

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

WHITNEY BEAUBIEN, as Personal
Representative of the Estate of CRAIG
BEAUBIEN,

Plaintiff,

v.

Case No.: 21-11000
Hon. Gershwin A. Drain

CHARU TRIVEDI, M.D., *et al.*,

Defendants.
_____ /

OPINION AND ORDER: (1) DENYING DEFENDANTS' DAUBERT MOTION [ECF Nos. 63] WITHOUT PREJUDICE; (2) REOPENING DISCOVERY; (3) DENYING PLAINTIFF'S MOTION TO STRIKE MICHAEL KRAUT AND/REQUEST FOR DAUBERT HEARING [ECF No. 64]; And (4) STRIKING DEFENDANTS' REPLY BRIEF [ECF No. 76].

I. INTRODUCTION

This is a medical malpractice action alleging that Defendant Charu Trivedi, M.D., breached the standard of care by failing to timely diagnose Plaintiff Whitney Beaubien's husband, Craig Beaubien, with terminal renal cell carcinoma. Mr. Beaubien passed away on June 18, 2023. Plaintiff's complaint also alleges a claim against the Toledo Clinic, Inc. d/b/a Toledo Clinic Cancer Centers medical malpractice. See ECF No. 61.

Presently before the Court is two matters. First is Defendants' Daubert Motion to Strike Dr. Russell Pachynski's Opinion Concerning Reduced Survival [ECF No. 63] (the "Pachynski Motion"). It was filed on October 12, 2023, and Plaintiff responded on October 27, 2023. Defendant replied on February 14, 2024 [ECF No. 76]. Because the reply is untimely filed without leave of court, however, it will be stricken. See E.D. Mich. L.R. 7.1 (e)(2).

Second, Plaintiff filed a Motion to Strike Michael Kraut, M.D., and/or Request for Daubert Hearing on October 12, 2023 [ECF No. 64] (the "Kraut Motion"). Defendant responded on December 26, 2023. Plaintiff did not reply.

Upon review of the parties' briefing, the Court concludes oral argument will not aid in the resolution of these matters. Accordingly, the Court will resolve the Plaintiff's Motion to Amend on the briefs. *See* E.D. Mich. L.R. 7.1(f)(2).

For the reasons set forth below, the Pachynski Motion is denied without prejudice, the Kraut motion is denied, and Defendants' reply brief is stricken.

II. Factual Background

On November 27, 2018, Mr. Beaubien began care with Dr. Trivedi for polycythemia after blood tests ordered by his primary care physician revealed Plaintiff's hematocrit (HCT)—his red blood cell count—was abnormally high at 53.3. Dr. Trivedi did not take any imaging studies to determine the cause of Plaintiff's high HCT. Her impression was Plaintiff's polycythemia was secondary

to smoking, dehydration, and sleep apnea. Dr. Trivedi ordered lab work and a test to rule out primary polycythemia. She suggested increased fluids, weight loss, smoking cessation and continued CPAP usage. She planned a phlebotomy if Plaintiff's HCT was above 50 at follow up. On December 13, 2018, Dr. Trivedi ordered a phlebotomy because Plaintiff's HCT remained above 50. She ordered another phlebotomy in February of 2019.

On June 23, 2019, Plaintiff went to Promedica Monroe Regional Hospital with complaints of severe headache lasting a week, slight visual/depth perception disturbance; mild left-sided weakness and nausea without vomiting. A CT scan and MRI revealed an 8.3-centimeter tumor in Plaintiff's kidney with metastasis to the brain, and multiple bilateral lung nodules. He was transferred to the University of Michigan Hospital on the same day and underwent a lung biopsy, which confirmed metastatic renal cell carcinoma ("RCC") to the lungs and brain.

On July 11, 2019, Plaintiff was seen by oncologist Bruce Redman, D.O., who explained metastatic RCC is not curable and that treatment would be palliative with the goal of prolonged time and quality of life. Treatment consisted of three modalities: (1) stereotactic radiotherapy to address the brain tumor; (2) targeted chemotherapy to attack the cancer directly; and (3) new immunotherapy treatment intended to trigger the body to mount an immune response to cancer. All of this was followed by surgery to resect the remains of the brain tumor.

Nearly forty months after his diagnosis of metastatic RCC to the brain, kidney and lungs, Plaintiff has had no recurrence of brain metastasis, however in June of 2021, he was diagnosed with liver metastasis, which continued to progress despite treatment.

Plaintiff's expert, Dr. Russell K. Pachynski, M.D., a board-certified oncologist, reviewed Plaintiff's medical records from Dr. Trivedi, the Monroe Regional Hospital, and the University of Michigan Hospital. He drafted a report that was published on July 25, 2022. In his report, Dr. Pachynski concludes it is "a virtual certainty that the primary tumor in the kidney was detectable with appropriate imaging[,]” such as ultrasound, CT scan or an MRI, if done in November of 2018 when Plaintiff first began treating with Dr. Trivedi and the Toledo Clinic. ECF No. 63-2, PageID.1126. In reaching his conclusion, Dr. Pachynski relied on the fact that in June of 2019, the renal tumor was 8.3 centimeters and had progressed to stage IV with lung and brain metastases. *Id.* He further explained:

Patients with more advanced disease (*i.e.* more metastatic tumor burden) typically have lived with their cancer for longer periods of time, as cancer – on average – tends to grow in an exponential manner in humans. Thus, it follows that a delay in diagnosis and treatment would result in more advanced disease, and thus lowered overall survival.

Id., PageID.1124. However, Dr. Pachynski could not opine on the size of the kidney tumor in November of 2018 and cannot determine when or where it first spread. ECF No. 40-5, PageID.411.

Dr. Pachynski further concluded that it is probable that the brain metastasis developed during the seven months Plaintiff's RCC remained undiagnosed and untreated. ECF No. 63-2, PageID.1125. Relying on peer reviewed studies, Dr. Pachynski concluded that, for patients with brain metastasis at the time of RCC diagnosis, only 50% of them were alive at 12 months compared to the 53% of patients who did not have brain metastasis at the time of diagnosis and were alive 48 months after diagnosis. *Id.* He found that Mr. Beaubien could have lived an additional 12 to 36 months if no brain metastasis was present in November of 2018 and an additional 9 to 12 months if the brain metastasis was present at that time. *Id.* As such, Dr. Pachynski opined that "given the totality of the circumstances, more likely than not, the delay in diagnosis and treatment of the patient's metastatic RCC would have led to a decrease in his overall survival." *Id.* at PageID.1124-1125.

Dr. Pachynski was deposed on August 2, 2022. At his deposition, he testified that it was more probable than not that the brain metastasis was not present in November of 2018. ECF No. 40, PageID.411. He further testified that he could not be certain whether micro metastatic disease was present in November of

2018. *Id.* He said that it was “certainly probable that [Mr. Beaubien] had metastatic disease at that point.” *Id.* He indicated that micro metastatic disease is present in many cancer patients, however the disease is not detectable by imaging. *Id.* at PageID.411-412.

Dr. Pachynski further opined that Plaintiff’s treatment in 2019 would not have included radiation for the brain tumor if the metastasis had not been present in November of 2018 and Plaintiff’s RCC was promptly discovered. *Id.* at PageID.413. However, the systemic treatment (chemotherapy) would have been the same—the targeted cabozantinib followed by the immunotherapies ipilimumab and nivolumab. *Id.* In his original Expert Report and at his deposition, Dr. Pachynski provided two general opinions: (1) that with earlier diagnosis Decedent could have lived an additional 12 to 36 months if the brain metastasis was not present in November 2018; and (2) an additional 9 to 12 months if they were present

Mr. Beaubien lived with cancer until his death on June 18, 2023, 54 months and 21 days following his initial November 2018 visit with Dr. Trivedi and 47 months and 24 days after his diagnosis. Following Mr. Beaubien’s death, Plaintiff submitted a “Supplemental Report”. ECF No. 63-2, PageID.1139. His report relies on relatively new data regarding the median overall survival (OS) for kidney cancer patients who participated in immunotherapies ipilimumab and nivolumab.

The report explains that “immunotherapy [Mr. Beaubien] received for kidney cancer had only been FDA approved the year prior, in April 2018...Thus, data informing us of expected survival in patients receiving this immunotherapy comparing those with and without brain metastasis is relatively new/recent.” ECF No. 63-2, PageID.1139. Based on the data he compiled, he updated Mr. Beaubien’s median OS to 47- 56 months without brain metastasis and 33 months with brain metastasis.

Defendants take issue with Dr. Pachynski’s supplemental report because it “impermissibly takes the analysis a step further to argue that because Decedent responded well to treatment—he lived 48 months from diagnosis when the overall survival for patients with brain metastasis is 33 months—he could have lived an additional two years had treatment started earlier assuming he had the same response to treatment and no brain metastasis.” ECF No. 63, PageID.1072. Specifically, Defendants maintain that Dr. Pachynski’s calculation of “what he calls [Mr. Beaubien’s] response ratio” “manipul[ates] a generally accepted metric in the oncology community—overall survival—to bolster Plaintiff’s claim [that Mr. Beaubien] could have lived longer with earlier diagnosis and treatment.” *Id.* Accordingly, Defendants aver that Dr. Pachynski’s supplemental report is unreliable and should be excluded under Fed. R. Evid. 702 (“Rule 702”).

In the Kraut Motion, Plaintiff seeks to exclude the Defendants' expert oncologist Michael Kraut, M.D. She argues that he is not qualified to render an expert opinion on causation as it relates to Mr. Beaubien's renal cell carcinoma because his expertise is lung cancer.

The Court will discuss the applicable law and analysis below.

III. Fed. R. Evid. 702

Under Rule 702, “a person with ‘specialized knowledge’ qualified by his or her ‘knowledge, skill, experience, training, or education’ may give opinion testimony if it ‘will assist the trier of fact to understand the evidence or to determine a fact in issue.’ ” *United States v. Johnson*, 488 F.3d 690, 698 (6th Cir. 2007) (quoting Fed. R. Evid. 702). “While a proposed expert witness’s qualification to testify ‘in the form of an opinion . . . is unquestionably a preliminary factual determination for the trial court . . . it is a determination which must be made upon the *evidence* of the witness' qualifications.” *Kingsley Assoc. Inc. v. Del-Met, Inc.*, 918 F.2d 1277, 1286 (6th Cir.1990) (emphasis added) (internal quotation omitted); See Fed. R. Evid. 104(a); and Fed. R. Evid. 702.

The burden on a party proffering expert testimony is to “show by a preponderance of proof that the expert whose testimony is being offered is qualified and will testify to scientific knowledge that will assist the trier of fact in

understanding and disposing of relevant issues.” *Sigler v. Am. Honda Motor Co.*, 532 F.3d 469, 478 (6th Cir. 2008).

Rule 702 governs the reliability of an expert’s opinion as well. It states that A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

Where a party challenges the testimony of an expert witness, FRE 702 triggers a court’s “gate-keeping role” to determine the admissibility of that testimony. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 597 (1993). “The task for the district court in deciding whether an expert's opinion is reliable is not to determine whether it is correct, but rather to determine whether it rests upon a reliable foundation, as opposed to unsupported speculation.” *In re Scrap Metal Antitrust Litig.*, 527 F.3d 517 (6th Cir. 2008). District courts enjoy

broad discretion in determining whether to admit or exclude expert testimony. *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 672 (6th Cir. 2010).

The Supreme Court in *Daubert* identified several factors that courts may consider in determining whether an expert opinion is reliable. This includes: (1) whether a theory or technique has been tested; (2) whether a theory has been subjected to peer review and publication; (3) whether a method has a high known or potential rate of error and whether there are standards controlling the technique's operation; and (4) whether the theory or technique enjoys a "general acceptance" within the relevant scientific community. *Johnson v. Manitowoc Boom Trucks, Inc.*, 484 F.3d 426, 429 (6th Cir. April 2007) (citing *Daubert.*, 509 U.S. at 579).

IV. Analysis

a. The Pachynski Motion

In their Motion, Defendants do not question Dr. Pachynski's qualifications. Instead, they maintain that his "method for calculating [Mr. Beaubien's] survival (utilizing what he terms a 'response ratio') lacks peer-review, it is not generally accepted, it cannot be tested, and it constitutes patent speculation (subject to high rate of error)." ECF No. 63, PageID.1077. "There is no authority in the field of oncology for the use of a deceased patient's treatment 'response ratio' to establish

how long that patient could have lived based on a theoretical different date of diagnosis and start of treatment[,]" Defendants say. *Id.*

In his report, Dr. Pachynski stated that, "[i]n the pivotal trial that led to the FDA approval, patients with metastatic kidney cancer without brain metastasis treated with the exact same immunotherapy that Mr. Beaubien received lived a median of 55.7 months (~ 4.6 years). At 6 years, approximately 40% of these patients are still alive." ECF No. 64-5, PageID.1520. In another study, "the expected survival with brain metastases treated with the same immunotherapy that Mr. Beaubien received had a median survival of 32.7 months[;]" those "without brain metastases had a median survival of 47.2 months." ECF No. 64-5, PageID.1520.

Dr. Pachynski opines that, because Mr. Beaubien responded well to the new immunotherapy despite having developed brain metastases, Mr. Beaubien "would have responded the same had he not developed brain metastases." ECF No. 68, PageID.1813. He arrives at this hypothesis by applying a "1.45x response ratio" to treatment. *Id.* Dr. Pachynski calculated the response ratio by dividing the number of months Mr. Beaubien survived from the date of his diagnosis (48 months) by the overall survival rate for patients with kidney cancer without brain metastases (33 months). ECF No. 64-5, PageID.1521. He then multiplied that ratio (1.45) by the overall survival rate for kidney cancer patients without brain metastases (52

months). *Id.* The result of this multiplication is a survival rate of 75.4 months, and because Mr. Beaubien survived for 48 months, Dr. Pachynski concluded that he would have lived 27 months longer had he been earlier diagnosed.

In discussing the reliability of Dr. Pachynski's method of calculating the response ratio, Plaintiff discusses his qualifications and experience in oncology and treatment renal cell carcinoma. She also cites scientific literature, which notes that "it is important to use multiple endpoints to assess changes in clinical course that occur as a result of the medical intervention." ECF No. 68, PageID.1812. While the Court understands that new data has emerged to indicate that patients who used the same immunotherapies as Mr. Beaubien have a different survival rate than those who did not use those immunotherapies, Dr. Pachynski does not assert that any new data calculates the survival rate by using a method similar to his calculations of the response ratio.

While the scientific literature discusses generally recognized endpoints medical practitioners use to assess changes in clinical course that occur as a result of the certain medical interventions, Plaintiff does not cite literature discussing the calculation of anything resembling a "response ratio." She does not assert that Dr. Pachynski's method in calculating the response ratio is generally accepted in the scientific community. She does not discuss the rate of error involved in performing these calculations. She does not say that other members of the scientific

community have employed similar methods to calculate anything like a “response ratio” to determine a patient’s survival rate based on how he/she would have responded to treatment had it began on an earlier date.

Without more information, the Court is unable to reach a conclusion regarding the reliability of Dr. Pachynski’s methods for calculating Mr. Beaubien’s “response ratio.” Plaintiff states that, “[t]o the extent that this Court finds that it needs additional clarification regarding Dr. Pachynski’s updated opinion, Plaintiff would voluntarily offer Defendants an opportunity to re-depose Dr. Pachynski on his updated opinion on overall survival. It would be highly prejudicial to Plaintiff if Dr. Pachynski’s opinion was stricken without him [having] an opportunity to expand upon it in a deposition.” ECF No. 68, PageID.1814. The Court will reopen discovery for the narrow purpose of allowing the parties to depose Dr. Pachynski about his supplemental report. Discovery will reopen on March 11, 2023 and close on April 11, 2023. If additional briefing—beyond what has already been filed—is required, the Court will impose a limit of five pages for all motions, responses, and replies.

Defendants’ Pachynski Motion is denied without prejudice to renewing it after discovery closes.

b. The Kraut Motion

Dr. Kraut opined in his Expert Report that (1) Mr. Beaubien “had such advanced metastatic disease in his brain and lungs” that it “would have been present when he established care with Dr. Trivedi; (2) the cancer would have been incurable even if diagnosed in November 2018 because it was in the retroperitoneal lymph nodes and otherwise already metastatic; (3) the primary kidney tumor would not have been resected with earlier diagnosis because the cancer was metastatic and also due to multiple comorbidities; and (4) the start of treatment did not have any impact on his lifespan.” ECF No. 67, PageID.1652.

Kraut’s opinions would clearly be helpful to the trier of fact in determining if the delay in diagnosis reduced Mr. Beaubien’s survival rate. The principal issue in Plaintiff’s motion pertains to Dr. Kraut’s qualifications. But “Plaintiff is not making an argument that Dr. Kraut is not a qualified oncologist.” ECF No. 64, PageID.1204. “He certainly is[,]” Plaintiff notes, however, “his area of expertise is lung cancer, not kidney cancer.” *Id.*

Dr. Kraut practiced in medical oncology for 40 years before retiring in January 2023. ECF No. 67-2, PageID.1668 His duties extended to teaching oncology fellows, residents, radiation oncology residents, and medical students. ECF No. 67-2, PageID.1668. He testified that in his career, he has been a co-investigator in two or three kidney cancer trials. *Id.* Dr. Kraut has treated patients

with kidney cancer, about 5% of the clinic’s patient population are being treated for kidney cancer. ECF No. 67-2, PageID.1701. He indicated that he has “a lot of experience” with immunotherapies on lung cancer and that the medical principle of immunotherapy for lung cancer is the same for renal cell carcinoma. ECF No. 67-2, PageID.1739. “The survivals in renal cell carcinoma with immune therapy are very similar to the survivals in lung cancer[,]” he said. *Id.* In the last three years, he had prescribed immunotherapies and/or targeted therapies for two patients. Further, Dr. Kraut has authored a substantial number of publications in medical oncology.

As a reminder, Rule 702 requires that an expert be qualified by “knowledge, skill, experience, training, or education.” Based Dr. Kraut’s knowledge, experience, training, and skill, the Court finds that he is qualified to give the expert opinion he proffers. Indeed, his experience—over a period of 40 years—involves diagnosis and treatment of renal carcinoma and lung cancer, including determinations of metastasis and lifespan for patients undergoing immunotherapies and targeted therapies.

V. CONCLUSION

For the reasons set forth above, the Pachynski Motion is **DENIED WITHOUT PREJUDICE**. Discovery will reopen on March 11, 2023 and close on April 11, 2023. If additional briefing—beyond what has already been filed—is

required, the Court will impose a limit of five pages for all motions, responses, and replies. The Kraut Motion is **DENIED**. Defendant's reply brief [ECF No. 76] is **STRICKEN**.

SO ORDERED.

Dated: March 11, 2024

/s/Gershwin A. Drain
GERSHWIN A. DRAIN
United States District Judge

CERTIFICATE OF SERVICE

Copies of this Order were served upon attorneys of record on March 11, 2024, by electronic and/or ordinary mail.

/s/ Lisa Bartlett
Case Manager