Final Order No. DOH-21-1852-5 -MQA

FILED DATE - DEC 2 7 2021
Department of Health

#### STATE OF FLORIDA BOARD OF MEDICINE

DEPARTMENT OF HEALTH,

Petitioner,

vs.

DOH CASE NO.: 2019-44651 LICENSE NO.: ME00107312

EDWIN R. LARSON, M.D.,

Respondent.

#### FINAL ORDER

THIS CAUSE came before the BOARD OF MEDICINE (Board) on December 3, 2021, in Orlando, Florida, for the purpose of considering Respondent's offer to voluntarily relinquish his license to practice medicine in the State of Florida. (Attached hereto as Exhibit A.) Said written offer of relinquishment specifically provides that Respondent agrees never again to apply for licensure as a physician in the State of Florida.

Upon consideration of the written offer of voluntary relinquishment, the charges, and the other documents of record, and being otherwise fully advised in the premises,

IT IS HEREBY ORDERED that Respondent's Voluntary Relinquishment of his license to practice medicine in the State of Florida is hereby ACCEPTED, and shall constitute discipline upon Respondent's license.

	This	Final		Order	shall	take	effect	upon	being	filed	with
the	Clerk	of	the	Depart	ment c	f Hea	lth.				

DONE AND ORDERED this 22nd day of December , 2021.

BOARD OF MEDICINE

Paul A. Vazquez
Paul A. Vazquez (Dec 22, 2021 12:04 EST)

Paul A. Vazquez, J.D., Executive Director For Zachariah P. Zachariah, M.D., Chair

#### CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Final Order has been provided by U.S. Mail to: Edwin R. Larson, M.D., 312 Sapphire Lake Drive, Unit 201, Bradenton, FL 34209 and Todd Smayda, Esq., Quintairos, Prieto, Wood & Boyer, P.A., 1410 North Westshore Blvd., Suite 200, Tampa, FL 33607; by email to: Chad Dunn, Chief Legal Counsel, Department of Health, at Chad. Dunn@flhealth.gov; and Edward A. Tellechea, Chief Assistant Attorney General, at Ed.Tellechea@myfloridalegal.com this day of December, 2021.

Omy R. Canaug Deputy Agency Clerk

FILED

DEPARTMENT OF HEALTH

DEPUTY CLERK

CLERK: Amanda Morales

DATE: SEP 1 7 2021

## STATE OF FLORIDA DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH, Petitioner,

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DOH Case No. 2019-44651

EDWIN R. LARSON, M.D. Respondent.

## **VOLUNTARY RELINQUISHMENT OF LICENSE**

Respondent, Edwin R. Larson, M.D., license No. 107312, hereby voluntarily relinquishes Respondent's license to practice medicine in the State of Florida and states as follows:

1. Respondent's purpose in executing this Voluntary Relinquishment is to avoid further administrative action with respect to this cause. Respondent understands that acceptance by the Board of Medicine (hereinafter the Board) of this Voluntary Relinquishment shall be construed as disciplinary action against Respondent's license pursuant to Section 456.072(1)(f), Florida Statutes. As with any disciplinary action, this relinquishment will be reported to the National Practitioner Data Bank as disciplinary action. Licensing authorities in other

I.ff.: 6.29.16

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states may impose discipline in their jurisdiction based on discipline taken in Florida.

- 2. Respondent agrees to never reapply for licensure as a medical doctor in the State of Florida.
- 3. Respondent agrees to voluntarily cease practicing medicine on December 1, 2021. Respondent further agrees that after December 1, 2021, he will refrain from the practice of medicine until such time as this Voluntary Relinquishment is presented to the Board and the Board issues a written final order in this matter. If Respondent is a records owner, Respondent agrees to notify the Board specifying the new records owner and where medical records can be found.
- 4. In Order to expedite consideration and resolution of this action by the Board in a public meeting, Respondent, being fully advised of the consequences of so doing, hereby waives the statutory privilege of confidentiality of Section 456.073(10), Florida Statutes, regarding the complaint, the investigative report of the Department of Health, and all other information obtained pursuant to the Department's investigation in the above-styled action. By signing this waiver, Respondent understands that the record and complaint

become public record and remain public record and that information is immediately accessible by the public. Respondent understands that this waiver of confidentiality is a permanent, non-revocable waiver.

- 5. In order to expedite consideration and resolution of this action by the Board in a public meeting, Respondent, being fully advised of the consequences of so doing hereby waives a determination of probable cause, by the Probable Cause Panel, or the Department when appropriate, pursuant to Section 456.073(4), Florida Statutes.
- 6. Upon the Board's acceptance of this Voluntary Relinquishment, Respondent agrees to waive all rights to seek judicial review of, or to otherwise challenge or contest the validity of, this Voluntary Relinquishment and of the Final Order of the Board incorporating this Voluntary Relinquishment.
- 7. Petitioner and Respondent hereby agree that upon the Board's acceptance of this Voluntary Relinquishment, each party shall bear its own attorney's fees and costs related to the prosecution or defense of this matter.
- 8. Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent in connection with the Board's consideration of this Voluntary Relinquishment. Respondent agrees that

3

consideration of this Voluntary Relinquishment and other related materials by the Board shall not prejudice or preclude the Board, or any of its members, from further participation, consideration, or resolution of these proceedings if the terms of this Voluntary Relinquishment are not accepted by the Board.

DATED this 17th day of September, 2021.

Édwin R. Larson, M.D.

STATE OF FLORIDA
COUNTY OF MANA 1 FC

Before me, personally appeared ELWIN LARSON, whose identity is known to me or who produced FL DL (type of identification) and who, under oath, acknowledges that his signature appears above.

Sworn to and subscribed before me this 4 day of

September, 2021.

NOTARY PUBLIC

My Commission Expires: 07-27-2024.

I:ff.: 6.29.16

# STATE OF FLORIDA DEPARTMENT OF HEALTH

DEPARTME	ENT	OF	HEALTH,	
ì	PET	ITI	ONER,	

v.
EDWIN R. LARSON, M.D.,
RESPONDENT.

## ADMINISTRATIVE COMPLAINT

CASE NO. 2019-44651

COMES NOW Petitioner, Department of Health, by and through its undersigned counsel, and files this Complaint before the Board of Medicine against Respondent, Edwin R. Larson, M.D., and in support thereof alleges:

- 1. Petitioner is the state agency charged with regulating the practice of medicine pursuant to section 20.43, Florida Statutes; chapter 456, Florida Statutes; and chapter 458, Florida Statutes.
- 2. At all times material to this Administrative Complaint, Respondent was a licensed physician within the state of Florida, having been issued license number ME 107312.

3. Respondent's address of record is 312 Sapphire Lake Drive, Unit

201, Bradenton, Florida 34209.

4. At all times material to this Administrative Complaint,

Respondent practiced at the Center for Revitalizing Psychiatry, located in

Sarasota, Florida.

5. From in or about May 2014 through in or about December 2015

Respondent treated Patient H.R. (hereinafter referred to as "H.R.") for

attention deficit hyperactivity disorder, behavior issues and mood symptoms.

6. Respondent treated H.R. with stimulant and antidepressant

medications, however, behavior issues and mood instability persisted.

7. On or about December 15, 2015, Respondent prescribed one

hundred twenty (120) Lamictal twenty-five (25) milligram tablets to H.R. at

sixteen (16) years of age; Lamictal is FDA approved for treating epilepsy and

maintaining treatment of bipolar disorder in patients over the age of eighteen

(18).

8. Lamictal contains a black box warning which lists the possibility

of developing serious rashes as result of taking Lamictal, including

developing Stevens-Johnson syndrome, a dangerous and potentially lethal

skin disorder; this risk appears to be heightened in pediatric and adolescent

patients.

9. Lamictal's prescribing information includes a warning which

indicates that exceeding the recommended initial dose, or exceeding the

recommended dose titration schedule, could increase the risk of

experiencing Stevens-Johnson Syndrome.

10. Lamictal's prescribing information indicates that the

recommended titration schedule for treatment of Bipolar Disorder is twenty-

five (25) milligrams daily for two (2) weeks, fifty (50) milligrams daily for two

(2) weeks, one hundred (100) milligrams daily for one week, and then two

hundred (200) milligrams daily thereafter.

11. Respondent advised H.R. take twenty-five (25) milligrams of

Lamictal for one (1) week, fifty (50) milligrams of Lamictal for one (1) week,

seventy-five (75) milligrams of Lamictal for one (1) week, and one hundred

(100) milligrams of Lamictal thereafter.

12. After H.R. took one hundred (100) milligrams of Lamictal for

approximately three (3) days during the fourth week, she developed a rash

with ocular involvement.

13. On or about January 7, 2016, H.R. was admitted to the Sarasota

Memorial Hospital after she developed a worsening rash with ocular

involvement; H.R. was diagnosed with Steven-Johnson Syndrome.

14. During the treatment period, Respondent failed to document the

Lamictal prescription titration schedule he prescribed to H.R.

15. During the treatment period, Respondent did not have adequate

justification, or failed to document having adequate justification, for

prescribing a titration regimen outside of that recommended by the

manufacturer to H.R.

16. During the treatment period, Respondent did not have adequate

justification, or failed to document having adequate justification, for

prescribing the off-label use of Lamictal to H.R., an adolescent.

17. During the treatment period, Respondent failed to discuss, or

failed to document discussing, the risks of developing Steven-Johnson

Syndrome due to taking Lamictal with H.R.

18. At all times material to this Administrative Complaint, the

prevailing professional standard of care required Respondent to treat H.R. in

the following manner:

a. avoid prescribing a titration regimen outside of that recommended by the manufacturer to H.R.;

b. avoid prescribing the off-label use of Lamictal to H.R., an adolescent; and

c. create adequate medical records which justify the course of treatment utilized for H.R.

d. discuss the risks of developing Steven-Johnson Syndrome due to taking Lamictal with H.R

## **COUNT I**

19. Petitioner re-alleges and incorporates paragraphs one (1) through eighteen (18) as if fully set forth herein.

20. Section 458.331)(1)(t)1., Florida Statutes (2015), provides that, notwithstanding section 456.072(2), Florida Statutes (2015), but as specified in section 456.50(2), Florida Statutes (2015), committing medical malpractice as defined in section 456.50, Florida Statutes (2015), constitutes grounds for disciplinary action. "Medical Malpractice" is defined in section 456.50(g), Florida Statutes (2015), as the failure to practice medicine in accordance with the level of care, skill, and treatment recognized in general law related to health care licensure. Section 458.331)(1)(t)1., Florida

18210

Statutes (2015), provides that the "level of care, skill, and treatment

recognized in general law related to health care licensure" means the

standard of care that is specified in section 766.102, Florida Statutes (2015),

which states as follows:

The prevailing professional standard of care for a given health

care provider shall be that level of care, skill, and treatment

which, in light of all relevant surrounding circumstances, is

recognized as acceptable and appropriate by reasonably prudent

similar health care providers.

21. Section 458.331)(1)(t)1., Florida Statutes (2015), directs the

Board of Medicine to give "great weight" to the provisions of section 766.102,

Florida Statutes (2015).

22. As set forth above, Respondent committed medical malpractice

by falling below the prevailing professional standard of care in his treatment

of H.R. by:

a. failing to justify prescribing a titration regimen outside of that

recommended by the manufacturer to H.R.;

b. failing to justify prescribing the off-label use of Lamictal to

H.R., an adolescent; and

Case Name: DOH v. Edwin R. Lawson, M.D. Case Number: 2019-44651

Page 6 of 11

c. failing to create adequate medical records which justify the course of treatment utilized for H.R.

d. failing to discuss the risks of developing Steven-Johnson Syndrome due to taking Lamictal with H.R

23. Based on the foregoing, Respondent violated section 458.331)(1)(t)1., Florida Statutes (2015), by committing medical malpractice in treatment of H.R. as outlined above.

## COUNT II

24. Petitioner re-alleges and incorporates paragraphs one (1) through eighteen (18) as if fully set forth herein.

25. Section 458.331(1)(m), Florida Statutes (2015), subjects a licensee to discipline for failing to keep legible, as defined by department rule in consultation with the board, medical records that identify the licensed physician or the physician extender and supervising physician by name and professional title who is or are responsible for rendering, ordering, supervising, or billing for each diagnostic or treatment procedure and that justify the course of treatment of the patient, including, but not limited to, patient histories; examination results; test results; records of drugs

Case Name: DOH v. Edwin R. Lawson, M.D. Case Number: 2019-44651

18212

prescribed, dispensed, or administered; and reports of consultations and

hospitalizations.

26. Rule 64B8-9.003(2), Florida Administrative Code (2015),

provides that a licensed physician shall maintain written legible records on

each patient in English, with sufficient detail to clearly demonstrate why the

course of treatment was undertaken. Further, rule 64B8-9.003(3), Florida

Administrative Code (2015), provides that the medical record shall contain

sufficient information to identify the patient, support the diagnosis, justify

the treatment and document the course and results of treatment accurately,

by including, at a minimum, patient histories; examination results, test

results; records of drugs prescribed, dispensed, or administered; reports of

consultations and hospitalizations; and copies of records or reports or other

documentation obtained from other health care practitioners at the request

of the physician and relied upon by the physician in determining the

appropriate treatment of the patient.

27. During H.R.'s treatment period, Respondent failed to keep legible

medical records which justified the course of treatment for H.R., and/or

satisfied the requirements of rule 64B8-9.0033(2), Florida Administrative

Code (2015), in one or more of the following ways:

a. by failing to document the Lamictal prescription titration

schedule he prescribed to H.R.;

b. in the alternative to the allegations contained in Paragraph 22

(a), by failing to document having adequate justification for

prescribing a titration regimen outside of that recommended

by the manufacturer to H.R.;

c. in the alternative to the allegations contained in Paragraph 22

(b), by failing to document having adequate justification for

prescribing the off-label use of Lamictal to H.R., an

adolescent; and

d. in the alternative to the allegations contained in Paragraph 22

(d), by failing to document discussing the risks of developing

Steven-Johnson Syndrome due to taking Lamictal with H.R.

28. Based on the foregoing, Respondent violated section

458.331(1)(m), Florida Statutes (2015) and rule 64B8-9.003, Florida

Administrative Code (2015), by failing to keep legible medical records which

justify the course of treatment for H.R., as outlined above.

WHEREFORE, Petitioner respectfully requests that the Board of

Medicine enter an order imposing one or more of the following penalties:

permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of the Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 23rd day of August, 2021.

FILED

DEPARTMENT OF HEALTH
DEPUTY CLERK

DATE: AUG 2 3 2021

Scott A. Rivkees, M.D. State Surgeon General

Jamal Burk

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JB/crv

PCP Date: August 20, 2021

PCP Members: Zachariah Zachariah, M.D. and Joy Tootle

## **NOTICE OF RIGHTS**

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

A request or petition for an administrative hearing must be in writing and must be received by the Department within 21 days from the day Respondent received the Administrative Complaint, pursuant to Rule 28-106.111(2), Florida Administrative Code. If Respondent fails to request a hearing within 21 days of receipt of this Administrative Complaint, Respondent waives the right to request a hearing on the facts alleged in this Administrative Complaint pursuant to Rule 28-106.111(4), Florida Administrative Code. Any request for an administrative proceeding to challenge or contest the material facts or charges contained in the Administrative Complaint must conform to Rule 28-106.2015(5), Florida Administrative Code.

Mediation under Section 120.573, Florida Statutes, is not available to resolve this Administrative Complaint.

## NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

Case Name: DOH v. Edwin R. Lawson, M.D.

Case Number: 2019-44651