**IN THE SUPERIOR COURT OF THE STATE OF DELAWARE**

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| DEBORAH CHAPMAN,<br><br>Plaintiff,<br><br>v.<br><br>ASTRAZENECA PHARMACEUTICALS LP; and ASTRAZENACE LP,<br><br>Defendants. | )<br>)<br>)<br>)<br>)<br>)<br>)<br>)<br>)<br>) | C.A. No. N17C-04-320 PPI |

Submitted: July 7, 2022[1]
Decided: October 3, 2022

*Upon Defendants' Motion to Exclude Opinion Testimony from Dr. Gaurav Jain under Delaware Rule of Evidence 702*
**GRANTED**

*Upon Defendants' Motion for Summary Judgment*
**GRANTED**

*Upon Defendants' Motion to Exclude Opinion Testimony from Dr. Robert Weiss under Delaware Rule of Evidence 702*
**MOOT**

## I. INTRODUCTION

This is a personal injury action involving product liability claims arising from the use of proton pump inhibitors ("PPI"). Plaintiff Deborah Chapman seeks damages for onset and chronic injuries purportedly caused by products manufactured and sold by AstraZeneca Pharmaceuticals LP and AstraZeneca LP (collectively "AstraZeneca").

[1] D.I. No. 119.

Now before the Court are three motions filed by AstraZeneca: (i) Defendants' Motion to Exclude Opinion Testimony from Dr. Gaurav Jain under Delaware Rule of Evidence 702 (the "Jain Motion"); (ii) Defendants' Motion to Exclude Opinion Testimony from Dr. Robert Weiss under Delaware Rule of Evidence 702 (the "Weiss Motion"); and (iii) Defendants' Motion for Summary Judgment (the "SJ Motion"). Ms. Chapman opposed all three motions. The Court held a hearing on the motions on June 6, 2022.[2] At the end of the hearing, the Court took the matters under advisement. The court reporter filed the official transcript on July 7, 2022.[3]

For the reasons stated below, the Court will **GRANT** the Jain Motion. The Court finds that Dr. Jain failed to provide admissible causation testimony as his opinions are not stated to a reasonable degree of medical probability. The Court will **GRANT** the SJ Motion because Ms. Chapman cannot demonstrate causation due to the exclusion of Dr. Jain's opinion. Because of the ruling on the Jain Motion and the SJ Motion, the Court need not reach the issues raised in the Weiss Motion.

## II. RELEVANT FACTS

AstraZeneca designed, manufactured, and sold the product Nexium.[4] Ms. Chapman ingested Nexium for approximately ten years to treat a chronic reflux condition.[5] Nexium is a PPI.[6] PPIs work by inhibiting a molecule in the stomach responsible for secretion of acid into the stomach to treat gastroesophageal reflux disease ("GERD") and several other chronic acid reflux conditions.[7]

[2] D.I. No. 117.
[3] D.I. No. 119.
[4] Chapman's Opp. to AstraZeneca's Mot. to Exclude Opinion Testimony from Dr. Robert Weiss at 3 (D.I. No. 90).
[5] *Id.*
[6] *Id.*
[7] *Id.*

In 1989, the United States Food & Drug Administration ("FDA") approved omeprazole (Prilosec), the first class of PPI used to treat GERD and other reflux related conditions.[8] Subsequently, the FDA approved six prescription PPI medications, including Nexium, for use.[9] In 2016, Ms. Chapman was diagnosed with chronic kidney disease ("CKD").[10] Ms. Chapman asserts that her use of AstraZeneca's Nexium caused the development and worsening of her CKD. Additionally, Ms. Chapman contends that AstraZeneca did not provide adequate warnings about the risks of Nexium causing CKD.[11]

Ms. Chapman's claims against AstraZeneca require Ms. Chapman to show that her CKD diagnosis and her injuries were directly and proximately caused by her ingestion of Nexium.[12] Additionally, Ms. Chapman must articulate evidence of both general and specific causation.[13] Ms. Chapman seeks to introduce testimony from Dr. Weiss and Dr. Jain to demonstrate causation.[14] AstraZeneca objects to the testimony of both Dr. Weiss and Dr. Jain.[15]

## III. APPLICABLE LAW

To be admissible, evidence must be relevant, meaning it has "any tendency to make the existence of any fact that is of consequence to the determination of the action

[8] AstraZeneca's Mot. to Exclude Opinion Testimony from Dr. Robert Weiss at 3 (D.I. No. 65).
[9] *Id.*
[10] Chapman's Opp. to AstraZeneca's Mot. to Exclude Opinion Testimony from Dr. Robert Weiss at 3 (D.I. No. 90).
[11] *Id.*
[12] *Id.*
[13] AstraZeneca's Mot. to Exclude Opinion Testimony from Dr. Robert Weiss at 13 (D.I. No. 65); AstraZeneca's Mot. to Exclude Opinion Testimony from Dr. Gaurav Jain at 4 (D.I. No. 63).
[14] Chapman's Opp. to AstraZeneca's Mot. to Exclude Opinion Testimony from Dr. Robert Weiss at 1 (D.I. No. 90); Chapman's Opp. to AstraZeneca's Mot. to Exclude Opinion Testimony from Dr. Gaurav Jain at 1 (D.I. No. 91).
[15] AstraZeneca's Mot. to Exclude Opinion Testimony from Dr. Robert Weiss at 1 (D.I. No. 65); AstraZeneca's Mot. to Exclude Opinion Testimony from Dr. Gaurav Jain at 1 (D.I. No. 63).

more probable or less probable than it would be without the evidence."[16] To determine relevance, the Court must examine the purpose for which the evidence is offered and whether it is of consequence to the action and advances the likelihood of asserted facts.[17] Under D.R.E. 403, the Court may exclude evidence where the danger of undue prejudice substantially outweighs its probative value.[18] Probative value concerns "the tendency of the evidence to establish the proposition that it is offered to prove."[19]

The admissibility of expert testimony is governed by Rule 702 of the Delaware Rules of Evidence ("Rule 702"). Rule 702 provides that:

> If scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.[20]

When applying Rule 702, Delaware Courts have adopted the U.S. Supreme Court's holdings in *Daubert v. Merrell Dow Pharmaceuticals*.[21] *Daubert* requires the trial judge to act as gatekeeper and determine whether the expert testimony is relevant and reliable and whether it will assist the trier of fact.[22] The Delaware Supreme has adopted a five-part test for the Court to consider when determining the admissibility of scientific or technical testimony. The Court must decide whether:

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[16] D.R.E. 401.
[17] *Sheehan v. Oblates of St. Francis de Sales,* 15 A.3d 1247, 1254 (Del. 2011).
[18] D.R.E. 403.
[19] *Getz v. State,* 538 A.2d 726, 731 (Del. 1988).
[20] D.R.E. 702.
[21] *See Bowen v. E.I. DuPont de Nemours & Co., Inc.*, 906 A.2d 787, 794 (Del. 2006) ("Though the United States Supreme Court's interpretations of F.R.E. 702 in *Daubert* and *Kumho* are only binding upon federal courts, this Court has expressly adopted their holdings as correct interpretations of D.R.E. 702") (internal citations omitted).
[22] *See id.*; *see also Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 582 (1993) (internal citations omitted).

> (i) the witness is qualified as an expert by knowledge, skill experience, training or education; (ii) the evidence is relevant and reliable; (iii) the expert's opinion is based upon information reasonably relied upon by experts in the particular field; (iv) the expert testimony will assist the trier of fact to understand the evidence or to determine a fact in issue; and (v) the expert testimony will not create unfair prejudice or confuse or mislead the jury.[23]

Applying that test, the Supreme Court has held that a doctor's testimony about what is possible "is no more valid than the jury's own speculation as to what is or is not possible."[24] To be admissible, the Court must determine that the medical experts opinions are "stated in terms of reasonable medical probability or a reasonable medical certainty."[25]

## IV. DISCUSSION

### A. THE JAIN MOTION

Ms. Chapman seeks to have Dr. Jain testify as a specific causation expert witness.[26] Dr. Jain has been licensed to practice medicine by the State of Alabama for fifteen years and has been double board certified by the American Board of Internal Medicine for thirteen years.[27] Dr. Jain provided an expert report as well as a rebuttal expert report to support his conclusion that his differential diagnosis of CKD in Mrs. Chapman was due to her chronic use of PPIs.[28] Dr. Jain's opinion is based on an

[23] *Cunningham v. McDonald*, 689 A.2d 1190, 1193 (Del. 1997).
[24] *O'Riley v. Rogers*, 69 A.3d 1007, 1011 (Del. 2013).
[25] *Id. See also, Riegel v. Aastad*, 272 A.2d 715, 718 (Del. 1970)(A medical expert witness's testimony concerning "possible medical consequences, rather than…reasonable medical probability" was impermissible speculation.).
[26] Chapman's Opp. to AstraZeneca's Mot. to Exclude Opinion Testimony from Dr. Gaurav Jain at 1 (D.I. No. 91).
[27] *Id*. at 2; *see also Barksdale Cert*., Ex A. *Jain Expert Report*; *Barksdale Cert*., Ex. C *Jain CV* (same).
[28] Chapman's Opp. to AstraZeneca's Mot. to Exclude Opinion Testimony from Dr. Gaurav Jain at 2 (D.I. No. 91); *see also Barksdale Cert*., Ex A. *Jain Expert Report*; *Barksdale Cert*., Ex. B *Jain Rebuttal Expert Report* (same).

evaluation of Ms. Chapman's medical history and reliance upon his medical education and clinical experience as a practicing Board Certified Nephrologist.[29]

AstraZeneca seeks to have Dr. Jain's testimony excluded.[30] First, AstraZeneca argues that Dr. Jain offered a speculative opinion that PPIs caused Ms. Chapman's CKD.[31] AstraZeneca contends that because Dr. Jain's opinion was not stated in terms of reasonable medical certainty the opinion is speculative and does not satisfy the requisite *Daubert* standard.[32] Second, AstraZeneca argues that Dr. Jain did not "rule out and rule in" alternative causes of Ms. Chapman's CKD.[33] AstraZeneca states that the processes employed by Dr. Jain fail to rule out or rule in alternative factors as the cause of Ms. Chapman's CKD.[34] AstraZeneca contends that Dr. Jain's processes means the doctor failed to employ a required scientific process to reach an acceptable conclusion or opinion.[35] Third, AstraZeneca notes that Dr. Jain's conclusions rely, in part, on Dr. Wiess's opinion for general causation.[36] AstraZeneca contends that if Dr. Weiss' testimony is excluded, Dr. Jain's conclusions fail and Ms. Chapman cannot demonstrate specific causation.[37] Therefore, AstraZeneca asserts that Dr. Jain is not able to opine on whether or not PPIs were the specific cause of Ms. Chapman's CKD.[38]

In response, Ms. Chapman argues that Dr. Jain's opinion relies on his education, over ten years of experience as a clinician and practitioner, peer-reviewed reports and

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[29] Chapman's Opp. to AstraZeneca's Mot. to Exclude Opinion Testimony from Dr. Gaurav Jain at 11 (D.I. No. 91).
[30] D.I. No. 63 (Br. in Support of Mot. to Exclude Opinion Testimony from Dr. Gaurav Jain at 1).
[31] *Id*.
[32] *Id*. at 1,5.
[33] *Id*. at 2-3.
[34] *Id*. at 5-6
[35] *Id*. at 7-8, 15-16.
[36] *Id*. at 4.
[37] *Id*. at 18.
[38] *Id*. at 19.

scientific journals published on PPIs, and thorough review of Ms. Chapman's medical history.[39] Ms. Chapman further declares that Dr. Jain's expert report and rebuttal report establish a basis for his conclusion that there is a strong connection between Ms. Chapman's chronic use of PPIs and her CKD.[40] Ms. Chapman states that Dr. Jain's differential diagnosis is a well-accepted and reliable methodology and one reasonably relied upon by experts in his field.[41] Ultimately, Ms. Chapman's position is that the exhaustive review and differential diagnoses by Dr. Jain establishes his expert testimony as admissible and that any additional challenges are amenable to cross examination for the jury to give effect to the weight of the testimony.[42]

### B. DR. JAIN'S OPINIONS

Dr. Jain has submitted an expert report.[43] In addition, the parties deposed Dr. Jain on October 8, 2021.[44] Dr. Jain, in part, states:

> Based on my review of her medical records, Ms. Deborah Chapman had the following medical conditions:
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> • Chronic lower back pain, dating as far back as 1993
> • Pseudotumor cerebri
> • Systemic Lupus Erythematosis(SLE) (based on joint pains and serologic testing, including ANA and anti-ds DNA), diagnosed in 2016
> • Diabetes Mellitus, which based on labs, has been generally well controlled
> • Hypertension, with intermittent periods of poor control, though she demonstrated compliance with physician visits and medications
> • Aortic valve replacement and coronary artery bypass surgery in 2019, after an episode of bacteremia and infective endocarditis involving the aortic valve
> • Chronic Kidney Disease stage III/IV: Labs revealed absence of chronic kidney disease, based on creatinine, till 2013[45]

[39] D.I. No. 91 (Opp. to AstraZeneca's Mot. to Exclude Opinion Testimony from Dr. Gaurav Jain at 1-3).
[40] *Id*. at 2-3.
[41] *Id*. at 9.
[42] *Id*. at 3, 6.
[43] D.I. No. 63 (Br. in Support, Ex. B)
[44] D.I. No. 63 (Br. in Support, Ex. A)
[45] Ex. B at 1-2.

Dr. Jain does set out his opinions later in his report. With respect to Ms. Chapman's chronic kidney disease, Dr. Jain opines as follows:

> Amongst intrinsic renal causes, she had more than one possibility that could have led to her chronic kidney disease.
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> In the leading differential diagnosis for this patient, in regards, to the intrinsic renal causes that could have caused her kidney disease, I considered the following:
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> 1. Chronic medical illness that can affect the kidneys, such as diabetes and hypertension.
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>    Based on a review of my records, the patient was diagnosed with diabetes around 2010. Some records suggest that she was taking metformin as early as 2005, although I'm not sure if it was used for pre-diabetes or diabetes at that time. Interestingly, the patient has almost always maintained a good glycemic control (HbA1C less than 7 on multiple occasions) and has been off medications on many occasions. I do not have records to suggest that she had other microvascular complications of diabetes like retinopathy. There is a mention of neuropathy, but I understand that she had chronic low back pain and neuropathy, so hard to differentiate if the neuropathy was related to the diabetes or her chronic back issues. The relatively short duration of diabetes, and the absence of retinopathy makes diabetic kidney disease less likely. Regarding her blood pressure, she had some challenges with uncontrolled blood pressure specially in 2015, 2017 and 2019, though her blood pressure was reasonably well controlled in 2013 when she was diagnosed with CKD. Of note, kidney disease is also related with worsening hypertension, and can contribute to cardiac illnesses. In addition, she was diagnosed with SLE in 2016, and SLE can have a component of kidney involvement; in her case though, based on her urinary findings, and the absence of persistent red cells in the urine, it is unlikely that SLE was a cause of her kidney disease.
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> 2. Vascular disease leading to decreased blood supply to the kidney: I did not find clear evidence in the medical records that this was the cause of her chronic kidney disease, so it is not a strong possibility, in my opinion.

3. Nephrotoxicity from medications: Ms. Chapman was on 3 medications, on a chronic basis that could potentially cause or contribute to her kidney disease
   a) Proton pump inhibitors
   b) Topiramate
   c) NSAIDs

Notably, based on her clinical records, she was not taking NSAIDs after 2013, so I do not suspect that to be the leading differential, especially after the medication was stopped. *I am concerned about the chronic long-term use of PPIs in her case (As early as 2004, 9 years before her diagnosis of CKD), despite underlying chronic kidney disease, which may have contributed to the worsening of her kidney disease. As is often the case in patients with multiple medical problems, it is impossible to discern if one particular agent was more likely then another to cause chronic kidney disease.* Under such circumstances, we must use our best judgment, and determine if a medication could be contributing to the patient's chronic kidney disease.

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*It is my medical opinion that the chronic use of PPIs in Ms. Chapman could have contributed to her developing and progressing chronic kidney disease. Ms. Chapman has a 10-28% chance of developing kidney failure over the next 5 years.*[46]

The report does not opine as to reasonable probability. The opinions are couched in terms of "could have contributed" and "may have contributed" to her chronic kidney disease. Dr. Jain does appear to rule out certain items as the cause for Ms. Chapman's CKD—e.g., vascular disease and SLE. However, Dr. Jain does not state that PPIs were the probable cause of Ms. Chapman's CKD. Instead, Dr. Jain opines that chronic use of PPIs "could have contributed" to Ms. Chapman developing CKD and/or causing her CKD to progress or worsen.

The Court reviewed Dr. Jain's deposition and his testimony there does not clarify the issue. Dr. Jain does not state that his opinions are rendered to a reasonable degree of

[46] Ex. B at 3-5 (emphasis added).

medical probability. The Court queried counsel for the parties if that direct question was asked and the parties confirmed that it was not asked.[47] The Court has not been provided with any other supporting testimony or expert report that specifically opines as to Ms. Chapman's chronic kidney disease and her use of proton pump inhibitors.

### C. APPLYING DELAWARE EVIDENCE LAW, THE COURT MUST GRANT THE JAIN MOTION.

Expert witnesses do not have to explicitly use the words "reasonable medical certainty," but the overall summation of the opinion must lend itself to that conclusion.[48] Experts will often use similar words. Delaware law provides for flexibility on the actual wording of expert testimony.[49]

However, the expert's opinion must allow the Court to conclude that the expert finds: (i) one option more probable or likely than the others; (ii) that, having weighed varying factors or consulting material from his field, the expert has eliminated other possible causes; or (iii) that the varying factors have led the expert to suspect that this one factor is more likely the cause of the issue than another. In the absence of specific testimony, the Court must find that the testimony fails to meet the required threshold.

Semantics must give way in the search for a fair and just result. The Court may not over-emphasize the distinction between words like 'possible,' 'probable,' 'reasonable certainty.' A 'could have' answer of a medical expert may not be isolated and considered alone. The opinion must be considered in the light of all the other evidence in the case.[50]

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[47] Tr. at 12-19; Tr. at 26-29.
[48] *See Moses v. Drake*, 109 A.3d 562, 568 (Del. 2015)(expert witnesses have some "leeway" in the language used to state their opinion).
[49] *See id.*
[50] *See id.*

The Court finds that Dr. Jain's opinion is too speculative to be admissible under applicable Delaware evidence law. The opinion does rule out some possible causes of Ms. Chapman's CKD but equivocates as to NSAIDs and other causes. Moreover, Dr. Jain admits that he finds it "impossible to discern if one particular agent was more likely than another to have caused" Ms. Chapman's CKD. Dr. Jain's opinions are stated in terms of possibility and not probability. Specifically, Dr. Jain opines that Ms. Chapman's chronic use of PPIs "could have contributed to her developing and progressing chronic kidney disease."

Ms. Chapman's lawyer could have probed this during Dr. Jain's deposition but did not ask those types of questions. Finally, Ms. Chapman fails to provide any other supporting evidence that would bolster Dr. Jain's opinion and allow the Court to determine that PPIs were the probable cause of Ms. Chapman's CKD.

Under these circumstances, the Court has no choice but to **GRANT** the Jain Motion. As such, the Court cannot let Dr. Jain to testify as to his opinions at trial.

## V. CONCLUSION

For the reasons stated above, the Court **GRANTS** the Jain Motion. The Court finds that Dr. Jain failed to provide admissible causation testimony as his opinions are not stated to a reasonable degree of medical probability. The Court **GRANTS** the SJ Motion because Ms. Chapman cannot demonstrate causation due to the exclusion of Dr. Jain's

opinion.[51] The Court does not need to address the Weiss Motion due to the Court's ruling on the Jain Motion.

Dated: October 3, 2022
Wilmington, Delaware

*/s/ Eric M. Davis*
Eric M. Davis, Judge

cc: File&ServeXpress

[51] *See, e.g., Vasquez v. Raymond Corp.*, 2019 WL 176106, at *6 (N.D. Ga. 2019).