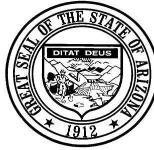

Arizona Medical Board

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FINAL MINUTES FOR BOARD REVIEW COMMITTEE B MEETING
Held on Wednesday, June 5, 2024
1740 W. Adams St., Board Room B • Phoenix, Arizona

Committee Members
Lois E. Krahn, M.D., Chair
Katie S. Artz, M.D., M.S.
Jodi A. Bain, M.A., J.D., LL.M.
David C. Beyer, M.D., F.A.C.R., F.A.S.T.R.O.
James M. Gillard, M.D., M.S., F.A.C.E.P., F.A.A.E.M.
Pamela E. Jones

GENERAL BUSINESS

A. CALL TO ORDER

Chairwoman Krahn called the Committee's meeting to order at: 12:29 p.m.

B. ROLL CALL

The following Committee members were present: Dr. Krahn, Dr. Artz, Ms. Bain, Dr. Gillard, and Ms. Jones.

The following Committee member was absent: Dr. Beyer.

ALSO PRESENT

The following Board staff participated in the meeting: Pat McSorley, Executive Director, Heather Foster, Public Records Coordinator, Amy Skaggs, SIRC Coordinator and Carrie Smith, Assistant Attorney General ("AAG") was also present.

C. OPENING STATEMENTS

Dr. Krahn provided an opening statement.

D. PUBLIC STATEMENTS REGARDING MATTERS LISTED ON THE AGENDA

No individuals addressed the Committee during the Public Statements portion of the meeting.

E. APPROVAL OF MINUTES

- February 6, 2024 Review Committee B Minutes; including Executive Session

  MOTION: Dr. Gillard moved to approve the February 6, 2024 Review Committee B Minutes; including Executive Session.
  SECOND: Dr. Artz.
  VOTE: The following Committee members voted in favor of the motion: Dr. Krahn, Dr. Artz, Ms. Bain, and Dr. Gillard. The following Committee member was absent: Dr. Beyer. The following Committee member abstained: Ms. Jones.
  VOTE: 4-yay, 0-nay,1-abstain, 0-recuse, 1-absent.
  MOTION PASSED.

LEGAL MATTERS

F. FORMAL INTERVIEWS

1. THIS CASE HAS BEEN PULLED FROM THE AGENDA.

G. FORMAL INTERVIEWS

1. MD-23-0462A, SCOTT G. EDWARDS, M.D., LIC. #48056
Dr. Edwards was present with council Cody Hall.

Board staff summarized that a Medical Consultant ("MC") opined that Dr. Edwards deviated from the standard of care by failing to ensure that necessary and appropriate surgical components were present, resulting in the cancellations of two surgeries. In addition, the MC opined that Dr. Edwards failed to properly supervise staff involved in the process of ensuring the availability of the proper components. Initial documentation identified a plan to utilize an implant manufactured by Stryker. This first surgery was scheduled at Banner Union Hills Surgery Center. The Director of Nursing documented that prior to the planned procedure, Dr. Edwards stated that he should have asked the Integra company instead of Stryker. An Integra representative was contacted and stated that he could have the implants ready following a three-hour delay and multiple implant sizes would be available except for the largest size. Dr. Edwards stated that he required the largest size for his patient. The sales representative replied that he could not supply the desired size on that day. In his written narrative, Dr. Edwards reportedly verbally confirmed with the Integra representative that his company provided pyrocarbon implants though no supporting documentation of this exchange was provided. The surgery was cancelled prior to the initiation of any anesthetic procedure. In his narrative, Dr. Edwards stated that he actually ordered implants from the Smith & Nephew orthopedic implant manufacturer online, not Stryker. Dr. Edwards suggested that the Stryker sales representative removed the Smith & Nephew representatives' acceptance of this case on the online platform and replaced it with his own acceptance of the request to provide implants for this case. Dr. Edwards stated that he verified in a phone conversation with the O.R. charge nurse approximately one week prior to the surgery, that Smith & Nephew components would be available for the operation. No documentation regarding this conversation was provided. Dr. Edwards explained that Smith & Nephew had recently acquired Integra in 2020, and he assumed that Integra still provided his desired type of implant. Dr. Edwards provided email communications between Dr. Edwards' surgery scheduler and an Integra company representative as well as a surgery scheduling form requesting Integra pyrocarbon arthroplasty implants. The email exchange confirmed Dr. Edwards' request for Integra polycarbon implants. The patient was taken to the O.R and general anesthesia was initiated it was discovered that the desired orthopedic implants were not present and the case was cancelled. In an email dated after the initiation of the Board's investigation, the scheduler stated, 'For clarification, when I received the email from Marshall (the PA) telling me that we had to reschedule the surgery because Stryker didn't have the parts, he specifically stated that it needed to be Integra.' Dr. Edwards stated that a partial wrist implant was provided for the second surgery but not the necessary finger implants.

Dr. Edwards provided an opening statement and stated that only one company makes pyrocabron technology for the upper extremities. Dr. Edwards explained that the PA originally booked the first case with Stryker and when they met to discuss the case he knew Stryker did not have them. Dr. Edwards explained that he contacted the surgical center to inform them that the surgery needs to be scheduled with the Smith & Nephew implant. Dr. Edwards further explained that the torque system which makes computer generated calls to request vendors for surgery and the vendor will accept or deny the request. Dr Edwards informed the Committee that the Stryker representative changed the request in the torque system from Smith & Nephew to Stryker. The Stryker representative stated that he changed the request because they thought it was a mistake. Dr. Edwards confirmed that in this case the pyrocarbon implant was needed. A Smith & Nephew representative was contacted and since they had the right implant but the wrong size, the surgery had to be cancelled. Regarding the second case, Dr. Edwards explained per the Smith & Nephew representative staff should call it the Integra implant. Dr. Edwards insisted not to have the patient placed under anesthesia until he could verify the implants himself. Per protocol the implant package cannot be opened until laminar flow must be established. During the time out they looked and realized that they were not the correct

implants. The Integra representative confirmed the implants were for the wrist and therefore the second surgery for JB was cancelled. Dr. Edwards stated he felt terrible for the miscommunication and the cancellation of the two surgeries and that the patient has every right to be upset. Dr. Edwards further stated that it is his responsibility to be sure that his patients are safe.

During questioning, Dr. Edwards stated that he uses pyrocarbon implants about once a year and silicone implants are much more common so he does about 13 a year. Dr. Edwards informed the Committee that he is employed by the CORE Institute but has hospital privileges throughout the Banner Healthcare system, including the CORE Institute hospital. Dr Edwards explained that the two surgeries were scheduled to be completed at two different Banner facilities for patient JB. The surgery locations were to accommodate the patient who was under a time constraint. Dr. Edwards explained that the first surgery was scheduled using the torque system to be with Smith & Nephew. The day of the surgery the Stryker representative was at the surgery center with silicone implants. The hospital placed blame on the Stryker representative for changing the surgery details in the torque system causing the cancellation. Dr. Edwards stated that he spoke directly with the representative on the phone and confirmed the implants where there prior to the second surgery. The Integra representative confirmed the implants were dropped off at the hospital the night before for sterilization. Dr. Edwards stated that in the future he will confirm the specificity of the implant with the representative. Dr. Edwards reiterated that during the timeout portion of the second surgery is when he was allowed to review the implant and noticed that it was for the incorrect joint. Dr. Edwards informed the Committee that he felt he did a lot to ensure that the implants were there but in hindsight could have been more thorough. Dr. Edwards noted that all the steps can be taken however; until the box is opened he cannot be sure that it is the correct implant. Dr. Edwards informed the Committee of the process of how the implants are placed in the OR and how they arrive at the surgery site for sterilization prior to surgery. Dr. Edwards stated that he spoke to the patient's wife about the wrong implant being provided and had to cancel the surgery. Dr. Edwards confirmed that there was no discussion of silicone implants, it was always pyrocarbon. Dr. Edwards explained that there are no back up sets since they are expensive and the suppliers will not allow extra sets to be sent. Regarding the RN's preoperative check list, Dr. Edwards opined that the nurse had no idea of what they were doing and that everyone played a role and since he was there, he opined it did not really matter.

Dr. Krahn inquired about referring this center for review to better understand the circumstances.

Ms. Smith informed the Committee that they can direct Board staff to refer the facility to the Department of Health Services for review of the incident.

Dr. Edwards confirmed in the first case there would be a three hour delay to get new implants, but when he asked about the size they did not have the correct size so the surgery was cancelled. Dr. Edwards explained that when he reviewed what occurred with the first surgery, it was initially booked incorrectly under Stryker, but it was changed to Smith & Nephew and the message went out to the surgery center. He spoke to the representative and looked into the Torque system to see what happened and why suddenly a different representative was there. Dr. Edwards opined that regarding the first case, there was not anything he could have done differently, and the communication was appropriate. Regarding the second surgery, Dr. Edwards stated that he cannot remember how he ordered the implants size but opined that he would have said to include the large sizes in the order form.

MOTION: Ms. Bain moved for the Board to enter into Executive Session to obtain legal advice pursuant to A.R.S. § 38-431.03(A)(3).
SECOND: Dr. Krahn.

VOTE: The following Committee members voted in favor of the motion: Dr. Krahn, Dr. Artz, Ms. Bain, Dr. Gillard, and Ms. Jones. The following Committee member was absent: Dr. Beyer.
VOTE: 5-yay, 0-nay, 0-abstain, 0-recuse, 1-absent.
MOTION PASSED.

The Board entered into Executive Session at 1:30 p.m.
The Board returned to Open Session at 1:37 p.m.
No legal action was taken by the Committee during Executive Session.

MOTION: Ms. Bain moved to return the case for further investigation to obtain additional information from 1) the surgical center to obtain information regarding the torque communication system 2) the hospital to obtain information regarding ordering and processing of implants in general including autoclave procedures and this case in particular and 3) from the vendors of the implants for the second procedure to explain process for ordering, tracking, receipt, and packaging of devices.
SECOND: Dr. Artz.
Dr. Gillard spoke against the motion and opined that the Committee has enough information to adjudicate this case right now.
VOTE: The following Committee members voted in favor of the motion: Dr. Krahn, Dr. Artz and Ms. Bain. The following Committee members voted against the motion: Dr. Gillard and Ms. Jones. The following Committee members were absent: Dr. Beyer.
VOTE: 3-yay, 2-nay, 0-abstain, 0-recuse, 1-absent.
MOTION PASSED.

H. FORMAL INTERVIEWS

1. THIS ITEM HAS BEEN PULLED FROM THE AGENDA

GENERAL BUSINESS

I. DISCUSSION REGARDING DEBRIEFING ON COMMITTEE PROCESSES

Dr. Krahn stated that it can be challenging switching Board rooms since the microphone systems are different.

Board staff informed the Committee that the microphone cannot be changed at this time but will investigate a solution to help mitigate the difficulties.

Committee member inquired about formal interview times being changed when a cancelation occurs.

Board staff explained that cancellations sometimes happen close to the meeting and staff is not able to reschedule the interview times.

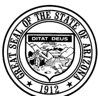
Dr. Artz asked about the process of case MD-23-0462A once the investigation is completed.

Ms. Smith explained that the case will return to Committee B as a Formal Interview with a staff review of the case.

J. ADJOURNMENT

MOTION: Ms. Jones moved for adjournment.
SECOND: Dr. Gillard.
VOTE: The following Committee members voted in favor of the motion: Dr. Krahn, Dr. Artz, Ms. Bain, Dr. Gillard, and Ms. Jones. The following Committee member was absent: Dr. Beyer.
VOTE: 5-yay, 0-nay, 0-abstain, 0-recuse, 1-absent.
MOTION PASSED.

The meeting adjourned at 1:50 p.m.



Patricia E. McSorley, Executive Director