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| **IN THE MATTER OF** | * | **BEFORE THE** |
| **PAUL J. MACKOUL, M.D.** | * | **MARYLAND STATE** |
| **Respondent** | * | **BOARD OF PHYSICIANS** |
| **License Number: D47612** | * | **Case Number: 2016-0842A** |

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## FINAL DECISION AND ORDER

Paul J. MacKoul, M.D. is a physician and board-certified obstetrician/gynecologist who specializes in OB/GYN surgery and treatment, and gynecologic oncology. Dr. MacKoul has been licensed by the Maryland State Board of Physicians ("Board") since 1995. On September 7, 2018, Disciplinary Panel A of the Board charged Dr. MacKoul with unprofessional conduct in the practice of medicine, gross overutilization of health care services, failure to meet appropriate standards for the delivery of quality medical care, and failure to keep adequate medical records, in violation of the Maryland Medical Practice Act, Md. Code Ann., Health Occ. §§ 14-404(a)(3)(ii), (19), (22), and (40), respectively. The charges followed a Board investigation and review of Dr. MacKoul's care of nine patients.[1, 2]

A six-day evidentiary hearing was held at the Office of Administrative Hearings before an Administrative Law Judge ("ALJ") on June 3, 4, 5, 6, 7 and 14, 2019. The evidence at the hearing included expert testimony from Lawrence Fitzpatrick, M.D., Robert Mesrobian, M.D., James Kondrup, M.D., Laurence Udoff, M.D., and Ernest Prentice, Ph.D. on behalf of Dr. MacKoul, who also testified on his own behalf and presented testimony from his research director and another fact witness. The State presented expert testimony from Ishrat Rafi, M.D. and Adil Shamoo, Ph.D.

[1] For purposes of confidentiality, the patients in this case are referred to as Patients 1 through 10 in this Final Decision and Order.

[2] Patient 7 was not operated on by Dr. MacKoul. The peer reviewers did not review Patient 7's records and no charges were filed pertaining to Patient 7.

Patient 10 also testified as a fact witness for the State. The ALJ admitted 67 documentary exhibits by the State, 36 documentary exhibits and 6 exhibits for demonstrative purposes from Dr. MacKoul. In addition, the ALJ accepted copies of pertinent case law, statutes and regulations presented by the parties and made them part of the record. The ALJ issued a Proposed Decision on September 4, 2019, recommending that the charges issued by Panel A be upheld with respect to Health Occ. §§ 14-404(a)(3)(ii), (19), and (22) for Patients 1, 2, 4, 5, 6, and 9, and § 14-404(a)(40) for Patient 3. The ALJ dismissed violations with respect to Patients 8 and 10. As a sanction, the ALJ recommended that Dr. MacKoul be placed on probation for two years, prohibited from engaging in human subject research for one year, required to submit his research protocol and IRB approval to the Board prior to commencing any research during the second year of probation, and required to take an ethics course. The ALJ also recommended that Dr. MacKoul be subject to a fine of $30,000.

Written exceptions and responses were filed by Dr. MacKoul and the State. Dr. MacKoul filed a Reply to the State's Response to his exceptions and the State filed a Sur-Reply. Both parties appeared before Disciplinary Panel B of the Board for an oral exceptions hearing on December 18, 2019. After considering the entire record in this case, including the investigative and prehearing record, the exhibits and testimony produced and arguments made at the evidentiary hearing before the ALJ, the Proposed Decision, and the parties' arguments during the exceptions process, Panel B now issues this Final Decision and Order.

## FINDINGS OF FACT

Panel B adopts the ALJ's proposed findings of fact numbered 1- 36. (The ALJ's Proposed Decision of September 4, 2019, is incorporated by reference into this Final Decision and Order and is appended to this Order as Attachment A). Except where indicated in this Final Decision and

Order, the Panel also adopts the ALJ's discussion on pages 19-28, 31-32, 41-46 and 55-76 of the Proposed Decision. The factual findings were proven by a preponderance of the evidence.

## CONSIDERATION OF EXCEPTIONS

Throughout his written and oral exceptions, and his response and reply to the State's response to the exceptions, Dr. MacKoul excepts generally to the ALJ's findings that he failed to meet standards of quality care, grossly overutilized health care services, engaged in unprofessional conduct in the practice of medicine, failed to keep adequate medical records, and violated federal regulations and the Maryland human subject research statute.

### I. Ethibond Sutures and Standard of Care Requirements

Of the nine patient charts reviewed by the State's peer reviewers, Dr. MacKoul performed a hysterectomy on six of those patients, Patients 1, 2, 4, 5, 6, and 9. The removal of the uterus in a hysterectomy procedure creates an opening between the interior of the vagina and the portion of the body cavity where the uterus was once located. This opening is the vaginal cuff. A surgeon must suture the vaginal cuff closed to prevent the contents of the body cavity, such as the bowels, from entering the vagina. If the vaginal cuff reopens, the complication is called vaginal cuff dehiscence (VCD).[3] In most hysterectomies from 2013 until 2016, Dr. MacKoul used non-absorbable Ethibond sutures when closing the vaginal cuff. He claimed to do so to prevent VCD. The ALJ reviewed testimony from the State's expert, Dr. MacKoul's expert, and Dr. MacKoul himself and found that his use of non-absorbable sutures violated the standard of care because the non-absorbable Ethibond sutures required a second surgery that would not have been necessary had the Vicryl absorbable sutures been used.

[3] Vaginal cuff dehiscence ("VCD") is a relatively rare but serious post-operative complication after a laparoscopic hysterectomy that can cause breakdown of the vaginal cuff or closure and lead to the expulsion of abdominal pelvic contents through the vaginal opening. This complication requires emergent surgical intervention. In his Board interview, Dr. MacKoul stated that the rates of suture breakdown in his high-volume practice are about one to two percent. (PM3620, Tr. 7; PM3625, Tr. 25)

The State's expert, Dr. Rafi, testified that Vicryl sutures, and absorbable sutures in general, have met the standard of care since, at least, 1996, because they made a second surgery unnecessary. Dr. MacKoul's expert, Dr. Kondrup, disagreed. He opined that both Vicryl and Ethibond met the standard of care. Dr. Kondrup testified that absorbable sutures could dissolve too quickly leading to VCD. However, the ALJ noted that Dr. Kondrup could not provide another example of the use of a new procedure that requires a second surgery meeting the standard of care. Dr. Kondrup himself did not use Ethibond sutures, because doing so would require a second surgery.

Ultimately Dr. MacKoul discontinued his use of Ethibond non-absorbable sutures. He explained, "I'm using Vicryl now. Vicryl's the standard, right. . . . It's the standard." Later at the hearing Dr. MacKoul claimed that "it's really difficult to identify what is the standard of care now for closure of a vaginal cuff."

The ALJ noted that Dr. MacKoul downplayed the risks of the second surgery and explained that the consent form provided to the patients before the second surgery undermined Dr. MacKoul's assertion. The consent form listed the following risks: "infection, bleeding, injury to bowel, bladder, uterers, pelvic pain, adhesions, pain with intercourse, and difficulty with sexual function." Prop. Dec. at 49. The second surgery involved more than merely removing the sutures. It also required the placement of a Vicryl stitch to stem bleeding, preparations similar to the first surgery, and insertion of an IV (for sedation). The ALJ also found that the literature provided by Dr. MacKoul on hysterectomies described the use of absorbable sutures but not the use of non-absorbable sutures. Considering these factors as well as the expert testimony, the ALJ concluded that using non-absorbable sutures was not within the standard of care.

The Panel agrees with the ALJ's conclusion. As Dr. Rafi stated in her peer review report, absorbable sutures meet the standard of care because non-absorbable sutures carry additional risks of infection, erosion of the vaginal cuff, scar tissue formation and the costs and risks associated with a second surgery.[4] As the ALJ noted in his Proposed Decision, a second surgery includes added risks including infection, bleeding, vaginal cuff opening, and injury to bowel. None of these risks would be present without a second surgery.[5] The Board also agrees that there are additional risks for leaving sutures in too long for patients who are not cleared for the second surgery.

Dr. MacKoul excepts to the ALJ's findings. He claims that the ALJ's findings contain confused and inconsistent logic. Specifically, he claims that the ALJ erred in making contradictory findings that (1) Dr. MacKoul's use of Ethibond sutures was outside the standard of care, but (2) that using non-absorbable sutures by a surgeon is not a deviation from the standard of care as a general proposition. Dr. MacKoul misunderstands the ALJ's finding. The ALJ found that Dr. MacKoul's use, in hysterectomies, of the Ethibond non-absorbable sutures was outside the standard of care because it required a second, unnecessary, surgery. The use of non-absorbable sutures that would not require a second surgery could be within the standard of care. For example, Dr. Rafi uses Ethibond sutures in cervical cerclages, a treatment for cervical weakness during pregnancy, to close the cervix and prevent a fetus from descending early. Dr. Kondrup also used Ethibond in a procedure for supporting a uterus suspension of the vagina. Neither of those procedures would require an additional otherwise unnecessary surgery and both Dr. Kondrup and

[4] Dr. MacKoul's Hysterectomy Consent form explained "the benefits of using Ethibond sutures" and the "risks of not removing the sutures" and the side effect of retained sutures, but did not explain the risks of the additional surgery or the alternative of absorbable sutures.

[5] While not central to the standard of care violation, the Panel agrees with the ALJ that it is questionable about whether Dr. MacKoul adequately counseled suture patients about the potential complications from the second surgery prior to the consent related to the first surgery. While the first consent form listed retained sutures as a rare risk, it did not mention the infection, bleeding, injury to bowel, bladder, ureters, pelvic pain etc. that were listed as risks during the second surgery.

Dr. Rafi did not use Ethibond sutures in closing the vagina cuff in hysterectomy cases. The ALJ consistently found that the use of Ethibond non-absorbable sutures is a violation of the standard of care for closing the vaginal cuff after a hysterectomy because it required a second, otherwise unnecessary, surgery. The ALJ found that, here, when the use of non-absorbable sutures after a hysterectomy requires a second surgery, the use of these sutures violates the standard of care. The Panel agrees.

Dr. MacKoul also appears to claim that the ALJ misunderstood his statement indicating that he was returning to the standard, i.e. Vicryl sutures. According to Dr. MacKoul, he meant that he was returning to the standard practice, not that he was returning to the standard of care. Dr. MacKoul's statements, however, demonstrate that he purposely did not follow the standard practice and was unsure of whether it met the standard of care when he testified, "it's really difficult to identify what is the standard of care" for closing a vaginal cuff. Regardless, the Panel finds that Dr. MacKoul's violation of the standard of care was based on his unnecessary use of Ethibond sutures, which necessitated an additional surgery. The violation is not based on his supposed admission.[6]

Finally, Dr. MacKoul argues that the ALJ should have considered that his motivation for choosing the Ethibond sutures was to prevent VCD and that the use of Ethibond sutures improved patient outcomes by decreasing incidents of VCD. The Panel does not accept Dr. MacKoul's claims. Even if Dr. MacKoul had been motivated to decrease occurrences of VCD, that does not

[6] The Board charged Dr. MacKoul with violating the standard of care for performing 3 GYN surgeries on Patient 3 without having first referred her to a fertility specialist. The ALJ considered the expert opinions of Dr. Rafi for the state and Dr. Udoff for the Respondent. The ALJ found that Dr. Udoff's testimony - that a hysteroscopy procedure involved minimal risk to the patient and reflected that Dr. MacKoul appropriately discussed the risks to her fertility in light of the fibroids - was more compelling. The ALJ did not find a violation of the standard of care and the State does not challenge that conclusion of the ALJ. Because there is no clear error, the Panel upholds the ALJ's conclusion regarding the standard of care pertaining to Patient 3.

prevent a finding of a standard of care violation. A resulting need for a second surgery should have been sufficient for him to desist from using non-absorbable sutures.

Dr. MacKoul's second point, that the surgery improved patient outcomes is misleading. The medical journal article he authored (Resp. Ex. 39), provides that the difference in VCD occurrences between the two types of stiches was not statistically significant. Moreover, using Ethibond sutures adds further risk. Any possible benefits of using Ethibond sutures to prevent VCD was outweighed by the risks of a second surgery. Using sutures that require a second otherwise unnecessary surgery violated the standard of care. Dr. MacKoul's exception is denied.

## II. Gross Overutilization of Health Care Services

Dr. MacKoul used Ethibond sutures (non-absorbable sutures) instead of absorbable sutures in over 500 hysterectomies from 2013 through 2016. The ALJ found that, in 264 of these cases, he used the Ethibond sutures so he could perform, and charge for, an additional procedure: the removal of the Ethibond sutures. In these cases, Dr. MacKoul removed the Ethibond sutures more than 90 days after the hysterectomy so that the suture removal would be classified as a separate procedure from the hysterectomy, enabling him to charge for an additional procedure: Dr. MacKoul "used Ethibond for the specific purpose of billing a second procedure to remove the sutures outside the global payment period." Prop. Dec. at 15, ¶ 19. Based on this conduct, the ALJ concluded that Dr. MacKoul grossly overutilized health care services.

Dr. MacKoul took exception to the ALJ's conclusion that he engaged in the gross overutilization of health care services. His argument is that he did not engage in gross overutilization because the costs were *de minimus.* First, he states that "the average charge of $152.23 [for suture removals] . . . is *de minimus.*"[7] Then he states that the ALJ's estimate of

[7] The $152.23 amount was determined by the ALJ as the average amount the insurance companies paid for the additional procedure. Dr. MacKoul charged approximately $1,500 for the procedure.

$52,000 as the ultimate cost of the unnecessary procedure, based upon the 264 patients upon whom he performed the suture removal after 90 days from the Ethibond hysterectomy, was also *de minimus.* Dr. MacKoul argues that, because the costs were *de minimus,* his actions do "not qualify as overutilization, let alone satisfy the higher showing of 'gross overutilization.'"

Dr. MacKoul's argument does not persuade the Panel, because the costs are neither essential nor dispositive in determining whether one engaged in gross overutilization. Dr. MacKoul does not provide any legal authority indicating that a finding of gross overutilization requires that the costs reach a certain minimum level, and the Panel is not aware of any such legal authority. Dr. MacKoul states that the General Assembly enacted the gross overutilization disciplinary ground, Health Occ. § 14-404(a)(19), "to deincentivise the overutilization of healthcare services, which drive up costs." While one of the reasons behind the Panel's authority to discipline physicians for grossly overutilizing health care services is to prevent unnecessary health care costs, this is certainly not the only reason behind this disciplinary ground. The authority to discipline physicians for grossly overutilizing health care services is also meant to prevent physicians from subjecting patients to the risks involved in unnecessary procedures. Dr. MacKoul unnecessarily subjected his patients who underwent the Ethibond hysterectomies to these risks.

Dr. MacKoul also makes the argument that the ALJ's projection of costs for the 264 patients was improper because the charging document alleged that the reviewers found gross overutilization in six of the nine cases reviewed. He relies upon COMAR 10.32.02.04B(2)(a), which states that, in cases in which the disciplinary panel delegates to OAH the issuance of findings of fact "only," the delegation to OAH is limited to making findings of fact on allegations which are disputed. This provision, however, is inapplicable, because the disciplinary panel did not delegate to OAH the issuance of proposed findings of fact "only." In addition to proposed

findings of fact, the disciplinary panel delegated to OAH the issuance of proposed conclusions of law and a proposed sanction. *See* COMAR 10.32.02.04B(1).

During the relevant period, in over 200 hysterectomies, Dr. MacKoul used non-absorbable sutures so he could perform, and charge for, a second procedure (the removal of the sutures). In this period, overall, Dr. MacKoul used Ethibond sutures in over 500 hysterectomies. Dr. MacKoul systemically used non-absorbable sutures resulting in an additional procedure for these patients. His use of non-absorbable sutures was unnecessary and was not medically justified. Dr. MacKoul argues that the "grossly" in "grossly overutilizes" can only be found in conduct that is extraordinary or outrageous. The Panel finds that his overutilization of health care services in this case was both extraordinary and outrageous. Dr. MacKoul grossly overutilized health care services in Patients 1, 2, 4, 5, 6, and 9. His exception is denied.

### III. Ligation of the Uterine Artery (the "Artery")

As part of the hysterectomy on Patients 1, 2, 4, 5, 6, and 9, Dr. MacKoul billed Current Procedural Terminology ("CPT") 37617 for ligation of the artery. The hysterectomy at issue in this case is a retroperitoneal hysterectomy ("hysterectomy"), which means that Dr. MacKoul gained access to the uterus through the patient's back. In a hysterectomy, the surgeon ligates the uterine artery at its origin, cutting off blood supply to the uterus. Providers typically bill under one CPT code pertaining to hysterectomies (here CPT 58554). The CPT for the hysterectomies at issue includes the ligation of the artery and the removal of the uterus. Dr. MacKoul, however, in addition to billing under the hysterectomy code, billed the cardiac procedural code (CPT 37617 "Ligation of the Abdomen[al] Artery"). *Finding of Fact 8.*

Dr. Rafi testified that, to safely perform a hysterectomy, ligation is essential and billing separately for the ligation was improper.

Terri Welter testified on behalf of Dr. MacKoul. She is a management consultant for the healthcare industry who assists with managed care contract negotiations and deals between providers and payors. According to Ms. Welter, billing codes in the thirty-thousands were generally used for cardiac procedures. A CPT code in the fifty-thousands were used for OB/GYN procedures. She stated that Dr. MacKoul was explicitly allowed to use CPT 37617 based on his fee schedule contracts with payors. She understood that Dr. MacKoul's procedures were complex cases with large fibroid tumors that required ligation of the artery and were performed "in a separate space." In her opinion, this was not "unbundling", rather, the ligation was a separate procedure from the hysterectomy that was performed only because of the complexity of the hysterectomy.

Dr. MacKoul acknowledges that CPT 37617 is not a common gynecologic code, but states that he had negotiated it as one of the fees that the insurers would pay for. He noted that the insurers reimbursed for this code, sometimes at levels higher than the hysterectomy itself. He also represented that he takes out very large uteri, up to 5,000 to 7,000 grams, and that his procedure, even with the additional billing code is still cost effective compared to a robotic procedure.

The ALJ framed the issue as whether Dr. MacKoul's contract with CareFirst authorized him to bill CPT 37617 in addition to the general hysterectomy code and, if so, whether it was appropriate under the contract. Noting that the size of a regular uterus is 70 grams, and that the patients' uteri were: 43.9, 150, 155, 184, 459, and 620 grams, the ALJ found that, except for one, these uteri were all double the size of a normal sized uterus. The ALJ concluded that Dr. MacKoul's billing was appropriate and regardless was a contractual dispute with CareFirst and recommended dismissal of the charges related to this issue.

The State took exception to the ALJ's conclusion, arguing that the artery needs to be ligated as part of performing a hysterectomy and that Dr. MacKoul should not have had separate bills for the ligation and the general hysterectomy. The State contends that this unbundling, therefore, constitutes gross overutilization of health care services.

Dr. MacKoul argues that the alleged unbundling was, as the ALJ suggested, a mere contractual dispute between CareFirst and him, and suggested that it is more appropriately addressed in a civil court action. Because CareFirst neither was brought to the hearing to support the charge nor contacted him about this coding charge, he claims that it is improper to sustain the charge. Dr. MacKoul also contends that the insurance companies agreed that he could charge for the procedure, and that, therefore, it was not overcharging.

The Panel does not adopt the ALJ's framing of this issue as a contract dispute. Overbilling by unbundling implicates the unprofessional conduct disciplinary ground under the Maryland Medical Practice Act. Dr. MacKoul's unbundling related to the ligation did not result in the performance of additional procedures and thus, did not implicate the gross overutilization ground. The main issue before the Panel is whether ligation of the artery was a regular part of the hysterectomies or whether it was of such a divergence from the usual hysterectomies, due to the complexity of the cases, that it was appropriately billed separately.

Removal of these uteri was not so overly complex that billing separately for ligation of the artery was appropriate.[8] The Panel accepts the testimony of the State's expert who has extensive experience performing this type of hysterectomy. The Panel does not find the testimony of Ms. Welter convincing. While the Panel credits the accuracy of her testimony that such a billing may be used in particularly complex cases, her testimony that these procedures rise to that level is not

[8] The Board does not find a violation for billing under the CPT code 58553, when four of the six uteri were under 250 grams because this was not specified in the charging documents and was not discussed by the parties at the hearing.

based upon by any medical expertise. Dr. MacKoul himself testified that his surgical center performs hysterectomies up to 5,000 to 7,000 grams and gives an example of a 2,000-gram uterus as a "very large" uterus.

Ultimately this issue is quite simple. Dr. MacKoul billed for ligating the artery, but this ligation was a standard and essential part of the hysterectomy. While most of the uteri removed were larger than an average healthy uterus, most were less than the 250-gram billing code that he billed under or the average uterus that he removed through this procedure. None were thousands of grams or otherwise in the range of large uteri for which a complex billing code would be justified. The Panel finds that Dr. MacKoul's separate billing for ligation of the artery is unprofessional conduct in the practice of medicine.

**IV. Biopsy of Vaginal Mucosa**

As part of the second surgery to remove the non-absorbable Ethibond sutures, Dr. MacKoul billed for three procedures: (1) "Destroy Vag[inal] Lesions Complex," (2) "Biopsy of Vagina [Mucosa]," and (3) "Remove Vaginal Foreign Body." The State's expert, Dr. Rafi, explained that the removal of the suture accounted for the third billing code, and understood that "there must have been some incising, cutting, in order to remove a suture" explaining the first billing code, but did not find a justification for the second billing code "Biopsy of Vagina [Mucosa]." She testified that "biopsy" is removal of tissue to be evaluated, and Dr. MacKoul charged $500 for the biopsy, but never sent it to a pathology laboratory for any evaluation. Dr. MacKoul acknowledged in his response to the peer reviewers that he did not send the tissue to pathology. He explained that the granulation tissue was a known reaction and sending it to pathology would only mean increasing the cost to the patient. Dr. MacKoul's expert, Dr. Kondrup testified that "biopsy" is "removing the tissue," and did not mention the requirement that the tissue be sent for evaluation. The ALJ

accepted Dr. Kondrup's interpretation, stating that the removal of the vagina mucosa was part of the procedure to remove the Ethibond sutures. The ALJ stated that there was no evidence that Dr. MacKoul should have billed a different code for the procedure.

Ultimately, the question is whether the Panel believes that biopsy means removal of tissue to be evaluated or simply removal of tissue without any evaluation of the tissue. Based on the Panel's experience and expertise, the Panel finds that the term biopsy means removal of tissue for purposes of evaluation, generally to determine whether the removed tissue is diseased. This is both the common usage of the word as well as the usage by medical professionals. The Panel finds that the incidental removal of granulated tissue around the sutures was not properly billed under the biopsy billing code because the tissue was not removed for evaluative purposes. Dr. MacKoul's billing for a biopsy that he did not perform for patients 1, 2, 4, 5, 6, and 9 is unprofessional conduct in the practice of medicine.

## V. Adequacy of Medical Records

Dr. MacKoul was alleged to have inadequate or inaccurate medical records regarding Patients 1, 2, 3, 4, 5, 6, and 9. The ALJ found that Dr. MacKoul failed to keep adequate medical records for only one patient, Patient 3. Dr. MacKoul took exception to the ALJ's finding.

### A. Patient 3

On October 3, 2014, in the operative note, Dr. MacKoul recorded removing *forty-five* fibroids during Patient 3's first surgery and "close to 1 Kg of fibroids." However, concerning Patient 3's first surgery, the pathologist recorded, on October 8, 2014, that Dr. MacKoul removed *twenty-five* fibroids, which weighed 510 grams. Dr. MacKoul subsequently noted in a medical chart, on October 22, 2014, that he removed *forty-five* fibroids. But, in a note dated July 6, 2015, Dr. MacKoul recorded removing *twenty-five* fibroids. But then, in a letter, dated July 23, 2015,

Dr. MacKoul again stated that he removed "*forty plus*" fibroids. Dr. MacKoul testified that he estimated that he removed forty-five fibroids and relies on the pathologist for the weight.

The State's expert, Dr. Rafi, stated that it was Dr. MacKoul's responsibility to accurately report the number and weight of the fibroids. Dr. MacKoul presented testimony from two experts on this issue. According to one of his experts, Dr. Kondrup, the surgeon makes an estimate of the weight and number of fibroids and relies on the pathologist for the exact number of fibroids and the exact weight of the fibroids: "it is common practice to make an estimate of the number of fibroids removed in the OR and leave the exactitude of the number and weight to the pathologist." His other expert, Dr. Udoff, testified that the exact number was irrelevant to the diagnosis.

The ALJ relied on Dr. Kondrup's testimony that the onus of providing the correct data on the weight and number of fibroids was on the pathologist. The ALJ found that there were twenty-five fibroids. The ALJ, thus concluded that, after the pathologist determined the number and the weight of the fibroids, Dr. MacKoul had a duty to accurately maintain Patient 3's records, and his documentation after receiving the pathology report of forty-five and "forty plus" fibroids was not accurately maintaining records. The ALJ, thus, found that Dr. MacKoul failed to maintain accurate records with respect to Patient 3.

On exceptions, Dr. MacKoul argues that there were, in fact, forty-five fibroids, and thus the ALJ erred in finding twenty-five. Dr. MacKoul relies on a photograph taken of the fibroids.

Based on the Panel's review of the photograph, the Panel finds that the exact number of fibroids is difficult to establish. While inconsistent recording is troubling, the more significant figure is the weight of the fibroids, which offers a better indication of the size of the masses than the number of fibroids.

Dr. MacKoul estimated the weight before the pathologist weighed the fibroids, and his records on the weight, after the pathologist weighed the fibroids, was consistent with the pathologist report. The Panel agrees with Dr. Udoff that the exact number of fibroids was irrelevant to the diagnosis. Additionally, as Dr. MacKoul points out, the photograph itself was a part of the records, meaning that subsequent physicians could see for themselves the sizes and number of fibroids. With respect to Patient 3, the Panel finds that Dr. MacKoul kept adequate medical records.

**B. Patients 1, 2, 4, 5, 6, and 9**

The ALJ did not find inadequate medical recordkeeping pertaining to Patients 1, 2, 4, 5, 6, and 9. The ALJ found that the State's expert's testimony was conclusory. The State did not file exceptions to these findings. The Panel adopts the ALJ's finding that Dr. MacKoul did not keep inadequate medical records for Patients 1, 2, 4, 5, 6, and 9.

## VI. Dr. MacKoul's Statements to Patient 10

On December 2, 2015, Dr. MacKoul performed a myomectomy[9] on Patient 10. Following the procedure, Patient 10 was in pain. Patient 10 and her mother called Dr. MacKoul's office several times to express her pain. Dr. MacKoul prescribed Percocet and recommended ibuprofen and Acetaminophen, but the patient continued to experience agonizing pain, and, on December 9, 2015, a week after the surgery, Patient 10 went to the emergency room at Hospital A, which performed an x-ray and told Dr. MacKoul that they thought the patient had an abscess. Dr. MacKoul transferred Patient 10 to Hospital B where he had privileges. When Dr. MacKoul first entered the patient's hospital room, he first stated to Patient 10 "This is overkill." He then told Patient 10 that he did not trust the doctors at Hospital A and that this was the first time something

[9] A surgical procedure to remove uterine fibroids.

like this had happened to one of his patients. Patient 10 felt that Dr. MacKoul did not take her complaints seriously. Patient 10 requested another physician consultation because she did not trust Dr. MacKoul after his "overkill" comment.

It was ultimately determined that a bowel blockage caused Patient 10's pain. On December 22, 2015, another physician removed a bowel blockage and Patient 10 was discharged on December 28, 2015.

Dr. MacKoul did not remember stating "this is overkill" but also did not deny making the comment. Rather, he claimed that he was merely educating the patient that she was suffering from a hematoma, not an abscess, and that the antibiotics were overtreatment. Dr. MacKoul also explained that he transferred Patient 10 to Hospital B because he did not have privileges at the other hospital.

The ALJ found Patient 10's testimony sincere and credible and without embellishment and Dr. MacKoul's testimony heartfelt and sensible. The ALJ concluded that the comments were inappropriate or inconsiderate from Patient 10's subjective viewpoint, but that accepting such comments as unprofessional would create a slippery slope and force the Board to find unprofessional any comments that a patient finds unprofessional.

The State argues that Dr. MacKoul's comments to Patient 10 were "disdainful, crass, and void of any therapeutic purpose whatsoever." Dr. MacKoul argues that his comments were only inappropriate or inconsiderate from Patient 10's subjective viewpoint and that, from the ALJ's objective viewpoint, the comments did not rise to the level of unprofessional conduct.

The Panel adopts the ALJ's findings. Although Dr. MacKoul's comments to Patient 10 caused distress, the Panel does not find that Dr. MacKoul's comment "this is overkill" by itself is unprofessional. Dr. MacKoul should continue to work on his interpersonal skills with patients, as

that issue was a concern to the Board in his prior disciplinary order. In this instance, the Panel does not find that his comments to Patient 10 rise to the level of unprofessional conduct.

## VII. Human Subject Research and Expert Opinions

### A. ALJ Findings and Conclusions

The ALJ found that Dr. MacKoul 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,[10] 21 C.F.R. § 50 *et seq.*,[11] 21 C.F.R. § 56 *et seq.*,[12] and the statutory provisions of Maryland law[13] governing human subject research. Prop. Dec. at 55-59, 67-68. Specifically, the ALJ determined that Dr. MacKoul (1) conducted prospective human subject research beginning in October, 2013 when he began placing Ethibond sutures to close the vaginal cuff in his post-laparoscopic hysterectomy patients; (2) intended, at that time, for his research to be eventually submitted for publication to enhance the general knowledge of the medical community; (3) was required to, but did not, obtain the approval of an Institutional Review Board ("IRB") before beginning this ongoing research, which continued until October, 2016; (4) formulated, in his mind,

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[10] Under the federal regulations: "Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." 45 C.F.R. § 46.102(d). A human subject is defined as:

> "a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information . . . must be individually identifiable (i.e. the identity of the subject is or may readily be ascertained by the investigator . . .) in order for obtaining the information to constitute research involving human subjects." 45. C.F.R. § 46.102(f).

[11] Non-absorbable surgical sutures are classified as a medical device for human use and human subject research regarding non-absorbable sutures is under the jurisdiction of the Federal Drug Administration ("FDA"). *See* 21 C.F.R. 50.3(b)(16)-(19). FDA regulations define a "human subject" as "an individual who is or who becomes a participant in research, either as a recipient of the test article, or as the control." 21 C.F.R. § 50.3(g). The regulations define "test article" as "any . . . medical device for human use . . ." 21 C.F.R. § 50.3(j). "Clinical investigation" is defined as "any experiment that involves a test article and one or more human subjects." 21 C.F.R. § 50.3(c). FDA regulations regarding the elements of informed consent are set forth in 21 C.F.R. § 50.25.

[12] 21 C.F.R. Part 56 contains the general standards regarding Institutional Review Boards ("IRBs").

[13] The Maryland Heath General Article provides: "A person may not conduct research using a human subject unless the person conducts the research in accordance with federal regulations on the protection of human subjects." Md. Code Ann., Health Gen. § 13-2002(a).

the intent to create a specific cohort of Ethibond patients, arranged to have the Ethibond patients treated at his ambulatory surgery center while his partner treated a second group of patients at a hospital using exclusively Vicryl sutures; and (5) failed to provide the suture patients with informed consent. The ALJ's findings were based on the statutes, case law and regulations[14] provided by the parties, and the documentary and testimonial evidence, including the sworn statements of Dr. MacKoul, the expert report and testimony of Dr. Shamoo, who testified for the State, and the expert report and testimony of Dr. Prentice, who testified on behalf of Dr. MacKoul.

**B. Exceptions to ALJ's Conclusions of Human Subject Research**

In his exceptions, Dr. MacKoul challenges the ALJ's findings and conclusions that he engaged in prospective human subject research. He claims that published website guidance on the applicable federal regulations from the Office for Human Research Protections ("OHRP") contradicts the ALJ's legal conclusions. Dr. MacKoul characterizes his surgical activities from 2013 to 2016 as quality improvement or clinical innovation, argues that the ALJ's interpretation and analysis of the federal regulations is legally erroneous, that the ALJ lacked expertise on the matter, and arbitrarily deferred to Dr. Shamoo's expert opinion. Dr. MacKoul also argues that the ALJ improperly disregarded an approval by Integ Review IRB in 2018 that purportedly validated his activities as retrospective record review. The record does not support Dr. MacKoul's contentions. Nor does the record support his assertions that the ALJ's overall findings of substandard care, gross overutilization of health care services, and unprofessional conduct are

[14] Pursuant to Md. Code Ann. State Gov't § 10-216(b), the Panel does not adopt the version of the post-2018 federal regulations cited by the ALJ on pages 59-67 of the Proposed Decision including the citation to a "clinical trial" as defined by 45 C.F.R. § 46.102(b) in those regulations. The ALJ accepted copies of the applicable laws and pre-2018 Health and Human Services ("HHS") regulations provided by the parties and made them part of the record. Prop. Dec. at 9. In this Final Decision and Order, Panel B has reviewed the pre-2018 regulations in the record. The Panel also modifies one of the titles on the list of Dr. MacKoul's exhibits admitted into evidence to reflect that Respondent's Exhibit 33 is titled "Northwell Health, Surgical Innovation vs. Research Activities Subject to IRB Review." Prop. Dec. at 8.

based exclusively on Dr. MacKoul's violation of the federal and state laws on human subject research. There is similarly no support for his argument that the charge and violation of human subject research laws infected the entire decision.

**C. Governing Federal Regulations and Maryland Law**

In discounting the ALJ's legal conclusions that he engaged in prospective, non-IRB approved human subject research, Dr. MacKoul essentially urges the Panel to accept excerpts from OHRP guidance and decision charts as controlling substitutes for the substantive federal regulations and Maryland law that he provided to the ALJ.[15] Contrary to Dr. MacKoul's arguments, OHRP guidance does not supersede the governing federal regulations or Maryland law. Rather, the OHRP emphasizes that the charts should not be used as substitutes for consulting the regulations and cautions that the full text of applicable regulatory provisions should be considered in making final decisions. Based on the Maryland statute and federal regulations presented by Dr. MacKoul and the State at the evidentiary hearing, the ALJ and Dr. Shamoo considered the statutory and regulatory text, as did Dr. Prentice, who provided expert testimony for Dr. MacKoul on the issue of human subject research. (Prop. Dec. at 9; Tr. 264-346) Dr. MacKoul offered Dr. Prentice as an expert on the federal statutes and regulations for human experimentation, IRB rules, surgical innovation, and quality improvement at the evidentiary hearing. (Tr. 370) To support his expert testimony, Dr. Prentice relied on the applicable federal regulations and the regulatory definition of research in 45 C.F.R. § 46. (Tr. 371-374, 384) In his expert report, Dr. Prentice confirmed that his opinion was largely confined to the issue of whether Dr. MacKoul violated the requirements of the

[15] At his six-day evidentiary hearing, Dr. MacKoul and the five experts who testified on his behalf did not present, refer to, or rely on the website guidance.

federal regulations at 45 C.F.R. § 46, Subpart A (Common Rule), and 21 C.F.R. §§ 50 and 56. (Resp. Exh. 4)

In any event, the guidance belatedly embraced by Dr. MacKoul in his exceptions does not compel or even suggest a contrary analysis of the regulatory provisions on human subject research and IRB requirements. Like Dr. MacKoul's arguments at the evidentiary hearing, the guidance to which he cites presupposes that his Ethibond versus Vicryl study from 2013 to 2016 involved quality improvement, clinical innovation, and retrospective record review. His exceptions arguments depend entirely on these same representations that the ALJ rejected as not credible. The ALJ did not find Dr. MacKoul's representations persuasive or credible because he determined that they were inconsistent with the nature of the actions taken by Dr. MacKoul from 2013-2016. Prop. Dec. at 55-59. The Panel agrees. Dr. MacKoul's description of his activities in his exceptions as quality improvement, clinical innovation, and retrospective record review does not make them so. His strained legal arguments and reliance on OHRP guidance as a novel substitute for the applicable federal regulations and Maryland law are without merit. The Panel gives no weight to these arguments. Pursuant to State Gov't § 10-213(i), the Panel has used "its experience, technical competence, and specialized knowledge" in evaluating the evidence in the documentary and testimonial record, including Dr. MacKoul's own account of his actions to the Board in 2016 and 2017. As set forth below, this evidence contradicts his representations.

**1. Written Response to the Complaint and Board Interview**

There was no dispute that Dr. MacKoul responded to a complaint from a health insurance company by submitting to the Board a document dated October 10, 2016 that was entitled "Vaginal Cuff Dehiscence After Laparoscopic Hysterectomy: Comparing Absorbable to Nonabsorbable Sutures." (St. Exh. 3) In April, 2017, Dr. MacKoul subsequently submitted a similar but updated version of this document dated October 31, 2016, with the same title. (St. Exh. 4, PM3638-3652)

Dr. MacKoul described the document as a manuscript of ongoing research on a comparison of vicryl to ethibond suture closure of the vaginal cuff at hysterectomy. He explained that the current study was exploratory in nature and the aim of the study was to compare the risk of cuff breakdown using absorbable versus nonabsorbable sutures for vaginal cuff closure. On May 1, 2017, the Board conducted a sworn interview with Dr. MacKoul at which he was represented by counsel. (St. Exh. 2, PM 3618-PM3628)

In his manuscript and testimonial interview, Dr. MacKoul labeled his activities from October 1, 2013 to October 1, 2016 as retrospective. He also stated that he and another surgeon in his two-physician practice performed hysterectomies on 885 private patients and collected and extracted detailed statistical data for that three-year period from a database that was prospectively maintained. With respect to materials and methods, he indicated that Vicryl was selected as the absorbable suture for one group of patients and Ethibond as the nonabsorbable suture for a separate group, with one surgeon predominantly using Ethibond and the other using Vicryl.

In the manuscript, Dr. MacKoul's research director, Louise van der Does, Ph.D., reported study results for each group by suture type. She referred to data statistics, performance of statistical analyses, and study outcomes for each group, and noted patient demographic characteristics, operative outcomes, vaginal cuff complications and VCD and clinical data of patients with cuff breakdown. Dr. van der Does also reported that the strengths of the study included the high number of cases, similar patient populations, all patients undergoing the same mode of 2-port, laparoscopic retroperitoneal hysterectomy, and the same mode of closure, all of which made possible a direct comparison between suture materials for the three-year study period.

During his interview, Dr. MacKoul reiterated that they started to use Ethibond for vaginal cuff closure in 2013. He testified that by doing such a large trial, they were identifying whether

the Ethibond suture was amenable to cuff closure, and whether it gave better rates of non-dehiscence versus Vicryl. He further testified that the rates were 0%, the power analysis required use of a large number of cases, hundreds of them, to get down to a variable and a power that allowed one to say its better than Vicryl. According to Dr. MacKoul, they had over 20 different research protocols ongoing, and a large research team gets involved whenever they do things such as this scientific endeavor.

When asked how he chose patients for the study, Dr. MacKoul stated that they were not actually picking out selective patients for what was really a suture study, nor trying to identify which patient was at high or low risk. Rather, they wanted to see whether or how the Ethibond suture worked, if it worked versus Vicryl, and if there were higher success rates versus Vicryl. He stated that the patients' past medical histories did not play a role in this trial, all of his patients had Ethibond, his partner was the control on Vicryl, and they stopped the study in October, 2016 once his research director accrued the number of patients required to hit the power analysis that made it a significant study. Dr. MacKoul maintained that doing it on 20 or 200 people was of no use, but at 800 it reached that analysis. He further testified that they figured it would take three years, and by looking at the volume, they were trying to see if they could stop or extend it, if required. According to Dr. MacKoul, they asked his research director every month if they needed to keep doing these and she said "a couple more, a couple more," they reached the point where she did her analysis and said they could stop, and they stopped. He testified that he had now gone back to using Vicryl because Vicryl is the standard. In Dr. MacKoul's view, the evidence showed that Ethibond had a significant potential for eliminating VCD and is statistically significant in this trial.

**2. Supplemental Response to the Peer Review**

In his later supplemental response to the peer review reports, Dr. MacKoul verified that his partner was the control arm of the study using absorbable (Vicryl) sutures, and he was the

investigational arm using Ethibond sutures trying to compare the outcomes of VCD between absorbable and nonabsorbable sutures. (St. Exh. 42, pp. 2-3) Patients were informed verbally of their option to use Ethibond or Vicryl sutures the day of surgery at the surgery center. Dr. MacKoul depicted his Ethibond study as a pilot study extending from 2013 to 2016, in which a total of 595 patients had Ethibond sutures placed, and Ethibond suture placement was terminated after accrual of patients was reached. (St. Exh. 42, p. 4)

**3. Panel B's Evaluation of the Evidence**

Dr. MacKoul's exceptions arguments echo his arguments from the evidentiary hearing and mischaracterize the nature and reality of his surgical activities and data recording from 2013-2016. His characterization of his activities as a retrospective study involving quality improvement or clinical innovation rather than research is inherently self-contradictory based on the facts of this case. As Dr. MacKoul observed in his updated manuscript, there were no prior studies or research in the gynecological literature exploring the use of absorbable versus non-absorbable sutures to prevent VCD. Based on its review of Dr. MacKoul's own account of his surgical activities to the Board in 2016 and 2017, the panel agrees with the ALJ that Dr. MacKoul engaged in prospective human subject research in his surgical interventions with hundreds of living individuals from 2013-2016. Dr. MacKoul's manuscript, sworn testimony and written response to the peer review highlighted his primary and deliberate intention to compare the risk of cuff breakdown using absorbable versus nonabsorbable sutures for vaginal cuff closure with two patient groups. The process that Dr. MacKoul began and continued from October, 2013 until October, 2016, was the systematic investigation process at issue, one that he figured would take three years.

His activities during this ongoing research process involved his use of a previously untried surgical intervention on 595 human subjects to determine if the Ethibond suture was amenable to

cuff closure and resulted in better rates of non-dehiscence versus Vicryl. These activities were geared to the creation, collection and recording of data from patient records that did not exist before October of 2013. The development, testing, and evaluation of Dr. MacKoul's hypothesis were based on his methodical, planned observations during the study. As the study progressed, Dr. MacKoul and his research team collected the necessary data to accomplish his primary aim of conducting statistical analyses and achieving a meaningful statistical comparison of the two different suture materials. At no point did he obtain the informed consent required by the federal regulations. After checking with his research director every month on whether they needed to extend the research process, he stopped using Ethibond sutures in October 2016, once she told him that she had accrued the number of patients required (885) to hit a statistically significant power analysis. Dr. MacKoul's exceptions arguments are contrary to his accounts to the Board. Based on its experience, technical competence, and specialized knowledge, the Panel rejects his contentions that his primary goal was innovation or quality improvement, or that his manuscript, Board interview, and supplemental response to the peer review constitute irrelevant circumstantial evidence. The Panel further rejects Dr. MacKoul's argument that his subjective beliefs concerning his actions were reasonable.

**D. Expert Opinions**

Dr. MacKoul also argues that the ALJ wrongly deferred to the opinion of Dr. Shamoo[16] over the opinion of Dr. Prentice. At the hearing, it was undisputed that both Dr. Shamoo and Dr. Prentice each had the requisite training, knowledge, and educational backgrounds to testify on the

[16] The charges of improper human subject research reflect the expert opinion of Dr. Shamoo, whose educational, experiential, and professional credentials in the areas of human subject research, IRB requirements, federal regulations, and Maryland law were accepted by the ALJ and unchallenged by Dr. MacKoul at the evidentiary hearing. (St. Exhs. 43, 44, 48, pp. 16-24; Tr. 271-72) There is no merit to Dr. MacKoul's argument that these charges were based on the opinion of Dr. Rafi, the Board's peer reviewer. The Panel denies his exception.

topic of human subject research. Both experts testified about surgical innovation and quality improvement, prospective and retrospective research, and the requirements for IRB approval. They agreed that IRB review and approval is required for prospective research but held divergent views on the nature of Dr. MacKoul's activities with the two groups of suture patients. Dr. Shamoo opined that Dr. MacKoul initiated and engaged in prospective human subject research from 2013 to 2016 and the federal regulations required him to obtain advance IRB approval for that process. Dr. Prentice disagreed with Dr. Shamoo's opinion and described Dr. MacKoul's activities as surgical innovation and quality improvement.

**1. Surgical Innovation and Quality Improvement**

Dr. Shamoo distinguished human subject research from patient treatment or innovation. He testified that research is for the public good and treatment or innovation is to enhance the wellbeing of an individual patient or handful of patients - for example, if a surgeon needs to use a non-absorbable suture in a unique or emergency situation. Dr. Shamoo noted that there was no documentation of an emergency in the hundreds of Ethibond surgical patients operated on by Dr. MacKoul during his study. (T. 298, 300-303) Based on a guidance article presented by Dr. MacKoul on surgical innovation versus IRB-required research activities (Resp. Exh. 33), Dr. Shamoo explained that IRB review and approval is not required for surgical innovation if: 1) a planned or unplanned innovation is being made for the care and treatment of an individual patient or class of patients; and 2) there are no plans to collect data and/or analyze results for general applicability or knowledge (i.e., to write up or provide to outside entities). Dr. Shamoo opined that Dr. MacKoul's own description of his Ethibond versus Vicryl surgical procedures on hundreds of patients from 2013 to 2016, and his ongoing data collection and analysis comparing suture

outcomes, established that these activities were consistent with prospective research and did not constitute either a pilot study or innovation.

Contrary to Dr. Shamoo, Dr. Prentice opined that Dr. MacKoul did not engage in a clinical investigation or research as defined in the Belmont Report and the federal regulations and was not required to obtain IRB approval because there was no indication that his use of nonabsorbable sutures was intended to contribute to generalizable knowledge. In his view, Dr. MacKoul's decisions were not motivated by anything but a desire to improve his patients' outcomes by lessening the risk of VCD. Dr. Prentice testified that when engaging in innovative therapy, one is not trying to collect valid scientific data, and the primary intent or motivation must be to benefit the patient. According to Dr. Prentice, the two objectives in clinical research are to benefit the patient and to obtain valid scientific data about the efficacy or safety of the particular study, which is a hoped-for outcome of the research. Dr. Prentice disagreed with Dr. Shamoo that the large number of patients in Dr. MacKoul's study required him to obtain IRB approval. Although he testified that there could be a situation where a surgical innovation is applied to one, ten, or thirty patients in an emergency, Dr. Prentice provided no specific opinion regarding the two groups of 885 patients operated on by Dr. MacKoul and his partner in the context of innovative therapy.

**2. Retrospective and Prospective Research**

Dr. Shamoo also distinguished a retrospective from a prospective study. He testified that a retrospective study does not involve interfering in the daily lives of patients or introducing any material into them but starts at time zero and looks backwards at existing patient records. As an example, Dr. Shamoo referenced epidemiologic studies from hospitals requiring permission from an IRB to review existing case reports and patient records and drawing conclusions on whether there are certain patterns. On the other hand, in a prospective study, one starts from time zero at

the beginning of the study and works for the future using a variable and observes how human subjects react to the variable, whether it's a drug or a suture device as in Dr. MacKoul's study. Patients are de-identified in both types of studies. An IRB is required if the purpose is to contribute to generalizable knowledge, typically through publication.

Dr. Prentice found it clear that Dr. MacKoul never engaged in a prospective study. He opined, however, that if Dr. MacKoul initiated a study involving an appropriate scientific design with standard randomization of patients to the two different suture types, such a study would be prospective and subject to the federal regulations. Dr. Prentice did not opine on the specific surgical actions taken by Dr. MacKoul in October, 2013, when he initiated his study of two groups of patients, with Vicryl selected as the absorbable suture for one group of patients and Ethibond as the nonabsorbable suture for a separate group. Nor did he opine on Dr. MacKoul's aim to compare the risk of cuff breakdown using the two different sutures for vaginal cuff closure throughout the planned three-year study.

On cross examination, Dr. Prentice acknowledged that he was not provided with and did not review Dr. MacKoul's manuscript dated October 31, 2016 in preparation for his testimony. According to Dr. Prentice, the Ethibond versus Vicryl study by Dr. MacKoul was a retrospective study because Dr. MacKoul testified in his Board interview that it was retrospective. Dr. Prentice further testified that Dr. MacKoul analyzed the data from the Ethibond study in a retrospective chart review that was approved and deemed exempt as a collection of existing data under 45 C.F.R. 46.101(b)(4)[17] by Integ Review IRB in 2018. Dr. Prentice's opinion was unsupported by any reliable documentary or testimonial evidence in the record showing that the 2018 IRB exemption

[17] 45 C.F.R. § 46.101(b)(4) exempts "research activities . . . involving the collection of existing data . . ..

letter related to Dr. MacKoul's study comparing Ethibond to Vicryl sutures.[18] Dr. Shamoo observed that the Integ Review IRB exemption dated April 27, 2018 (Resp. Exh. 32), was granted in 2018 after the data reviewed by the IRB was already obtained, accumulated and in existence. In Dr. Shamoo's opinion, the 2018 IRB did not grant permission and exemption for the Ethibond versus Vicryl comparison process started in 2013 and had nothing to do with approval of the process throughout the 2013-2016 three-year period. The Panel agrees with Dr. Shamoo. The 2018 IRB exemption letter does not include an attached protocol and does not indicate that the IRB reviewed the Ethibond data that Dr. MacKoul collected from 2013-2016.

In his exceptions, Dr. MacKoul argues that the ALJ and Dr. Shamoo did not give any deference to the approval that Dr. MacKoul received from Integ Review IRB for his retrospective study. He further argues that the study was solely for the purpose of quality improvement and therefore exempt until he decided to publish the results. *Id.* In addition, Dr. MacKoul argues that the ALJ mistakenly relied on Dr. Shamoo's opinion that an intent to publish transformed Dr. MacKoul's study from a quality improvement study into a prospective research project. Dr. Shamoo, however, considered not only Dr. MacKoul's plan to systematically gather data over three years and perform statistically significant analyses, but the totality of Dr. MacKoul's actions. Dr. Shamoo noted Dr. MacKoul's overriding goal of comparing a nonabsorbable suture to an

[18] In his exceptions, Dr. MacKoul states that the IRB approved his study in 2017. MacKoul Exceptions, p. 10. The Accepted Manuscript presented by Dr. MacKoul at the evidentiary hearing also shows an IRB date of 11/2017. The title of the document is: "A Retrospective Review of Vaginal Cuff Dehiscence: Comparing Absorbable to Nonabsorbable Sutures." (Resp. Exh. 16) It was undisputed that the title of the study exempted by the IRB was "Patient Characteristics and Surgical Outcomes of Minimally Invasive Gynecologic Surgery in an Ambulatory Surgery Center," and that the Integ Review IRB letter exempting Dr. MacKoul's study noted that the research is not FDA-regulated and was dated April 27, 2018. (Resp. Exh. 32) Dr. MacKoul's research director - Dr. Van der Does - agreed that the IRB approval letter had a different name for the exempted study but stated that it related to Dr. MacKoul's retrospective Ethibond study. She also testified that the study took place from October 2013 to April, 2018 and was unable to explain why the IRB date was 11/2017. (Tr. 672-73) Dr. van der Does also acknowledged that surgical sutures are FDA-regulated and did not know why the IRB letter stated that the research was not FDA-regulated. (Tr. 680)

absorbable suture, his use of the variable Ethibond suture as the investigational arm and Vicryl as the control arm of the study, and his observations about the reactions of the study participants to the variable. The Panel finds that Dr. MacKoul's characterization of his actions as quality improvement is inapplicable to the reality of his conduct from October 1, 2013 with the hundreds of unknowing participants in his research study. The Panel denies his exception. Dr. MacKoul also speculates that his failure to obtain IRB approval before initiating the 2013-2016 prospective research would have resulted in an IRB determination of non-compliance and non-approval, and a referral for investigative and enforcement action. He provides no basis for his theoretical assertions. The Panel denies his exception.

**3. Panel B's Evaluation of Expert Testimony**

The ALJ discussed the bases for the respective opinions of Dr. Shamoo and Dr. Prentice and found that Dr. Shamoo's opinion was more persuasive and credible. Prop. Dec. at 41-44; 45-46; 55-59. In carefully considering the opinions of Dr. Shamoo and Dr. Prentice, the Panel has focused on the factual foundations and legal reasoning for their opinions as well as their professional qualifications. The Panel has used its knowledge and expertise to evaluate the expert evidence on this issue, and its evaluation of the respective opinions of each expert is based on the logic, credibility, and persuasiveness of their opinions as it relates to the totality of the evidence presented at the hearing. The Panel agrees with the ALJ that Dr. Shamoo properly based his opinion on the specific activities undertaken by Dr. MacKoul from 2013 to 2016 instead of Dr. MacKoul's claims about the nature of his activities and intentions. Dr. Prentice did not have an adequate factual foundation for his opinions and merely accepted and relied on Dr. MacKoul's subjective representations of his surgical activities from 2013 to 2016 at face value. Although Dr. Prentice provided objective distinctions between innovation and clinical research and prospective

and retrospective studies in his testimony, his acceptance of Dr. MacKoul's self-serving representations underscores the extent to which Dr. Prentice then ignored his distinctions and the facts, reality, and context of Dr. MacKoul's actions.

Considered against the backdrop of Dr. MacKoul's statements in his October 31, 2016 manuscript from 2013 - 2016, and his testimonial description and explanations to the Board about his surgical activities, Dr. Prentice's belief that Dr. MacKoul's only purpose was innovation and the improvement of the quality of patient care does not hold up. His opinion is implausible and is directly contradicted by the systematic nature and methods of Dr. MacKoul's surgical interventions and his research team's accrual of detailed statistical data for that three-year period.

While Dr. MacKoul's placement of Ethibond sutures may have had the incidental effect of benefiting some of the 595 Ethibond patients in the study who may have been at risk for VCD, Dr. MacKoul testified that he did not select patients based on their particular risks or medical histories for the study. Dr. MacKoul's primary motivation in his study was to obtain valid scientific data about the efficacy or safety of Ethibond versus Vicryl sutures, and to compare success rates. Dr. Prentice ignored Dr. MacKoul's own sworn account of his surgical activities to the Board, which provides no indication that his primary focus was innovation, quality improvement, the benefit of individual patients, or a selection of high or low risk patients for those purposes.

Dr. MacKoul's exceptions arguments overlook the strong factual and legal bases for Dr. Shamoo's opinion and the record evidence on which he relied. The Panel rejects Dr. MacKoul's claim that the ALJ arbitrarily deferred to the opinion of Dr. Shamoo and denies his exception on this issue. As a physician licensed by the Board, Dr. MacKoul was ethically and legally required to conduct human subject research in accordance with the protections afforded by the federal

regulations and § 13-2002 of the Health General Article. His failure to do so constitutes unprofessional conduct in the practice of medicine.

## CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact and discussion of the State's and Dr. MacKoul's exceptions, as set forth above, the Panel concludes that Dr. MacKoul: is guilty of unprofessional conduct in the practice of medicine, in violation of Health Occ. § 14-404(a)(3)(ii); grossly overutilized health care services, in violation of Health Occ. § 14-404(a)(19); and failed to meet appropriate standards as determined by appropriate peer review for the delivery of quality medical and surgical care performed in an outpatient facility, office, hospital, or any other location in this State, based on his care of Patients 1, 2, 4, 5, 6 and 9, in violation of § 14-404(a)(22). Dr. MacKoul did not violate the standard of care with respect to his care of Patient 3, 8, or 10. The Panel does not find that Dr. MacKoul failed to keep adequate medical records for any patient and the charge of a failure to keep adequate medical records is dismissed.

## SANCTION

Dr. MacKoul has a disciplinary history with the Board. In 2009, he was reprimanded and fined $2,500 for failing to report disciplinary action against his medical license in the District of Columbia on his application for renewal of his Maryland medical license. St. Exh. 46. In 2014, the Board again reprimanded him and ordered him to complete a Board-approved intensive course on physician-patient interactions because he failed to adequately counsel a patient to see a urologist prior to surgery, failed to review the patient's chart for pre-surgical clearance, failed to adequately communicate with the patient and her family the day of surgery about delays in the surgery, and became abusive and combative toward the patient and her family. On that occasion, Dr. MacKoul lied to a patient's family, and blamed them for stating that he could not avoid keeping the patient

waiting because he was involved in another surgery, a claim that was found to be untrue based on an examination of the timing of the surgeries (objective fact) and the testimony of other witnesses. St. Exh. 47.

The Panel agrees with the ALJ that a familiar theme of Dr. MacKoul's prior disciplinary history involved a liberal application of "alternative facts" in explaining his unprofessional actions and a failure to provide truthful, relevant information to the Board as required on his licensure renewal application. His actions in this case are consistent with the patterns of unprofessionalism and dishonesty apparent in Dr. MacKoul's prior misconduct. The Panel has taken into consideration that one of the aggravating factors when determining a sanction is that "[p]revious attempts to rehabilitate the offender were unsuccessful." COMAR 10.32.02.09 B(6)(k). As he did in 2009 and 2014, Dr. MacKoul continues to violate the professional norms of his profession and has shown no meaningful understanding of or commitment to ethical practice. In keeping with its mission, the Board's obligation is to protect the welfare of the public, and the imposition of progressive discipline is a disciplinary tool essential to the Board's mission.

Based on Dr. MacKoul's successive violations, and his demonstrated propensity for dishonest behavior and explanations, it is apparent that the Board's previous attempts to rehabilitate him were unsuccessful, and that he has learned little or nothing from the Board's remedial efforts. The Panel will not ignore its deterrent function in this case. The Panel will impose a suspension for one month, probation for a minimum of two years, and a $50,000 fine. To address the Panel's specific concerns regarding Dr. MacKoul's violation of the governing human subject research laws, he is required to take and successfully complete an ethics course with a focus on ethical issues and human participant protections in human subject research. Dr. MacKoul is prohibited from engaging in any human subject research during the first year of probation. He may

engage in human subject research during the second year of probation and is required to submit his research protocol and IRB approval to the Board for review and approval prior to commencing the research.

## ORDER

It is, by an affirmative vote of a majority of the quorum of Disciplinary Panel B, hereby:

**ORDERED** that the medical license of Paul J. MacKoul, M.D., License No. D47612, is **SUSPENDED** for a minimum period of **ONE (1) MONTH**[19]; and it is further

**ORDERED** that the suspension goes into effect **THIRTY (30) CALENDAR DAYS** after the effective date of this Final Decision and Order, so as to provide Dr. MacKoul with sufficient time to arrange for the transition of his patients to other health care providers; and it is further

**ORDERED** that during the suspension, Dr. MacKoul:

(1) shall not:

(a) practice medicine;

(b) take any actions after the effective date of this Final Decision and Order to hold himself out to the public as a current provider of medical services;

(c) authorize, allow or condone the use of his name or provider number by any health care practice or any other licensee or health care provider;

(d) function as a peer reviewer for the Board or for any hospital or other medical care facility in the state;

(e) prescribe or dispense medications;

(f) perform any other act that requires an active medical license.

(2) shall establish and implement a procedure by which his patients may obtain their medical records without undue burden and notify all patients of that procedure; and it is further

[19] If Dr. MacKoul's license expires during the period of suspension, the suspension and any conditions will be tolled.

**ORDERED** that Dr. MacKoul shall not apply for early termination of suspension; and it is further

**ORDERED** that, after the minimum period of suspension imposed by the Final Decision and Order has passed, Dr. MacKoul may submit a written petition for termination of suspension. After a determination that Dr. MacKoul has complied with the relevant terms of this Final Decision and Order, the disciplinary panel may administratively terminate Dr. MacKoul's suspension through an order of the disciplinary panel; and it is further

**ORDERED** that upon termination of the suspension, Dr. MacKoul shall be placed on **PROBATION** for a minimum of **TWO (2) YEARS.**[20] During probation, Dr. MacKoul shall comply with the following terms and conditions of probation:

1. Within **THREE (3) MONTHS** of the commencement of the probationary period, Dr. MacKoul is required to take and successfully complete an ethics course addressing ethical issues and human participant protection in human subject research. The following terms apply:

> (a) it is Dr. MacKoul's responsibility to locate, enroll in and obtain the disciplinary panel's approval of the course before the course is begun;
>
> (b) the disciplinary panel will accept a course taken in-person or over the internet during the state of emergency;
>
> (c) Dr. MacKoul must provide documentation to the disciplinary panel that he has successfully completed the course;
>
> (d) the course may not be used to fulfill the continuing medical education credits required for license renewal;
>
> (e) Dr. MacKoul is responsible for the cost of the course.

[20] If Dr. MacKoul's license expires during the period of probation, the probation and any conditions will be tolled.

2. During the first year of probation, Dr. MacKoul is prohibited from engaging in any human subject research.

3. During the second year of probation, Dr. MacKoul may engage in human subject research and is required to submit his research protocol and IRB approval to the Board for review and approval prior to commencing the research.

4. Within **TWO (2) YEARS,** Dr. MacKoul shall pay a civil fine of **FIFTY THOUSAND DOLLARS ($50,000.00)**. The Payment shall be by money order or bank certified check made payable to the Maryland Board of Physicians and mailed to P.O. Box 37217, Baltimore, Maryland 21297. The Board will not renew or reinstate Dr. MacKoul's license if Dr. MacKoul fails to timely pay the fine to the Board; and it is further

**ORDERED** that Dr. MacKoul shall not apply for early termination of probation; and it is further

**ORDERED** that after Dr. MacKoul has fully and satisfactorily complied with all terms and conditions of probation, and the minimum period of probation imposed by the Final Decision and Order has passed, Dr. MacKoul may submit a written petition for termination of probation. After consideration of the petition, the probation may be terminated through an order of a disciplinary panel. Dr. MacKoul may be required to appear before the disciplinary panel to discuss his petition for termination. The disciplinary panel may grant the petition to terminate the probation, through an order of the disciplinary panel, if Dr. MacKoul has successfully complied with all of the probationary terms and conditions and if there are no pending complaints related to the charges; and it is further

**ORDERED** that if Dr. MacKoul allegedly fails to comply with any term or condition imposed by this Final Decision and Order, Dr. MacKoul shall be given notice and an opportunity

for a hearing. If the disciplinary panel determines there is a genuine dispute as to a material fact, the hearing shall be before an Administrative Law Judge of the Office of Administrative Hearings followed by an exceptions process before a disciplinary panel; and if the disciplinary panel determines there is no genuine dispute as to a material fact, Dr. MacKoul shall be given a show cause hearing before a disciplinary panel; and it is further

**ORDERED** that after the appropriate hearing, if the disciplinary panel determines that Dr. MacKoul has failed to comply with any term or condition imposed by this Final Decision and Order, the disciplinary panel may reprimand Dr. MacKoul, place Dr. MacKoul on probation with appropriate terms and conditions, or suspend or revoke Dr. MacKoul's license to practice medicine in Maryland. The disciplinary panel may, in addition to one or more of the sanctions set forth above, impose a civil monetary fine on Dr. MacKoul; and it is further

**ORDERED** that Dr. MacKoul is responsible for all costs incurred in fulfilling the terms and conditions of this Final Decision and Order; and it is further

**ORDERED** that the effective date of the Final Decision and Order is the date the Final Decision and Order is signed by the Executive Director of the Board or her designee. The Executive Director signs the Final Decision and Order on behalf of the disciplinary panel which has imposed the terms and conditions of the Final Decision and Order; and it is further

**ORDERED** that this Final Decision and Order is a public document. See Md. Code Ann., Health Occ. §§ 1-607, 14-411.1(b)(2) and Gen. Prov. § 4-333(b)(6).

***Signature on File***

03/09/2021
Date

Christine A. Farrelly, Executive Director
Maryland State Board of Physicians

## NOTICE OF RIGHT TO PETITION FOR JUDICIAL REVIEW

Pursuant to Md. Code Ann., Health Occ. § 14-408, Dr. MacKoul has the right to seek judicial review of this Final Decision and Order. Any petition for judicial review shall be filed within thirty (30) days from the date of mailing of this Final Decision and Order. The cover letter accompanying this final decision and order indicates the date the decision is mailed. Any petition for judicial review shall be made as provided for in the Administrative Procedure Act, Md. Code Ann., State Gov't § 10-222 and Title 7, Chapter 200 of the Maryland Rules of Procedure.

If Dr. MacKoul files a petition for judicial review, the Board is a party and should be served with the court's process at the following address:

Maryland State Board of Physicians
Christine A. Farrelly, Executive Director
4201 Patterson Avenue
Baltimore, Maryland 21215

Notice of any petition should also be sent to the Board's counsel at the following address:

Noreen Rubin
Assistant Attorney General
Maryland Department of Health
300 West Preston Street, Suite 302
Baltimore, Maryland 21201

# ATTACHMENT A

| | | |
|---|---|---|
| **MARYLAND STATE BOARD OF** | * | **BEFORE NICOLAS ORECHWA,** |
| **PHYSICIANS** | * | **AN ADMINISTRATIVE LAW JUDGE** |
| **v.** | * | **OF THE MARYLAND OFFICE** |
| **PAUL MACKOUL, M.D.,** | * | **OF ADMINISTRATIVE HEARINGS** |
| **RESPONDENT** | * | |
| **LICENSE No.: D47612** | * | **OAH No.: MDH-MBP2-71-19-01732** |

* * * * * * * * * * * * *

# PROPOSED DECISION

STATEMENT OF THE CASE
ISSUES
SUMMARY OF THE EVIDENCE
PROPOSED FINDINGS OF FACT
DISCUSSION
PROPOSED CONCLUSIONS OF LAW
PROPOSED DISPOSITION

## STATEMENT OF THE CASE

On September 7, 2018, a disciplinary panel of the Maryland State Board of Physicians (Board) issued charges against Paul MacKoul, M.D. (Respondent), alleging violations of the State law governing the practice of medicine. Md. Code Ann., Health Occ. §§ 14-101 through 14-508, and 14-601 through 14-607 (2014 & Supp. 2018). Specifically, the Board charged the Respondent with violating the following:

- section 14-404(a)(3)(ii) of the Health Occupations Article (unprofessional care in the practice of medicine);
- section 14-404(a)(19) of the Health Occupations Article (gross overutilization of health care services);
- section 14-404(a)(22) of the Health Occupations Article (failure to meet the standard of quality care); and

- section 14-404(a)(40) of the Health Occupations Article (failure to keep adequate medical records).[1]

The disciplinary panel to which the complaint was assigned forwarded the charges to the Office of the Attorney General for prosecution. Another disciplinary panel delegated the matter to the Office of Administrative Hearings (OAH) for issuance of Proposed Findings of Fact, Proposed Conclusions of Law, and a Proposed Disposition. Code of Maryland Regulations (COMAR) 10.32.02.03E(5); COMAR 10.32.02.04B(1).

I held a hearing on June 3, June 4, June 5, June 6, June 7 and June 14, 2019, at the OAH in Hunt Valley, Maryland. Health Occ. § 14-405(a) (Supp. 2018); COMAR 10.32.02.04D. H. Kenneth Armstrong, Esquire, represented the Respondent, who was present. Victoria Pepper, Assistant Attorney General and Administrative Prosecutor, represented the State of Maryland (State). I closed the record on June 14, 2019, after the parties presented their closing arguments.

Procedure in this case is governed by the contested case provisions of the Administrative Procedure Act, the Rules for Hearings before the Board of Physicians, and the Rules of Procedure of the OAH. Md. Code Ann., State Gov't §§ 10-201 through 10-226 (2014 & Supp. 2018); COMAR 10.32.02; COMAR 28.02.01.

## ISSUES

1. Did the Respondent violate the following provisions of the applicable law:
   - section 14-404(a)(3)(ii) of the Health Occupations Article (unprofessional care in the practice of medicine);
   - section 14-404(a)(19) of the Health Occupations Article (gross overutilization of health care services);

[1] Unless cited otherwise, all citations to the Health Occupations Article shall be to the 2018 Supplement.

- section 14-404(a)(22) of the Health Occupations Article (failure to meet the standard of quality care); and
- section 14-404(a)(40) of the Health Occupations Article (failure to keep adequate medical records)?

2. If so, what sanctions are appropriate?

## SUMMARY OF THE EVIDENCE

Exhibits

I admitted the following exhibits into evidence on behalf of the Board:

Bd. Ex. 1 - April 12, 2016 Complaint from the CareFirst Special Investigations Unit

Bd. Ex. 2 - May 12, 2017 Transcript of the Board's interview with the Respondent

Bd. Ex. 3 - The Respondent's draft research manuscript, received by the Board November 2, 2016

Bd. Ex. 4 - The Respondent's revised research manuscript, received by the Board April 11, 2017

Bd. Ex. 5 - Patient 10's[2] Complaint to the Board, dated June 22, 2016[3]

Bd. Ex. 6 - The Respondent's response to Patient 10's Complaint

Bd. Ex. 7 - certification of records and the Respondent's office records with regard to Patient 1

Bd. Ex. 8 - certification of records and Respondent's Center for Innovative GYN Care ("ISC") records with regard to Patient 1

Bd. Ex. 9 - billing record with regard to Patient 1

Bd. Ex. 10 - certification of records and the Respondent's office records with regard to Patient 2

Bd. Ex. 11 - certification of records and the Respondent's ISC records with regard to Patient 2

Bd. Ex. 12 - billing record with regard to Patient 2

Bd. Ex. 13 - certification of records and the Respondent's office records with regard to Patient 3

[2] The Patients at issue in this matter shall be referred to by numbers to protect their privacy.
[3] The Board abandoned all charges related to Patient 10's complaint with the exception of one charge of unprofessional care in the practice of medicine.

Bd. Ex. 14 - certification of records and the Respondent's ISC records with regard to Patient 3

Bd. Ex. 15 - billing record with regard to Patient 3

Bd. Ex. 16 - certification of records and the Respondent's office records with regard to Patient 4

Bd. Ex. 17 - certification of records and the Respondent's ISC records with regard to Patient 4

Bd. Ex. 18 - billing record with regard to Patient 4

Bd. Ex. 19 - certification of records and the Respondent's office records with regard to Patient 5

Bd. Ex. 20 - certification of records and the Respondent's ISC records with regard to Patient 5

Bd. Ex. 21 - billing record with regard to Patient 5

Bd. Ex. 22 - certification of records and the Respondent's office records with regard to Patient 6

Bd. Ex. 23 - certification of records and the Respondent's ISC records with regard to Patient 6

Bd. Ex. 24 - billing record with regard to Patient 6

Bd. Ex. 25 - certification of records and the Respondent's office records with regard to Patient 7

Bd. Ex. 26 - certification of records and the Respondent's ISC records with regard to Patient 7

Bd. Ex. 27 - billing record with regard to Patient 7

Bd. Ex. 28 - certification of records and the Respondent's office records with regard to Patient 8[4]

Bd. Ex. 29 - certification of records and the Respondent's ISC records with regard to Patient 8

Bd. Ex. 30 - billing record with regard to Patient 8

Bd. Ex. 31 - certification of records and the Respondent's office records with regard to Patient 9

Bd. Ex. 32 - certification of records and the Respondent's ISC records with regard to Patient 9

Bd. Ex. 33 - billing record with regard to Patient 9

Bd. Ex. 34 - records and the Respondent's office records with regard to Patient 10

Bd. Ex. 35 - Respondent's ISC records with regard to Patient 10

Bd. Ex. 36 - records from [redacted] with regard to Patient 10

[4] Although I admitted the exhibits related to Patient 8, I neither reviewed nor considered them because the State abandoned all charges with regard to Patient 8.

Bd. Ex. 37 - an excerpt of records from [redacted] with regard to Patient 10

Bd. Ex. 38 - billing record with regard to Patient 10

Bd. Ex. 39 - Curriculum Vitae (CV) of Ishrat Rafi M.D.

Bd. Ex. 40 - Peer review report with regard to charges under sections 14-401(a)(22) and (40) of the Health Occupations Article authored by Ishrat Rafi, M.D.

Bd. Ex. 41 - Peer review report with regard to charges under sections 14-404(a)(3)(ii) and (19) of the Health Occupations Article authored by Ishrat Rafi, M.D.

Bd. Ex. 42 - the Respondent's supplemental response received by the Board, November 7, 2017

Bd. Ex. 43 - CV of Adil Shamoo, Ph.D.

Bd. Ex. 44 - correspondence from Adil Shamoo, Ph.D., to the Board, dated September 7, 2018

Bd. Ex. 45 - Advisory Letter, June 15, 2015[5]

Bd. Ex. 46 - Consent Order, April 8, 2009

Bd. Ex. 47 - Final Decision and Order (case numbers 2009-0608 & 2010-0128) with attached Proposed Decision, June 3, 2014

Bd. Ex. 48 - Statement of Charges under the Maryland Medical Practice Act, September 7, 2018

Bd. Ex. O - Postoperative Instructions from ISC concerning Laparoscopic Hysterectomy procedures

Bd. Ex. O1 - documents with regard to various studies conducted by ISC staff

Bd. Ex. O2 - study protocol entitled "Impact of Suture Type, Material and Technique on Vaginal Cuff Dehiscence Rates Following Laparoscopic Hysterectomy"

Bd. Ex. O3 - various academic articles, abstracts and documents regarding Obstetrics and Gynecological (OB/Gyn) surgery

Bd. Ex. O4 - abstract and article entitled "Value-Based Comparison of Minimally Invasive Hysterectomy Approaches"

Bd. Ex. O5 - abstract and article entitled "Comparison of Laparoscopically-Assisted Abdominal Myomectomy to the Most Common Myomectomy Procedures"

[5] I admitted Bd. Ex's 45, 46, and 47 but, per discussion with counsel, I neither reviewed nor considered them until I reached the issue of proposed sanctions.

Bd. Ex. O6 - various abstracts and articles regarding OB/Gyn procedures

Bd. Ex. O7 - [redacted] OB/Gyn progress note with regard to Patient 1, September 16, 2014

Bd. Ex. O8 - [redacted] OB/Gyn progress note with regard to Patient 2, December 17, 2014

Bd. Ex. O9 - blank Hysterectomy consent form

Bd. Ex. O10 - [redacted] Women's Care, progress note with regard to Patient 3, December 11, 2014

Bd. Ex. O11 - images from ISC regarding Patient 3, October 3, 2014 and July 17, 2015

Bd. Ex. O12 - various progress notes with regard to Patient 4

Bd. Ex. O13 - various progress notes with regard to Patient 5

Bd. Ex. O14 - various progress notes with regard to Patient 7

Bd. Ex. O15 - various progress notes with regard to Patient 8

Bd. Ex. O16 - various progress notes with regard to Patient 9

Bd. Ex. O17 - various progress notes with regard to Patient 10

Bd. Ex. O18 – various records from CareFirst, correspondence between the Respondent and the Board, various letters and reports from the Respondent's experts

I admitted the following exhibits into evidence on behalf of the Respondent:

Resp. Ex. 1 - Respondent's CV

Resp. Ex. 2 - Report and CV of Lawrence Fitzpatrick, M.D.

Resp. Ex. 3 - WITHDRAWN

Resp. Ex. 4 - Report and CV of Ernest D. Prentice, Ph.D.

Resp. Ex. 5 - WITHDRAWN

Resp. Ex. 6 - Report and CV of Robert Mesrobian, M.D.

Resp. Ex. 7 - Report and CV of James Kondrup, M.D.

Resp. Ex. 8 - NOT ADMITTED[6]

Resp. Ex. 9 - Report and CV of Laurence Udoff, M.D.

[6] The exhibit concerns Patient 8.

Resp. Ex. 10 - "Surgery of Female Incontinence," edited by Stuart L. Stanton and Emil A. Tanagho

Resp. Ex. 11 - "Controversies and Innovations in Urological Surgery," edited by Clive Gingell and Paul Abrams

Resp. Ex. 12 - "ACOG[7] Innovative Practice: Ethical Guidelines," Number 352, December 2006

Resp. Ex. 13 - Ethibond Suture package insert

Resp. Ex. 14 - "Wound Closure Manual," David L. Dunn, M.D. Ph.D., Jay Phillips Professor and Chairman of Surgery, University of Minnesota

Resp. Ex. 15 - "Nezhat's Operative Gynecologic Laparoscopy and Hysteroscopy," edited by Camran Nezhad et al.

Resp. Ex. 16 - accepted manuscript to appear in The Journal of Minimally Invasive Gynecology

Resp. Ex. 17 - "Minimally Invasive Surgery, Analysis of a Standardized Technique for Laparoscopic Cuff Closure Following 1924 Total Laparoscopic Hysterectomies," Katherine A. O'Hanlan et al.

Resp. Ex. 18 - American Journal of Obstetrics & Gynecology, May 2018, "Laparoscopic vs. Transvaginal Cuff Closure After Total Laparoscopic Hysterectomy: A Randomized Trial by the Italian Society of Gynecologic Endoscopy," Stefano Uccella, M.D., Ph.D., et al.

Resp. Ex. 19 – JSLS,[8] "Vaginal Cuff Dehiscence: Risk Factors and Associated Morbidities," Noga Fuchs, Weizman, M.D., et al.

Resp. Ex. 20 - Cureus, "Vaginal Cuff Closure in Minimally Invasive Hysterectomy: A Review of Training, Techniques, and Materials," Katherine Smith, Aileen Caceres

Resp. Ex. 21 - The Journal of Minimally Invasive Gynecology, "Use of Bidirectional Barbed Suture in Laparoscopic Myomectomy: Evaluation of Perioperative Outcomes, Safety, and Efficacy," J. I. Einarsson, M.D., MPH, et al.

Resp. Ex. 22 - The Journal of Minimally Invasive Gynecology, "The Use of Bidirectional, Barbed Suture in Laparoscopic Myomectomy and Total Laparoscopic Hysterectomy," James A. Greenberg, M.D., et al.

Resp. Ex. 23 - British Journal of Surgery (Abstract), "Meta-Analysis of Techniques for Closure of Midline Abdominal Incisions," Van T. Riet M

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[7] American College of Obstetricians and Gynecologists

[8] Journal of the Society of Laparoscopic Surgeons

Resp. Ex. 24 - Sunday Posters, "Reduction of Vaginal Cuff Dehiscence in Total Laparoscopic Hysterectomy with Use of Un-barbed Monofilament Suture," Peter Schultze, M.D.

Resp. Ex. 25 - International Journal of Surgery Case Reports, "Post-Coital Vaginal Cuff Dehiscence with Small Bowel Evisceration after Laparoscopic Type II Radical Hysterectomy: A Case Report," Ilker Kahramanoglu

Resp. Ex. 26 - Reviews in Obstetrics & Gynecology, "Advances in Suture Material for Obstetric and Gynecologic Surgery," James A. Greenberg, M.D., Rachel M. Clark, M.D.

Resp. Ex. 27 - Brazilian Journal of Videoendoscopic Surgery, "Vaginal Cuff Closure After Laparoscopic Total Hysterectomy," William Kondo et al.

Resp. Ex. 28 - The Journal of Minimally Invasive Gynecology, "Small-Diameter Hysteroscopic Metroplasty for a Septate Uterus After Open-Assisted Laparoscopic Radical Trachelectomy," Adimasa Takasashi, M.D. Ph.D., et al.

Resp. Ex. 29 - Instruments and Methods, "Laparoscopic Sacral Copopexy for Vaginal Vault Prolapse," Ceana H. Nezhad, M.D., et al.

Resp. Ex. 30 - Frequency Tables: #Days from DOS[9] to Suture Removal

Resp. Ex. 31 - Education Certificates for the Respondent and his staff

Resp. Ex. 32 - Integ Review IRB,[10] Membership Roster

Resp. Ex. 33 - Integ Review IRB, Membership Roster

Resp. Ex. 34 - "Systematic Review and Meta-Analysis, A Systematic Review," Marike L. Broekman (M.D., Ph.D., J.D.) et al.

Resp. Ex. 35 - The Respondent's contracts

Resp. Ex. 36 - Anatomical Drawings/photographs of small bowel obstruction and ilieus

Resp. Ex. 37 - Anatomical Drawings/photographs of small bowel obstruction and ilieus

Resp. Ex. 38 – Picture of Fibroids

Resp. Ex. 39 – The Journal of Minimally Invasive Gynecology, "A Retrospective Review of Vaginal Cuff Dehiscence: Comparing Absorbable and Nonabsorbable Sutures," Paul MacKoul M.D., Natalya Danilyants, M.D., Vanessa Sarfoth, M.D., Louise van der Does, Ph.D., and Nilofar Kazi, B.A.

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[9] The exhibit does not define this acronym. However, taken in context, it is assumed it refers to "Date of Surgery."

[10] Institutional Review Board

On behalf of the Respondent, I also admitted the following exhibits for demonstrative purposes only:

Resp. Dem. Ex. 1 - handwritten definitions of "Retro" versus "Prosp"

Resp. Dem. Ex. 2 - uterine artery ligation medical illustration

Resp. Dem. Ex. 3 - human abdomen medical illustration

Resp. Dem. Ex. 4 - large cardboard visual presentation entitled "Sutures Used in GYN Surgery"

Resp. Dem. Ex. 5 - Handwritten drawing

Resp. Dem. Ex. 6 - Handwritten drawing

In addition I accepted the following copies of case law, statutes, and regulations provided by the parties. While not evidence, I have made these copies part of the record. COMAR 28.02.01.22B(3):

- Health Gen. §§ 13-2001 through 13-2004 and §§ 13-2101 through 13-2103
- 45 C.F.R. § 46 et seq.
- 21 C.F.R. § 50 et seq.
- 21 C.F.R. § 56 et seq.
- "Off-Label" and Investigational Use of Marketed Drugs, Biologics and Medical Devices, January 1998 from www.fda.gov
- *Halikas v. University of Minnesota*, 856 F. Supp. 1331 (D. Minn. 1994)
- *Grimes v. Kennedy Krieger Institute, Inc.*, 782 A.2d. 807 (Md. 2001)
- *Bogner v. Vanderbilt University*, No. M2015-00669-COA-R3-CV, 2017 WL 716011 (Tenn. Ct. App. Feb. 23, 2017)
- *In re Otero County Hospital Association, Inc.*, 527 BR 719 (D.N.M. 2015)
- *TD v. New York State Office of Mental Health*, 228 A.D. 2d 95 (N.Y. App. Div. 1996)

Testimony

The following witnesses testified on behalf of the Board:

- Patient 10;
- Ishrat Rafi, M.D. (Dr. Rafi), who I accepted as an expert in gynecological (GYN) surgery, the diagnosis and treatment of GYN issues, surgical procedures, anesthesia usage for GYN procedures, medical billing and documentation, application of the appropriate standard of care for the treatment of GYN surgical patients, and the adequate documentation of care and treatment and Current Procedural Terminology codes; and
- Adil Shamoo, Ph.D. (Dr. Shamoo), who I accepted as an expert in the history of human subject research, legal requirements for an institutional review board (IRB), regulations regarding IRBs, the Maryland State statute regarding IRBs, the ethical requirements of an IRB, the components of informed consent, and the appropriate informed consent for an IRB.

The Respondent testified in his own behalf and presented the following witnesses:

- Dr. Ernest Prentice, Ph.D. (Dr. Prentice), who I accepted as an expert in the federal and state statutes concerning human experimentation, the definition of human experimentation, the definition of surgical innovation, the definition of quality improvement, and the rules for IRBs and their exceptions;
- Dr. James Fitzpatrick, M.D. (Dr. Fitzpatrick), who I accepted as an expert in professional conduct pursuant to section 14-404(a)(3)(ii) of the Health Occupations Article (unprofessional care in the practice of medicine), as it relates to general communications between patient and physician;

- Dr. Robert Mesrobian, M.D. (Dr. Mesrobian), who I accepted as an expert in general anesthesia as well as the anesthesia risk posed to Patients 1, 2, 4, 5, 6 and 9 during a second surgery for the removal of sutures;
- Dr. James Kondrup, M.D. (Dr. Kondrup), who I accepted as an expert in GYN surgery and techniques, the Respondent's management of Patients 1, 2, 4, 5, 6 and 9, the management of Patient 3 as it relates to fertility issues, the billing associated with the Respondent's treatments, the consents associated with the Respondent's treatments, the documentation associated with the Respondent's treatments, and the placement of sutures in GYN surgery;
- Dr. Laurence Udoff, M.D. (Dr. Udoff), who I accepted as an expert in reproductive endocrinology, in particular, the relationship between himself and other physicians concerning the management of patients with fibroids versus the management of patients with infertility and the order in which the treatment of those two issues is administered;
- Terri Welter, Principal at ECG Management; and
- Dr. Louise van der Does (Dr. van der Does), the Respondent's Director of Research.

## PROPOSED FINDINGS OF FACT

Having considered all of the evidence presented, I find the following facts by a preponderance of the evidence:

1. At all times relevant to this proceeding, the Respondent was a licensed physician in the State of Maryland.

2. The Respondent is a surgeon specializing in OB/GYN surgery and treatment. In addition, he has training in GYN oncology and through that training, he is skilled in advanced GYN surgery techniques.

3. The Respondent is the Director of Innovations Surgery Center (ISC), which he operates with his partner, Natalya Danilyants, M.D. (Dr. Danilyants). ISC is an ambulatory surgery center (ASC). It has the facilities and resources available to perform surgeries. However, it does not have an intensive care unit (ICU), blood bank, or other types of support services. The Respondent performs GYN surgeries at the ISC. In addition, he has privileges and performs surgeries at [redacted].

4. The Respondent routinely performs two common GYN surgeries: Myomectomies and Hysterectomies. A Myomectomy is a surgery to remove fibroids from within a uterus. A Hysterectomy is a surgery to remove the uterus.[11] The Respondent performs approximately 500 Hysterectomies per year. Some of those Hysterectomies involve patients with above average sized uteri and fibroids.

5. When performing a Hysterectomy, a GYN surgeon must take measures to decrease the patient's risk of bleeding excessively. The surgeon can approach this issue by ligating[12] the uterine artery. Ligation of the uterine artery (uterine artery ligation) can require the GYN surgeon to enter the retroperitoneal space[13] and navigate a variety of blood vessels and nerves. Typically OBY/GYN surgeons are not trained in this specific procedure. GYN

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[11] Hysterectomies can also include removal of the fallopian tubes and ovaries.

[12] Ligate means to "tie or bind with a ligature." The Free Dictionary, https://medical-dictionary.thefreedictionary.com/ligate (last visited Aug. 28, 2019).

[13] The Peritoneum is "[t]he serious membrane lining the walls of the abdominal and pelvic cavities (parietal peritoneum) and investing contained viscera (visceral peritoneum), the two layers enclosing a potential space, the peritoneal cavity." The Free Dictionary, https://medical-dictionary.thefreedictionary.com/peritoneum (last visited Aug. 28, 2019). The retroperitoneal space is "the space between the peritoneum and the posterior abdominal wall." The Free Dictionary, https://medical-dictionary.thefreedictionary.com/retroperitoneal+space (last visited Aug. 6, 2019).

oncologists are trained in this procedure. The Respondent, as a GYN oncologist, received training and is skilled in this procedure.

6. The Respondent contracts with various insurance companies to receive reimbursement after performing procedures. Various medical procedures are assigned Current Procedural Terminology (CPT) codes. When making a claim to an insurance company, the provider will utilize the CPT code associated with the procedure performed. The insurance company will then, pursuant to its contract with the provider, reimburse the provider for the procedure associated with that CPT code.

7. CPT codes in the 50,000 range concern OB/GYN procedures. CPT codes in the 30,000 range concern cardiology procedures.

8. The CPT code for uterine artery ligation is 37617. Typically providers will only bill the CPT code for hysterectomies when performing that procedure. The Respondent would typically bill the CPT codes for both the hysterectomy procedure and the uterine artery ligation.

9. Removal of the uterus during a hysterectomy creates an opening between the interior of the vagina and the portion of the body cavity where the uterus was once located. This opening is called the vaginal cuff. A surgeon must suture the vaginal cuff closed to prevent the contents of the body cavity (e.g. the bowels) from entering the vagina.

10. There are a variety of sutures from which a GYN surgeon can choose to close the vaginal cuff. Examples of sutures are absorbable, which do not require removal and non-absorbable, which require removal. Vicryl is a common absorbable suture used to close vaginal cuffs. Ethibond is a common non-absorbable suture. Ethibond is a suture approved by the Food and Drug Administration (FDA) for soft tissue closure. Ethibond and Vicryl are similar in feel and look.

11. The placement of Ethibond sutures requires patients to return for a second surgery to have the Ethibond sutures removed. That second surgery requires preparation, anesthesia, the placement of an additional absorbable suture, and some recovery time. Removal of Ethibond sutures does not require general anesthesia, but does require the patient be sedated beyond local anesthesia. The patient must be cleared medically prior to being sedated for removal of the Ethibond sutures. Once the patient is sedated, the suture removal procedure typically lasts less than ten minutes.

12. The placement of Vicryl or other absorbable sutures does not require a second procedure.

13. If the sutures are not in place long enough, if they fail, or if they fail to heal the vaginal cuff appropriately, a complication called vaginal cuff dehiscence (VCD) can occur. When VCD occurs the contents of the body cavity enter the vagina. In some cases, the contents exit the vagina opening and go outside the body. Common causes of VCD are sexual intercourse or straining to go to the bathroom.

14. VCD is an uncommon complication. However, it is serious, expensive, complicated to treat and presents a risk of mortality to the patient. Incidents of VCD at the Respondent's practice are rare.

15. Prior to October of 2013, the Respondent primarily used Vicryl when suturing the vaginal cuff. At the time, the Respondent and Dr. Danilyants performed approximately 500 to 600 hysterectomies per year. On one occasion, a patient of Dr. Danilyants experienced VCD, which caused her bowels to exit her body through her vagina. Dr. Danilyants had sutured that patient's vaginal cuff with Vicryl.

16. In October of 2013, the Respondent commenced prospective research to determine whether Ethibond sutures, which remained in the body longer than Vicryl, decreased

incidences of VCD. The Respondent decided to use his hysterectomy patients from October 2013 prospectively as human subjects for his research. At the time he began the Ethibond suture research in October 2013, the Respondent intended to publish its results and disseminate them for the sake of the medical profession's general knowledge. Dr. Danilyants continued to suture the vaginal cuffs of her patients with Vicryl. The Respondent used Dr. Danilyants's patients as the control arm of his study.

17. Prospective research using human subjects requires the approval of an IRB. The Respondent did not obtain IRB approval prior to the commencement of his research in October of 2013. The Respondent neither informed his patients he was conducting human subject research nor did he obtain their consent to do so.

18. The global payment period[14] for hysterectomies is ninety days. If performed within ninety days of a hysterectomy, the Ethibond suture removal procedure is considered follow-up care and not billed to insurance. If performed after the ninety days, the Ethibond suture removal procedure is billable. If granulation tissue forms and needs to be removed outside the global payment period, the removal of that tissue is billed separately as well.

19. On or about April 13, 2016, the Board received a complaint (Complaint A) from CareFirst Blue Cross Blue Shield (CareFirst). Complaint A alleged that the Respondent closed the vaginal cuffs of his hysterectomy patients at his ASC[15] with non-absorbable Ethibond sutures, which was not the standard of quality care. The Respondent used Ethibond for the specific purpose of billing a second procedure to remove the sutures outside the global payment period. This would include billing for the removal of granulation tissue, which formed as a result

[14] The global payment period is the period between the original procedure and any follow-up procedures to the original procedure. If the follow-up procedures are performed within the global payment period, they are not billed. If they are performed outside the global payment period, they are billed as separate procedures.
[15] The complaint also alleged the Respondent sutured hysterectomy patients with Ethibond at his ASC because it allowed him to bill an additional "facility fee" for the procedure to remove the sutures.

of the Ethibond sutures. Complaint A also alleged, generally, that the Respondent would improperly bill procedures.

20. At the Board's request, Dr. Rafi peer reviewed the charts of ten of the Respondent's patients (individually, Patient 1, Patient 2, Patient 3 through Patient 10 or collectively, e.g., Patients 1, 2, 3 etc.[16]).[17]

21. The Respondent performed hysterectomies on Patients 1, 2, 4, 5, 6 and 9. With the exception of Patient 6, the Respondent removed an above average uterus from each of those Patients. The Respondent billed code 37617 for ligation of the uterine artery for Patients 1, 2, 4, 5, 6 and 9.

22. The Respondent closed the vaginal cuff in Patients 1, 2, 4, 5, 6 and 9 using Ethibond sutures. In all those cases the Patients returned for a second procedure to have the sutures removed. The Respondent removed the sutures more than ninety days after the hysterectomy for Patients 1, 2, 4, 5, 6 and 9. For Patients 4, 5, 6 and 9, insurance reimbursed the Respondent for the second surgery. Insurance did not reimburse the Respondent for the second surgery on Patients 1 and 2.

23. Patients 2, 5, 6 and 9 signed consent forms with regard to the placement of the Ethibond sutures. Patients 1 and 4 did not. The Respondent documented discussing the procedure with Patients 1, 2, 4, 5, 6 and 9. The Respondent did not advise the referring physicians of Patients 1, 2, 4, 5, 6 and 9 of his placement of the non-absorbable Ethibond sutures.

24. When performing the suture removal procedure, the anesthesiologist placed Patients 1, 4, 5, 6 and 9 under Monitored Anesthesia Care (MAC) anesthesia or another form of

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[16] As shall be addressed below, Patient 10 filed her own complaint with the Board against the Respondent. While Dr. Rafi may have reviewed Patient 10's records in light of the allegations in Complaint A, the only issues before me with regard to Patient 10 concern two discrete allegations in her complaint.

[17] A physician other than the Respondent treated Patient 7, and thus she is not subject to this decision. The Board declined to pursue any allegations with regard to Patient 8, and thus she is not subject to this decision.

anesthesia. The anesthesia Patients 1, 4, 5, 6 and 9 received does not render the patient completely unconscious as does general anesthesia. However, it requires medical clearance and the insertion of an IV into the patient. The anesthesiologist placed Patient 2 under general anesthesia due to the necessity to perform a procedure unrelated to the suture removal.

25. When removing the sutures on Patients 1, 2, 4, 5, 6 and 9, the Respondent removed vagina mucosa[18] as well. The Respondent billed for the removal of the vagina mucosa for Patients 1, 2, 4, 5, 6 and 9. The vagina mucosa did not require examination in the pathology lab.

26. The Respondent performed a myomectomy on Patient 3. After completion of Patient 3's myomectomy, the Respondent recorded removal of 45 fibroids weighing more than 250 grams from Patient 3's uterus. The Respondent sent the fibroids to the pathology lab, which recorded receiving 25 fibroids weighing 510 grams.

27. After receiving the pathology report and later correctly documenting removal of 25 fibroids from Patient 3, the Respondent wrote a letter to Dr. Udoff stating he removed "40 plus" fibroids from Patient 3's uterus.

28. To maintain fertility in a patient, uterine fibroids must be removed.

29. Patient 3 wished to maintain her fertility. The Respondent discussed with Patient 3 the risk posed to her fertility by fibroids and the treatment of those fibroids. Patient 3 acknowledged she understood those risks.

30. The Respondent performed three procedures on Patient 3: the myomectomy, a follow-up procedure to address some complications, and a hysteroscopy. The Respondent performed the hysteroscopy of Patient 3's uterus to examine the condition of its interior and

[18] Granulation tissue which forms around the sutures.

determine the viability of fertility treatment. After the hysteroscopy, the Respondent referred Patient 3 to Dr. Udoff for a fertility consultation.

31. Dr. Udoff would have sent Patient 3 back to the Respondent had the Respondent not performed the hysteroscopy and determined the condition of Patient 3's uterus. The hysteroscopy procedure is low risk and its performance is not unusual.

32. On December 2, 2015, the Respondent performed a myomectomy on Patient 10 at his ASC. Patient 10 experienced severe pain after waking up from the myomectomy. The Respondent discharged her from the ASC around 8:00 p.m. the day of the myomectomy.

33. Patient 10 continued to experience severe pain in the days following her myomectomy. As a result, on December 9, 2015, her family transported her to the Emergency Room (ER) at [redacted]. The ER Staff at [redacted] spoke to the Respondent who requested Patient 10 be transferred to [redacted]. [redacted] transferred Patient 10 to [redacted] on December 9, 2015. When the Respondent first saw Patient 10 in her room at the [redacted] ICU, he immediately stated "this is overkill" upon entering the room. He then explained that he requested she be transferred to [redacted] because he did not trust the doctors at [redacted].

34. The Respondent was practicing medicine on all Patients at issue in the Board's charges.

35. The Respondent has privileges at [redacted] but not [redacted].

36. The Board previously disciplined the Respondent.

## DISCUSSION

The Board is Maryland's "governmental agency responsible for investigating and disciplining physicians for professional misconduct." *Cornfeld v. Bd. of Physicians*, 174 Md. App. 456, 481 (2007). "The Board's mission [is] to regulate the use of physician's licenses in Maryland in order to protect and preserve the public health." *Id.* at 481 (internal quotation marks and citations omitted). The purpose for the Board's disciplinary authority is to protect the public, not to punish physicians. *McDonnell v. Comm'n on Med. Discipline*, 301 Md. 426, 436 (1984).

The grounds for reprimand, probation, suspension, or revocation of a medical license under the Act include the following:

> (a) *In general.* – Subject to the hearing provisions of § 14-405 of this subtitle, a disciplinary panel, on the affirmative vote of a majority of the quorum of the disciplinary panel, may reprimand any licensee, place any licensee on probation, or suspend or revoke a license if the licensee:
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> . . . .
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> (3) Is guilty of:
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> . . . .
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> (ii) Unprofessional conduct in the practice of medicine;
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> . . . .
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> (19) Grossly overutilizes health care services;
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> . . . .
>
> (22) Fails to meet appropriate standards as determined by appropriate peer review for the delivery of quality medical and surgical care performed in an outpatient surgical facility, office, hospital, or any other location in this State;
>
> . . . .
>
> (40) Fails to keep adequate medical records as determined by appropriate peer review.

Health Occ. § 14-404(a)(3)(ii), (28) and (36).

The Board's charges against the Respondent, which I will address in turn, can be distilled to the following:

- That the Respondent engaged in unprofessional conduct in the practice of medicine by making inappropriate or inconsiderate comments to Patient 10 while she was in her hospital room;

- That the Respondent failed to meet the appropriate standards of care with regard to Patient 3 by performing three GYN surgeries on Patient 3 without referring her to a fertility specialist;
- That the Respondent failed to keep adequate medical records with regard to Patient 3 by inaccurately documenting the number and weight of fibroids removed during Patient 3's myomectomy;
- That the Respondent failed to meet the appropriate standards of care with Patients 1, 2, 4, 5, 6 and 9 by, after performing their hysterectomies, suturing their vaginal cuffs with removable, instead of absorbable, sutures. That the Respondent failed to meet the appropriate standard of care by using removable sutures that required Patients 1, 2, 4, 5, 6 and 9 to return for a second procedure that required anesthesia;
- That the Respondent grossly overutilized health care services by suturing Patients 1, 2, 4, 5, 6 and 9 with removable sutures, which required a second procedure.
- That the Respondent grossly overutilized health care services by billing for ligation of the uterine artery during the hysterectomies performed on Patients 1, 2, 4, 5, 6 and 9 when that procedure is typically part of the hysterectomy procedure already billed;
- That the Respondent failed to keep adequate medical records with regard to Patients 1, 2, 4, 5, 6 and 9 by removing granulation tissue when he removed their sutures and billing for a biopsy of the granulation tissue, but not sending the granulation tissue to the pathology lab;

- That the Respondent failed to keep adequate medical records with regard to Patients 1, 2, 4, 5, 6 and 9 by not documenting the placement of removable Ethibond sutures in their charts; and
- That the Respondent engaged in unprofessional conduct in the practice of medicine by conducting human subject research on Patients 1, 2, 4, 5, 6 and 9 without IRB approval.

**The charges concerning Patient 10**

The Board called Patient 10 as a witness in support of the charges related to her. Patient 10 testified that the Respondent performed a myomectomy on her on December 2, 2015. In the days that followed, Patient 10 called the Respondent's office several times to report severe pain. After she changed medications to no avail, she went to the ER at [redacted], which admitted her shortly after midnight on December 9, 2015. However, around 9:00 or 10:00 a.m. that same morning, [redacted] transferred Patient 10 to the [redacted] ICU at the Respondent's request. When the Respondent arrived at Patient 10's room at the [redacted] ICU, he immediately said, "This is overkill." He then remarked, "Oh, I had to get you out of [redacted]" and expressed a distrust of the staff at [redacted].

Patient 10 testified that she took the Respondent's "overkill" statement as a mockery of her condition and felt the Respondent implied she was exaggerating her level of pain. She further did not understand why the Respondent needed to transfer her to [redacted]. She felt the staff at [redacted] took genuine good faith efforts to address her pain level and determine its source. The Respondent's comment besmirched those efforts.

The Respondent called Dr. Fitzpatrick, who I qualified as an expert in professional conduct pursuant to section 14-404(a)(3)(ii) of the Health Occupations Article (unprofessional care in the practice of medicine), as it relates to general communications between patient and

physician. Dr. Fitzpatrick testified that he has worked as a surgeon for over thirty years. As of the date he testified, Dr. Fitzpatrick was the chairman of surgery at [redacted]. Part of Dr. Fitzpatrick's duties as chairman of surgery concern reviewing the conduct of members of his staff, a duty he has performed for thirty years.

With regard to the Respondent's statement to Patient 10 about "overkill," Dr. Fitzpatrick opined that the Respondent did not act unprofessionally in making the comment. Dr. Fitzpatrick testified that he would expect any physician in the State of Maryland to provide their honest opinion about a matter concerning the Patient's welfare. He further testified that the term "overkill" is a generic term used by physicians when they believe a patient is receiving more care than required. Finally, Dr. Fitzpatrick opined that transfers from hospital to hospital are not uncommon. Physicians often wish to see their own patients since they are most familiar with them. However, Dr. Fitzpatrick added on cross examination that when transferring patients, he tends to stress the positive aspects of the new hospital and refrains from disparaging the old hospital.

The Respondent testified he did not specifically recall making the "overkill" comment, but did not deny making it. On the date Patient 10 was transferred to the [redacted] ICU, she was diagnosed upon transfer with an abscess. The Respondent needed to consider various options to address Patient 10's condition. However, when he arrived at [redacted] and reviewed Patient 10's chart, the Respondent found no signs of the presence of an abscess. He opined that Patient 10 more likely suffered from a hematoma. He testified that after a myomectomy, it is not uncommon to accidentally diagnose an abscess instead of a hematoma.[19] A hematoma requires less aggressive treatment than an abscess, thus when the Respondent saw Patient 10 being treated for an abscess as opposed to a hematoma, he remarked the treatment was "overkill."

[19] The Respondent defined abscess as "technically a collection of puss. It's an infection and it can be a severe infection." He defined hematoma as "a collection of blood." Tr. vol. 5, at 743.

With regard to his request that Patient 10 be transferred from [redacted] to [redacted], the Respondent testified that he lacked privileges at [redacted]. Even if he did have privileges at [redacted], the Respondent testified he is familiar with the staff at [redacted]. He knows the surgeons and interventional radiologists. He knows the doctors who can best address his patients' diagnosis.[20]

I found Patient 10's testimony sincere and credible. Her testimony was consistent with her statements in her complaint, and I do not find she embellished any of her allegations. However, Patient 10's testimony, along with her complaint, essentially constitutes the sum total of the State's case concerning these charges. Ostensibly, the State contends that because the Respondent's comments[21] were inappropriate or inconsiderate from Patient 10's own subjective viewpoint, the Respondent provided unprofessional care in the practice of medicine. Accepting the State's position means accepting the notion that if any patient feels a physician's comment or comments are inappropriate, that physician is guilty of unprofessional care in the practice of medicine. That is a slippery slope.

I did not find Dr. Fitzpatrick's testimony abundantly helpful. Dr. Fitzpatrick, while highly skilled and experienced, testified in generalities as to the Respondent's comments.[22] His testimony failed to apply those comments to the context of Patient 10's particular experience. I give greater weight to the Respondent's testimony on this issue. I found the Respondent's testimony on this particular issue heartfelt and sensible. He provided reasonable and rational explanations as to why he made the comments. He did not disparage Patient 10 either in his response to the Board or his testimony.

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[20] On or about August 2, 2016, the Respondent provided the Board with a Response to Patient 10's complaint. Bd. Ex. 6.

[21] To be clear, my analysis is confined only to two comments made by the Respondent: 1) his "overkill" comment and 2) his explanation as to why he transferred Patient 10 from [redacted] to [redacted].

[22] Given Dr. Fitzpatrick's report (Resp. Ex. 2) consists mostly of opinions on charges related to Patient 10, which the State dropped, it is clear his expertise is more focused on issues other than professionalism.

Patient 10 was in obvious distress. However, viewing the Respondent's particular comments from a purely objective standpoint, I do not find they rise to the level of unprofessional care in the practice of medicine. Accordingly, I shall recommend the charges with regard to Patient 10 be dismissed.

**The charges concerning Patient 3**

CareFirst's complaint to the Board focused on the Respondent's use of Ethibond sutures in Hysterectomies. However, when reviewing the ten patient records, Dr. Rafi, the Board's peer reviewer, raised concerns unrelated to CareFirst's complaint. Those concerns resulted in the charges related to Patient 3. The Respondent performed three procedures on Patient 3 to address uterine fibroids and some associated complications. However, he left her uterus intact. Dr. Rafi's review raised the following concerns: 1) that the Respondent performed three surgeries on Patient 3 without first addressing her fertility concerns (failure to maintain the standard of quality care) and 2) that the Respondent inaccurately counted and measured the fibroids he removed from Patient 3's uterus (failure to keep adequate medical records).

The issue of Patient 3's Fertility

On September 11, 2014, the Respondent performed an ultrasound of Patient 3's uterus. That ultrasound revealed eleven fibroids varying in size from two to five centimeters. On October 3, 2014, the Respondent performed a myomectomy on Patient 3 and removed fibroids.[23] The Respondent then saw Patient 3 for a follow-up visit on October 22, 2014. At that time he advised Patient 3 that a hysteroscopic evaluation of her uterus would be necessary to rule out, among other things, adhesions to the uterus. The Respondent also discussed with Patient 3, at length, the risks to her fertility associated with treatment of her fibroids.[24] On January 16, 2015,

[23] The amount and weight of fibroids removed shall be specifically addressed in the portion of this discussion concerning the Respondent's failure to keep adequate medical records with regard to Patient 3.
[24] Bd. Ex. 14, at PM 3886.

the Respondent performed a follow-up surgery on Patient 3. In this surgery the Respondent laparoscopically performed a lysis of adhesions in Patient 3's uterus, repaired a rupture in Patient 3's uterus (Hysterrorhaphy), and a chromopertubation to determine whether the fallopian tubes were blocked or open. On July 17, 2015, the Respondent performed a third procedure, a hysteroscopy. During this procedure, the Respondent inserted a tube into Patient 3's uterus, to examine the condition of its lining. On July 23, 2015, the Respondent referred Patient 3 to Dr. Udoff for a consultation concerning In Vitro Fertilization.

In support of its charge of failure to maintain the standard quality of care on this issue, the State called Dr. Rafi, the peer reviewer, as its expert witness. Dr. Rafi is the interim chair of the OB/GYN department at [redacted]. She completed her OB/GYN residency in 2000 and has been a practicing physician in that field since that time. In particular, since at least 2012, Dr. Rafi has been the Minimally Invasive Director for the OB/GYN department at [redacted]. In that role she teaches laparoscopic skills and assists in GYN surgeries. She credentials all new providers on advanced laparoscopic skills. Dr. Rafi is skilled in performing both hysterectomies and myomectomies. She has published articles on OBY/GYN and public health issues.

Dr. Rafi testified she reviewed Patient 3's records and opined that the Respondent did not meet the standard quality of care when he performed the third procedure, the hysteroscopy, on Patient 3. She opined that he should have sent her to a fertility specialist first. At the time of the third surgery Patient 3 was thirty-seven years old and expressed a desire to possibly bear children in the future. Dr. Rafi opined that performing an invasive procedure such as a hysteroscopy on Patient 3's uterus ran the risk of creating more scar tissue on the center of the uterus. The scar tissue could further compromise Patient 3's already precarious chances of conceiving. Further, the hysteroscopy exposed Patient 3 to another round of anesthesia, subjecting her to additional

risk. Dr. Rafi suggested other non-invasive procedures as better alternatives to exploring the condition of the interior of Patient 3's uterus. She suggested a uterine biopsy or a hysterosalpingogram (HSG)[25] as alternatives and opined that those procedures or similarly less invasive ones would be the standard of care.[26]

In support of his case, the Respondent called Dr. Udoff as his expert. Dr. Udoff is board certified in OB/GYN and is a subspecialist in endocrinology and infertility. He completed his formal training in 1997. He has taught courses on infertility and reproductive issues at the University of Maryland and the University of Utah. In addition, he has published articles on infertility issues.

Dr. Udoff did not agree that the Respondent breached the standard of quality care by not referring Patient 3 to a fertility specialist prior to the third surgery. First, Dr. Udoff testified that management of fibroids takes precedence over fertility. Thus, if the Respondent referred Patient 3 prior to assessing the condition of Patient 3's uterus, Dr. Udoff would have sent Patient 3 back to the Respondent so the Respondent could complete that task. Not fully addressing a patient's fibroids can result in fertility and conception complications such as miscarriage.

In terms of the procedure used to explore the uterus to determine viability for fertility, Dr. Udoff opined that the Respondent had several choices. However, he disagreed with Dr. Rafi that HSG would be the preferred procedure. Dr. Udoff testified that HSG is an older technology with a lower rate of sensitivity and thus a high chance of missing a clinically significant finding. HSG is still used and does allow a physician to see inside the uterus, see defects, and see if the

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[25] HSG is "a special x-ray using dye to look at the womb (uterus) and fallopian tubes." *MedlinePlus*, https://medlineplus.gov/ency/article/003404.htm (last visited Aug. 28, 2019).

[26] Prior to calling Dr. Udoff to the stand, Counsel for the Respondent moved to strike Dr. Rafi's testimony with regard to HSG and other alternatives to hysteroscopy. Counsel argued Dr. Rafi made no such claim in her report and the State made no such allegation in its charging document. The State countered, in short, that the charging document provided the Respondent with adequate notice of the State's case. I advised the parties I would take the motion under advisement and address it in this decision. Having had the opportunity to carefully consider Dr. Rafi's testimony I find it to be reasonably in accord with paragraph 33a in the charging document. Accordingly, the Respondent's Motion to Strike is denied.

fallopian tubes are open. However, HSG provides only a few angles of the uterus and is prone to providing false positives, especially with regard to fallopian tube blockages.

Dr. Udoff testified an HSG in Patient 3's case would be purely diagnostic. If uterine abnormalities are discovered, then another procedure, a hysteroscopy, would need to be performed. By performing a hysteroscopy at the outset, a physician could address the abnormalities during the hysteroscopy (i.e. provide treatment through the hysteroscope). Dr. Udoff conceded, however, that the hysteroscopy procedure was riskier than the HSG; however, any risk associated with the hysteroscopy was low. Dr. Udoff did not testify that the Respondent's choice of performing the hysteroscopy on Patient 3 was unusual in any way. In his report, Dr. Udoff noted that the Respondent counselled Patient 3 on her various treatment options. Thus, Patient 3 could have chosen a different treatment path. Dr. Udoff found the approach the Respondent took to be reasonable under the circumstances.

On this issue, I give more weight to Dr. Udoff's opinion than I do to Dr. Rafi's. While I found Dr. Rafi's concerns to be reasonable and well based in her expertise, she seemed to constrain her opinion to the issue of whether the hysteroscopy was riskier than the HSG. Her opinion was a conclusion without much detail. Dr. Udoff provided detailed testimony about the advantages and disadvantages of each procedure. He provided an informed opinion as to why the Respondent took a reasonable tact in treating Patient 3. I heard no evidence that the hysteroscopy procedure is rarely or never used by OB/GYNs under the same circumstances as Patient 3. I further heard no evidence that the hysteroscopy procedure presents a more than minimal risk to the Patient (from the standpoint of fertility or otherwise). Additionally, Dr. Udoff steadfastly testified, as a fertility specialist, that he would have sent Patient 3 back to the Respondent until the Respondent was assured the fibroids and health of Patient 3 were adequate. Patient 3's records reflect that the Respondent discussed the risks to her fertility in light of her fibroids. Bd.

Ex. 13, at PM 3864. The State presented no evidence to call that into question. Accordingly, I shall recommend the charge of failure to maintain the standard quality of care with regard to Patient 3 be dismissed.

The issue of the Respondent's accounting of Patient 3's fibroids

When reviewing Patient 3's records, Dr. Rafi noted discrepancies in how the Respondent recorded the amount and weight of the fibroids he removed from Patient 3's uterus. The Respondent performed Patient 3's myomectomy on October 3, 2014. In his operative note, the Respondent noted Patient 3 had "5 or more intramural myomas and/or intramural myomas with total weight greater than 250g."[27] Bd. Ex 13, at PM 3854. In the same operative note, the Respondent notes removal of forty-five fibroids from Patient 3. In a report completed on October 8, 2014, the Pathologist notes the Respondent removed twenty-five fibroids with an aggregate weight of 510 grams. *Id.* at PM 3856. However, in a chart note dated October 22, 2014, the Respondent notes the removal of forty-five fibroids from Patient 3. *Id.* at PM 3858. In a chart note from July 6, 2015, the Respondent notes the removal of twenty-five fibroids, consistent with the Pathologist's report. *Id.* at PM 3864. However, in a letter to Dr. Udoff dated July 23, 2015, the Respondent references the removal of forty plus fibroids from Patient 3. *Id.* at PM 3867. Dr. Rafi testified that the responsibility for accurately documenting the size and weight of the fibroids falls upon the Respondent. The discrepancy between the amount and weight of the fibroids documented by the Respondent and the Pathologist is indicative of the Respondent's failure to maintain adequate medical records. This would be important in the case of a patient like Patient 3 since the amount of fibroids may play a role in how her fertility treatment is approached by fertility specialists to whom the Respondent might refer Patient 3.

[27] If her testimony is understood correctly, Dr, Rafi took this to mean each myoma was 250 grams or more.

The Respondent called Dr. Kondrup and Dr. Udoff to provide opinions on this issue. Dr. Kondrup completed his OB/GYN training in 1988. He is board certified in OB/GYN and has served as both a treating physician and an assistant clinical professor of medicine. Dr. Kondrup has published numerous articles on the subject of OB/GYN surgery. Dr. Kondrup testified that when removing fibroids, due to time constraints, the surgeon does not weigh the fibroids. That task is left to the Pathologist. With regard to counting the fibroids, Dr. Kondrup wrote the following in his report:

> At the time of removal, the surgeon makes an estimate in both weight and number [of fibroids]. The surgeon always relies upon the pathologist for the exact number of small fibroids, and the exact weight of the fibroids when they are together for weighing. . . . When removing as many fibroids as were removed in Patient 3, it is common practice to make an estimate of the number of fibroids removed in the OR and leave the exactitude of the number and weight to the pathologist.

Resp. Ex. 7, at 4.

At the hearing, Dr. Kondrup testified that a surgeon might specifically count the number of fibroids removed if he or she knows in advance how many should be removed:

> You estimate what you do. Sometimes we'll count fibroids just to be sure we don't leave them inside the abdomen. So, for example, the – the nurse will put on a board a little score list. So, we took out 13, we went to get 13 out of the body. Every surgeon is different. Once we get 12 and we spent the next hour looking for number 13, which we eventually found.

Tr. vol. 4, at 527.

Dr. Udoff testified that in terms of Patient 3's treatment, the removal of twenty-five or forty-five fibroids was irrelevant given the Patient's overall diagnosis of a "massively enlarged fibroid uterus."[28] At no point did Dr. Udoff testify that the removal of forty-five versus twenty-five fibroids from Patient 3's uterus is significant to any future fertility treatment. At the hearing,

[28] In his report, Dr. Udoff does question why the operating note lists forty-five fibroids removed while the pathology report lists twenty-five removed. Resp. Ex. 9, at 1. However, he does not conclude that discrepancy is indicative of a failure to maintain accurate records on the part of the Respondent.

the Respondent testified he relies on the Pathologist for the weight of the fibroids. However, he maintained he estimated he removed approximately forty-five fibroids from Patient 3.

On the issue of the counting of fibroids in the OR, I am more persuaded by Dr. Kondrup's testimony than I am by Dr. Rafi's testimony. I found Dr. Rafi's testimony on this issue to be conclusory. She provided little detail as to how she arrived at the conclusion the physician bears the responsibility for accurately accounting for the weight and number of fibroids in the OR. In contrast, Dr. Kondrup provided more detail regarding the rationale as to why a GYN surgeon might estimate the amount of fibroids, and when he or she might need to be more accurate. Both Dr. Kondrup and Dr. Udoff provided sound opinions as to why, in the instance of Patient 3, the Respondent's accuracy in counting and weighing the fibroids in the OR was not critical, and why he appropriately relied upon the pathology report.

However, questions still remain as to whether the Respondent maintained accurate records with regard to Patient 3. There is no dispute that on October 3, 2014, the Respondent initially estimated he removed forty-five fibroids from Patient 3. There is no dispute that the October 8, 2014 pathology report lists twenty-five fibroids removed from Patient 3. At no point during the proceedings did the Respondent take the position the pathologist erred in listing twenty-five fibroids. He presented no evidence to question the accuracy of the pathology report. He, in turn, did not explain why his subsequent treatment notes are not consistent with the pathology report. In his October 22, 2014 chart note, he incorrectly lists forty-five fibroids. In his July 6, 2015 chart note, he correctly lists twenty-five fibroids. However, approximately two weeks later in a July 23, 2015 referral letter to Dr. Udoff, the Respondent incorrectly reports he removed "forty plus" fibroids from Patient 3.

If the Respondent takes the position that he relies on the pathology report for an accurate accounting of the fibroids, then his records with regard to Patient 3 should consistently reflect the pathology report's findings. They don't. While it is understood that the specific number of fibroids removed from Patient 3 might be irrelevant to her overall treatment, that does not absolve the Respondent of his duty to accurately maintain Patient 3's records. I find this to be particularly true with regard to the Respondent's referral to Dr. Udoff. While the specific number of fibroids may not have been a concern of Dr. Udoff's with regard to Patient 3, that might not be the case with regard to other patients. Such a lack of attention to detail if applied to other patients could be to their detriment. Accordingly, I shall uphold the charge of failure to keep adequate medical records as it relates to Patient 3.

**The charges concerning Patients 1, 2, 4, 5, 6 and 9**

Dr. Rafi examined the charts of Patients 1, 2, 4, 5, 6 and 9 (collectively "the suture patients") in light of CareFirst's complaint with regard to the Respondent's use of non-absorbable Ethibond sutures in Hysterectomies. Based on Dr. Rafi's review of the charts, the Board alleged the Respondent failed to meet the appropriate standards of care with the suture patients by suturing their vaginal cuffs with non-absorbable (Ethibond) sutures, instead of absorbable (Vicryl) sutures. The Board alleged the Respondent failed to meet the appropriate standard of care and grossly overutilized health care services by using Ethibond sutures because a second procedure was required to remove the Ethibond sutures that involved, among other things, placing the sutures patients under anesthesia. The Board alleged the Respondent grossly overutilized health care services by billing the suture patients separately for ligation of the uterine artery when performing their hysterectomies. The Board alleged the Respondent failed to keep adequate medical records with regard to the suture patients because, during the procedures to remove the Ethibond sutures, the Respondent billed the suture patients' insurance for a biopsy

of removal of granulation tissue, but did not send that tissue to the pathology lab. The Board alleged the Respondent further failed to note his use of the non-absorbable Ethibond sutures in charts of all but one of the suture patients. Finally, the Board alleged the Respondent engaged in unprofessional conduct in the practice of medicine by conducting prospective human subject research on the suture patients without obtaining IRB approval. I find the Respondent's treatment of the suture patients, as it relates to the Board's charges, can be categorized as follows:

| | Patient 1 | Patient 2 | Patient 4 | Patient 5 | Patient 6 | Patient 9 |
|---|---|---|---|---|---|---|
| Date of Hysterectomy | 11/6/14 | 12/31/14 | 11/25/14 | 12/11/14 | 2/4/15 | 12/31/14 |
| Ethibond used to close the vaginal cuff? | YES | YES | YES | YES | YES | YES |
| Written consent for Ethibond signed at Hysterectomy procedure? | NO | YES | NO | YES | YES | YES |
| Uterine Artery Ligation procedure performed with Hysterectomy? | YES | YES | YES | YES | YES | YES |
| Uterine Artery Ligation procedure billed separately to the Patient's insurance under CPT code 37617? | YES | YES | YES | YES | YES | YES |
| Date of Ethibond removal procedure | 2/12/15 | 4/2/15 | 2/26/15 | 3/13/15 | 5/8/15 | 4/1/15 |
| Days between Hysterectomy and Ethibond removal procedures | 99 | 93 | 94 | 93 | 94 | 92 |
| Written consent to perform Ethibond removal procedure signed the date of that procedure? | YES | YES | YES | YES | YES | YES |
| Time of removal procedure | 14:13 to 14:16 | 9:44 to 10:47 | 12:12 to 12:17 | 13:17 to 13:23 | 8:54 to 8:59 | 10:27 to 10:31 |
| Muscosa removed? | YES | YES | YES | YES | YES | YES |
| Vicryl sutures placed at Ethibond removal procedure? | YES | YES | YES | YES | YES | YES |
| Anesthesia used during Ethibond removal procedure[29] | MAC | GEN | MAC | IV[30] | MAC | MASK[31] |

[29] All information regarding anesthesia type is taken from the Patients' Anesthesia Interoperative Record (AIR). The corresponding operative reports for all suture Patients not consistent with the AIR. The operative reports list the anesthesia used as Laryngeal Mask Anesthesia (LMA). The AIR and operative report for Patient 2 are consistent in reporting the use of General Anesthesia.

[30] Dr. Mesrobian testified he was unaware of why IV was checked on the AIR and implied it was a mistake. He opined based on the records that Patient 5 was not placed under general anesthesia. Tr. vol. 4, at 486.

[31] Like with Patient 5, Dr. Mesrobian did not know why MASK was checked on the AIR or what it meant. But he opined, based on Patient 9's records, that she was not placed under general anesthesia. *Id.* at 490.

57105 "Biopsy of Vagina"

Dr. Rafi testified that during the second surgery to remove the Ethibond sutures (second surgery), the Respondent billed CPT code 57105 for "Biopsy of Vagina." This signified the Respondent removed vagina mucosa[32] during the procedure. Dr. Rafi testified that none of the suture patients' records contained a lab report from a pathologist concerning the removal of the vagina mucosa. Dr. Rafi opined that "biopsy" connotes the sending of the removed tissue to the pathology lab. The absence of a pathologist's report corresponding to that biopsy amounts to a failure to keep adequate medical records on the part of the Respondent.

Dr. Kondrup testified on behalf of the Respondent on this issue. Dr. Kondrup opined that biopsy simply means removing tissue. Therefore, if the Respondent removed the vagina mucosa, then he billed the correct code for biopsy of the vagina mucosa. Dr. Kondrup went on to opine that he rarely, if ever, sends vagina mucosa to pathology unless the patient has a history of cancer. To send every sample without any suspicion of abnormality would be an unnecessary cost to the patient. The Respondent testified that he removed the vagina mucosa, but did not send it to the pathology lab, because the patient would incur an additional $100.00 charge. The Respondent testified he knows the vagina mucosa derives from the placement of the sutures and is thus benign. Therefore he did not need to send the vagina mucosa to the pathology lab.

Having reviewed the evidence on this issue, I agree with the Respondent. The Respondent removed the vagina mucosa as part of the procedure to remove the Ethibond sutures and billed for its removal. Other procedures at issue in this case involve sending tissue to the pathologist. For example, Patient 3's myomectomy took place on October 3, 2014. The Respondent sent Patient 3's fibroids to the pathologist. The pathologist issued a report on October 8, 2014. There is no code for "biopsy" of anything in Patient 3's billing records

[32] Granulation tissue that the Respondent removed when removing the Ethibond sutures.

regarding the removal of the fibroids. However, the Respondent clearly sent the fibroids to the pathologist. The pathologist generated a report and no doubt issued her own bill to Patient 3. With regard to the suture patients, the Respondent exercised his professional judgment and declined to send the vagina mucosa to the pathologist. I find no evidence in the record to question that judgment. While the Respondent did use CPT code 57105 "biopsy of vagina," the word "biopsy" appears to be a misnomer in the billing records. Dr. Rafi testified repeatedly she was "confused" by the use of code 57105 – but I heard no evidence that the Respondent should have billed a different code for this procedure. Accordingly, I shall recommend the charges with regard to this issue be dismissed.

37617 "Ligation of the Abdominal Artery"

In her peer review report and her testimony at the hearing, Dr. Rafi questioned why the Respondent billed CPT code 37617 for ligation of the abdominal artery in conjunction with the hysterectomies he performed on the suture patients. Dr. Rafi opined that ligating the uterine artery[33] to curtail blood loss during a hysterectomy is part and parcel to the entire procedure. Accordingly, the ligation and hysterectomy should be billed together and not "unbundled" and billed separately as the Respondent did with the suture patients. Ligation of the abdominal artery by entering the retroperitoneal space is a more complicated procedure. The procedure requires the surgeon to ligate the artery at a higher space, which is a safer way to perform a hysterectomy. Performing this specific procedure, however, requires advanced training. Although ligation of the abdominal artery is a more sophisticated procedure requiring advanced training, Dr. Rafi opined that the Respondent should only have billed CPT code 58554, which is the code for the hysterectomy procedure itself – not 58554 and 37617. Dr. Rafi opined that even if the surgeon were to ligate the internal iliac artery, which is an artery not attached to the uterus, but in

[33] The major artery supplying blood to the uterus. Tr. vol. 1, at 132.

conjunction with the uterine artery, he or she would still not bill a separate code for the ligation, because the ligation is still a required part of the procedure.

The Respondent called Dr. Kondrup and Terri Welter (Ms. Welter), a principal at ECG Management, a consulting firm for the healthcare industry. Dr. Kondrup explained the procedure associated with the ligation of the abdominal artery and vaguely testified that he reviewed the Respondent's billing contracts and agreed with them. Ms. Welter testified she assists with managed care contract negotiations and deals with relationships between providers and payors.

Ms. Welter testified that the Respondent engaged her firm in the summer of 2016 to assist in contract negotiations with insurers, including CareFirst. During the negotiations, she performed a "look back" to 2010 at the procedures for which the Respondent billed. The "look back" included procedures the Respondent billed to CareFirst. Ms. Welter explained that codes in the 50,000 range concern OB/GYN procedures and codes in the 30,000 range concern cardiac procedures. It is not common for an OB/GYN specialist such as the Respondent to use codes in the 30,000 range. However, in performing the look back, Ms. Welter discovered that the Respondent treats complex cases and his contracts historically allowed him to bill code 37617. In particular, Ms. Welter testified, "So as I understood, -- there's very complex cases where you would have large fibroid tumors that would require for ligation of the artery to be done in a separate space." Tr. vol. 5, at 633. Ms. Welter further testified that under the National Correct Coding Initiative (NCCI), billing code 37617 with code 58554 or other hysterectomy codes was allowable.

The Respondent provided a somewhat different rationale for performing the ligation of the abdominal artery and billing code 37617 as a separate procedure. The Respondent testified that he ligates the internal iliac artery when performing hysterectomies at his ASC. The ASC does not have a blood bank or an ICU and thus taking the extra precaution of ligating the internal

iliac artery and lessening the chances of blood loss makes the procedure safer in the ASC setting. The Respondent testified that the average weight of a uterus is 70 grams.[34] However, the uteri he removes at his ASC are routinely much larger and trickier to address. In addition, the Respondent asserted that CareFirst allowed the Respondent to place code 37617 in his "ASC column," thus allowing him to treat patients at the ASC.[35]

The parties agree that 37617 is a code that concerns a procedure whereby a provider ligates an artery outside the area of the uterus to cut off blood flow to the uterus and safely perform a hysterectomy. The parties agree that performing this procedure requires specialized knowledge and training, which the Respondent possesses. The parties further agree that 37617 is a separate code from the codes associated with hysterectomies. The disagreement between the parties appears to be a) whether the Respondent's contract with CareFirst authorized him to bill 37617 in addition to the general hysterectomy codes and b) if so, whether the Respondent's billing of code 37617 was appropriate under the terms of his contract with CareFirst.

The Respondent submitted his schedules and contracts with CareFirst and other insurers as Resp. Ex. 35. The schedules in Resp. Ex. 35, which go back to 2009, all include code 37617 as a billable procedure. The exhibit also contains snapshots of searches on CareFirst's website from June 20, 2013, showing code 37617 as a billable procedure. Resp. Ex. 35, at 95.

Paragraph 1.6 of the Respondent's contract with CareFirst defines "medically necessary" as follows:

> MEDICALLY NECESSARY describes the use of a service or supply which is commonly and customarily recognized as appropriate in the diagnosis and treatment of a Member's illness or injury; appropriate with regard to standards of good medical practice; not solely for the convenience of the member, his or her physician, Hospital, or other health care provider; and the most appropriate supply or level of service which can be safely provided to the Member. The decision as

[34] The State presented no evidence to contradict this assertion.
[35] The Respondent then went on to testify about the cost saving associated with treating patients at the ASC versus the hospital. I find this testimony, while interesting, to be irrelevant to the issue before me.

to whether a service or supply is Medically Necessary for purposes of payment by Corporation rests with Corporation's Medical Director or his or her designee, however, such a decision will in no way affect Group's[36] determination of whether medical treatment is appropriate as a matter of medical judgment.

Paragraph 2.3 of the Respondent's contract with CareFirst, entitled "Standards of Care," reads as follows:

> Group will provide services to members in accordance with the professional standards of care with which such services are furnished to all persons treated by Group. The quality and availability of services will be no less than the quality and availability of services provided to all persons treated by Group.

Paragraph 2.4 of the Respondent's contract with CareFirst, entitled "Relationship with Members," reads as follows:

> Corporation will not be liable for nor will it exercise control or direction over the methods or professional judgments relied upon by Group and Group's employees or representatives in providing services pursuant to this Agreement. Group will be solely responsible for supervising and controlling Group's employees or representatives to assure that such services are provided in a manner that complies with generally accepted standards of care.

Paragraph 5.9 of the Respondent's contract with CareFirst entitled "Claim Payment" reads in pertinent part as follows:

> Corporation shall pay any claim within forty (40) days of receipt of the claim except where the obligation of Corporation to pay a claim is not reasonably clear due to the existence of a reasonable basis supported by specific information available for review by Group that:
>
> a. The claim is determined by Corporation not to be a clean claim due to a good faith determination or dispute regarding (i) the manner in which the claim form was completed or submitted, (ii) the eligibility of Member for coverage, (iii) the responsibility of another carrier for all or part of the claim, (iv) the amount of the claim or the amount currently due under the claim, (v) the benefits covered, or (vi) the manner in which services were accessed or provided; or
> b. The claim was submitted fraudulently

With regard to the suture patients, the Respondent performed all procedures at his ASC.

[36] Defined as the licensed health care practitioner (i.e. the Respondent).

The weights[37] of the uteri removed from the suture patients were as follows:

Patient 1 - 184 grams (Bd. Ex. 7, at PM 3672)

Patient 2 - 620 grams (Bd. Ex. 11, at PM 3762)

Patient 4 - 155 grams (Bd. Ex. 17, at PM 4063)

Patient 5 - 150 grams (Bd. Ex. 19, at PM 4118)

Patient 6 - 43.9 grams (Bd. Ex. 22, at PM 4204)

Patient 9 - 459 grams (Bd. Ex. 31, at PM 4392)

With the exception of Patient 6, all uteri are at least twice the weight of an average seventy gram uterus. Looking at this data from the suture patients and assuming the Respondent's contract with CareFirst allowed him to bill code 37617 for larger uteri at the ASC, or when just performing procedures at the ASC, the Respondent appears to have, in general, appropriately billed code 37617. The language of the Respondent's contract with CareFirst seems to allow him leeway with regard to making informed medical decisions in the best interests of his patients. However, per the contract, those decisions are subject to review and veto by CareFirst.

At the hearing, the State, on cross examination, questioned both the Respondent and Ms. Welter concerning a peer review CareFirst performed in 2015 of the Respondent's billing of code 37617 (2015 peer review). The State alleged that as a result of the 2015 peer review, CareFirst ultimately denied billing for code 37617. Both Ms. Welter and the Respondent denied knowledge of the 2015 peer review one way or another. I did not find their testimony on this issue credible. Ms. Welter performed her "look back" in 2016. I do not find it credible that the look back would not reveal the presence (or absence) of the 2015 peer review. The Respondent testified clearly and concisely about his billing practices and procedures. However, when

[37] As determined in the pathology report associated with each suture patient.

questioned by the State about the 2015 peer review, his testimony took a seismic shift toward ignorance and befuddlement. I do not find it credible the Respondent would not be aware of the 2015 peer review, especially since it concerned a procedure integral to his practice at the ASC. Thus, I find CareFirst performed some form of peer review in 2015. At the hearing, Counsel for the Respondent objected to the State cross examining Ms. Welter and the Respondent about the 2015 peer review. I overruled the objection. The Respondent and Ms. Welter testified that the Respondent's contract with CareFirst allowed him to bill 37617 in conjunction with hysterectomies. I found the simple question of whether or not they knew CareFirst performed a peer review in 2015 appropriate in light of that testimony.

The more important questions are what was the exact nature of the 2015 peer review and if CareFirst denied billing for code 37617 as a result of that peer review, why? The State chose not to answer those questions in its case in chief. It did not call any representatives from CareFirst. It neither listed the 2015 peer review documents in its prehearing statement nor listed them as an exhibit. Instead the State attempted to introduce the 2015 peer review documents on cross examination of the Respondent as rebuttal. The Respondent objected, and I sustained the objection.

I find the State could have, and should have, introduced the 2015 peer review documents in its case in chief. The issue of whether the Respondent properly billed code 37617 in light of his contract with CareFirst goes to the heart of this particular charge. Whether any contractual dispute the Respondent may have had with CareFirst over billing code 37617 rises to a level of what the Board alleges in its charging document is unknown. Given CareFirst is the party who filed the complaint with the Board, there is no doubt the State could have called a representative from CareFirst in its case in chief. That witness could have testified not only about the 2015 peer review documents, but also the general propriety of the Respondent billing of code 37617.

In addition, I find the State had nothing to rebut. Had Ms. Welter and the Respondent testified as to the specific contents of the 2015 peer review on direct examination by Respondent's counsel, that might be the case. However, they provided no such testimony. The Respondent's testimony on this issue was, for the most part, consistent with his written response to the Board, which the State had the opportunity to review well in advance of the hearing. Bd. Ex. 42. In light of that, the State could have presented the evidence in its case in chief.

As stated above, the Respondent had a contract to bill code 37617. In light of the evidence presented, there is nothing in the record to lead me to believe he inappropriately billed code 37617 with regard to the suture patients. I only find evidence of some vague contractual dispute between the Respondent and CareFirst. Accordingly, I shall recommend the charges with regard to code 37617 be dismissed.

The placement of the Ethibond Sutures

*The State's Case*

Dr. Rafi testified that her review of the charts revealed that the Respondent used non-absorbable Ethibond sutures to close the vaginal cuffs of the suture patients after performing their hysterectomies. Dr. Rafi opined that since at least 1996, the standard of care in suturing the vaginal cuff was the use of absorbable sutures, in particular absorbable Vicryl sutures. The reason the standard of care is to use absorbable as opposed to non-absorbable sutures concerns the necessity of having the patient return for a second surgery. Dr. Rafi noted that the second surgery required most[38] of the suture patients to undergo Monitored Anesthesia Care (MAC) which, while not rendering the patients as unconscious as general anesthesia (which is the highest level of anesthesia), still placed the patients in "twilight sleep" and not far from the level

[38] As noted in the chart above, Patient 2 underwent general anesthesia due to the Respondent performing certain additional procedures unrelated to the removal of the Ethibond sutures. Patient 5 underwent IV, which is less than general anesthesia, and Patient 9 underwent MASK which is less than general.

of general anesthesia. In addition, the removal of the Ethibond sutures and/or the removal of vagina mucosa caused bleeding, which required the Respondent to place an additional Vicryl suture in the suture patients even after removing the Ethibond sutures. Dr. Rafi noted, with the exception of Patient 1 and Patient 4, the suture patients signed a consent form the day of their hysterectomy wherein they acknowledged and consented to the placement of Ethibond sutures. However, Dr. Rafi noted that the charts revealed no evidence the Respondent counseled the suture patients on the risks and benefits of using Ethibond versus Vicryl sutures.

Dr. Rafi further testified that her review of the charts of the suture patients revealed that the Respondent performed the second surgery more than ninety days after the first surgery. This placed the second surgery outside the "global billing period," meaning that it is billed as a second procedure as opposed to being considered in conjunction with the first surgery (i.e. the hysterectomy) for billing purposes. Other physicians referred the suture patients to the Respondent to perform their hysterectomies. After performing the hysterectomies, the Respondent wrote a status letter to the referring physician informing them how the patient tolerated the hysterectomy. Dr. Rafi noted that in those status letters, the Respondent did not inform the referring physicians that he used Ethibond sutures to close the vaginal cuff, which would in turn require the patients to undergo the second surgery. Finally, Dr. Rafi opined that she learned the Respondent was performing a study and since that study concerned human research, the study required IRB approval. Dr. Rafi saw no evidence the Respondent received IRB approval prior to commencing the study.

On the issue of whether the Respondent should have obtained IRB approval prior to commencing the study, the State called Dr. Shamoo. Dr. Shamoo has a Ph.D in bio-physics and is a professor at the University of Maryland School of Medicine. For the past twenty-five years, Dr. Shamoo has either taught or otherwise been involved in issues of ethics and regulatory

compliance in human subject studies. In particular, Dr. Shamoo was involved in the drafting and creation of the statute in Maryland concerning the regulation of human subject research. Dr. Shamoo has taught and written extensively about IRB requirements in human subject research.

Dr. Shamoo testified that he reviewed the charges and the Respondent's response to the Board in preparation for his testimony. Dr. Shamoo testified when human subject research concerns any drug or device regulated by the FDA, special protections are in place through the Office of Human Research Protections. Maryland is one of the states that requires the application of all federal laws when performing research on human subjects. The federal regulations contain certain exemptions for human subject research, for example, educational purposes. However, an IRB must still determine whether the human subject research is exempt. The federal regulations also contain eight requirements to be sure human subjects have adequate informed consent to participate in the research. In particular, the human subject must be informed as to the risks and benefits of the treatment, alternatives to the treatment, and the purpose of the research. Dr. Shamoo noted that the difference between treatment and research is the following: treatment is for the benefit of the patient and research is for the benefit of the public.

Dr. Shamoo testified as to two types of studies: prospective and retrospective. He defined a prospective study as starting at "time zero" and working toward the future using a variable and observing how the human subjects react to that variable. A retrospective study is again starting at "time zero," but working backward to review data already in existence from patients' records, with assurances in place that the confidentiality of the patients is maintained. Dr. Shamoo opined that IRB approval is required for a prospective study. IRB approval is required for a retrospective study as well if the purpose of the study is to enhance the public good and provide generalizable knowledge. Publication is a hallmark of generalizable knowledge.

Dr. Shamoo reviewed the Respondent's response to the Board (Bd. Ex. 42) and his testimony to the Board (Bd. Ex. 2). Dr. Shamoo opined that while the Respondent claimed to be conducting a retrospective study, in reality the Respondent conducted a prospective study. First, Dr. Shamoo pointed to the Respondent's testimony to the Board where the Respondent references stopping his study once he "accrued the number [of Ethibond suture patients] to reach a certain power." (Bd. Ex. 2, at PM 3622). In other words, the Respondent obtained a statistically significant number of patients by which he could compare to a separate group of patients (i.e. Vicryl patients). Dr. Shamoo also noted the Respondent's reference to Dr. Danilyants using Vicryl sutures on her patients and being the control arm of the study. (Bd. Ex. 42, at 2-3). By doing so, the Respondent introduced a second variable to the study making it consistent with prospective research. Dr. Shamoo dismissed the Respondent's contentions that the study was simply a "pilot study" and that in any event the AAGL[39] sanctioned the study.

With regard to the Respondent's study being a pilot study, Dr. Shamoo opined that pilot studies only concern a handful of patients—not hundreds as present in the Respondent's study. In addition, he opined that any opinion of the AAGL does not absolve the Respondent of his duty to comply with federal regulations concerning human subject research. Dr. Shamoo also opined that the Respondent did not perform innovation by placing the Ethibond sutures in the hysterectomy patients at his ASC. Just like a pilot study, innovation concerns one or perhaps a handful of patients—not hundreds.

Ethibond and other sutures are regulated by the FDA. The label on the Ethibond package lists the various approved uses for Ethibond sutures. Suturing of the vaginal cuff is not a use specifically listed on the label. Thus, in using the Ethibond sutures, the Respondent was using them in an "off label" manner. The State asked Dr. Shamoo to provide an opinion as to whether

[39] American Association of Gynecologic Laparoscopists.

the Respondent's use of Ethibond in an off label manner exempted him from obtaining IRB approval. Dr. Shamoo opined that the issue of whether the Respondent was using Ethibond in an off label manner was not relevant to the issues in this case.[40]

Dr. Shamoo also opined that the Respondent's placement of the Ethibond sutures was neither innovation nor quality improvement. Those activities, he testified, do not involve the collection of data on multiple patients and are rather more informal. They involved perhaps one or a handful of patients. Dr. Shamoo further testified that although the Respondent obtained IRB approval for his study in 2018, that approval concerned data already in existence and not approval of the process the Respondent instituted starting in October of 2013.

*The Respondent's Case*

Dr. Kondrup and Dr. Mesrobian testified on behalf of the Respondent. Dr. Mesrobian testified about the type of anesthesia the Respondent used during the second surgeries of the suture patients and any risks associated with the use of that anesthesia. Dr. Mesrobian opined that the anesthesia risk to the suture patients during the second surgery was minimal and not significant. The MAC anesthesia used was not general anesthesia but rather a light form of sedation. He noted that the records of the suture patients revealed that they received the proper consent for the anesthesia at the second surgery and the second surgeries were low risk and therefore appropriately performed at the Respondent's ASC. Dr. Mesrobian, however, did testify that as a general proposition, patients need to be medically cleared a second time when undergoing surgery that requires a MAC level of anesthesia.

Dr. Kondrup testified that surgeons have a variety of sutures from which to choose in closing the vaginal cuff. Vicryl is the common suture used, however, barbed sutures are beginning to become more prevalent. Dr. Kondrup opined that Vicryl usually dissolves down in

[40] Dr. Shamoo did not expound on this particular conclusion.

six weeks. However, that dissolution can occur more quickly, thus increasing the risk of VCD. Dr. Kondrup has explored the use of other sutures in closing the vaginal cuff. However, the sutures he does use are all absorbable, and he has never used Ethibond sutures in closing the vaginal cuff[41] because they require a second procedure for removal. Dr. Kondrup opined, however, that the Respondent was within the standard of quality care because he intended to remove the Ethibond sutures as opposed to leave them in permanently.

Dr. Prentice testified on the issue of the requirement of IRB approval for the Respondent's suture study. Dr. Prentice was a professor at the University of Nebraska who obtained tenure in 1981. At Nebraska he served as a professor of anatomy as well as IRB director from 1981 to 1985 and the assistant and then associate dean of research from 1985 until 2000.

Dr. Prentice testified that surgical innovation equates to any deviation from what is considered standard practice. However, it does not necessarily equate to research or experimentation. The federal regulations[42] define research as an activity designed to develop or contribute to generalized knowledge. Maryland law requires compliance with that regulation. However, if surgical innovation radically departs from the standard practice, then a practitioner is arguably obligated to perform that innovation in the form of a clinical trial. Dr. Prentice used Baby Fae[43] as an extreme example of a radical departure.

Dr. Prentice reviewed the package label for Ethibond sutures. He concluded that while the sutures are not specifically approved for GYN surgery, they are approved for placement in soft tissue. Thus, their use in closing the vaginal cuff was arguably not off label. However, even assuming the use was off label, Dr. Prentice opined the use was not a radical departure from the

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[41] Dr. Kondrup did testify that he uses Ethibond sutures when repairing the uterosacral ligament. However, that is an entirely different procedure.
[42] 45 C.F.R. § 46.
[43] An infant born in 1984 with a serious heart condition. Surgeons at Loma Linda University transplanted her heart with a baboon's heart.

standard of care. Because the Respondent's use of Ethibond was not a radical departure from the standard of care, the numbers of patients in which he placed the Ethibond sutures was inconsequential (in contradiction to Dr. Shamoo's testimony).

Dr. Prentice reviewed the Respondent's testimony to the Board. He took the position that the Respondent was simply engaging in appropriate surgical innovation. He opined that because the Respondent claimed he was performing a retrospective study that might lead to a prospective randomized trial in the future, the Respondent need not have obtained IRB approval when he began to use Ethibond to close the vaginal cuff in October 2013.

The Respondent additionally called Dr. Van der Does.[44] Dr. Van der Does testified that she began to work for the Respondent in April of 2014 as a consultant. She became the full time director of research in December of 2014. The Respondent first discussed the issue of his placement of Ethibond sutures in the vaginal cuff around August or September of 2016. On October 10, 2016, she issued a preliminary draft report for internal purposes only to get a sense of whether Ethibond outperformed Vicryl. Dr. Van der Does and the Respondent then submitted an abstract of the Ethibond study to the AAGL in the Spring of 2017. Although they submitted the abstract in the Spring of 2017, Dr. Van der Does did not feel the Respondent had enough Ethibond suture patients to reach a statistically significant sample size. Dr. Van der Does testified she and the Respondent did not obtain IRB approval prior to submission of the abstract because she did not feel they needed one. When reviewing the data the research team took care to de-identify the patients and ensure their anonymity.

Dr. Van der Does and the Respondent received a positive response to their submission of the abstract to the AAGL. In light of that, they decided to perform a larger retrospective study on the Ethibond suture patients. For this larger retrospective study, they sought IRB approval, which

[44] Dr. Van der Does is not a medical doctor. She has a Ph.D. in policy analysis with a concentration in statistics and organizational behavior.

they obtained in April of 2018. The IRB approved the research because it was retrospective and the patients were de-identified.

*Analysis*

Having considered the evidence and arguments of both parties, I find the Respondent's use of Ethibond sutures to close the vaginal cuff to be outside the standard of quality care. First, the Respondent himself could not state for certain whether the use of the Ethibond sutures fell within the standard of quality of care. At the hearing he testified that "it's really difficult to identify what is the standard of care now for closure of a vaginal cuff." Tr. vol. 5, at 752. However, in his interview under oath with the Board on May 1, 2017, he testified as follows:

> Q: So moving forward, if the patient wasn't part of the trial, would you just use the Ethibond suture?
> A: No, I'm using Vicryl now. Vicryl's the standard, right.
> Q: Uh-huh.
> A: It's the standard. This is something that's very valuable, but I'm now going back to the standard after the retrospective review was completed.

Bd. Ex. 2, at PM 3625.

If Vicryl was the standard in May of 2017, I find it more likely than not it was the standard when the Respondent began to use Ethibond in October of 2013. I found Dr. Rafi's testimony on this issue convincing. She assuredly testified that Vicryl, and absorbable sutures in general, has been the standard of care since 1996 because no second surgery is required for removal. I found Dr. Kondrup's testimony on this issue much less convincing. Dr. Kondrup opined that the Respondent did not deviate from the standard of care because his choice of sutures was within his professional discretion and compared the choice to the choice of surgical instruments. In his report, Dr. Kondrup referenced the use of Ethibond sutures in GYN surgery, but only in the context of a procedure suspending the uterosacral ligament. What Dr. Kondrup could not do is provide an example of any other instance where a surgeon's decision to deviate to a new procedure that requires a second surgery is within the standard of quality care. Indeed, Dr.

Kondrup seemed to shy away from such a situation in his own practice. When asked if he used Ethibond sutures to close the vaginal cuff in his own surgeries, he testified he did not, with the rationale that doing so would require a second surgery. In his published article in the *Journal of Minimally Invasive Gynecology* (JMIG) the Respondent writes, "The use of nonabsorbable sutures in vaginal cuff closure has not been previously described in the literature." Resp. Ex. 39, at 4. It is difficult to believe that a surgical technique that has never been discussed can be considered a standard of quality care.

The Respondent attempted to downplay the seriousness of the second surgery. It is true that the second surgeries were short. As noted in the chart above, all the procedures, with the exception of Patient 2's, were shorter than ten minutes. However, simply because the procedure was short does not mean it did not place the Patients at risk. I find the Respondent's two consent forms illustrate the serious nature of the placement of the Ethibond sutures. The first consent form, which all the suture patients with the exception of Patient 1 and Patient 4 signed on the dates of their hysterectomies, reads as follows with regard to the placement of the Ethibond sutures:

> I understand that non-absorbable sutures, specifically Ethibond, will be used for closure of the vaginal cuff. I understand the benefits of using Ethibond sutures to include prevention of [VCD] after [the hysterectomy] either complete or partial. I understand the risks of not removing the sutures, which include possible erosion into the vaginal tissue causing pain, bleeding, scarring, difficulty with intercourse and sexual function, infection, formation of granulation tissue, injury to the bladder, ureters and vagina. I fully understand that these sutures need to be removed 3 months after the procedure and this has been explain to me by my physician. I also understand that in rare cases, all the sutures may not be removed (retained), and may cause the above symptoms. Retained sutures may require reoperation for removal to include removal of the sutures, granulation tissue removal and vaginal surgical revision (rare).

Bd. Ex. 20, at PM 4140.[45]

[45] This is the consent form signed by Patient 5 as an example. The others contain the same language.

However, the consent form that all the suture patients signed on the date of the second surgery reads in pertinent part as follows:

> The [second surgery] has been explained to me and I have been provided with the necessary information for me to evaluate the risks and benefits of the proposed treatment. These risks include infection, bleeding, injury to bowel, bladder, ureters, pelvic pain, adhesions, pain with intercourse, and difficulty with sexual function.

*Id.* at PM 4177.[46]

First, it is questionable whether the Respondent adequately counseled the suture patients as to the potential complications from the second surgery prior to their consent to the placement of the Ethibond sutures at the first surgery.[47] None of the risks associated with the second surgery (e.g. infection, bleeding, injury to bowel, etc.) are present on the first consent form. Furthermore, if the second surgery did not entail risk, I find the Respondent would not have had the suture patients sign such a detailed consent form prior to commencing the second surgery.

I credit Dr. Mesrobian's testimony that the anesthesia used on the suture patients at the second surgery placed them at low risk. He exhibited sound knowledge of the various anesthesia types and the anesthesia process. However, like with any procedure, risk still exists. I agree with the State that such risk would not exist with Vicryl or other absorbable sutures. Moreover, the second surgery required the suture patients be reevaluated and medically cleared for the anesthesia. The question then becomes, what if the patient cannot be cleared a second time for the second surgery? Do the sutures simply stay in? If so, how would the Respondent reconcile that with his caution to the suture patients in the first consent form where he warns them that the Ethibond sutures must be removed? While the likelihood of a patient not being cleared for the

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[46] This is the consent form signed by Patient 5 as an example. The others contain the same language.

[47] In his JMIG article the Respondent writes, "Of note, we identified 4 patients with some degree of cuff dehiscence at the time of Ethibond removal, allowing for debridement and repair of the vaginal cuff in a controlled environment. We suspect that these 4 cases occurred due to incomplete healing and from the force of suture removal." Resp. Ex. 39, at 4 (emphasis added).

second surgery is most likely low, it is still a risk that would not be present with the placement of Vicryl sutures.

The second surgery was clearly more complicated than simple suture removal. All the suture removal patients required the placement of a Vicryl stitch at the second surgery to stem bleeding. They all required the preparations similar to the first surgery. They could not shower for twenty-four hours after the surgery.[48] They all required the insertion of an IV.[49] I find exposing the suture patients to the second surgery exposed them to the risks associated with any surgery (e.g. infection). I do not find the simple choice of non-absorbable over absorbable sutures by a surgeon to be a deviation from the standard of quality care as a general proposition. The deviation from the standard of quality care is manifested in the need for the second surgery and the risks associated with that surgery.

The Respondent presented no evidence of any analogous instances that have not been found to be departures from the standard of quality care—not just in GYN surgery but any surgery. The Respondent presented articles on the issue of suture choice. I found the opinions in some of those articles somewhat contradictory to the Respondent's position. For example, in an article entitled "Vaginal Cuff Closure after Laparascopic Total Hysterectomy," the authors write that the ideal suture for closing the vaginal cuff should "be absorbable, but maintain reasonable tensile strength for at least 2 to 4 weeks."[50] Resp. Ex. 27, at 145. In an article entitled "Advances in Suture Material for Obstetric and Gynecologic Surgery," the authors discuss the challenges faced with suturing the vaginal cuff. They go on to write:

> Given these variables, the ideal suture for vaginal cuff closure should inhibit bacterial growth, elicit minimal tissue reactivity, be pliable, and maintain a reasonable amount of tensile strength for at least 2 to 4 weeks **even though**

[48] *See, e.g.*, Bd. Ex. 8, at PM 3749.
[49] *See, e.g., id.* at PM 3750.
[50] Dr. Kondrup testified that Vicryl usually breaks down around six weeks. But he has seen it last longer or shorter than that. Tr. vol. 4, at 533-34.

> **absorbable**. This suture is not chromic gut, which has been demonstrated to lead to more postoperative granulation tissue. Reasonable choices would include one of the multifilament polyglycolic acid based sutures[51] if stiffness is a greater concern than capillarity, or one of the delayed absorption monofilament materials such as polydioxanone or polyglyconate if minimizing inflammation is the goal. If one of the delayed absorption monofilaments is selected.

Resp. Ex. 26, at 155-56 (emphasis added). Accordingly, I shall recommend the charge of failure to abide by the standard of quality care for patients 1, 2, 4, 5, 6 and 9 be upheld.

I further find the Respondent grossly overutilized health care services by placing Ethibond in the suture patients. The Respondent's rationale for switching to the Ethibond sutures was to prevent instances of VCD. The parties agree that VCD is a devastating complication of a hysterectomy. When asked about the rate of VCD in his own practice, the Respondent testified as follows:

> Yes. This is a high-volume surgical practice. So, when you're doing 500/600 hysterectomies a year and you're closing with a suture that allows VCD to occur, the number of cases is going to be higher. So, if you have a 2 percent breakdown rate leading to VCD -- and VCD in this case is bowel moving outside the vagina. That **could be** 12 to 15 patients a year and that can be quite difficult to have.

Tr. vol. 5, at 702-03 (emphasis added). However, when asked why he decided to switch to the Ethibond, the Respondent cited only one VCD case, a Vicryl patient of Dr. Danilyants. VCD was a horrendous complication and experience for that patient. However, the Respondent provided no specific annual average of actual VCD cases from his practice. In his written response to the Board, the Respondent only vaguely says throughout his practice he and his partners have been "plagued" by incidents of VCD in outlying areas of the State not accessible to his practice. Bd. Ex. 42, at 3-4. In his May 1, 2017 sworn statement to the Board, the Respondent testified to the VCD case from Dr. Danilyants's Vicryl patient. He further testified that "over the course of 10, 15 years" his practice has had "multiple patients" experience VCD. Bd. Ex. 2, at PM 3621. The

[51] These sutures are absorbable. *Dolphin Sutures*, https://www.dolphinsutures.com/pga-sutures (last visited Aug. 28, 2019).

Respondent's October 10, 2016 draft Ethibond study result report likewise does not contain specific statistics on historic VCD rates in his practice. Bd. Ex. 3. It does, however, provide examples of rates from other studies. Those rates span the general range from 0.13% to 7.4% over multiple years and under various circumstances. His accepted manuscript in JMIG cites a general incidence rate of 0.3% to 3.1%, however, no specific data as to his own practice. Resp. Ex. 16, at 5. The Respondent comes closest to citing specific numbers in his published manuscript in JMIG, where he states three patients from the Ethibond study cohort and twelve patients from the Vicryl control arm experienced spontaneous VCD. Resp. Ex. 39, at 3-4. The Respondent concludes this difference did not achieve statistical significance.

Without specific data regarding the incidence of VCD at the Respondent's own practice (prior to the study), it is difficult to determine whether the end (the desired decrease of VCD rates) justifies his means (the use of Ethibond sutures that require a second surgery). The results of the study published in JMIG certainly do not bear that out. Even assuming the Respondent's own historic VCD rate is on the higher end (e.g. 3.1%) that is still a low incidence. The placement of Ethibond and required second surgery to remove them creates additional risks to the patients. While Ethibond may decrease the overall risk of VCD, the presence of risk associated with the placement of Ethibond and the need for a second surgery calls into question whether the overall risk to the Respondent's patients has truly been mitigated. Additionally, in his published JMIG article the Respondent writes:

> Although we did not have a sufficient number of VCD cases to detect a statistically significant difference between the 2 groups, some of these patients had risk factors associated with poor healing (e.g, obesity and smoking). Arguably, we believe that these patients could have developed VCD had a weaker suture material, such as Vicryl, been used.

Resp. Ex. 39, at 5.

It would seem the risk factors associated with poor healing and how to address them would be *a priori* knowledge not requiring some lengthy empirical exploration. The Respondent perhaps could have specifically targeted those at risk patients with Ethibond. That would be an awful lot closer to innovation than the Respondent's actual course of conduct.

Furthermore, the second surgery generates costs that are not present with the placement of Vicryl or other absorbable sutures. The Respondent testified he picked ninety days as the amount of time he left the Ethibond sutures in patients to ensure adequate healing. As indicated in the chart above, the Respondent did not perform the second surgery on the suture patients until a couple days beyond the ninety day mark. The ninety day mark coincides with the end of the global billing period for the hysterectomy procedure. Thus, because the Respondent performed the second surgery beyond the ninety days, he could bill for the second surgery.

The Respondent provided no reason as to why he waited until after the ninety days to perform the second surgery on the suture patients. He testified that sixty percent of all the Ethibond patients had their surgeries beyond the ninety days. In his published JMIG article the Respondent writes that "it may be beneficial to delay Ethibond suture removal beyond 90 days, as the three cases of spontaneous complete VCD in the Ethibond group occurred at postoperative days 91, 101 and 104. However, the longer the suture stays in the body, the greater the risk of a negative inflammatory reaction." Resp. Ex. 39, at 4. Insurance paid the Respondent for the six suture patients' second surgery as follows:

Patient 1 - $0.00 (Bd. Ex. 9, at PM 3754)

Patient 2 - $0.00 (Bd. Ex. 12, at PM 3850)

Patient 4 - $247.54 (Bd. Ex. 18, at PM 4109)

Patient 5 - $262.09 (Bd. Ex. 21, at PM 4197)

Patient 6 - $247.54 (Bd. Ex. 24, at PM 4283)

Patient 9 - $156.22 (Bd. Ex. 33, at PM 4476)

This equates to an average of $152.23 for the six suture patients. In his response to the Board, the Respondent indicated he placed Ethibond sutures in 595 total patients. If he performed the second surgery on sixty percent of those patients outside the global payment period, that equates to 357 patients to whom he billed insurance for the second surgery. Assuming he received an insurance payment for two-thirds of the 357 patients (as was the case with the suture patients), that equates to payment received for 264 patients. Assuming he received $152.23 (the average payment for the suture patients) for each of those 264 patients, that equates to a total payout of $52,272.00.[52]

$52,272.00 is most likely a miniscule amount in comparison to the total gross proceeds of the Respondent's practice for the period where he was placing the Ethibond sutures. However, the question becomes did all those 264 patients actually need Ethibond to prevent VCD? What was their actual risk? The Respondent's comments in his published JMIG article seem to indicate he already knew who the best candidates for Ethibond might be (smokers and the obese). There is no evidence all, or even a slight majority of those patients fell into that category. Accordingly, I shall recommend the charge of gross overutilization of health care services with regard to the suture patients be upheld.

I do not find the Respondent failed to keep adequate medical records with regard to the suture patients as charged by the State. While I do find the Respondent deviated from the standard of care by placing the Ethibond sutures in the suture patients, I do not find he failed to keep adequate medical records by failing to notify the suture patients' referring physicians. I found Dr. Rafi's testimony on this issue conclusory and without explanation. I heard no evidence

[52] The Respondent testified he did not "balance bill" (i.e. charge the patient the balance of the fee not reimbursed for the second surgery). The billing records of the suture patients are consistent with that testimony.

as to how the issue of the Ethibond sutures would be relevant to the referring physician. I contrast this with the issue of Patient 3's medical records. With regard to Patient 3, the Respondent actually provided inaccurate information to a physician to whom he was referring Patient 3. That is a different scenario. The records for Patients 1 and 4 did not contain signed consent forms. However, the records for those patients do contain statements that the Respondent discussed the procedure with them.[53] Accordingly, I shall recommend the charge of failure to keep adequate medical records with regard to the suture patients be dismissed.

In his response to the Board, the Respondent claimed he was conducting a study on whether the placement of Ethibond sutures decreased the incidence of VCD. The question before me is whether the Respondent should have obtained IRB approval prior to commencing the study. Having considered the evidence and testimony of the experts, I find the Respondent conducted prospective human subject research beginning in October 2013 when he began placing Ethibond sutures in his hysterectomy patients at his ASC. I further find that the Respondent, at that time, intended for his research to eventually be submitted for publication to enhance the general knowledge of the medical community. I find the Respondent should have, but did not, obtain IRB approval when he commenced his research in October 2013. The Respondent took two basic positions on this issue: 1) that he was performing innovation to improve the overall results of his practice and 2) that his study was a retrospective, not prospective study. Having reviewed the Respondent's testimony and the evidence presented, I find neither position credible.

On or around October 2013, I find the Respondent formulated in his mind, the intent to create a specific cohort of Ethibond patients. He specifically arranged to have the Ethibond patients treated at his ASC while Dr. Danilyants treated the Vicryl patients at [redacted]. In his

[53] Whether the Respondent provided adequate information to the Patients, I find, is a different issue.

November 7, 2017 response to the Board, the Respondent characterizes Dr. Danilyants as the "control arm of the study." Bd. Ex. 42, at 2. The Respondent referred to Dr. Danilyants in the same manner in his May 1, 2017 sworn statement to the Board. Bd. Ex. 2, at PM 3624. Thus, the Respondent started at point zero (October 2013), identified a variable (the Ethibond patients at his ASC), and a control variable (the Vicryl patients treated by Dr. Danilyants at [redacted]). The Respondent then allowed three years to pass while he placed Ethibond sutures in 595 patients, subjecting them to a second surgery (and its associated risks). He neither informed those patients they were the subject of research nor did he obtain their consent to be the subjects of research.

Both Dr. Shamoo and Dr. Prentice agreed a practitioner would require IRB review prior to engaging in a prospective study. The issue becomes whether the Respondent engaged in a prospective study in October of 2013. On that issue, I am more persuaded by Dr. Shamoo's opinion than Dr. Prentice's opinion. I find that Dr. Prentice accepted the Respondent's representations of his intentions at face value. For example, in his report Dr. Prentice states he finds it "clear" that the Respondent never engaged in a prospective study. Resp. Ex. 4, at 4. However, he provides no opinion on the Respondent's actions in October 2013 (i.e. setting up a cohort of Ethibond patients and a control cohort of Vicryl patients). A prime example of Dr. Prentice using the Respondent's representations as the basis for his opinion is contained in the following exchange between the State and Dr. Prentice:

> Q. And if you look at the bottom of page 36 of the transcript, he responds -- Dr. MacKoul responds, we figured it would take three years by looking at the volume. We are just trying to see if we can stop it further or have it extend, if required. But now we're all using Vicryl -- I'm using Vicryl. Do you see that? So, is -- so, is it still your contention that this is a retrospective study of existing data?

A. It is **because Dr. MacKoul testified -- and it's in the -- it's in his transcript in a number of places that his intent was to do a** -- a randomized prospective study or research, clinical trial if you will. And he wanted to get enough data to support the -- the parameters that would be necessary to have a valid prospective clinical trial.
That was his intent and he can keep on analyzing the the outcome data from the innovative practice, i.e. utilizing Ethibond, until the cows came home. Okay. But, eventually, he wanted to get to the point where he felt I have enough information, I understand the clinical parameters sufficiently well that I'm ready to move on to have a -- a prospective clinical trial initiated and, indeed, as you probably know, he did submit a protocol to Integra IRB for a prospective trial.
It was approved by Integra. He never initiated it.

Tr. vol. 3, at 422-23 (emphasis added).

Dr. Shamoo laid a better foundation for his opinion. I found Dr. Shamoo's opinion that the Respondent engaged in a prospective study to be based upon the Respondent's actions. For example, Dr. Shamoo specifically opined that the Respondent's use of a control arm with his study was consistent with a prospective study. Tr. vol. 2, at 292-93. Dr. Shamoo rendered his opinion based upon an action the Respondent actually took—not the Respondent's subjective contention as to the nature of his actions.

The Respondent may have had the benefit of his practice in mind when he commenced his Ethibond study in October of 2013. However, at the time he commenced the Ethibond study, I find it more likely than not that he intended to submit the results for publication. Thus, I find he intended the results to be generalized knowledge for the benefit of the profession. The Respondent had a research team at his practice and hired Dr. Van der Does as its head. Dr. Van der Does testified that when the Respondent first hired her part-time in early 2014 he asked that she draft a white paper on the subject of two port laparoscopic hysterectomy procedures. Tr. vol. 5, at 656. However, she learned the Respondent really wanted to publish the article in a peer

reviewed journal. *Id.* When Dr. Van der Does became the full-time head of research at the end of 2014, she learned another doctor at the Respondent's practice received IRB approval for a study on hysterectomy approaches. *Id.* The Respondent no doubt paid Dr. Van der Does and other members of his research team. In light of this, I do not find it credible the Respondent would create a formal research team and engage in a study the size and length of the Ethibond study without an intent to publish the results at the outset. Indeed, the Respondent did take steps to publish, and ultimately did publish, the results. Resp. Ex. 39.

The Respondent contended that he was performing innovation in order to improve his practice and that he was in compliance with ACOG guidelines. The Respondent is free to innovate. However, as discussed above, I find he clearly moved beyond innovation into human subject research. At the hearing, both Dr. Shamoo and Dr. Prentice testified with regard to the Respondent's use of Ethibond (an FDA regulated product) in an off-label manner. This discussion concerned the lack of any specific mention on the Ethibond package insert of Ethibond's use in GYN surgery. Assuming the Respondent used Ethibond in an off-label manner,[54] Dr. Prentice opined that the Respondent did not violate any regulations since he was performing an innovation in his practice and not research. In his report, Dr. Prentice asserted that such use was within ACOG guidelines. He writes:

> In fact, FDA recognizes that physicians often use marketed products for off-label use in the best interest of patients. FDA guidance states, "Use of a marketed product in this manner when the intent is the practice of medicine does not require submission of an investigational New Drug Application (IND), Investigational Device Exemption (IDE), or review by an [IRB]."[55]

Resp. Ex. 4, at 2.

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[54] At the hearing, Dr. Prentice testified that because Ethibond was approved for use in soft tissues, the Respondent's use of it in closing the vaginal cuff might be considered "on label" use.

[55] Dr. Prentice cites https://www.fda.gov/Regulatoryinformation/Guidance/ucm126486.htm as the source of this quote.

Dr. Shamoo opined that the Respondent is bound by the FDA guidelines and Maryland law, not the ACOG guidelines. I agree with Dr. Shamoo. The Respondent may say he is performing surgical innovation, but as discussed above, the facts suggest otherwise. Again, I find Dr. Prentice relied more on what the Respondent said (which is self-serving) as opposed to what the Respondent actually did. Furthermore, there is no evidence that adherence to ACOG guidelines equates to adherence to the FDA guidelines and Maryland law. I find the Respondent was bound by FDA guidelines and Maryland law.

Section 13-2002 of the Maryland Health General Article reads in full as follows:

> (a) A person may not conduct research using a human subject unless the person conducts the research in accordance with the federal regulations on the protection of human subjects.
>
> (b) Notwithstanding any provision in the federal regulations on the protection of human subjects that limits the applicability of the federal regulations to certain research, subsection (a) of this section applies to all research using a human subject.

Thus, I find the Respondent, as a licensed Maryland physician whose ASC was located in Maryland, was subject to the federal regulations on human subject research.

45 C.F.R. § 46.102, entitled "Definitions for the purposes of this policy," reads in pertinent part as follows:

> (b) Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.
>
> . . . .
>
> (e)(1) Human subject means a living individual about whom an investigator (whether professional or student) conducting research:
>
> . . . .
>
> (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
>
> (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
>
> . . . .

(2) Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

(3) Interaction includes communication or interpersonal contact between investigator and subject.

. . . .

(h) IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

. . . .

(j) Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

. . . .

(l) Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:

(1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

45 C.F.R. § 46.104, entitled "Exempt Research," reads in full as follows:

(a) Unless otherwise required by law or by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the categories in paragraph (d) of this section are exempt from the requirements of this policy, except that such activities must comply with the requirements of this section and as specified in each category.

(b) Use of the exemption categories for research subject to the requirements of subparts B, C, and D: Application of the exemption categories to research subject to the requirements of 45 CFR part 46, subparts B, C, and D, is as follows:

(1) Subpart B. Each of the exemptions at this section may be applied to research subject to subpart B if the conditions of the exemption are met.

(2) Subpart C. The exemptions at this section do not apply to research subject to subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

(3) Subpart D. The exemptions at paragraphs (d)(1), (4), (5), (6), (7), and (8) of this section may be applied to research subject to subpart D if the conditions of the exemption are met. Paragraphs (d)(2)(i) and (ii) of this section only may apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph (d)(2)(iii) of this section may not be applied to research subject to subpart D.

(c) [Reserved]

(d) Except as described in paragraph (a) of this section, the following categories of human subjects research are exempt from this policy:

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).

(3)(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human

subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E–Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

(ii) [Reserved]

(6) Taste and food quality evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed, or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental

contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by § 46.111(a)(8).

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with § 46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § 46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by § 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and

(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

45 C.F.R. § 46.116, entitled "General Requirements for Informed Consent," reads in pertinent part as follows:

(a) . . . .

(2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

. . . .

(4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

. . . .

(5) Except for broad consent obtained in accordance with paragraph (d) of this section:

(i) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might

not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

(ii) Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

. . . .

(b) Basic elements of informed consent. Except as provided in paragraph (d), (e), or (f) of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

. . . .

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

. . . .

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and

(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

(ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

45 C.F.R. § 46.117, entitled "Documentation of Informed Consent," reads in full as follows:

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the informed consent form.

(b) Except as provided in paragraph (c) of this section, the informed consent form may be either of the following:

(1) A written informed consent form that meets the requirements of § 46.116. The investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative.

(2) A short form written informed consent form stating that the elements of informed consent required by § 16.116 have been presented orally to the subject or the subject's legally authorized representative, and that the key information required by § 46.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject or the subject's legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the subject's legally authorized representative, in addition to a copy of the short form.

(c)(1) An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

(i) That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

(ii) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or

(iii) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

(2) In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

I find the Respondent violated the provisions of the above quoted federal regulations. I find starting in October 2013, he engaged in a clinical trial as defined by 45 C.F.R. § 46.102(b). He made the conscious choice at that time to prospectively assign two groups: the Ethibond experiment group and the Vicryl control group. I do not find the Respondent exposed the Ethibond patients to minimal risk as defined by 45 C.F.R. § 46.102(j). For reasons stated earlier in this decision, I find the second surgery exposed the Ethibond patients to discomfort greater than what they can expect to encounter in daily life or during the performance of routine physical or psychological examinations or tests. I find the Respondent engaged in research as defined by 45 C.F.R. § 46.102(l) because the Respondent, starting in October 2013, intended the Ethibond study to contribute to generalized knowledge. I do not find the Respondent's Ethibond study falls under any of the exemptions contained in 45 C.F.R. § 46.104, as it was prospective research he began in October 2013.

I further find, based upon review of the records in evidence from the suture patients, that the Respondent did not provide them with informed consent as required by 45 C.F.R. § 46.116. I do not find he afforded the suture patients the opportunity to discuss and consider whether to participate in the Ethibond study. The suture patients signed their consent forms[56] (for both surgeries) the day of the procedure. Furthermore, I do not find the Respondent provided the suture patients with information they would need to make an informed decision as required by 45 C.F.R. § 46.116(4). The first consent form, which most of the suture patients signed the date of their first surgery (the hysterectomy), only advises them of the placement of the Ethibond sutures and the need for their removal. It is not until the second consent form, which all suture patients

[56] As noted above, Patient 1 and Patient 4 did not even sign consent forms for their first surgery.

signed the date of the second surgery, that they are advised of the specific risks of that second surgery. The Respondent failed to inform the suture patients that the study concerns research and the purpose of the research and the appropriate alternative procedures or courses of treatment. Accordingly, I shall recommend that the charge of unprofessional care in the practice of medicine with regard to the suture patients be upheld.

Sanctions

In closing, the State sought to impose the disciplinary sanctions of a three month suspension of the Respondent's medical license; the placement of the Respondent's medical license on probation for a period of two years, that during the first year of his probationary period the Respondent perform no human research and that during the second year of his probationary period the Respondent may engage in human subject research provided he submit his research protocol and IRB approval to the Board for review and approval prior to commencing the research; the requirement that the Respondent apply to the Board for termination of his probation at its conclusion; the requirement that the Respondent participate in an "intensive" in-person tutorial in ethics with a focus on research ethics that is in addition to the Respondent's mandatory continuing education requirement. Health Occ. § 14-404(a); COMAR 10.32.02.09A and B; COMAR 10.32.02.10.[57]

Under the applicable law, the Board also may impose a fine instead of or in addition to disciplinary sanctions against a licensee who is found to have violated section 14-404. Health Occ. § 14-405.1(a) (2014); COMAR 10.32.02.09. The State sought a fine of $50,000.00.

[57] As noted above, "COMAR" refers to the Code of Maryland Regulations.

In considering which sanctions to recommend, I have considered the mitigating and aggravating factors in COMAR 10.32.02.09B(5) and (6) as follows:

Mitigating Factors:

(a) The absence of a prior disciplinary record;

- The Respondent has a prior disciplinary record, which I shall discuss below.

(b) The offender self-reported the incident;

- The Respondent did not self-report.

(c) The offender voluntarily admitted the misconduct, made full disclosure to the disciplinary panel and was cooperative during the disciplinary panel proceedings;

- The Respondent did not voluntarily admit misconduct. However, I heard no evidence he did not cooperate during the disciplinary panel proceedings. Based on that I give this factor slight weight in mitigation.

(d) The offender implemented remedial measures to correct or mitigate the harm arising from the misconduct;

- The Respondent testified he stopped using the Ethibond sutures because his study ended. I do not find that applies to this factor.

(e) The offender made good faith efforts to make restitution or to rectify the consequences of the misconduct;

- I find the same with this factor as I do with factor (d).

(f) The offender has been rehabilitated or exhibits rehabilitative potential;

- The Respondent steadfastly denied wrongdoing from the inception of the Board's investigation through the hearing on the merits.

(g) The misconduct was not premeditated;

- Per my discussion above, I find the Respondent knowingly and intentionally engaged in the misconduct.

(h) There was no potential harm to patients or the public or other adverse impact;

- I find the Respondent placed the suture patients in potential harm. There is no evidence his conduct actually harmed any of them.

(i) The incident was isolated and is not likely to recur.

- The placement over the Ethibond sutures took place over a period of years. The Respondent does not believe he committed wrongdoing and for that reason, I cannot find it is not likely to recur.

Aggravating Factors:

(a) The offender has a previous criminal or administrative disciplinary history;

- The Respondent has a prior administrative disciplinary history. There is no evidence of a criminal history.

(b) The offense was committed deliberately or with gross negligence or recklessness;

- For the reasons set forth in the discussion above, I find the Respondent committed the offenses deliberately (planned the human subject research and did not obtain an IRB) and recklessly (he performed numerous procedures outside the standard of quality care). I do not find evidence he acted with gross negligence.

(c) The offense had the potential for or actually did cause patient harm;

- I find the Respondent's offenses had the potential to cause the suture patients harm. I find no evidence he actually caused the suture patients harm.

(d) The offense was part of a pattern of detrimental conduct;

- The Respondent's study took place over a period of years and thus was a pattern of detrimental conduct.

(e) The offender committed a combination of factually discrete offenses adjudicated in a single action;

- There were six suture patients at issue in this case, which were combined into each charge.

(f) The offender pursued his or her financial gain over the patient's welfare;

- The Respondent, without explanation, performed the second surgery on the suture patients outside the global billing period.

(g) The patient was especially vulnerable;

- There is no evidence the Respondent provided adequate informed consent to the suture patients prior to the first surgery as to the risks associated with the

placement of the Ethibond sutures. There is no evidence the suture patients knew they were participants in human subject research.

(h) The offender attempted to hide the error or misconduct from patients or others;

- There is no evidence the Respondent informed the suture patients he was conducting human subject research on them.

(i) The offender concealed, falsified or destroyed evidence, or presented false testimony or evidence;

- There is no evidence the Respondent concealed, falsified or destroyed evidence. Per the discussion above, I did find certain aspects of the Respondent's testimony and certain assertions made by him or attributed to him in the exhibits not credible.

(j) The offender did not cooperate with the investigation; or

- There is no evidence the Respondent did not cooperate with the investigation

(k) Previous attempts to rehabilitate the offender were unsuccessful.

- The Board previously sanctioned the Respondent. In light of the Respondent's conduct in this matter, I do not find any previous attempts to rehabilitate the Respondent to be successful.

The Respondent's prior disciplinary history

The State provided evidence of the Respondent either being disciplined or cautioned by the Board on three occasions. That evidence is contained in State's exhibits 45, 46, and 47 (collectively "the discipline exhibits"). I admitted the discipline exhibits into evidence with the rest of the State's exhibits. However, at the pre-hearing conference and again at the hearing, I ruled that I would not review or consider those exhibits unless and until I reached the issue of sanctions. I did not review the discipline exhibits until I completed drafting the above discussion addressing the State's charges.

In a consent order signed April 8, 2009, the Board reprimanded the Respondent and fined him $2,500.00 for failing to report pending disciplinary action against his District of Columbia medical license on an application for renewal of his Maryland medical license. Bd. Ex 46. On

June 3, 2014, the Board reprimanded the Respondent and ordered he complete a Board approved intensive course on physician-patient interactions. Bd. Ex. 47. The June 3, 2014 order arose out of an incident where the Board found the Respondent failed to adequately counsel a patient to see a urologist prior to surgery, failed to review the patient's chart for pre-surgical clearance, failed to adequately communicate with that patient and her family the day of her surgery about delays in the surgery, and became abusive and combative toward that patient and her family. On June 15, 2015, the Board sent the Respondent a letter advising him of its closure of an investigation stemming from another patient's complaint. Bd. Ex 45. The Board, however, cautioned the Respondent to be aware of a certain complication that can arise from laparoscopic abdominal myomectomies.

In reviewing the Respondent's prior disciplinary history, a familiar theme emerges. Both of the Respondent's reprimands involve either failing to provide information he knew or should have known to provide (his false assertion on his application to renew his Maryland license) or a liberal application of "alternative facts" when explaining his actions to the Board.

For example, according to the June 3, 2014 reprimand, the Respondent asserted he could not avoid keeping the patient waiting because he was involved in another surgery. However, the Board found that not to be true based upon an examination of the timing of the surgeries (an objective fact) and the testimony of other witnesses. I find the Respondent's representations to the Board in this case, especially on the issue of his Ethibond study, to be in line with some of the behavior for which the Board previously reprimanded him.

In his closing statement, Counsel for the Respondent implored me not to recommend the Board place the Respondent on probation. He argued that if placed on probation, the Respondent would, among other things, lose his board certifications and have his contracts with insurers voided. In essence, the net effect on the Respondent's livelihood would be no different than

suspension or a revocation. The State, who I afforded the opportunity to provide rebuttal argument, neither denied nor objected to those assertions and characterizations.

I find a recommendation of a sanction harsher than a reprimand to be warranted. While I am recommending several of the charges be dismissed, the ones I recommend be upheld illustrate grave violations by the Respondent. I find the Respondent grotesquely abdicated his solemn and fundamental duty of trust to his patients. I further find the Board's previous reprimands ineffective in curtailing the Respondent's behavior. If anything, he upped the ante. This is mystifying given the evidence before me indicates the Respondent, from a technical standpoint, is a highly skilled, highly competent, highly accomplished, and highly intelligent physician.

I recommend the Board adopt the following sanctions the State requested:

- That the Respondent be placed on probation for two years;[58]
- That the Respondent be prohibited from engaging in any human subject research for the first year of his probationary period;
- That the Respondent may engage in human subject research during the second year of probation provided he submit his research protocol and IRB approval to the Board for review and approval prior to commencing the research;
- That the Respondent must apply for reinstatement at the conclusion of his probationary period;
- That the Respondent participate in an "intensive" in-person tutorial in ethics with a focus on research ethics, that this tutorial not be included toward the Respondent's mandatory continuing education requirement;

[58] I adopt this requested sanction for two reasons: 1) I find it is warranted by the facts and circumstances of this case and 2) having found the Respondent grossly overutilized health care services with regard to the suture patients in violation of section 14-404(a)(19) of the Health Occupations Article, I find this is the minimum sanction allowable under COMAR 10.32.02.10B(19). That regulation also requires a Reprimand as a minimum sanction.

- That the Respondent pay a fine of $30,000.00 payable within six months of the Board's final order.

Given I did not recommend all the State's charges be upheld, I shall not recommend the Respondent be placed on a three month suspension. For the same reason, I recommended a reduced fine of $30,000.00 payable within six months.

## PROPOSED CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact and Discussion, I conclude as a matter of law that with regard to Patient 3, the Respondent violated section 14-404(a)(40) of the Maryland Health Occupations Article (failure to keep adequate medical records) and with regard to Patients 1, 2, 4 ,5, 6 and 9, the following sections of the Maryland Health Occupations Article: 14-404(a)(3)(ii) (unprofessional conduct in the practice of medicine), 14-404(a)(19) (gross overutilization of health care services),[59] and 14-404(a)(22) (failure to meet the standard of quality care).[60] As a result, I conclude that the Respondent is subject to the following disciplinary sanctions:

- That the Respondent be placed on probation for two years;
- That the Respondent be prohibited from engaging in any human subject research for the first year of his probationary period;
- That the Respondent may engage in human subject research during the second year of probation provided he submit his research protocol and IRB approval to the Board for review and approval prior to commencing the research;
- That the Respondent must apply for reinstatement at the conclusion of his probationary period;

[59] As to placement of the Ethibond sutures only.
[60] As to placement of the Ethibond sutures only.

- That the Respondent participate in an "intensive" in-person tutorial in ethics with a focus on research ethics, that this tutorial not be included toward the Respondent's mandatory continuing education requirement.

COMAR 10.32.02.09.

I further conclude that the Respondent is subject to a fine of $30,000.00 for the cited violations. Md. Code Ann., Health Occ. § 14-405.1(a) (2014); COMAR 10.32.02.09.

## PROPOSED DISPOSITION

I **PROPOSE** that charge of failure to keep adequate medical records with regard to Patient 3 filed by the Maryland State Board of Physicians against the Respondent on September 7, 2018 be **UPHELD**; and

I **PROPOSE** that the charges of unprofessional conduct in the practice of medicine, gross overutilization of health care service, and failure to meet standards of care with regard to Patients 1, 2 ,4, 5, 6 and 9 filed by the Maryland State Board of Physicians against the Respondent be **UPHELD**; and

I **PROPOSE** that the remaining charges filed by the Maryland State Board of Physicians on September 7, 2018 be **DISMISSED**; and

I **PROPOSE** that the Respondent receive the following sanctions

- That the Respondent be placed on probation for two years;
- That the Respondent be prohibited from engaging in any human subject research for the first year of his probationary period;
- That the Respondent may engage in human subject research during the second year of probation provided he submit his research protocol and IRB approval to the Board for review and approval prior to commencing the research;

- That the Respondent must apply for reinstatement at the conclusion of his probationary period;
- That the Respondent participate in an "intensive" in-person tutorial in ethics with a focus on research ethics, that this tutorial not be included toward the Respondent's mandatory continuing education requirement;
- That the Respondent pay a fine of $30,000.00 payable within six months of the Board's final order; and

I **PROPOSE** that the Respondent be ordered to pay a fine of $30,000.00 payable within six months of the date of the Board's final order.

September 4, 2019
Date Decision Issued

Nicolas Orechwa
Administrative Law Judge

NO/sw
#181423

## NOTICE OF RIGHT TO FILE EXCEPTIONS

Any party adversely affected by this proposed decision may file written exceptions with the disciplinary panel of the Maryland State Board of Physicians that delegated the captioned case to the Office of Administrative Hearings (OAH), and request a hearing on the exceptions. Md. Code Ann., State Gov't § 10-216(a) (2014); COMAR 10.32.02.05. Exceptions must be filed within fifteen (15) days of the date of issuance of this proposed order. COMAR 10.32.02.05B(1). The exceptions and request for hearing must be addressed to the Disciplinary Panel of the Board of Physicians, 4201 Patterson Avenue, Baltimore, MD, 21215-2299, Attn: Christine A. Farrelly, Executive Director.

A copy of the exceptions should be mailed to the opposing attorney, and the other party will have fifteen (15) days from the filing of exceptions to file a written response addressed as above. *Id.* The disciplinary panel will issue a final order following the exceptions hearing or other formal panel proceedings. Md. Code Ann., State Gov't §§ 10-216, 10-221 (2014); COMAR 10.32.02.05C. The OAH is not a party to any review process.

**Copies Mailed To:**

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