



Department of Health

KATHY HOCHUL
Governor

MARY T. BASSETT, M.D., M.P.H.
Commissioner

KRISTIN M. PROUD
Acting Executive Deputy Commissioner

February 15, 2022

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Paul MacKoul, M.D.
[REDACTED]

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Paul Tsui, Esq.
New York State Department of Health
Bureau of Professional Medical Conduct
Corning Tower Building, 25th Floor
Empire State Plaza
Albany, New York 12237

RE: In the Matter of Paul MacKoul, M.D.

Dear Parties:

Enclosed please find the Determination and Order (No. 22-029) of the Hearing Committee in the above referenced matter. This Determination and Order shall be deemed effective upon the receipt or seven (7) days after mailing by certified mail as per the provisions of §230, subdivision 10, paragraph (h) of the New York State Public Health Law.

As prescribed by the New York State Public Health Law §230, subdivision 10, paragraph (i), (McKinney Supp. 2015) and §230-c subdivisions 1 through 5, (McKinney Supp. 2015), "the determination of a committee on professional medical conduct may be reviewed by the Administrative Review Board for professional medical conduct." Either the Respondent or the Department may seek a review of a committee determination.

All notices of review must be served, by certified mail, upon the Administrative Review Board and the adverse party within fourteen (14) days of service and receipt of the enclosed Determination and Order.

The notice of review served on the Administrative Review Board should be forwarded to:

Jean T. Carney, Administrative Law Judge
New York State Department of Health
Bureau of Adjudication
Riverview Center
150 Broadway – Suite 510
Albany, New York 12204

The parties shall have 30 days from the notice of appeal in which to file their briefs to the Administrative Review Board.

Six copies of all papers must also be sent to the attention of Judge Carney at the above address and one copy to the other party. The stipulated record in this matter shall consist of the official hearing transcript(s) and all documents in evidence.

Parties will be notified by mail of the Administrative Review Board's Determination and Order.

Sincerely,

A solid black rectangular box redacting the signature of Dawn MacKillop-Soller.

Dawn MacKillop-Soller
Acting Chief Administrative Law Judge
Bureau of Adjudication

DXM: cmg
Enclosure

STATE OF NEW YORK : DEPARTMENT OF HEALTH
STATE BOARD FOR PROFESSIONAL MEDICAL CONDUCT

COPY

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: IN THE MATTER :
: :
: OF :
: :
: PAUL MACKOUL, M.D. :
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DETERMINATION
AND
ORDER
BPMC-22-029

A Notice of Referral Proceeding and Statement of Charges dated September 23, 2021 were served upon Paul MacKoul, M.D. (Respondent) pursuant to PHL § 230(10)(d)(i). (Exhibit 1.) The Respondent submitted an answer to the charges on October 25, 2021. On December 13, 2021, the Department issued an Amended Statement of Charges. (Exhibit 1-A.) The Respondent submitted an answer to the Amended Statement of Charges on December 14, 2021. This case involves charges brought against the Respondent under PHL § 230(10)(p), having committed professional misconduct as defined in Educ. Law § 6530(9)(b) and § 6530(9)(d).

A pre-hearing conference was held on December 7 and December 13, 2021, and a hearing was held on December 13, 2021, all by WebEx videoconference. Pursuant to § 230(10)(e) of the Public Health Law (PHL), JONATHAN ECKER, M.D., Chairperson, REID T. MULLER, M.D., and PAUL J. LAMBIASE, duly designated members of the State Board for Professional Medical Conduct, served as the hearing committee in this matter. NATALIE BORDEAUX served as the administrative officer. The Department appeared by Paul Tsui, Esq. The Respondent was represented by Michael Kelton, Esq., and testified on his own behalf. In addition, the Respondent called Anesthesiologist Henry Lue, M.D., and Mimi Zaw-Pham, practice manager for the Respondent's surgery center, as character witnesses. The Hearing Committee received and examined documents from the Department (Exhibits 1, 1-A, 2-5, and

11) and the Respondent (Exhibits A-C, L-O). A transcript of the proceeding was made.

Deliberations were held on February 1, 2022.

After consideration of the entire record, the Hearing Committee issues this Determination and Order. All findings, conclusions, determinations, and orders herein are unanimous.

The Hearing Committee sustained the charges that the Respondent committed professional misconduct as defined in Educ. Law § 6530(9)(b) and § 6530(9)(d) and determined to impose a six-month suspension of the Respondent's medical license, stay the suspension in its entirety, and impose a two-year period of probation with conditions upon both his ability to practice medicine and conduct human subject research in the state of New York.

FINDINGS OF FACT

1. The Respondent was authorized to practice medicine in the State of New York on July 28, 2017, by the issuance of license number 290599. (Exhibit 3.)
2. On March 9, 2021, the Maryland State Board of Physicians (Maryland Board) issued a Final Decision and Order, whereby it determined to suspend the Respondent's Maryland medical license for one month, then to place the Respondent on probation for a minimum of two years, with conditions. The Respondent was also ordered to pay a \$50,000 fine. This determination was based upon the Respondent's treatment of six patients (1, 2, 4, 5, 6, and 9), and a review of his patient records and billings of procedures for over 500 hysterectomies performed from 2013 through 2016. The Maryland Board found:
 - The Respondent's use of non-absorbable Ethibond sutures to close the vaginal cuff after performing hysterectomies deviated from the standard of care because a second surgery was required to remove the sutures, which would not have been necessary if

absorbable sutures had been utilized, and which exposed patients to additional risks including infection, bleeding, vaginal cuff opening, and bowel injury.

- In over 200 hysterectomies, the Respondent used Ethibond sutures in order to perform, and charge for, the removal of the sutures as an additional procedure by removing the sutures more than 90 days after the hysterectomy, a gross overutilization of health care services.
- The Respondent billed for biopsies for patients 1, 2, 4, 5, 6, and 9 that he did not perform and billed separately for each hysterectomy and uterine artery ligation (cutting off the blood supply to the uterine artery), even though the latter procedure is encompassed within the hysterectomy Current Procedural Terminology (CPT) Code.
- From 2013 through 2016, the Respondent violated federal regulations at 45 CFR Part 46, 21 CFR § 50 *et. seq.*, and 21 CFR § 56 *et. seq.*, and Maryland law regarding human subject research by conducting prospective human subject research, with the intent to publish the results and disseminate them for the medical profession's general knowledge, without obtaining the informed consent of Ethibond suture patients and without obtaining requisite approval from an Institutional Review Board (IRB).
(Exhibit 4.)

3. On May 10, 2021, the Maryland Board terminated the Respondent's suspension, and placed him on probation for a minimum of two years. During his probationary period, the Respondent is required to complete an ethics course with a focus on ethical issues and human participant protections in human subject research. The Respondent is barred from engaging in any human subject research during the first year of probation. The Respondent is permitted to engage in human subject research during the second year of probation if he submits his research

protocol and IRB approval to the Maryland Board for review and approval prior to commencing such research. (Exhibit 5.)

DISCUSSION

By disciplinary order dated March 9, 2021, the Maryland Board determined to suspend the Respondent's medical license for at least one month, followed by a minimum two-year probation period, during which he is required to successfully complete an ethics course addressing ethical issues and human participant protection in human subject research. He is barred from engaging in any human subject research during the first year of probation and is only permitted to engage in human subject research during the second year of probation after submitting his research protocol and IRB approval to the Maryland Board. The Respondent was also ordered to pay a \$50,000 fine. (Exhibit 4.) On May 10, 2021, the Respondent's suspension was terminated, and his minimum two-year probation period commenced. (Exhibit 5.)

The disciplinary action by the Maryland Board was based upon findings pertaining to the Respondent's treatment of six patients (patients 1, 2, 4, 5, 6, and 9), as well as a review of the Respondent's medical documentation for over 500 hysterectomies that he performed between the years 2013 and 2016. (Exhibit 4.)

The Department charged the Respondent with two Specifications of Charges of professional misconduct under Educ. Law § 6530. The Hearing Committee sustained both specifications.

First Specification: Educ. Law § 6530(9)(b) - having been found guilty of improper professional practice or professional misconduct by a duly authorized professional disciplinary agency of another state where the conduct upon which the finding was based would, if

committed in New York State, constitute professional misconduct under the laws of New York state.

The Department's December 13, 2021 Amended Statement of Charges alleges that the Respondent's misconduct in Maryland described in the March 9, 2021 order would, if committed in New York, constitute professional misconduct as defined in: (1) Educ. Law § 6530(3), practicing the profession with negligence on more than one occasion (factual allegation C.1); (2) Educ. Law § 6530(5), practicing the profession with incompetence on more than one occasion (factual allegation C.2); (3) Educ. Law § 6530(16), a willful or grossly negligent failure to comply with substantial provisions of federal, state, or local laws, rules or regulations governing the practice of medicine (factual allegation C.3); and (4) Educ. Law § 6530(35), ordering of excessive tests, treatments, or use of treatment facilities not warranted by the condition of the patient (factual allegation C.4). (Exhibit 1-A.)

The Hearing Committee did not agree that the Respondent's conduct would, if committed in New York, constitute practicing with incompetence on more than one occasion under Educ. Law § 6530(5). As the Maryland Board's March 9, 2021 order did not include findings that the Respondent lacked the skill or knowledge necessary to practice medicine, the Hearing Committee had no basis upon which to conclude that the Respondent practiced incompetently.

The Hearing Committee concurred that the Respondent's actions would, if committed in the state of New York, constitute practicing medicine with negligence on more than one occasion under Educ. Law § 6530(3) because the Maryland Board had determined that the Respondent failed to meet appropriate standards of care in his treatment of patients 1, 2, 4, 5, 6,

and 9 by using non-absorbable sutures which required a second surgery that would have been unnecessary if he had used absorbable sutures.

In addition, the Hearing Committee agreed that the Respondent's actions would, if committed in the state of New York, constitute a willful or grossly negligent failure to comply with substantial provisions of federal, state, or local laws, rules or regulations governing the practice of medicine under Educ. Law § 6530(16). The Maryland Board held that the Respondent violated federal regulations at 45 CFR Part 46, 21 CFR § 50 *et. seq.*, and 21 CFR § 56 *et. seq.*, and Maryland law regarding human subject research from 2013 through 2016 by conducting prospective human subject research, with the intent to publish the results and disseminate them for the medical profession's general knowledge, without obtaining the informed consent of Ethibond suture patients and without obtaining requisite approval from an Institutional Review Board (IRB). The Hearing Committee found that the Respondent's actions constituted a serious and intentional failure to comply with applicable legal requirements pertaining to human subject research.

The Hearing Committee also agreed that the Respondent's actions would, if committed in the state of New York, constitute the ordering of excessive tests, treatments, or use of treatment facilities not warranted by the condition of the patient under Educ. Law § 6530(35). In over 200 hysterectomies performed from 2013 to 2016, the Respondent removed the non-absorbable sutures more than 90 days after the hysterectomy, without medical justification, so that the suture removal would be classified as a separate procedure that enabled him to charge for an additional procedure. In addition, the Maryland Board held that the Respondent billed for biopsies for patients 1, 2, 4, 5, 6, and 9 that he did not perform, and billed separately for the hysterectomy and ligation of the uterine artery (cutting off the blood supply to the uterine artery) for those

patients, even though the latter procedure is encompassed within the hysterectomy CPT Code.

The First Specification is sustained.

Second Specification: Educ. Law § 6530(9)(d) - having his license to practice medicine revoked, suspended or having other disciplinary action taken by a duly authorized professional disciplinary agency of another state, where the conduct resulting in the revocation, suspension or other disciplinary action involving the license would, if committed in New York state, constitute professional misconduct under the laws of New York state.

For this specification, the Department again charges that the Respondent's actions would constitute professional misconduct under Educ. Law §§ 6530(3), (5), (16), and (35) if committed in New York. For the reasons previously set forth with respect to the First Specification, the Hearing Committee did not agree that the Respondent's actions would, if committed in New York, constitute practicing the profession with incompetence on more than one occasion pursuant to Educ. Law § 6530(5). However, as discussed regarding the First Specification, the Hearing Committee agreed that the Respondent's actions would, if committed in New York, constitute negligence on more than one occasion (Educ. Law § 6530(3)); a willful or grossly negligent failure to comply with substantial provisions of federal, state, or local laws, rules or regulations governing the practice of medicine (Educ. Law § 6530(16)); and ordering of excessive tests, treatments, or use of treatment facilities not warranted by the condition of the patient under Educ. Law § 6530(35). Therefore, the Hearing Committee determined that the Respondent violated Educ. Law § 6530(9)(d) and sustained the Second Specification.

DETERMINATION AS TO PENALTY

The Department requested revocation of the Respondent's license, or, alternatively, a minimum three-year suspension, with an actual one-year suspension term, followed by a

minimum three-year probation period with a practice and billing monitor and limitations on the Respondent's ability to conduct human subject research in the state of New York, and a minimum \$10,000 fine. The Respondent asked the Hearing Committee to consider imposing the penalty of censure and reprimand, a fine not to exceed \$10,000, and/or probation.

The Hearing Committee carefully considered the Maryland Board's findings and determinations. The Hearing Committee deemed a fine redundant, as the Respondent was already ordered to pay a fine by the Maryland Board, and the professional misconduct did not occur in the state of New York. The Hearing Committee also saw no benefit in revoking the Respondent's medical license, as his knowledge and skills could benefit patients in the state of New York.

While the Hearing Committee recognized that the Maryland Board's findings concentrated substantially upon the Respondent's billing, the Hearing Committee noted that those billings invariably reflected deviations from standards of professional medical practice and were not rooted in faulty or fraudulent claims. For these reasons, the Hearing Committee concluded that supervision by a practice monitor would adequately and effectively address concerns raised regarding the Respondent's medical practice and, ultimately, his billing practices.

In balancing the Respondent's skills with the recognition of his exhibited pattern of disregard for rules and past disciplinary history, the Hearing Committee determined to suspend the Respondent's New York medical license for six months, stay the suspension, and impose a two-year period of probation, during which the Respondent may practice medicine in New York only under the supervision of a practice monitor and may engage in human subject research in

New York only upon obtaining legally required prior approval from an IRB and submitting that approval to the Director of OPMC.

The Hearing Committee deemed the Respondent's actions materially significant and serious. Although it ultimately determined to stay the suspension, the Respondent is advised that future professional misconduct may result in more severe penalties.

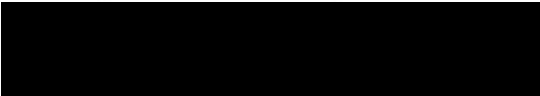
ORDER

IT IS HEREBY ORDERED THAT:

1. The First and Second Specifications of professional misconduct set forth in the Statement of Charges are **SUSTAINED**.
2. Pursuant to PHL § 230-a(2)(a), the Respondent's license to practice medicine in the state of New York is suspended for a period of six months, the entirety of which is stayed.
3. Pursuant to PHL § 230-a(9), the Respondent is placed on probation for two years, subject to the conditions provided in the Terms of Probation (Appendix I) and tolled when the Respondent is not engaged in the practice of medicine in the state of New York.
4. This Order shall be effective upon service on the Respondent in compliance with PHL § 230(10)(h).

DATED: 2/11, 2022

DeWitt, New York


Jonathan Ecker, M.D., Chairperson
Reid T. Muller, M.D.
Paul J. Lambiase

Paul MacKoul, M.D. – Direct Referral

To: Paul MacKoul, M.D.



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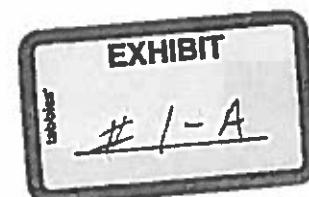
IN THE MATTER
OF
PAUL MACKOUL, M.D.

AMENDED
STATEMENT
OF
CHARGES

Paul Mackoul, M.D., the Respondent, was authorized to practice medicine in New York State on or about July 28, 2017 by the issuance of license number 290599 by the New York State Education Department.

FACTUAL ALLEGATIONS

A. On or about March 9, 2021 the Maryland State Board of Physicians (hereinafter, "Maryland Board") issued a Final Decision and Order (hereinafter, "Maryland Order") that concluded that the Respondent had engaged in unprofessional conduct in the practice of medicine, grossly overutilized health care services, and failed to meet appropriate standards of care for the delivery of quality medical care. Pursuant to the Maryland Order, the Respondent's license to practice medicine in the State of Maryland was suspended for a minimum of one month. Upon termination of the suspension, the Respondent was to be placed on probation for a minimum of two years with terms and conditions. The Maryland Board's disciplinary action taken against the Respondent was based upon the Respondent's treatment of nine patients and the performance of over 500 hysterectomies performed between 2013 and 2016 in which the Respondent used non-absorbable Ethibond sutures when closing the vaginal cuff rather than absorbable sutures. The Maryland Board found this violated accepted standards of care by exposing the patients to the risks of an unnecessary



second surgery. The Maryland Board also found that Respondent engaged in unprofessional conduct in the practice of medicine with regard to the suture patients by violating the relevant federal regulations at 45 C.F.R. Part 46, 21 C.F.R. §50 et seq., 21 C.F.R. §56 et seq., and the statutory provisions of Maryland law governing human subject research.

B. On or about May 10, 2021, by an Order Terminating Suspension and Imposing Probation, the Respondent was placed on probation for a minimum of two years with terms and conditions. The Respondent was required to take and successfully complete an ethics course addressing ethical issues and human participant protection in human subject research. During the first year of probation, the Respondent was prohibited from engaging in any human subject research. During the second year of probation, the Respondent may engage in human subject research and is required to submit his research protocol and IRB approval to the Maryland Board for review and approval prior to commencing research. The Respondent was also ordered to pay a fine of \$50,000.00.

C. The conduct resulting in the Maryland Board disciplinary actions against the Respondent would constitute misconduct under the laws of New York State pursuant to the following sections of New York state law:

1. New York Education Law §6530(3) (Practicing the profession with negligence on more than one occasion); and/or
2. New York Education Law §6530(5) (Practicing the profession with incompetence on more than one occasion); and/or
3. New York Education Law §6530(16) (A willful or grossly negligent failure to comply with substantial provisions of federal, state, or local laws, rules, or regulations governing the practice of medicine); and/or
4. New York Education Law §6530(35) (Ordering of excessive tests, treatments, or use of treatment facilities not warranted by the condition of the patient).

SPECIFICATION OF CHARGES

FIRST SPECIFICATION

HAVING BEEN FOUND GUILTY OF PROFESSIONAL MISCONDUCT

Respondent is charged with committing professional misconduct as defined in N.Y. Educ. Law § 6530(9)(b) by having been found guilty of improper professional practice or professional misconduct by a duly authorized professional disciplinary agency of another state where the conduct upon which the finding was based would, if committed in New York state, constitute professional misconduct under the laws of New York state as alleged in the facts of the following:

1. The facts of Paragraphs A, B and C and C1, C and C2, C and C3, and/or C and C4.

SECOND SPECIFICATION

HAVING HAD DISCIPLINARY ACTION TAKEN

Respondent is charged with committing professional misconduct as defined in N.Y. Educ. Law § 6530(9)(d) by having the Respondent's license to practice medicine revoked, suspended or having other disciplinary action taken, or having the Respondent's application for a license refused, revoked or suspended or having voluntarily or otherwise surrendered the Respondent's license after a disciplinary action was instituted by a duly authorized professional disciplinary agency of another state, where the conduct resulting in the revocation, suspension or other disciplinary action involving the license or refusal,

revocation or suspension of an application for a license or the surrender of the license would, if committed in New York state, constitute professional misconduct under the laws of New York state as alleged in the facts of the following:

2. The facts of paragraphs A, B and C and C1, C and C2, C and C3, and/or C and C4.

DATE: December 13, 2021
Albany, New York


JEFFREY J. CONKLIN
Acting Deputy Counsel
Bureau of Professional Medical Conduct

APPENDIX I

Terms of Probation

1. Respondent's conduct shall conform to moral and professional standards of conduct and governing law. Any act of professional misconduct by Respondent as defined by Educ. Law § 6530 or § 6531 shall constitute a violation of probation and may subject Respondent to an action pursuant to PHL § 230(19).
2. Respondent shall maintain active registration of his license with the New York State Education Department Division of Professional Licensing Services, and shall pay all registration fees.
3. Respondent shall provide the Director, Office of Professional Medical Conduct (OPMC), Riverview Center, 150 Broadway, Suite 355, Albany, New York 12204 with the following information, in writing, and ensure that this information is kept current: a full description of his employment and practice; all professional and residential addresses and telephone numbers within and outside New York State; and all investigations, arrests, charges, convictions or disciplinary actions by any local, state or federal agency, institution or facility. Respondent shall notify OPMC, in writing, within 30 days of any additions to or changes in the required information.
4. Respondent shall cooperate fully with and respond in a timely manner to OPMC requests to provide written periodic verification of his compliance with these terms. Upon the Director of OPMC's request, Respondent shall meet in person with the Director's designee.
5. The probation period shall toll when Respondent is not engaged in active medical practice in New York State for a period of 30 consecutive days or more. Respondent shall notify the Director of OPMC, in writing, if he is not currently engaged in, or intends to leave, active medical practice in New York State for a consecutive 30-day period. Respondent shall then notify the Director again at least 14 days before returning to active practice. Upon Respondent's return to active practice in New York State, the probation period shall resume and Respondent shall fulfill any unfulfilled probation terms and such additional requirements as the Director may impose as reasonably relate to the matters set forth in the Determination and Order or as are necessary to protect the public health.
6. The Director of OPMC may review Respondent's professional performance. This review may include but shall not be limited to: a review of office records, patient records, hospital charts, and/or electronic records; and interviews with or periodic visits with Respondent and staff at practice locations or OPMC offices.
7. The Respondent shall practice medicine only when his practice is monitored by a physician specializing in gynecologic oncology, proposed by the Respondent and subject to the written approval of the Director of the OPMC. The practice monitor shall visit the Respondent at each and every location in which he practices, on a random unannounced basis at least monthly, and shall examine the records maintained by the Respondent. The review will determine whether the Respondent's medical practices are conducted in accordance with generally accepted standards of practice. Any perceived deviation of

- accepted standards of medical practices or refusal to cooperate with the practice monitor shall be reported within 24 hours to the OPMC. The Respondent shall remain solely responsible for all expenses associated with monitoring, including fees, if any, to the practice monitor. The Respondent shall cause the monitor to report quarterly, in writing, to the Director of the OPMC.
8. The Respondent only engage in human subject research in the state of New York only after receiving the written approval of an IRB and submitting the approval to the Director of OPMC.
 9. The Respondent shall maintain medical malpractice insurance coverage with limits no less than \$2 million per occurrence and \$6 million per policy year, in accordance with PHL § 230(18)(b). Proof of coverage shall be submitted to the Director of OPMC prior to the Respondent's practice after the effective date of this Order.
 10. The Respondent shall comply with all terms, conditions, restrictions, requirements, and penalties to which he is subject pursuant to the Order and shall assume and bear all costs related to compliance. Upon receipt of evidence of non-compliance with, or any violation of these terms, the Director of OPMC and/or the Board may initiate a violation of probation proceeding, and/or any other such proceeding against the Respondent as may be authorized by law.