications, obtain consultations for developing complications, and apply diagnostic and corrective measures once complications arose).

[33] AS 08.64.331(f).

conclusion relied primarily on the testimony of Dr. Nolan, bolstered by product literature and a reference book. But we conclude that this evidence is insufficient to support the Board's finding of incompetence.

Dr. Nolan, the Division's only medical witness, testified that he was board certified in internal medicine and endocrinology.[34] He testified that his practice usually involves patients who have diabetes or some kind of thyroid disease; many of his diabetic patients "have weight problems," but he does not use any drug therapy specifically for weight loss. Indeed, when asked by the Division at the outset of its investigation whether he "perform[ed] the type of practice which is in dispute in this matter," he answered "No," explaining that he did not prescribe the medicines at issue. He testified at the hearing that he has not prescribed phentermine "in many years" because he found it to be ineffective "in the long run" and because "it's very controversial."

Dr. Nolan nonetheless did not review any recent studies of phentermine before forming his opinions in the case and, despite his role as an expert witness, admitted that he "ha[d]n't researched it out that carefully." He testified that he had reviewed the "package insert"; the online entry for phentermine in the *Physician's Desk Reference*, which contains the same manufacturer-provided information as the package insert; and *Lexicomp's Drug Information Handbook*, which he described as a more reliable sourcebook prepared by the American Pharmacists' Association. He described the package insert as contraindicating the use of phentermine for patients with "cardiac

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[34] Dr. Nolan described internal medicine as including "a whole list of . . . different subspecialities: pulmonary disease, cardiology, gastrointestinal, rheumatology, dermatology, endocrinology," and he defined endocrinology as the "study of endocrines, . . . which are the ductless glands in your body: the pituitary, the thyroid, the adrenal, outlet cells in the pancreas, parathyroid, things like that." *See also Endocrinology*, STEDMAN'S MEDICAL DICTIONARY (28th ed. 2006).

disease," and he testified that contraindications in package inserts are clear statements to physicians not to prescribe a drug under the given circumstances. He also testified that the *Drug Information Handbook* contains a "severe warning" against the use of "stimulants . . . in patients with . . . cardiomyopathy." Dr. Nolan admitted, however, that "the package insert [for a drug] may or may not be totally reliable" and that a physician should not rely solely upon the *Drug Information Handbook* either. But he also testified that he had asked seven cardiologists whether they would "consider using phentermine in a patient with known cardiomyopathy," and they all answered, "Absolutely not." He concluded that Dr. Odom should not have prescribed phentermine to treat S.Q.'s obesity because of her history of cardiomyopathy, and that doing so was below the standard of care.

The manufacturer's literature for phentermine clearly states that the drug is contraindicated for patients with cardiovascular disease, though whether that includes S.Q.'s asymptomatic peripartum cardiomyopathy is a debatable issue, one that the ALJ noted but did not decide.[35] The Division argued for a broad interpretation of the contraindications and warnings as applying to all kinds of heart diseases and conditions, and the Board ostensibly adopted that interpretation. But we need not consider this issue ourselves; regardless of whether phentermine's manufacturer intended cardiomyopathy to be among the listed contraindications, the evidence disproportionately supports a conclusion that the contraindications do not establish a relevant standard of care, and

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[35] Dr. Nolan testified that cardiomyopathy is a form of cardiovascular disease. Both of Dr. Odom's experts testified that S.Q.'s condition, peripartum cardiomyopathy, is a disease of the heart muscle rather than the vascular system, is thus not a cardiovascular disease, and is not among phentermine's listed contraindications.

furthermore that Dr. Odom's prescription of phentermine to S.Q. was within the standard of care for physicians who practice in his field.

Dr. Bryman, one of Dr. Odom's expert witnesses, is a physician licensed in Alaska and several other states who practices primarily in bariatrics. He has served on the American Board of Bariatric Medicine and is active in the American Society of Bariatric Physicians. He testified that he is "very familiar" with phentermine; he has prescribed it in his practice for over 20 years, has lectured on the drug, and has defended other physicians' use of the drug. As the ALJ summarized Dr. Bryman's testimony, "phentermine is routinely prescribed for anorectic [appetite-suppressant] purposes by bariatric physicians nationwide."

Dr. Bryman also addressed phentermine's contraindications. He strongly supported Dr. Odom's view that contraindications on drug labels generally are not binding on physicians and do not establish a standard of care,[36] and that the product literature on phentermine in particular was outdated and misleading. While disputing that cardiomyopathy is a cardiovascular disease, he discussed several studies indicating that phentermine did not cause the adverse cardiovascular effects the product literature warns about. Both Dr. Bryman and Dr. Rouzier, Dr. Odom's other expert witness, testified that phentermine's contraindications and warnings regarding its use with cardiac patients were

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[36] The ALJ cited several federal cases in support of this proposition. *See Planned Parenthood Sw. Ohio Region v. Dewine*, 696 F.3d 490, 496 n.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."); *id.* ("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 12 FDA DRUG BULLETIN 1, at 4-5 (1982), http://www.circare.org/fda/fdadrugbulletin_041982.pdf)).

based on 50-year-old research on amphetamines, a chemically related but fundamentally different compound with much different effects, and that the drug's literature had not been updated despite new studies showing that "phentermine does not have any of those properties that . . . amphetamines [have]." Dr. Bryman testified that the FDA had recently approved a new drug containing phentermine based on studies that showed no adverse cardiovascular effects at all. He testified that about 30% of his own patients had some form of heart disease and were referred to him by their cardiologists, and that he prescribed phentermine to patients with cardiomyopathy.

Dr. Bryman noted that S.Q.'s medical records showed no increase in her heart rate or blood pressure while she was on phentermine, and that in fact, because of her obesity and cardiomyopathy, she was "a perfect patient for" the drug. He concluded "with certainty that [Dr. Odom] practiced to the standard of care like a reasonable doctor would treat a patient and not allow her to continue her obesity and worsen her condition. So he intervened appropriately, in my opinion, and she got better." Dr. Rouzier, too, testified adamantly that the best treatment for S.Q.'s obesity was weight loss and that phentermine was a safe and effective way to promote it.

The ALJ who presided over the evidentiary hearing noted that 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 of the accusation." The ALJ contrasted the Division's expert witness, Dr. Nolan, who "has little clinical experience with phentermine," with Dr. Odom's expert witness, Dr. Bryman, who had "substantial clinical experience with phentermine, including the use of phentermine for patients referred by cardiologists." The ALJ concluded that "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." We agree with this conclusion. The evidence detracting

from the Board's decision is dramatically disproportionate to the evidence in support of it, meaning that we cannot conscientiously say that the supporting evidence is substantial.[37]

Finally, the Division's proposal for action — the Board's final decision — cited an earlier Medical Board decision in support of the proposition that a doctor's prescription contrary to manufacturer-provided contraindications can show a breach of the standard of care. *In re Bartling* dealt in part with a claim that a doctor had prescribed an opioid to a patient who was not opioid tolerant, "contrary to FDA warnings" listed on the product's packaging.[38] The Board concluded that the patient actually was opioid tolerant and therefore there was no violation of the standard of care.[39] But the Board noted the testimony of two experts that "the warning was a guide, and that in some cases it is medically appropriate to prescribe [the drug] to a patient who is not opioid tolerant" despite the warnings.[40] And the Board in *Bartling* did not have to address issues like those in this case about whether more recent research and clinical experience undermined the credibility of the product literature. *Bartling* does not support the Board's decision in this case.[41]

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[37] *See Shea v. State, Dep't of Admin., Div. of Ret. & Benefits*, 267 P.3d 624, 634 n.40 (Alaska 2011).

[38] OAH No. 12-0221-MED at 9 (July 19, 2013).

[39] *Id.* at 10.

[40] *Id.*

[41] The Board's decision also cites cases from other jurisdictions in which doctors were found to have inappropriately prescribed phentermine to patients with cardiac problems. *Zac v. Riffel*, 115 P.3d 165, 170 (Kan. App. 2005) (expert testified that phentermine should not have been prescribed to a patient with left ventricular (continued...)

C. The Medical Board's Conclusion That Dr. Odom's Prescription Of Thyroid Hormone Fell Below The Standard Of Care In His Field Of Practice Was Not Supported By Substantial Evidence.

The Medical Board also adopted as its final decision the Division's argument that Dr. Odom's conduct was "unprofessional, incompetent, and below the standard of care" when he prescribed thyroid hormone to S.Q. The Board apparently accepted the ALJ's relevant factual findings: that Dr. Odom prescribed Armour Thyroid in late June 2007 with a beginning dosage of 120 milligrams a day, increasing to 180 milligrams after two weeks and 240 milligrams after four weeks, and that he decreased it to 180 milligrams in September after S.Q. reported jitteriness on the 240-milligram dose. While the ALJ found no breach of the standard of care in this chronology, the Board reached two much different conclusions: (1) that Dr. Odom prescribed an excessive dosage of thyroid hormone, and (2) that it was inappropriate to prescribe thyroid hormone along with phentermine given the risks associated with using the two drugs in combination. Dr. Odom argues that these findings are not supported by substantial evidence, and again we agree with him.

The Medical Board adopted the Division's argument that S.Q. "received too much thyroid too soon" because "the product literature state[s] that for hypothyroidism, the usual starting dose [of Armour Thyroid] was 30mg, with increments of only 15mg every 2 to 3 weeks," whereas S.Q. started with 120 milligrams and reached 240

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[41](...continued)
dysfunction)*; Fletcher v. Pa. Prop. & Cas. Ins. Guar. Ass'n*, 27 A.3d 299, 302 (Pa. Cmmw. 2011) (malpractice damages awarded, in part, because phentermine was inappropriately prescribed to a patient with coronary artery disease); *Ancier v. State, Dep't of Health*, 166 P.3d 829, 834 (Wash. App. 2007) (doctor inappropriately prescribed 180,000 medications, including phentermine, over the internet; expert testified that phentermine is dangerous for patients with cardiovascular disease). None of these cases address S.Q.'s particular malady, asymptomatic peripartum cardiomyopathy.

milligrams five weeks later. The Board's decision is supported by the testimony of Dr. Nolan, who did not prescribe Armour Thyroid in his own practice but opined that Dr. Odom prescribed too much of it, basing his opinion on what he read in the *Drug Information Handbook* and the manufacturer's literature. Dr. Nolan testified that the *Drug Information Handbook* says the "recommended adult dosage" of Armour Thyroid is "[f]ifteen to 30 milligrams initially."

But the *Drug Information Handbook* and the manufacturer's literature both use the word "recommended" only in conjunction with pediatric dosages, which range from 15 milligrams to "over 90" milligrams. The manufacturer's literature does state that the "usual starting dose" is 15 to 30 milligrams, to be scaled up by 15 milligrams every few weeks. And the manufacturer's literature and the *Handbook* agree that "[m]ost patients require 60 to 120 mg/day." But neither the manufacturer's literature nor the *Handbook* supports the Board's necessary extrapolation: that S.Q. was among "most patients" for whom the "usual starting dose" was the only medically appropriate one, and that prescribing dosages other than the usual ones was necessarily unsafe or below the standard of care.

Aside from the dosages listed in the *Drug Information Handbook* and the manufacturer's literature, the only evidence of a proper dosage at the hearing came from Dr. Odom and his expert witness, Dr. Rouzier, who regularly teaches courses in hormone replacement for "various medical academies" including the American Academy of Family Physicians. Dr. Odom testified that the "average" adult dosage is 4 grains (240 milligrams) per day. Dr. Rouzier testified that the "standard" dosage is between 2 and 4 grains (120 to 240 milligrams) per day. Dr. Rouzier also testified that S.Q.'s dosages — from 120 milligrams to 240 milligrams then back down to 180 milligrams per day — were "very appropriate" and "within the range of what's standard and available . . . for us to prescribe." According to Dr. Rouzier, S.Q.'s dosage even at its highest "was

a standard, middle-of-the-range, middle-run dose. Not too high, not too low." He also testified that the drug manufacturer makes 4 grain, 5 grain, and 6 grain tablets; the manufacturer's literature and the *Drug Information Handbook* confirm that 4 grain and 5 grain tablets (240 and 300 milligrams) are available, which runs counter to the Medical Board's conclusion that S.Q.'s lower dosages were necessarily "excessive."

Dr. Rouzier's and Dr. Odom's estimates of "standard" dosages are indeed higher than what the *Drug Information Handbook* lists as usual maintenance doses ("[u]sually 60-120 mg/day"), but every patient cannot be the usual patient.[42] The manufacturer's literature adds, "The dosage of thyroid hormones . . . must in every case be individualized according to patient response and laboratory findings." Dr. Rouzier testified accordingly that some patients achieve the best results from taking significantly higher doses of thyroid hormone than those prescribed to S.Q. According to Dr. Rouzier, S.Q.'s dosages were within the safe range.

The Division presented some evidence about the risks of excessive thyroid hormone. The manufacturer's literature notes that "[e]xcessive doses of thyroid result in a hypermetabolic state," essentially inducing hyperthyroidism.[43] Dr. Nolan testified that too much thyroid hormone can eventually lead to atrial fibrillation and bone loss, and Dr. Rouzier testified that extremely high doses could lead to "palpitations [and] tachycardia." But Dr. Rouzier also testified that if a patient starts seeing side effects like

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[42] Dr. Rouzier explained that "normal" simply refers to "an average of the population" rather than what might be best for a particular patient. And Dr. Bryman explained that "normal" can differ between patients at a healthy weight and those who are obese, just as "normal" will differ between pediatric and geriatric patients.

[43] Hyperthyroidism is "[a]n abnormality of the thyroid gland in which secretion of thyroid hormone is usually increased and no longer under regulatory control of hypothalamic-pituitary centers." *Hyperthyroidism*, STEDMAN'S MEDICAL DICTIONARY (28th ed. 2006).

jitteriness (as S.Q. did), the dosage can simply be scaled back, and the drug's effect will dissipate in less than 24 hours. This is consistent with the manufacturer's literature, which suggests that overdoses of Armour Thyroid be treated by simply reducing or temporarily discontinuing the usual dosage. And the Division failed to establish how much thyroid hormone is too much.[44] Again, we cannot conscientiously say that the Medical Board's finding that Dr. Odom prescribed an excessive dosage of Armour Thyroid is supported by substantial evidence.

Similarly unsupported is the Board's conclusion that S.Q. "received too much thyroid hormone too soon." There was little evidence on this issue presented at the hearing. In Dr. Nolan's rebuttal testimony he referred to the dosage as being "excessive to start with," apparently by referencing only the "usual dosages" entry in the *Drug Information Handbook*. But again, there is no basis in the record for inferring that a physician breaches the standard of care unless he treats every patient as the "usual" patient. Given the strong contrary testimony of Dr. Odom and Dr. Rouzier, we conclude that substantial evidence does not support the Board's finding that a starting dosage differing from those listed in the *Drug Information Handbook* indicated a breach of the standard of care.

The Medical Board also accepted the Division's argument that it was unsafe for Dr. Odom to combine thyroid hormone and phentermine when prescribing for S.Q. In support of this argument the Division cited only the product literature for Armour Thyroid, which reads in part, "Larger doses may produce serious or even life-threatening

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[44] Dr. Nolan testified that in his experience, "most people [taking] around 3 or 4 grains [180 to 240 milligrams] of dessicated thyroid per day will have perturbation of thyroid function, which is not desirable." But Dr. Nolan also admitted that he never prescribes Armour Thyroid, and that he believes the use of Armour Thyroid to be "substandard and unconventional." He testified that practitioners in the field of endocrinology have sought to remove Armour Thyroid from the market.

manifestations of toxicity, particularly when given in association with sympathomimetic amines [e.g., phentermine] such as those used for their anorectic effects." But this warning is explicitly directed toward the drug's use "[i]n euthyroid patients," meaning patients with normal thyroid gland function.[45] Whether S.Q. had normal thyroid gland function was another disputed issue. Dr. Nolan testified that she did, based on laboratory tests showing thyroid levels within the normal range. The ALJ's recommended decision, however, described the symptoms that led Dr. Odom to his clinical diagnosis of hypothyroidism and noted the dispute between physicians who rely on lab tests to determine normal thyroid function and those who "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." But this dispute was ultimately irrelevant, because, as the ALJ concluded, "the Division's accusation did not allege that Dr. Odom misdiagnosed hypothyroidism," but rather that, assuming S.Q. had hypothyroidism, he prescribed too much thyroid hormone to treat it.

Besides the manufacturer's literature, Dr. Nolan also testified that "excess thyroid hormone and [p]hentermine is not a good combination"; "[t]he risks of using phentermine with high doses of Armour Thyroid in persons with established cardiomyopathy is not a good idea. It's just too risky." But Dr. Nolan did not explain why the combination was unsafe, nor did his testimony shed light on whether he believes phentermine combined with lower doses of thyroid hormone would be within the standard of care.[46]

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[45] *See Euthyroidism*, STEDMAN'S MEDICAL DICTIONARY (28th ed. 2006).

[46] The Board's decision does not appear to rely on the *Drug Information Handbook* for its findings about the use of thyroid hormone and phentermine in (continued...)

Finally, both Dr. Rouzier and Dr. Bryman, who were able to testify from their own direct experience treating patients in Dr. Odom's fields of practice, concluded that Dr. Odom was acting within the standard of care in prescribing phentermine and thyroid hormone to S.Q. Dr. Rouzier testified, "The only thing that helps [obese, hypothyroid] patients is weight loss. Get the fat off. . . . How do you do that? Phentermine and thyroid."

Having reviewed the record, "we cannot 'conscientiously' find the evidence supporting the [Board's] decision to be 'substantial.' "[47] The record does not support the Medical Board's conclusion that Dr. Odom prescribed excess thyroid hormone to S.Q., or that it was unsafe or incompetent to prescribe phentermine in combination with thyroid hormone.

D. The Medical Board's Decision Must Be Reversed.

We conclude that the Division failed to prove that Dr. Odom "lack[s] sufficient knowledge, skills, or professional judgment in that field of practice in which [he] engages."[48] We note that the legislature has expressly warned against "bas[ing] a

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[46](...continued)
combination. The *Handbook* does not suggest that combining the two drugs is unsafe. The *Handbook*'s section on phentermine advises prescribing physicians to "[a]void concomitant use" of phentermine with several drugs but not including thyroid hormone, and the *Handbook* does not include thyroid hormone in the list of drugs for which phentermine may increase or decrease the effect or toxicity. Nor does the *Handbook*'s section on thyroid hormone warn against combining it with phentermine.

[47] *Shea v. State, Dep't of Admin., Div. of Ret. & Benefits*, 267 P.3d 624, 634 n.40 (Alaska 2011).

[48] *See* 12 AAC 40.970 (defining "professional incompetence").

The Division argues on appeal that "Dr. Odom's 'field of practice' in this context was the prescribing of controlled substances and other drugs and he was not free
(continued...)

finding of professional incompetence solely on the basis that a licensee's practice is unconventional or experimental in the absence of demonstrable physical harm to a patient."[49] The Division disclaims any intent to violate this statutory directive, but it is hard to overlook the fact that this case, involving no "demonstrable physical harm to a patient," resulted in the Board excessively sanctioning the respondent for an approach that the evidence showed was commonly taken by physicians in his field of practice.[50] We conclude that the Medical Board lacked sufficient evidence to support its findings and that the Medical Board abused its discretion by revoking Dr. Odom's medical license.

V. CONCLUSION

For the foregoing reasons, we REVERSE the superior court's decision affirming the decision of the Medical Board to revoke Dr. Odom's medical license.

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[48](...continued)
to ignore contraindications or dosage limits merely by claiming that he was a weight loss or an antiaging physician." We reject the argument that "the prescribing of controlled substances" is itself a field of practice; this would presumably allow any medical professional with prescribing authority to testify about the standard of care for prescribing drugs in a specialty of which the witness has no knowledge or practical experience. While the applicable definition of incompetence is regulatory rather than statutory, it is noteworthy that in the analogous context of medical malpractice cases the legislature has mandated that only those experts who practice in the defendant's "field or specialty" are qualified to offer opinions on the standard of care. AS 09.55.540(a)(1). It would seem incongruous to require something less when a physician's license is at stake.

[49] AS 08.64.326(a)(8)(A).

[50] As the ALJ properly noted, Dr. Nolan's opinion was "the view of the American Association of Clinical Endocrinologists. Dr. Odom and Dr. Rouzier subscribe to an alternative view, accepted by many clinicians in their field of practice."

In the Supreme Court of the State of Alaska

David M. Odom, M.D., Appellant, v. **State of Alaska, Division of Corporations**, Appellee.	)	Supreme Court No. **S-16151** **Order** Petition for Rehearing Date of Order: **2/9/2018**

Trial Court Case # **3AN-14-08082CI**

Before: Stowers, Chief Justice, Winfree, Maassen, Bolger, and Carney, Justices.

Having considered the petition for rehearing filed by the State of Alaska, Division of Corporations, Business & Professional Licensing, the response filed by David M. Odom, and the supplemental briefing of both parties,

IT IS ORDERED that the petition is **GRANTED** as follows:

1. Opinion No. 7187, issued 8/11/2017 is **WITHDRAWN**.

2. Opinion No. 7220, is issued on this date in its place.

3. The opinion as modified declines to adopt a "clear and convincing evidence" burden of proof for actions to revoke medical licenses; minor editing changes reflect this modification. The opinion is otherwise unchanged.

Entered by direction of the court.

Clerk of the Appellate Courts

/s/

Marilyn May

cc: Supreme Court Justices
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