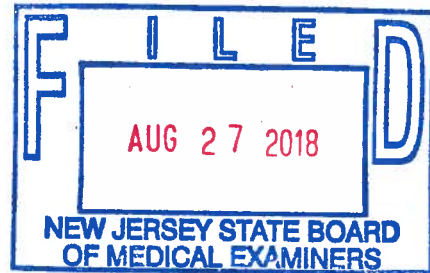


GURBIR S. GREWAL
ATTORNEY GENERAL OF NEW JERSEY
Division of Law
124 Halsey Street
P.O. Box 45029
Newark, New Jersey 07101



By: David M. Puteska
Deputy Attorney General
Tel: 973-648-2972
David.Puteska@law.njoag.gov
Attorney Identification No. 301995

nunc pro tunc December 30, 2016

STATE OF NEW JERSEY
DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF MEDICAL EXAMINERS &
DRUG CONTROL UNIT

IN THE MATTER OF THE LICENSE TO
PRACTICE MEDICINE AND SURGERY AND NJ
CDS REGISTRATION OF

KENNETH SUN, M.D.
LICENSE NO. 25MA06318400
CDS REG. NO. D06831900

Administrative Action

CONSENT ORDER

This matter was opened to the New Jersey State Board of Medical Examiners ("Board") by Gurbir S. Grewal, Attorney General of New Jersey, by David M. Puteska, Deputy Attorney General, appearing, upon receipt of information evidencing that the Kenneth P. Sun, M.D. ("Respondent"), indiscriminately prescribed controlled dangerous substances ("CDS") in reckless disregard of his patients' health, safety, and welfare and also violated several regulations governing the practice of medicine in the State of New Jersey. Because, in the Attorney General's view, this conduct palpably demonstrated a clear and imminent danger to the public health, safety, and welfare within the meaning of N.J.S.A. 45:1-22, an application for temporary suspension of licensure was contemplated. Prior to such filing, upon the parties being desirous of resolving this matter on an interim basis, and without the institution of formal disciplinary proceeding, Respondent voluntarily agreed to execute a Consent Order that, effective December 30, 2016, suspended his license "pending further Order of

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the Board.” As established by the findings of fact that the Board hereby makes below, the Board now concludes that Respondent’s misconduct provides grounds to revoke his license pursuant to N.J.S.A. 45:1-21.

First, Respondent prescribed a highly-potent sublingual spray formulation of fentanyl, an opioid approximately fifty times more powerful than heroin and one hundred times more powerful than morphine, to at least eight non-cancer patients for whom such a drug was contraindicated. This drug, called Subsys, is so dangerous that it has been made subject to a restricted distribution regulatory regime that governs all healthcare practitioners’ access to it and the only five other drugs of its kind. In the Attorney General’s view, because of its grave risks, Subsys, as a general matter, should only be prescribed for the treatment of cancer patients who are suffering from breakthrough cancer pain and who are already receiving, and are tolerant to, around-the-clock opioid therapy for their underlying persistent cancer pain.

By prescribing Subsys to patients who did not suffer from breakthrough cancer pain, Respondent jeopardized his patients’ welfare in reckless or willful disregard of its unequivocal and well-established risks, and disregarded parameters pertaining to its appropriate use, notwithstanding his express acknowledgment that he understood those risks and his commitment to abide by restrictions on prescribing of Subsys.

Second, between 2013 and 2015, the manufacturer of Subsys, Insys Therapeutics (“Insys”) paid Respondent more than \$117,000 for advisory and consulting services and participation as a Subsys-promoting speaker at Insys-sponsored and Insys-organized informational events. Pecuniary benefits in the amounts that Respondent accepted appear to have, and can readily be seen as having, improperly influenced Respondent and encouraged his Subsys prescribing. Because a “reasonable person would recognize” that the purpose for which Insys paid Respondent such a substantial amount

of money was to promote his Subsys prescribing, Respondent's acceptance of said monies constitutes repeated violations of N.J.A.C. 13:35-6.17(c)(1).

Third, Respondent committed several violations of the Board's regulations regarding the prescribing of CDS for pain management, with respect to the eight Subsys patients whose medical records the Attorney General subpoenaed. For all of them, Respondent failed to "periodically make reasonable efforts" to stop the use of the prescribed opioid or to take any other steps "in an effort to reduce the potential for abuse or the development of physical or psychological dependence." N.J.A.C. 13:35-7.6(d)(3). Moreover, Respondent failed to "keep accurate and complete medical records" for each of the eight Subsys patients at issue in violation of N.J.A.C. 13:35-7.6(g) and in some instances maintained within his patient record documentation which mischaracterized the patient diagnoses and/or the etiology of their pain.

In light of the above, the Board holds that Respondent's conduct, as described herein, constitutes (1) gross negligence, or gross incompetence that endangered the health, welfare, and safety of his patients; (2) professional misconduct; and (3) violations of the provisions of certain several statutes and/or regulations administered by the Board and 4) the indiscriminate prescribing of controlled dangerous substances. Such conduct, therefore, provides grounds for the Board to revoke his medical license pursuant to N.J.S.A. 45:1-21(b), (c), (e), (h), and (m).

Respondent, desiring to resolve this matter without the institution of a formal disciplinary proceeding, and it appearing that Respondent has read the content and terms of the within Order in their entirety and, neither admitting or denying, the violations described herein, understands their meaning and effect, and, upon the advice of counsel, agrees to be bound by all of the terms herein, and the Board, finding the within disposition to be adequately protective of the public health, safety, and welfare, and further finding that good cause exists for the entry of this Order:

IT IS, THEREFORE, ON THIS 27th DAY OF AUGUST, 2018,

ORDERED AND AGREED THAT:

1. Effective nunc pro tunc December 30, 2016 ("Effective Revocation Date"), Respondent's license to practice medicine and surgery in the State of New Jersey shall be, and hereby is, revoked.

2. Respondent shall not be eligible to be granted a license to practice medicine and surgery for thirty-six (36) months from the Effective Revocation Date.

3. The period of revocation will be tolled for any length of time that Respondent practices in another jurisdiction.

4. Respondent's New Jersey CDS Registration, pursuant to the authority of the Acting Director of the New Jersey Division of Consumer Affairs (the "Director") under N.J.S.A. 24:21-9 et seq., is revoked nunc pro tunc December 30, 2016. This CDS Registration revocation is independent of any action taken by the Board, the United States Drug Enforcement Administration ("DEA") or any other law enforcement or licensing authority. A copy of this Consent Order, signed by the Director, will be filed with the Division's Drug Control Unit. Upon filing a reapplication for his medical license, Respondent may also reapply for his New Jersey CDS Registration.

5. Respondent shall return his original New Jersey license, current biennial registration and his CDS registration to William V. Roeder, Executive Director, New Jersey State Board of Medical Examiners, P.O. Box 183, Trenton, New Jersey 08625-0183.

6. Respondent shall continue to be barred from engaging in the practice of medicine and surgery in this State until such time as he seeks and is granted reinstatement. This means that the Respondent shall, among other things, refrain from all patient contact and shall not issue any prescriptions for, or dispense, medications of any kind, including but not limited to CDS.

7. Respondent shall comply with N.J.A.C. 13:35-6.5(h), the Board regulation for practice closure. Within ten (10) days of the filing of this Consent Order, Respondent is to notify William V. Roeder, Executive Director, State Board of Medical Examiners, 140 East Front Street, PO Box 183, Trenton, New Jersey 08625-0183 as to where his patient records are secured, and how patients may obtain them.

8. Respondent shall immediately advise the Drug Enforcement Administration of this Order, and, specifically, that his license to practice medicine and surgery in the State of New Jersey has been revoked.

9. Respondent shall be precluded from managing, overseeing, supervising or influencing the practice of medicine or the provision of health care services to patients in the State of New Jersey.

10. Respondent shall not charge, receive or share in any fee for professional services rendered by others. Respondent shall be permitted to collect accounts receivable with respect to professional services that he rendered prior to the effective date of the Interim Consent Order temporarily suspending his license.

11. Before reapplying for his license Respondent shall provide the Board with proof that he has taken and successfully completed courses in (i) medical ethics; (ii) recordkeeping; and (iii) the safe use and prescribing of opioids for the management of acute and chronic pain (should Respondent wish to resume prescribing CDS upon his return to practice) which are approved in advance by the Board. Successful completion means that all sessions were attended, all assignments were properly and appropriately completed and a passing grade was achieved which was unconditional and without reservation. Respondent shall bear the cost of the courses and shall not use any credits obtained through the courses towards the fulfillment of his biennial continuing medical education requirement.

12. Respondent is assessed a civil penalty of \$60,000 pursuant to N.J.S.A. 45:1-25.

13. Respondent is assessed \$13,800 in attorney's fees in this matter pursuant to N.J.S.A. 45:1-25.

14. Payment of civil penalties and costs pursuant to Paragraphs twelve (12) and thirteen (13) of this Consent Order, in the total amount of \$73,800, shall be made in forty-eight (48) equal monthly installments of \$1,537.50 commencing on January 1, 2020 regardless of whether or not Respondent's reapplication for a New Jersey medical license has been granted. Each payment shall be due on the first business day of each month. Failure to make any payment timely shall result in the entire balance being due and owing. Respondent may prepay at any time. Interest on all financial assessments shall accrue in accordance with Rule of Court 45:42-

11. All payments shall be made by certified bank check, certified check, money order, wire transfer or credit card payable to the State of New Jersey and sent to the State Board of Medical Examiners, c/o Mr. William Roeder, Executive Director, New Jersey Board of Medical Examiners, P.O. Box 183, Trenton, New Jersey 08625. Any other form of payment will be rejected and will be returned to the party making payment. In the event that a monthly payment is not received within five days of its due date, the entire balance of the civil penalty and costs shall become due and owing. A Certificate of Debt shall be filed pursuant to N.J.S.A. 45:1-24 to protect the judgment.

15. As part of his reapplication for licensure Respondent shall appear before a Committee of the Board to demonstrate his fitness to resume practice, at a minimum demonstrating his compliance with all of the terms contained herein or subsequently ordered as a condition of obtaining his license, successful completion of the agreed upon coursework and payment of all penalties and costs. Respondent shall be permitted to appear before a Committee of the Board six months prior to the conclusion of his bar to being granted a license. Respondent

agrees that this allowance is merely to afford Respondent and the Board advance time to begin the process to address his reapplication but that a grant of his application for licensure cannot occur prior to the completion of the entire thirty-six (36) month period detailed above. The Board expressly reserves the right to impose additional restrictions and/or limitations if licensure is granted including, but not limited to, (a) prohibiting him from accepting remuneration of any kind from any pharmaceutical company in exchange for services characterized as speaking, advising, or consulting services; (b) limiting, in full or in part, the Respondent's New Jersey Controlled Dangerous Substances Registration; (c) requiring him to hire a Board-approved monitor to review, among other things, the appropriateness of Respondent's care and treatment of patients whose pain he treats with opioid medications of any kind; and/or (d) requiring him to complete certain appropriate continuing medical education ("CME") credits in addition to a licensee's ordinary CME obligations.

16. Respondent shall cooperate with the Board, Director and Attorney General (the "State") in this litigation or any litigation, investigation and/or proceeding related to CDS prescribing. Respondent's cooperation is material to the State and shall include, but is not limited to: voluntarily and promptly appearing, without a subpoena and at his own expense, to serve as a witness at any legal proceeding in order to testify completely and truthfully, subject to and without waiving any constitutional rights or privileges; voluntarily and promptly attending and completing any meetings requested by the State; and voluntarily and promptly responding to the State's requests for documents or evidence, subject to and without waiving any constitutional rights or privileges. Failure to cooperate pursuant to this paragraph shall be considered a breach of this consent order subjecting Respondent to additional disciplinary sanction.

17. The terms of the "Directives Applicable to Any Medical Board Licensee who is Disciplined or Whose Surrender of Licensure or Cessation of Practice has been Ordered or Agreed Upon," attached hereto as Exhibit 1, are expressly incorporated herein by reference.

18. The parties hereby stipulate that entry of this Consent Order is without prejudice to further action by this Board, the Attorney General, the Drug Control Unit, the Director of the Division of Consumer Affairs or any other law enforcement entities resulting from Respondent's conduct prior or subsequent to entry of this Order. The parties also stipulate that the entry of this Consent Order is without any admissions by Respondent.

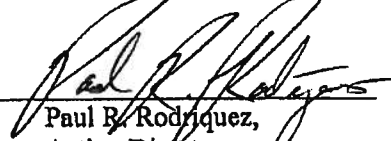
19. This Consent Order shall be a final disposition of the Verified Administrative Complaint filed in this matter and docketed by the Office of Administrative Law as BDS 18669-2017. The Board shall retain jurisdiction to enforce the terms of this Order.

NEW JERSEY STATE BOARD OF MEDICAL EXAMINERS


By: 

Paul Carniol, M.D.,
Board President

NEW JERSEY DIVISION OF CONSUMER AFFAIRS

By: 
Paul B. Rodriguez,
Acting Director

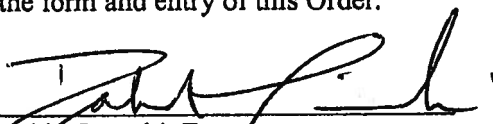
I have read the within Consent Order in its entirety and I agree to be bound by all of its terms. I understand the meaning and effect of this Order, and I understand that the entry of this Order carries serious legal consequences. Consent is hereby given to the Board to enter this Order.



Kenneth P. Sun, M.D.

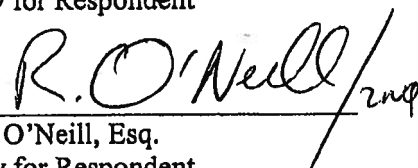
7/31/18
Date

Consent is hereby given as to the form and entry of this Order.



Zabid Ourashi, Esq.
Attorney for Respondent

8/7/18
Date



Ryan L. O'Neill, Esq.
Attorney for Respondent

8/7/18
Date

Exhibit 1

**DIRECTIVES APPLICABLE TO ANY MEDICAL BOARD LICENSEE
WHO IS DISCIPLINED OR WHOSE SURRENDER OF LICENSURE
OR CESSATION OF PRACTICE HAS BEEN ORDERED OR AGREED UPON**

APPROVED BY THE BOARD ON AUGUST 12, 2015

All licensees who are the subject of a disciplinary order or surrender or cessation order (herein after, "Order") of the Board shall provide the information required on the addendum to these directives. Failure to provide the information required may result in further disciplinary action for failing to cooperate with the Board, as required by N.J.A.C. 13:45C-1 et seq: Paragraphs 1 through 4 below shall apply when a licensee is suspended, revoked, has surrendered her or her license, or entered into an agreement to cease practice, with or without prejudice, whether on an interim or final basis. Paragraph 5 applies to licensees who are the subject of an order which, while permitting continued practice, contains probationary terms or monitoring requirement.

1. Document Return and Agency Notification

The licensee shall promptly forward to the Board office at Post Office Box 183, 140 East Front Street, 2nd floor, Trenton, New Jersey 08625-0183, the original license, current biennial registration and, if applicable, the original CDS registration. In addition, if the licensee holds a Drug Enforcement Agency (DEA) registration, he or she shall promptly advise the DEA of the licensure action. (With respect to suspensions of a finite term, at the conclusion of the term, the licensee may contact the Board office for the return of the documents previously surrendered to the Board. Prior to the resumption of any prescribing of controlled dangerous substances, the licensee shall petition the Director of Consumer Affairs for a return of the CDS registration if the basis for discipline involved CDS misconduct. In addition, at the conclusion of the term, the licensee should contact the DEA to advise of the resumption of practice and to ascertain the impact of that change upon her/her DEA registration.)

2. Practice Cessation

The licensee shall cease and desist from engaging in the practice of medicine in this State. This prohibition not only bars a licensee from rendering professional services, but also from providing an opinion as to professional practice or its application, or representing him/herself as being eligible to practice. (Although the licensee need not affirmatively advise patients or others of the revocation, suspension, surrender or cessation, the licensee must truthfully disclose her/her licensure status in response to inquiry.) The licensee subject to the order is also prohibited from occupying, sharing or using office space in which another licensee provides health care services. The licensee subject to the order may contract for, accept payment from another licensee for rent at fair market value for office premises and/or equipment. In no case may the licensee subject to the order authorize, allow or condone the use of her/her provider number by any health care practice or any other licensee or health care provider. In situations where the licensee has been subject to the order for less than one year, the licensee may accept payment from another professional who is using her/her office during the period that the licensee is (suspended), subject to the order for the payment of salaries for office staff employed at the time of the Board action.

A licensee whose license has been revoked, suspended or subject to a surrender or cessation order for one (1) year or more must immediately take steps to remove signs and take affirmative action to stop advertisements by which her/his eligibility to practice is represented. The licensee must also take steps to remove her/his name from professional listings, telephone directories, professional stationery, or billings. If the licensee's name is utilized in a group practice title, it shall be deleted. Prescription pads bearing the licensee's name shall be destroyed. A destruction report form obtained from the Office of Drug Control (973-504-6558) must be filed. If no other licensee is providing services at the location, all medications must be removed and returned to the manufacturer, if possible, destroyed or safeguarded. (In situations where a license has been suspended for less than one year, prescription pads and medications need not be destroyed but must be secured in a locked place for safekeeping.)

3. Practice Income Prohibitions/Divestiture of Equity Interest in Professional Service Corporations and Limited Liability Companies

A licensee subject to the order shall not charge, receive or share in any fee for professional services rendered by him/herself or others while barred from engaging in the professional practice.¹ The licensee may be compensated for the reasonable value of services lawfully rendered and disbursements incurred on a patient's behalf prior to the effective date of the Board order.

A licensee who is a shareholder in a professional service corporation organized to engage in the professional practice, whose license is revoked, surrendered or suspended or who is ordered to cease practice for a term of one (1) year or more shall be deemed to be disqualified from the practice within the meaning of the Professional Service Corporation Act. (N.J.S.A. 14A:17-11). A disqualified licensee shall divest him/herself of all financial interest in the professional service corporation pursuant to N.J.S.A. 14A:17-13(c). A disqualified licensee who is a member of a limited liability company organized pursuant to N.J.S.A. 42:1-44, shall also divest him/herself of all financial interest. Such divestiture of the licensee's interest in the Limited Liability Company or professional service corporation shall occur within 90 days following the entry of the order rendering the licensee disqualified to participate in the applicable form of ownership. Upon divestiture, a licensee shall forward to the Board a copy of documentation forwarded to the Division of Revenue and Enterprise Services demonstrating that the interest has been terminated. If the licensee is the sole shareholder in a professional service corporation or sole member of the limited liability company, the corporation must be dissolved within 90 days of the licensee's disqualification unless it is lawfully transferred to another licensee and documentation of the valuation process and consideration paid is also provided to the Board.

4. Medical Records

If, as a result of the Board's action, a practice is closed or transferred to another location, the licensee shall ensure that (during the three (3) month period) immediately following the effective date of the disciplinary order, a message will be delivered to patients calling the former office

¹ This bar on the receipt of any fee for professional services is not applicable to cease and desist orders where there are no findings that would be a basis for Board action, such as those entered adjourning a hearing.

premises, advising where records may be obtained. The message should inform patients of the names and telephone numbers of the licensee (or her/her attorney) assuming custody of the records. The same information shall also be disseminated by means of a notice to be published at least once per month for three (3) months in a newspaper of general circulation in the geographic vicinity in which the practice was conducted. If the licensee has a website, a notice shall be posted on the website as well.

At the end of the three month period, the licensee shall file with the Board the name and telephone number of the contact person who will have access to medical records of former patients. Any change in that individual or her/her telephone number shall be promptly reported to the Board. When a patient or her/her representative requests a copy of her/her medical record or asks that record be forwarded to another health care provider, the licensee shall promptly provide the record without charge to the patient.

5. Probation/Monitoring Conditions

With respect to any licensee who is the subject of any order imposing a probation or monitoring requirement or a stay of an active suspension, in whole or in part, which is conditioned upon compliance with a probation or monitoring requirement, the licensee shall fully cooperate with the Board and its designated representatives, including the Enforcement Bureau of the Division of Consumer Affairs, in ongoing monitoring of the licensee's status and practice. Such monitoring shall be at the expense of the disciplined practitioner.

(a) Monitoring of practice conditions may include, but is not limited to, inspection of the professional premises and equipment, and inspection and copying of patient records (confidentiality of patient identity shall be protected by the Board) to verify compliance with the Board Order and accepted standards of practice.

(b) Monitoring of status conditions for an impaired practitioner may include, but is not limited to, practitioner cooperation in providing releases permitting unrestricted access to records and other information to the extent permitted by law from any treatment facility, other treating practitioner, support group or other individual/facility involved in the education, treatment, monitoring or oversight of the practitioner, or maintained by a rehabilitation program for impaired practitioners. If bodily substance monitoring has been ordered, the practitioner shall fully cooperate by responding to a demand for breath, blood, urine or other sample in a timely manner and providing the designated sample.

6. Payment of Civil and Criminal Penalties and Costs.

With respect to any licensee who is the subject of any order imposing a civil penalty and/or costs, the licensee shall satisfy the payment obligations within the time period ordered by the Board or be subject to collection efforts or the filing of a certificate of debt. The Board shall not consider any application for reinstatement nor shall any appearance before a committee of the Board seeking reinstatement be scheduled until such time as the Board ordered payments are satisfied in full. (The Board at its discretion may grant installment payments for not more than a 24 months period.). As to the satisfaction of criminal penalties and civil forfeitures, the Board will consider a reinstatement application so long as the licensee is current in her or her payment plans.

**NOTICE OF REPORTING PRACTICES OF BOARD
REGARDING DISCIPLINARY ORDERS/ACTIONS**

All Orders filed by the New Jersey State Board of Medical Examiners are "government records" as defined under the Open Public Records Act and are available for public inspection, copying or examination. See N.J.S.A. 47:1A-1, et seq., N.J.S.A. 52:14B-3(3). Should any inquiry be made to the Board concerning the status of a licensee who has been the subject of a Board Order, the inquirer will be informed of the existence of the Order and a copy will be provided on request. Unless sealed or otherwise confidential, all documents filed in public actions taken against licensees, to include documents filed or introduced into evidence in evidentiary hearings, proceedings on motions or other applications conducted as public hearings, and the transcripts of any such proceedings, are "government records" available for public inspection, copying or examination.

Pursuant to N.J.S.A. 45:9-22, a description of any final board disciplinary action taken within the most recent ten years is included on the New Jersey Health Care Profile maintained by the Division of Consumer Affairs for all licensed physicians. Links to copies of Orders described thereon are also available on the Profile website. See <http://www.njdoctorlist.com>.

Copies of disciplinary Orders entered by the Board are additionally posted and available for inspection or download on the Board of Medical Examiners' website. See <http://www.njconsumeraffairs.gov/bme>.

Pursuant to federal law, the Board is required to report to the National Practitioner Data Bank (the "NPDB") certain adverse licensure actions taken against licensees related to professional competence or conduct, generally including the revocation or suspension of a license; reprimand; censure; and/or probation. Additionally, any negative action or finding by the Board that, under New Jersey law, is publicly available information is reportable to the NPDB, to include, without limitation, limitations on scope of practice and final adverse actions that occur in conjunction with settlements in which no finding of liability has been made. Additional information regarding the specific actions which the Board is required to report to the National Practitioner Data Bank can be found in the NPDB Guidebook issued by the U.S. Department of Health and Human Services in April 2015. See <http://www.npdb.hrsa.gov/resources/npdbguidebook.pdf>.

Pursuant to N.J.S.A. 45:9-19.13, in any case in which the Board refuses to issue, suspends, revokes or otherwise places conditions on a license or permit, the Board is required to notify each licensed health care facility and health maintenance organization with which a licensee is affiliated and every other board licensee in this state with whom he or she is directly associated in private medical practice.

In accordance with an agreement with the Federation of State Medical Boards of the United States, a list of all disciplinary orders entered by the Board is provided to the Federation on a monthly basis.

From time to time, the Press Office of the Division of Consumer Affairs may issue press releases including information regarding public actions taken by the Board.

Nothing herein is intended in any way to limit the Board, the Division of Consumer Affairs or the Attorney General from disclosing any public document.