COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF MEDICINE

Commonwealth of Pennsylvania Bureau of Professional and Occupational Affairs	**File Nos.:**	**15-49-03582** **15-49-14986**
vs.		
John Francis Mitchell, M.D., Respondent	**Docket No:**	**2257-49-17**

CONSENT AGREEMENT AND ORDER

PARTIES

1. The Commonwealth of Pennsylvania, Department of State, Bureau of Professional and Occupational Affairs ("Commonwealth") and **John Francis Mitchell, M.D.** ("Respondent") stipulate as follows in settlement of the above-captioned case.

APPLICABLE LAW

2. This matter is before the State Board of Medicine ("Board") pursuant to the Medical Practice Act, Act of December 20, 1985, P.L. 457, No. 112, ("Act"), *as amended*, 63 P.S. §§ 422.1-422.53; the Medical Care Availability and Reduction of Error ("Mcare") Act, Act of March 20, 2002, P.L. 154, No. 13, *as amended*, 40 P.S. §§ 1303.101-1303.910; and/or the Act of July 2, 1993, P.L. 345, No. 48 ("ACT 48"), *as amended*, 63 P.S. §§ 2201-2207.

LICENSURE STATUS

3. At all relevant and material times, Respondent held the following license to practice as a medical physician and surgeon in the Commonwealth of Pennsylvania: license no. MD020824E, which was originally issued on July 1, 1978, and which is currently set to expire on December 31, 2018.

STIPULATED FACTS

4. The Respondent admits that the following allegations are true:

a. Absent further Board action, Respondent's license may be renewed, reactivated or reinstated thereafter upon the filing of the appropriate documentation and payment of the necessary fees.

b. Respondent's last known office address, as on file with the Board is: 1605 N Cedar Crest Blvd. Suite 502, Allentown Pa 18104.

c. At all times relevant herein, Respondent provided office psychiatric pharmacotherapy to five patients: FC, PC, RK, AK and LP.

d. At all times relevant herein, Respondent provided Vyvanse to these five patients at greater than the maximum 70 mg dose as recommended by the manufacturer in their Food and Drug Administration (FDA) labeling.

e. Respondent's use of Vyvanse with respect to these five patients was accompanied by simultaneous prescriptions for other similar medications without documentation in the medical records that would explain or justify the use of said medications.

PATIENT FC

f. From on or about January 18, 2013 until in or about June 2014, Respondent provided treatment to male patient FC, date of birth March 24, 1991.

g. According to Respondent's medical records, FC suffered from depression, anxiety, seasonal allergies, and stress from his parents' ongoing divorce; however, there is no documentation in the medical record to support these diagnoses.

h. Without documenting reasons in the medical record to support his diagnoses and the reasons to begin prescribing controlled medications, Respondent immediately began prescribing twice daily Clonazepam, 2 mg, and Vyvanse, 70 mg as well as caution legend drug Cymbalta, 60 mg

i. By prescribing Vyvanse at 140 mg/day, to FC, Respondent was exceeding the typical 70 mg maximum daily dose indicated by the manufacturer in their FDA labeling.

j. The medical record maintained by Respondent for FC had insufficient or inadequate documentation of the following:

- documentation, justification, testing, counseling to the patient, as well as informed consent for the medications being prescribed including but not limited to the off label Vyvanse and its risks and benefits;
- vital signs or other physical examination, objective symptoms, and/or re-evaluation of FC's condition that would justify the medications being prescribed including but not limited to the off label Vyvanse
- documentation as to whether the medication prescribed was effective, the risks and benefits of prescribing said medication, or whether consultation or referral to other treating physicians/specialists was considered; or whether blood-alcohol or similar testing, laboratory drug testing or pill counts were being

performed to confirm that FC was not multi-sourcing medications from other providers, using street drugs or alcohol.

PATIENT PC

k. From on or about November 2012 until in or about 2016, Respondent treated PC, a male patient with a date of birth of May 14, 1990.

l. According to Respondent's medical records, PC suffered from "ADD," (Attention Deficit Disorder), bipolar with recurring depression, restlessness, fatigue and binge eating; however, there is no documentation in the medical record to support these diagnoses.

m. Without documenting reasons in the medical record to support his diagnoses and the reasons to begin prescribing medications to PC, Respondent immediately began prescribing a variety of medications including controlled substances Adderall Extended Release, 30 mg in morning and Adderall Immediate Release, 10 mg in the evening and Lunesta, 3 mg as well as caution legend drug Lamotrigine, 25 mg.

n. At PC's second visit, without documenting reasons in the medical records, Respondent continued prescribing Adderall and Lamotrigine but added two additional controlled substances: Provigil, 200 mg and Trazadone (Restoril), 150 mg. and on PC's third visit, without documenting reasons in the medical records prescribed an additional controlled substance, Xanax, 0.5 mg to PC.

o. Over the next several months, without documenting reasons in the medical record Respondent increased the dosages of Xanax and Adderall for PC.

p. In 2014, Respondent began to simultaneously prescribe two additional controlled substances to PC: Dexedrine 20 mg a day and Vyvanse, 70 mg twice a day (140 mg); the Vyvanse prescribed which was two times the typical maximum daily dose indicated by the manufacturer in their FDA labeling.

q. In 2015, Respondent also began prescribing Prozac, a caution legend drug and increased the Vyvanse dosage to 70 mg, three times per day (210 mg), which was three times the 70 mg typical daily dose indicated by the manufacturer in their FDA labeling.

r. The medical record maintained by Respondent for PC had insufficient or inadequate documentation of the following:

- documentation, justification, testing, counseling to the patient, as well as informed consent for the medications being prescribed including but not limited to the off label Vyvanse and its risks and benefits;
- vital signs or other physical examination, objective symptoms, and/or re-evaluation of PC's condition that would justify the medications being prescribed, including but not limited to, the off label Vyvanse;
- documentation as to whether the medication prescribed was effective, the risks and benefits of prescribing said medications, or whether consultation or referral to other treating specialists was considered; or whether blood-alcohol or similar testing, laboratory drug testing or pill counts were being performed to confirm that

PC was not multi-sourcing medications from other providers using street drugs or alcohol.

PATIENT RK

s. From on or about January 2011 until on or about October 2015, Respondent provided treatment to male patient RK, date of birth August 2, 1960.

t. According to Respondent's medical records, RK suffered from "ADHD" (Attention Deficit Hyperactivity Disorder), IED (Intermittent Explosive Disorder); however, there is no documentation and/or testing in the medical record to support these diagnoses.

u. In 2011, without documenting reasons for the medication or dosage, Respondent began prescribing to RK, Vyvanse 70 mg twice daily, which is two times greater than the typical 70 mg daily dose indicated by the manufacturer in their FDA labeling, and then later, once again without documenting reasons, increased the Vyvanse to 280 mg per day, which is four times greater than the typical 70 mg dose indicated by the manufacturer in their FDA labeling.

v. The medical record maintained by Respondent for RK had insufficient or inadequate documentation of the following:

- Documentation, justification, testing, counseling to the patient, as well as informed consent for the medications being prescribed including but not limited to the off label Vyvanse and its risks and benefits;
- Vital signs or other physical examination, objective symptoms, re-evaluation of RK's condition that would justify the medications being prescribed, including but not limited, to the off label Vyvanse;

- Documentation as to whether the medication prescribed was effective, the risks and benefits of prescribing said medications, or whether consultation or referral to other treating physicians/specialists was considered; or whether blood-alcohol or similar testing, laboratory drug testing or pill counts were being performed to confirm that RK was not multi-sourcing medications from other providers, using street drugs or alcohol.

PATIENT AK

w. From on or about November 2005 and continuing through 2015 Respondent provided treatment to female patient AK, date of birth July 10, 1971.

x. According to Respondent's medical records, AK suffered from bipolar disorder, insomnia, personality disorder, eating disorder chronic fatigue syndrome, and had a family history of alcoholism in her mother; however, there is no documentation in the record to support these diagnoses.

y. Without documenting justification for said medications, Respondent simultaneously prescribed sedative hypnotic medications and/or would change the dosages of the medications including but not limited to Xanax. Ambien, as well as Vyvanse which was prescribed at a rate of 280 mg per day, which is four times greater than the typical maximum daily dose of 70 mg as indicated by the manufacturer in their FDA labeling.

z. Without documenting reasons in the medical record, Respondent would switch to other medications, including but not limited to, Diazepam, Dexedrine, Zolpidem, Temazepam, Klonopin, Clonazepam and Valium as well as caution legend drugs such as Abilify, Risperidone and Seroquel.

aa. The medical record maintained by Respondent for AK had insufficient or inadequate documentation of the following:

- documentation, justification, testing, counseling to the patient, as well as informed consent for the medications being prescribed including but not limited to the off label Vyvanse and its risks and benefits;
- vital signs or other physical examination, objective symptoms, reevaluation of AK's condition that would justify the medications being prescribed including the off label Vyvanse;
- documentation as to whether the medications prescribed were effective, the risks and benefits of prescribing said medications, whether consultation or referral to other treating physicians/specialists was considered; or whether blood-alcohol or similar testing or pill counts were being performed to confirm that AK was not multi-sourcing medications from other providers, using street drugs or alcohol.

PATIENT LP

bb. From in or about 2007 through 2011, LP, a male patient, date of birth, July 16, 1951, saw Respondent five times; commencing in 2013 Respondent began seeing LP as a patient on a regular basis.

cc. According to Respondent's medical record, it appears LP suffered from Bipolar Disorder, Autism, as well as neck and back pain; however, there is no documentation in the medical record to support these diagnoses.

dd. Respondent initially prescribed Vyvanse at 50 mg, once per day but without documenting reasons in the medical record doubled the dose to 50 mg twice per day, which is more than the typical maximum daily dose of 70 mg as indicated by the manufacturer in FDA labeling.

ee. On June 24, 2013, without documenting reasons in the medical record, Respondent tripled LP's Vyvanse dosage to 50 mg three times a day, or 150 mg per day, which is more than twice the typical maximum daily dose of 70 mg per day as indicated by the manufacturer in FDA labeling.

ff. On June 29, 2013, without documenting reasons in the medical record, Respondent later increased LP's Vyvanse to 60 mg three times per day, or 180 mg, and then again in December 2013 to 60 mg, four times a day, or 240 mg, which is significantly more the 70-mg typical maximum daily dose as indicated by the manufacturer in FDA labeling.

gg. The medical record maintained by Respondent for LP had insufficient or inadequate documentation of the following;

- documentation, justification, testing, counseling to, LP that would justify the medications being prescribed as well as informed consent for the medications being prescribed including but not limited to the off label Vyvanse and its risks and benefits;
- vital signs or other physical examination, objective symptoms, reevaluation of LP's that would justify medications being prescribed including but not limited to the off label Vyvanse;

- documentation as to whether the medication prescribed was effective, the risks and benefits of prescribing said medications, or whether consultation or referral to other treating physicians/specialists was considered; or whether blood-alcohol or similar testing laboratory drug testing or pill counts were being performed to confirm that LP was not multi-sourcing medications from other providers, using street drugs or alcohol.

ALLEGED VIOLATIONS

5. The Commonwealth alleges that the Board is authorized to suspend, revoke, or otherwise restrict Respondent's license under Sections 41 and 42 of the Act, 63 P.S. §§ 422.41 & 422.42; and/or impose a civil penalty upon Respondent under Sections 39 through 42 of the Act, 63 P.S. §§ 422.39-422.42, and /or Section 5(b)(4) of ACT 48, 63 P.S. § 2205(b)(4); and/or impose the costs of investigation upon Respondent under Section 5(b)(5) of ACT 48, 63 P.S. § 2205(b)(5), because Respondent violated the Act at:

a. 63 P.S. § 422.41(6) and the Board's regulations at 49 Pa Code §16.61 in that Respondent failed to comply with the Board's regulations when prescribing controlled substances to his patients; and

b. 63 P.S. § 422.41(8) in that Respondent was guilty of immoral and unprofessional conduct with respect to his prescribing of Vyvanse at dosages greater than manufacturer's recommendations and prescribing Vyvanse together with simultaneous prescriptions for other similar medications without adequate documentation in the medical record to justify the use of said medications.

PROPOSED ORDER

6. The parties, intending to be legally bound, consent to the issuance of the following

Order in settlement of this matter:

a. The Board finds that it is authorized to suspend, revoke, or otherwise restrict Respondent's license under Sections 41 and 42 of the Act, 63 P.S. §§ 422.41 & 422.42; and/or impose a civil penalty upon Respondent under Sections 39 through 42 of the Act, 63 P.S. §§ 422.39-422.42, and/or Section 5(b)(4) of ACT 48, 63 P.S. § 2205(b)(4); and/or impose the costs of investigation upon Respondent under Section 5(b)(5) of ACT 48, 63 P.S. § 2205(b)(5), because Respondent violated the Act at:

(1) 63 P.S. §422.41(6) and the Board's regulations at 49 Pa. Code §16.61 in that Respondent failed to comply with the Board's regulations when prescribing controlled substances to patients; and

(2) 63 P.S. §422.41(8) in that Respondent was guilty of immoral and/or unprofessional conduct with respect to his prescribing Vyvanse at dosages greater than manufacturer's recommendations and prescribing Vyvanse together with simultaneous prescriptions for other similar medications without adequate documentation in the medical record to justify the use of said mediations.

COSTS OF INVESTIGATION

b. An assessment for the **COSTS OF INVESTIGATION** of three thousand five hundred dollars ($3500.00) is levied upon Respondent. The full sum of the costs of investigation of three thousand five hundred dollars ($3500.00) shall be tendered by Respondent with this executed Consent Agreement and shall be paid by certified check, cashier's check, attorney's check, or money order issued by a usual, customary, and reputable issuer (e.g. U.S. Postal Money Order, Western Union Money Order, etc).

Payment shall be made payable to the "Commonwealth of Pennsylvania" and shall be valid for a period of at least one hundred eighty (180) days. Respondent agrees that payment shall only be made by one of the methods indicated above and shall not be made by uncertified personal or corporate check.

REMEDIAL EDUCATION

c. Respondent shall attend and successfully complete thirty (30) hours in intensive courses in controlled substance prescribing; medical documentation and ethics and professionalism within six months of the date of this Order. The intensive courses shall be offered by a program approved by the Board. Respondent shall seek Board approval prior to taking said courses.

d. Respondent shall also comply with all the following terms and conditions pertaining to completion of the remedial education hours:

(1) Credits specified in this Order shall be subject to the approval of the Board and in compliance with either the initial education or the continuing education regulations of the Board;

(2) To the extent that the remedial education courses require Respondent to pass an examination for Respondent to be eligible for initial or continuing education credits, Respondent must take and successfully pass such examination for the remedial education courses to satisfy the requirement of this Order.

(3) Respondent shall submit acceptable proof of successful completion of the remedial professional education courses to the Board's Board Administrator within six months of the date of this Order. Respondent shall note the file number and docket number of this matter on any

documentation submitted to the Board Administrator. The address for the Board's Administrator is:

Suzanne Zerbe
State Board of Medicine
2601 N 3rd Street
P.O. Box 2649
Harrisburg, PA 17105-2649

(4) Acceptable Proof of completion of the thirty (30) additional hours of remedial education shall consist of an official school transcript, a certificate or letter of completion prepared by the sponsor of the remedial education course or a printout prepared by the sponsor indicating the completed courses. Proof shall contain course titles, completion dates, final grade (if course is graded), and number of class hours or continuing professional education (CPE) credits awarded. Acceptable proof shall not consist of receipts, course outlines or agendas, cancelled checks, payment acknowledgments, or self-prepared records, among other documents.

(5) Respondent shall authorize the course provider to send a course assessment to the Board's Board Administrator;

(6) The additional hours of remedial education in this Order shall be completed in addition to the hours that Respondent shall take in this or subsequent reporting periods for the renewal of his license. Credit hours required in this Order may not be used from any previous reporting period, nor may they be used in any subsequent biennial period for the renewal of Respondent's license to practice as

a medical physician and surgeon. Respondent may not use credit hours required in this Order for purposes of satisfying any initial or continuing education requirement of any other authorization to practice the profession.

(7) Pending payment of costs of investigation and successful completion of the remedial education requirements outlined herein Respondent will have an unrestricted license which will remain unrestricted upon successful completion of the terms of this Consent Agreement.

FAILURE TO TIMELY AND SUCESSFULLY COMPLETE THE REMEDIAL EDUCATION AS REQUIRED BY CONSENT AGREEMENT AND ORDER

e. If the Respondent fails to submit acceptable proof of successful completion of the Remedial Education within the time frame set forth in this Consent Agreement and Order, Respondent's license to practice as a medical physician and surgeon and any and all authorizations to practice the profession issued by the Board and held by **Respondent shall be IMMEDIATELY AND INDEFINITELY SUSPENDED until such time as Respondent does provide the Board's Board Administrator with acceptable proof of successful completion of the Remedial Education as required by this Consent Agreement.**

f. This Order constitutes disciplinary action by the Board and shall be reported to other licensing authorities and any applicable national licensing databank as a disciplinary action by the Board.

g. This case shall be deemed settled and discontinued upon the Board issuing an Order adopting this Consent Agreement.

ADMISSIBILITY OF CONSENT AGREEMENT IN FUTURE PROCEEDINGS

7. Respondent agrees that if Respondent is charged with a violation of an Act enforced by this Board in the future, this Consent Agreement and Order shall be admitted into evidence without objection in that proceeding.

ACKNOWLEDGMENT OF NOTICE AND WAIVER OF HEARING

8. Respondent acknowledges receipt of an Order to Show Cause in this matter. Respondent knowingly and voluntarily waives the right to an administrative hearing in this matter, and knowingly and voluntarily waives the following rights related to that hearing: to be represented by counsel at the hearing; to present witnesses and testimony in defense or in mitigation of any sanction that may be imposed for a violation; to cross-examine witnesses and to challenge evidence presented by the Commonwealth; to present legal arguments by means of a brief; and to take an appeal from any final adverse decision.

ACKNOWLEDGMENT OF RIGHT TO ATTORNEY

9. Respondent acknowledges that he is aware that he has the right to consult with, and/or be represented by, private legal counsel of Respondent's choosing and at Respondent's expense when reviewing, considering and accepting the terms of this Consent Agreement. To the extent that Respondent is not represented by legal counsel, Respondent has knowingly elected to proceed without the assistance of legal counsel.

WAIVER OF CLAIM OF COMMINGLING AND OTHER CONSTITUTIONAL CLAIMS

10. Respondent expressly waives any constitutional rights and issues, such as commingling of prosecutorial and adjudicative functions by the Board or its counsel, which may arise or have arisen during the negotiation, preparation and/or presentation of this Consent Agreement. Respondent specifically agrees that if the Board rejects this agreement, it may assume that the facts and averments as alleged in this Consent Agreement are true and correct for

the limited purpose of recommending a sanction, based on those assumed facts, that would be acceptable to the Board before hearing the case. In the event that the Board does assume the facts and averments as alleged in this Consent Agreement are true for purposes of making a recommendation as to an acceptable sanction, such action shall not constitute commingling of prosecutorial and adjudicative functions by the Board or its counsel, and the Respondent expressly waives any constitutional rights and issues related to alleged commingling, bias, or violation of due process rights to have an unbiased and impartial adjudicator in any subsequent hearing. If a hearing is subsequently held, neither this Consent Agreement nor the proposed terms of settlement may be admitted into evidence and any facts, averments, and allegations contained in the Consent Agreement must be proven at hearing unless otherwise separately stipulated. This paragraph is binding on the participants even if the Board does not approve this Consent Agreement.

NO MODIFICATION OF ORDER

11. Respondent agrees, as a condition of entering into this Consent Agreement, not to seek modification at a later date of the Stipulated Order adopting and implementing this Consent Agreement without first obtaining the express written concurrence of the Prosecution Division.

AGREEMENT NOT BINDING ON OTHER PARTIES

12. The Office of General Counsel has approved this Consent Agreement as to form and legality; however, this Consent Agreement shall have no legal effect unless and until the Board issues the stipulated Order.

EFFECT OF BOARD'S REJECTION OF CONSENT AGREEMENT

13. Should the Board not approve this Consent Agreement, presentation to and consideration of this Consent Agreement and other documents and matters by the Board shall not prejudice the Board or any of its members from further participation in the adjudication of this

matter. This paragraph is binding on the participants even if the Board does not approve this Consent Agreement.

ENTIRE AGREEMENT

14. This agreement contains the whole agreement between the participants; provided however, that the captions printed in the various provisions of this agreement are for ease of reading only and are not to be interpreted as forming any part of this agreement. There are no other terms, obligations, covenants, representations, statements or conditions, or otherwise, of any kind whatsoever concerning this agreement.

AGREEMENT DOES NOT PREVENT ADDITIONAL DISCIPLINE BASED ON OTHER COMPLAINTS

15. Nothing in this Order shall preclude the Prosecution Division for the Commonwealth from filing charges or the Board from imposing disciplinary or corrective measures for violations or facts not contained in this Consent Agreement;

VERIFICATION OF FACTS AND STATEMENTS

16. Respondent verifies that the facts and statements set forth in this Consent Agreement are true and correct to the best of Respondent's knowledge, information and belief. Respondent understands that statements in this Consent Agreement are made subject to the criminal penalties of 18 Pa.C.S.A. §4904 relating to unsworn falsification to authorities.

Anita P. Shekletski
Senior Prosecutor in Charge

DATED: 1/23/18

John Francis Mitchell, M.D.
Respondent

DATED: 1-22-2018

Todd S. Miller, Esquire
Attorney for Respondent

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF MEDICINE

Commonwealth of Pennsylvania Bureau of Professional and Occupational Affairs	**File Nos.:**	**15-49-03582** **15-49-14986**
vs.		
John Francis Mitchell, M.D., Respondent	**Docket No:**	**2257-49-17**

ORDER

AND NOW, this 9th day of February 2018, the **STATE BOARD OF MEDICINE** ("Board") adopts and approves the foregoing Consent Agreement and incorporates the terms of paragraph 6, which shall constitute the Board's Order and is now issued in resolution of this matter.

This Order shall take effect immediately.

BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

Ian J. Harlow
Commissioner

BY ORDER:
STATE BOARD OF MEDICINE

Bruce A. Brod, M.D.
Chair

For the Commonwealth:

Anita P. Shekletski, Esquire
2601 North Third Street
P.O. Box 69521
Harrisburg, PA 17106-9521

Respondent 's Counsel:

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611 North Nineteenth Street
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DATE OF MAILING: February 9, 2018