

United States District Court
Northern District of California

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

RICHARD CANTY, et al.,
Plaintiffs,
v.
DEPUY ORTHOPAEDICS INC., et al.,
Defendants.

Case No. [14-cv-05407-JSW](#)

**ORDER DENYING DEFENDANTS’
MOTION TO EXCLUDE OPINIONS
OF DRS. VELYVIS AND BURSTEIN
AND DENYING IN PART AND
REQUIRING BRIEFING IN PART
DEFENDANTS’ MOTION FOR
SUMMARY JUDGMENT**

Re: Dkt. Nos. 34, 35, 36

Now before the Court are motions filed by Defendants DePuy Orthopaedics, Inc. n/k/a Medical Device Business Services, Inc., DePuy, Inc., Johnson & Johnson, Johnson & Johnson Services, Inc., and Johnson & Johnson International (collectively, “Defendants”). The motions are: (1) motion to exclude the opinions of John H. Velyvis, M.D.; (2) motion to partially exclude certain opinions of Albert H. Burstein, Ph.D.; and (3) motion for summary judgment.

Having considered the parties’ papers and authority, the Court DENIES Defendants’ motion to exclude the opinions of Dr. Velyris; DENIES Defendants’ motion to partially exclude certain opinions of Dr. Burstein; and DENIES IN PART Defendants’ motion for summary judgment and requires additional briefing in part.

BACKGROUND

Plaintiffs Richard and Betsy Canty allege that a defective metal-on-metal hip implant (“the Implant”) manufactured and sold by Defendants caused Mr. Canty to sustain various injuries. Mr. Canty began to experience hip discomfort in 2008 and in 2009 received a total hip replacement

1 using the Implant. Three years later, Mr. Canty began to experience stiffness and pain and, in
2 January of 2013, experienced excruciating right hip and groin pain. After right hip aspiration
3 disclosed dark black liquid, he was diagnosed with right total hip infection and emergency surgery
4 was performed to revise the Implant using a polyethylene liner. Following this revision surgery,
5 the infection returned and after removal of the prosthesis and implantation of antibiotics, Mr.
6 Canty underwent his fourth surgery, a right revision total hip arthroplasty.

7 As a result of his injuries, Plaintiffs brought claims based on negligence, strict products
8 liability based on failure to warn and design defect, fraud and fraudulent concealment, negligent
9 misrepresentation, and breach of the implied warranty of merchantability. Ms. Canty also brings
10 an additional claim for loss of consortium. This case was originally filed in this Court on
11 December 10, 2014, and then transferred on February 9, 2015, before a Multi-District Litigation
12 Court (“MDL”) for pretrial coordination before the United States District Court for the Northern
13 District of Texas, Honorable Ed Kinkeade presiding. Judge Kinkeade stayed all of the cases
14 pending the outcomes of a series of bellweather trials. Although the majority of the cases in the
15 MDL were resolved, after failing to settle, this matter was remanded to this Court.

16 On September 16, 2022, Judge Kinkeade issued a scheduling order in the MDL action,
17 setting discovery and motion dates, including the deadlines for filing for all dispositive motions or
18 *Daubert* motions for December 16, 2022. At the case management conference before this Court
19 upon remand, the parties filed a joint case management conference statement referring to this
20 earlier scheduling order and this Court set trial and pretrial dates. (*See* Dkt. No. 29, Order dated
21 May 30, 2023.) In that order, the Court set the last day to hear *Daubert* motions as May 20, 2024.
22 (*Id.* at 1.)¹

23 Defendants move to exclude all or portions of the opinions of Plaintiffs’ experts.
24 Defendants also move for summary judgment.

25 _____
26 ¹ Accordingly, the Court finds that Defendants’ *Daubert* motions to exclude testimony from
27 Plaintiffs’ experts are not late. However, the Court did not reset the deadline to file dispositive
28 motions. Accordingly, the Court finds that although the pending motion for summary judgment is late, it shall order further substantive briefing, taking into account this Court’s ruling on the motions to exclude experts and with the goal of resolving on the merits the remainder of issues raised in that motion as a matter of law.

1 ANALYSIS

2 **A. Legal Standard on a Motion to Exclude.**

3 Under Federal Rule of Evidence 702, expert witness opinion evidence is admissible if: (1)
4 the witness is qualified as an expert by knowledge, skill, experience, training, or education; (2) the
5 expert’s scientific, technical, or other specialized knowledge may help the trier of fact to
6 understand the evidence or to determine a fact in issue; (3) the testimony is based on sufficient
7 facts or data; (4) the testimony is the product of reliable principles and methods; and (5) the
8 expert’s opinion reflects a reliable application of the principles and methods to the facts of the
9 case.

10 The party proffering an expert bears the burden to show the testimony is admissible.
11 *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592 n.10 (1993). A district court’s inquiry
12 into admissibility “is a flexible one.” *Alaska Rent-A-Car, Inc. v. Avis Budget Grp., Inc.*, 738 F.3d
13 960, 969 (9th Cir. 2013) (citation omitted). In evaluating proffered expert testimony, the trial
14 court is “a gatekeeper, not a fact finder.” *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010)
15 (citation and quotation marks omitted). “The district court’s gatekeeping can be performed
16 through numerous procedures – such as motion in limine briefing and oral argument, voir dire, and
17 cross-examination at trial.” *United States v. Holguin*, 51 F.4th 841, 852 (9th Cir. 2022).

18 “[T]he trial court must assure that the expert testimony ‘both rests on a reliable foundation
19 and is relevant to the task at hand.’” *Primiano*, 598 F.3d at 564 (quoting *Daubert*, 509 U.S. at
20 597). “This entails a preliminary assessment of whether the reasoning or methodology underlying
21 the testimony is scientifically valid and whether that reasoning or methodology properly can be
22 applied to the facts in issue.” *Daubert*, 509 U.S. at 592-93. The purpose of the *Daubert* inquiry is
23 “to make certain that an expert, whether basing testimony upon professional studies or personal
24 experience, employs in the courtroom the same level of intellectual rigor that characterizes the
25 practice of an expert in the relevant field.” *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150
26 (1999). “Expert opinion testimony is relevant if the knowledge underlying it has a valid
27 connection to the pertinent inquiry. And it is reliable if the knowledge underlying it has a reliable
28 basis in the knowledge and experience of the relevant discipline.” *Daubert*, 509 U.S. at 565

1 (citation and internal quotation omitted). A trial court is not required “to admit opinion evidence
2 that is connected to existing data only by the *ipse dixit* of the expert.” *Kumho Tire*, 526 U.S. at
3 158 (1999) (quoting *General Elec. Co. v. Joiner*, 552 U.S. 136, 146 (1997)).

4 “Shaky but admissible evidence is to be attacked by cross examination, contrary evidence,
5 and attention to the burden of proof, not exclusion.” *Primiano*, 598 F.3d at 564 (citation omitted).
6 The judge is “supposed to screen the jury from unreliable nonsense opinions, but not exclude
7 opinions merely because they are impeachable.” *Alaska Rent-A-Car*, 738 F.3d at 969. Simply
8 put, “[t]he district court is not tasked with deciding whether the expert is right or wrong, just
9 whether [their] testimony has substance such that it would be helpful to a jury.” *Id.* at 969-70. In
10 applying Rule 702, the Ninth Circuit “contemplates a broad conception of expert qualifications.”
11 *Hangarter v. Provident Life & Accident Ins. Co.*, 373 F.3d 998, 1018 (9th Cir. 2004) (cleaned up).
12 In addition, alternative or opposing opinions or tests do not “preclude the admission of the
13 expert’s testimony – they go to the weight, not the admissibility.” *Kennedy v. Collagen Corp.*,
14 161 F.3d 1226, 1231 (9th Cir. 1998). “Disputes as to the strength of [an expert’s] credentials,
15 faults in his use of [a particular] methodology, or lack of textual authority for his opinion, go to
16 the weight, not the admissibility, of his testimony.” *Id.* (quotation omitted).²

17 **B. Motion to Exclude Opinions of Dr. Velyvis.**

18 Defendants move to exclude the expert opinions of Dr. Velyvis on several bases: (1) his
19 general causation opinion that the Implant is associated with an increased risk of infection
20 compared to other implants is not reliable because he does not provide scientific support; (2) his
21 training is in orthopedic medicine and is therefore unqualified to testify about issues pertaining to
22 product defect, product testing, or compliance with FDA requirements; (3) his regulatory and
23 training opinions are inadmissible because they are not rooted in objective scientific standards.

24 Plaintiffs contend the Dr. Velyvis bases his opinions on his in-person examination of Mr.
25 Canty, his review of Plaintiff’s pre- and post- initial implantation medical records, his review of
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27 ² The Court recognizes the recent amendments to Rule 702 and has performed its critical gate-
28 keeping function to find that the doctor’s principles and methods are reliably applied to the case-
specific facts.

1 transcripts of the depositions of the two implanting surgeons, his education as a biomedical
2 engineer and doctor of medicine, his training and experience as a practicing orthopedic surgeon
3 who performs total hip replacement surgeries, and his study and knowledge of the scientific
4 literature, including many peer-reviewed epidemiological studies and articles. Dr. Velyvis cites
5 48 peer-reviewed publications in his expert report to support his opinion that “[w]hen there is the
6 creation of exuberant metal debris in particles for a prolonged period of time, which can lead to
7 inflammation of the tissues, standing fluid, that the chances of infection go up extremely high.
8 And that revisions will be needed for failure, not only for the infection, but also for osteolysis and
9 pain and loosening due to the creation of the metal particles and metal ions.” (*See* Dkt. No. 50-3,
10 Velyvis Deposition at 92:8-24, 103:18-24.) To the extent Defendants challenge the doctor’s
11 reliance of the 48 publications, that objection goes to the weight of his testimony, not its
12 admissibility.

13 In addition, having reviewed Dr. Velyvis’ extensive training and positions as an orthopedic
14 surgeon, the Court finds him qualified to testify his theory of causation for Plaintiff’s injuries.
15 (*See* Dkt. No. 50-2, Velyvis CV.) The doctor identified objective evidence that he claims support
16 his position, namely the operative report indicating the presence of red blackened fluid aspirated
17 from Mr. Canty’s hip, fluid in the tendinous area, and a positive strep viridans culture, as well as
18 the reported symptoms experienced by the patient. He testified that “any tissue that has blackened
19 stain means that the cells contain metal particles, which is completely abnormal, and this is the
20 beginning stages of the creation of a pseudotumor. So once you see pus and fluid and metal-
21 stained particles, whether the particles are already necrotic or becoming necrotic, it’s in any case
22 an abnormal situation. It’s not good.” (Dkt. No. 50-3, Velyvis Deposition at 77:13-16, 78:5-13.)

23 In rendering this opinion, Dr. Velyvis relied on his own experience performing orthopedic
24 surgeries as well as following the literature and attending meetings in which this type of issue has
25 been discussed on a population-wide basis. (*See id.* at 78:18-20, 79:2-6.) Based also on his
26 understanding of the consensus in the orthopedic community, he testified that “certain implants
27 have been proven and shown to have an increased risk of failure including infection” and that the
28 Implant has an increased chance of causing infection, based on multicentered studies and registries

1 that track implants. (*See id.* at 82:23-24, 83:10-22.) The Court finds that Dr. Velyvis is qualified
2 to testify about his opinions of causation in this matter.

3 **C. Motion to Partially Exclude Certain Opinions of Dr. Burstein.**

4 Also before the Court is Defendants’ motion to partially exclude certain opinions of Dr.
5 Albert Burstein, a biomechanical engineer who seeks to testify at trial on the mechanics of the hip
6 joint and hip implant design, to which Defendants have no objection. Dr. Burstein is also
7 proffered to testify about the effects of debris particles, including the particle threshold for
8 osteolysis, lubrication issues in implant design, failure analysis, and the truthfulness of
9 Defendants’ marketing. It is these latter opinions that Defendants seek to exclude.

10 These opinions have been determined to be reliable and admissible by the MDL Court in
11 *In re DePuy Orthopaedics, Inc.*, 2016 WL 6271474 (N.D. Tex. Jan. 5, 2016). The MDL Court
12 found that “Dr. Burstein’s lengthy experience as an engineer and designer of orthopedic implants
13 has informed his familiarity an expertise with the materials used in such implants, including the
14 results of decades of research on the effect of the wear debris particles caused by materials used in
15 such implants.” *Id.* at *10. The MDL Court also found that Dr. Burstein could perform a failure
16 analysis on the Plaintiffs’ “retrieved implants and opine as to the nature and cause of Plaintiffs’
17 injuries.” *Id.* The Court similarly found that “Dr. Burstein’s analysis of lubrication issues in his
18 implant design and failure analysis work qualify him to opine on the same despite the fact that his
19 degrees are in the field of mechanical engineering rather than tribology, and ... while not a
20 marketing expert, [he] is sufficiently qualified to compare Defendants’ marketing messages with
21 the underlying research.” *Id.* The MDL Court found that Dr. Burstein’s methodology underlying
22 his evaluation of implants “regarding their associated particle thresholds is objectively verifiable
23 and subject to repetition and cross-examination, and based upon reliable data.” *Id.*³

24 On August 15, 2023, the district court in Western District of Missouri rejected the same
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26 ³ Again, approximately 10 months later, the MDL Court rejected these same arguments against
27 Dr. Burstein. The Court again found that Dr. Burstein was qualified as an expert to testify about
28 materials used in implants, the wear of debris particles, causation of injuries, analysis of
lubrication issues, and marketing comparison. *In re DePuy Orthopaedics, Inc.*, 2016 WL
9560113, at *5 (N.D. Tex. Oct. 3, 2016).

1 arguments made here by Defendants and found that although the rulings by the MDL Court were
2 not binding, “they are nonetheless persuasive, particularly because the MDL court had the benefit
3 of greater familiarity, both in terms of breadth and depth, with Pinnacle Ulmet cases.” *William K.*
4 *Winkelmeyer, M.D. v. DePuy Orthopaedics, Inc.*, 2:13-cv-04058-MDH. Similarly, here, the Court
5 finds the MDL’s twice-held conclusion to admit the testimony of Dr. Burstein, while not binding,
6 is persuasive. Based on the report and submissions Dr. Burstein relied upon here, the Court finds
7 that Dr. Burstein is qualified to testify about his opinions in this matter. The Court therefore
8 adopts the same holding as the MDL Court and for the same reasons given in that proceeding.

9 **D. Motion for Summary Judgment.**

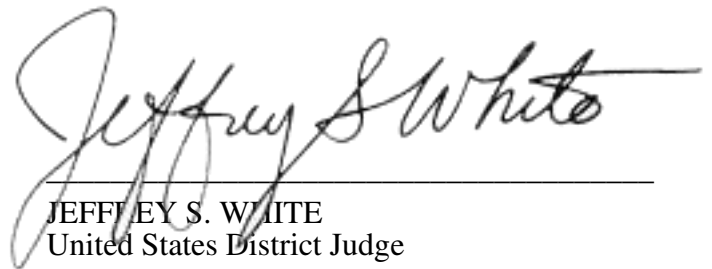
10 The Court finds that Defendants’ motion for summary judgment is late-filed. However,
11 the Court shall address the merits of the arguments made in that motion. The first contention that
12 Plaintiffs cannot prevail because there is no admissible evidence of medical causation fails due to
13 this Court’s holding on the motions to exclude experts. Defendants also move for summary
14 judgment on Plaintiffs’ claims based on fraud and failure to warn, as well as for Plaintiffs’ claims
15 for strict liability sounding in design defect, their claim for breach of the implied warranty of
16 merchantability, and Ms. Canty’s loss of consortium claim.

17 Due to the late filing of the motion, Plaintiffs did not respond substantively to these
18 arguments. The Court HEREBY SETS the deadline for an opposition to the motion for summary
19 judgment of June 18, 2024. The reply, if any, shall be filed no later than June 28, 2024. Should
20 the Court determine a hearing is necessary, it will be set by further order. Otherwise, the pending
21 motion for summary judgment shall be resolved on the papers in due course.

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IT IS SO ORDERED.

Dated: June 4, 2024



JEFFREY S. WHITE
United States District Judge